

**Supporting Statement for Programs for
All-inclusive Care of the Elderly (PACE)
and Supporting Regulations Contained in
42 CFR 460.12 - 460.210
42 CFR 460.10 – 460.202
(HCFA-1903 Regulation)
(CMS-1201 Regulation)
(CMS-R-244 PRA Package)**

A. Background

The Consolidated Omnibus Reconciliation Act of 1985 authorized the original demonstration waiver for On Lok Senior Health Services, which serves the elderly in San Francisco's Chinatown. The Omnibus Reconciliation Act of 1986 authorized CMS (formerly 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 PACE demonstration replicated a unique model of service delivery for a small number of very frail community dwelling elderly, most of whom were eligible for nursing home placement, as determined by standards established by participating states.

The Balanced Budget Act (BBA) of 1997 authorized coverage of the Program of All-inclusive Care for the Elderly (PACE) under the Medicare program and as a State option under Medicaid. On November 24, 1999, HCFA-1903-IFC, Programs of All-Inclusive Care for the Elderly (PACE), 64 FR 66234, was published, establishing requirements for PACE centers under Medicare and Medicaid. PACE is a pre-paid, capitated plan that provides comprehensive health care services to frail, older adults in the community, who are eligible for nursing home care according to State standards. Services are furnished through an adult day health center, which is staffed and equipped to provide multidisciplinary care at participant's homes and at inpatient facilities if warranted by the participant's medical condition. Programs must apply for approval and are evaluated in terms of specific criteria. Only a limited number of programs can be approved.

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, (BIPA) amended the PACE statute to provide authority for CMS to modify or waive PACE regulatory provisions. CMS-1201-IFC, Programs of All-inclusive Care for the Elderly (PACE); Program Revisions, published October 1, 2002, 67 FR 61496, established a process through which existing and prospective PACE organizations may request a waiver of Medicare and Medicaid regulatory requirements.

The Medicare Prescription Drug, Improvement and Modernization and Act of 2003 (MMA) mandates a three-year limit on all proposed rules being made final. Section 902 of this provision must be completed by December 8, 2006.

B. Justification

1. Need and Legal Basis

Section 4801 of Pub. Law 105-33, the BBA of 1997, 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 the BBA authorized the establishment of PACE as a State option under Medicaid. It amended title XIX of the Act by adding section 1934, which directly parallels the provisions of section 1894. Section 4803 of the BBA addresses implementation of PACE under both Medicare and Medicaid, the effective date, timely issuance of regulations, priority and special consideration in processing applications, and transition from PACE demonstration project waiver status.

Section 903 of Pub. Law 106-554, the Medicare, Medicaid, and SCHIP Benefits Improvement Act of 2000 (BIPA) amended section 1894 and 1943 to provide authority for CMS to modify or waive PACE regulatory provisions.

PACE organizations must demonstrate their ability to provide quality community-based care for the frail elderly who meet their State's nursing home eligibility standards using capitated payments from Medicare and the state. The model of care includes 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 is controlled. Physician, therapeutic, ancillary, and social support services are provided in the participant's residence or on-site at the adult day health center. PACE programs must provide all Medicare and Medicaid covered services including hospital, nursing home, home health, and other specialized services. Financing of this model is accomplished through prospective capitation of both Medicare and Medicaid payments.

As mandated by the BBA, this rule is based on the protocol used during the demonstration projects. In accordance with BBA and BIPA, it establishes application and waiver procedures; program agreement requirements; sanction, enforcement, and termination procedures; PACE organization administrative and service requirements; participant rights; quality assessment and performance improvement requirements; participant enrollment and disenrollment procedures, payment provisions, and data collection, record maintenance and reporting requirements. In short, this comprehensive rule, and the information collection requirements it contains, is necessary to ensure that only appropriate organizations are selected to become PACE organizations and that CMS has the information necessary to monitor the care provided to the frail, vulnerable population served.

2. Information Users

CMS and the State Administering Agencies will use the information to select PACE organizations and monitor their performance.

3. Improved Information Technology

Although we considered using technology to reduce burden on PACE organizations, the information collection requirements do not lend themselves to this. Assessing increased use of information technology will be part of the PACE program evaluation process.

4. Duplication of Similar Information

These information collection requirements (ICR) do not duplicate similar information collections.

5. Small Businesses

These ICRs do not have a significant economic impact on small businesses.

6. Less Frequent Collection

If CMS would collect this information less frequently, we would be out of compliance with the law. In addition, collection of certain information is intended to monitor providers to ensure adequate treatment and services for this vulnerable population.

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

HCFA-1903-IFC was published in the Federal Register on Wednesday, November 24, 1999. CMS-1201-IFC was published in the Federal Register on October 1, 2002. CMS has quarterly meetings with the National PACE Association, which represents the current and prospective PACE organizations, to discuss various issues surrounding the regulation. The 2006 final rule will respond to the public comments received on both the 1999 interim final rule and the 2002 interim final rule.

9. Payment/Gift to Respondent

There were no payments or gifts to respondents.

10. Confidentiality

CMS has established requirements in the regulation that assure the confidentiality of both patient medical records and applicable provider information.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimate (Total Hours & Wages)

A. The following ICRs and associated burden are subject to the PRA.

460.12 Application requirements.

Section 460.12(a)(1) states that in order for CMS to determine whether an entity qualifies as a PACE organization, an individual authorized to act for the entity must submit to CMS 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 CMS. 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.

Section 460.12(a)(2) States must develop a SPA. We estimate it will take 25 entities 20 hours each to complete the SPA this requirement for a total annual burden of 500 hours. **THIS REQUIREMENT WAS DELETED IN THE 2002 IFC**

460.26 CMS evaluation of waiver requests.

Section 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 8 hours to complete these requirements for a total annual burden of 200 hours. This estimate is based on a waiver request being submitted by a PACE organization separately from its application. We believe the burden with this requirement for the State will be reduced if the waiver request is submitted with the application.

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 20 hours to complete the requirements of this section for a total annual burden of 500 hours.

460.30 Program agreement requirement.

In summary, section 460.30(a) and (b) state that a PACE organization must have an agreement with CMS 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, CMS, and the State administering agency.

Since CMS prepares the program agreement, the burden associated with this requirement is the time and effort of officials at the state and the PACE organization 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 460.30(c) provides that CMS may only sign program agreements with PACE organizations that are located in States with approved State Plan amendments electing PACE as an optional benefit under their Medicaid State plan.

The burden associated with this requirement is the time and effort for a State to develop its State Plan amendment to elect PACE as an optional Medicaid benefit and to write an

assurance to CMS 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.

460.68 Program Integrity

In summary, Section 460.68(b)(1) require the PACE organizations to develop written policies and procedures for handling direct or indirect conflict of interest by a member of the governing body or an immediate family member. While the requirement to furnish these materials is subject to the PRA, the burden associated with that requirement is captured in section 460.12(a)(1). **THIS REQUIREMENT IS BEING ADDED IN THE 2006 FINAL RULE.**

Section 460.68(b)(2) requires that in the event of a direct or indirect conflict of interest by a member of the governing body or an immediate family member, the PACE organization must document the disclosure. We estimate each PACE organization will take 30 minutes to complete this requirement. There are approximately 54 organizations for a total annual burden of 27 hours. **THIS REQUIREMENT IS BEING ADDED IN THE 2006 FINAL RULE.**

460.70 Contracted Services

In summary, Section 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 requirement is the ongoing time associated with the PACE organization's 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 CMS and the State administering agency.

While the requirement to furnish a copy of each signed contract for inpatient care is subject to the Paperwork Reduction Act (PRA), the initial burden associated with this requirement is captured in section 460.12, the 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 CMS 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. **THIS REQUIREMENT IS DELETED IN THE 2006 FINAL RULE.**

460.71 Oversight of direct participant care

In summary, Section 460.71(a) requires a PACE organization to develop a competency evaluation program to ensure that contractors providing direct participant care 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 5 hours developing the program for each of the 11 required interdisciplinary team members (this figure will vary depending on processes already in place prior to issuance this rule) for a total of 55 hours. Implementation of the program will require a minimum of two (2) per staff annually. Assuming a PACE organization has an average staff (employees and contractors) of 150, implementation will consume a total of 300 hours annually. Maintaining the program and verifying the qualifications and competency for all new direct participant care staff and contractors is estimated to require a minimum of two (2) hours per individual for an average of 10 new staff and contractors in a given year or 20 hours annually. The total for the 54 PACE organizations could be as high as 375 hours annually. There will be approximately 54 PACE organizations for a total annual burden of 20,250 hours.

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 section 460.12, application requirements. We estimate that each PACE organization will take 1 hour to maintain the 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.

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 section 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 section 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.

460.102 Interdisciplinary 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.

460.104 Participant assessment

Section 460.104(c)(3)(iii) specifies a timeframe for the multidisciplinary team to conduct a reassessment and notify the participant (or designated representative) of its decision to approve or deny the request for a change in services. The team must provide its decision as expeditiously as the participant's condition requires but no later than 72 hours after the date the multidisciplinary team receives the request for the reassessment. The team may extend the timeframe in accordance with this section if it documents the 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 it needs additional time to respond to the reassessment request. Therefore, the burden associated with this requirement is (8 participants x 10 minutes) x 54 PACE organizations = 72 annual hours of burden.

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 languages 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 languages 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 languages 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.

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 participants x 5 minutes) x 54 PACE organizations = 720 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 participants x 10 minutes) x 54 PACE organizations = 72 annual hours of burden.

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 services or payment, the PACE 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 participants x 5 minutes) x 54 PACE organizations = 720 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 CMS, the State administering agency, and the participant.

The burden associated with this requirement is the time and effort for a PACE organization to notify CMS, 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 participant notifications x 5

minutes) + (4 CMS notifications x 5 minutes) + (4 State notifications x 5 minutes)] x 54 organizations = 54 annual hours of burden for all organizations.

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, or both, assist the participant in filing Medicare and Medicaid appeals, 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, and forwarding the appeal to the appropriate external entity. We estimate that, on average, there will be 2 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 participants x 1 hour) x 54 organizations = 108 annual hours of burden.

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.

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 CMS 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 CMS 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 CMS and the State agency is estimated to be 5 minutes each, for a total of (25 applicants x 10 minutes) x 54 organizations = 225 total annual hours.

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 participants 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 participant information to CMS 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 participant information to CMS 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.

460.160 Continuation of enrollment

In summary, section 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.

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.

460.190 Monitoring during trial period

Section 460.190(a) states that during the trial period, CMS, 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.

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.

460.202 Participant health outcomes data

In summary, section 460.202(a) and (b) states that a PACE organization must establish and maintain a health information system that collects, analyzes, integrates, and reports data necessary to measure the organizations performance, including outcomes of care furnished to participants. A PACE organization must also furnish data and information pertaining to its provision of participant care in the manner, and at the time intervals, specified by CMS and the State 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 to CMS and the State administering agency pertaining to its provision of participant care. While the requirement to demonstrate the "establishment" of a system is subject to the PRA, the burden associated with that requirement is captured in section 460.12, application requirements. Therefore, the remaining burden associated with this section is the requirement to furnish information specified by CMS and the State administering agency. We estimate that each PACE organization will take 100 hours (50 hours for CMS 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.

460.208 Financial statements

Section 460.208(a)(1) states that not later than 180 days after the organizations 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 organizations 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 section 460.12, application requirements (Paragraph A, above).

460.22 Service area designation

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

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.

460.52 Transitional care following termination

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

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 organizations relationship to the corporate board and to any parent, affiliate, or subsidiary corporate entities.

460.68 Program Integrity

In summary, Section 460.68(b)(1) require the PACE organizations to develop written policies and procedures for handling direct or indirect conflict of interest by a member of the governing body or an immediate family member. While the requirement to furnish these

materials is subject to the PRA, the burden associated with that requirement is captured in section 460.12(a)(1). **THIS REQUIRMENT IS BEING ADDED IN THE 2006 FINAL RULE.**

Section 460.68(c)(2) states that if an applicant seeking approval as a PACE organization believes an exception is warranted, it must include a request for an exception in its application. **THIS REQUIRMENT WAS DELETED IN THE 2002 IFC.**

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.

460.82 Marketing

Section 460.82(b)(2) states that CMS 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 the organization's marketing information.

460.102 Multidisciplinary team

Section 460.102(g)(2) states that if an applicant seeking approval as a PACE organization believes a waiver of the restrictions of 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. **THIS REQUIRMENT WAS DELETED IN THE 2002 IFC.**

460.104 Participant Assessment

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.

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.

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.

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 timeframes for response, which may be used by a participant to address noncoverage or nonpayment of a service.

460.132 Quality assessment and performance improvement plan

Section 460.132(a) requires a PACE organization to have a written plan that describes the organization's quality assessment and performance improvement program.

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 section 460.132(b), quality assessment and performance improvement plan (Paragraph A, above).

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.

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 is contained in sections 460.202, participant health outcomes data, and 460.208, financial statements (Paragraph A, above).

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 CMS and the State administering agency.

Section 460.200(c) states that a PACE organization must submit to CMS and the State administering agency all reports that CMS 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 section 460.208, financial statements (Paragraph A, above).

460.204 Financial recordkeeping and reporting requirements.

Section 460.204(a) states that a PACE organization must provide CMS 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 solicit comments on this determination and request any data on the additional determination.

460.52 Transitional care following termination

Section 460.52(b) states that an entity whose PACE program agreement is terminated must provide assistance to each participant in obtaining necessary transitional care through appropriate referrals and making the individual's medical records available to new providers.

460.70 Contracted services

Section 460.70(a) states that the PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization.

Section 460.70(c) states that a list of contractors must be on file at the PACE center and a copy must be provided to anyone upon request.

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.

460.74 Infection control

Section 460.74(b) states that the PACE organization must establish, implement, and maintain a documented infection control plan.

460.82 Marketing

Section 460.82(a) states that a PACE organization must inform the public about its program and give prospective participants the following written information: an adequate description of the PACE organization's enrollment and disenrollment policies and requirements; PACE enrollment procedures; description of benefits and services; premiums; and other information necessary for prospective participants to make an informed decision about enrollment.

Section 460.82(d) states that marketing materials must inform a potential participant that he or she must receive all needed health care (other than emergency or urgently needed services) from the PACE organization or from an entity authorized by the PACE organization. All

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

460.98 Service delivery

Section 460.98(a) states that a PACE organization must establish and implement a written plan to furnish care that meets the needs of each participant in all care settings 24 hours a day, every day of the year.

460.100 Emergency and urgent care

Section 460.100(a) states that a PACE organization must establish and maintain a written plan to handle emergency and urgent care.

460.102 Interdisciplinary team

In summary, Section 460.102(d) states that the interdisciplinary team is responsible for the initial assessment, periodic reassessments, plan of care, and coordination of 24 hour care delivery. Each team member must regularly inform the interdisciplinary team of the medical, functional, and psychosocial condition of each participant; and document changes in a participant's condition in the participant's medical record consistent with documentation policies established by the medical director.

460.104 Participant assessment

In summary, section 460.104 states that the interdisciplinary team must explain why it denies a participant's request for services, inform participant's of additional appeal processes available, and document all assessment and reassessment information in the participant's medical record.

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.

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.

460.112 Specific rights to which a participant is entitled

Section 460.112(b)(1) states that a participant has the right to be fully informed in writing of the services available from the PACE organization.

Section 460.112(b)(2) states that a participant has the right to have the enrollment agreement fully explained in a manner understood by the participant.

Section 460.112(e)(2) states that a participant has the right to have the PACE organization explain advance directives and to establish them, if the participant so desires.

Section 460.112(e)(3) states that a participant has the right to be fully informed of his or her health and functional status by the interdisciplinary team and to participate in the development and implementation of the plan of care.

Section 460.112(e)(6) states that a participant has the right to be given reasonable advance notice, in writing, of any transfer to another treatment setting, and the justification for it, due to medical reasons or for the participant's welfare, or that of other participants. The PACE organization must document the justification in the participant's medical record.

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.

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.

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.

460.154 Enrollment agreement.

Section 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.

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.

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.

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.

460.200 Maintenance of records and reporting of data.

Section 460.200(e) states that a PACE organization must safeguard the confidentiality of any information that identifies a particular participant; establish and implement procedures that govern the use and release of a participant's information before releasing personal information that is not required by law to be released.

Section 460.200(f)(1) states that a PACE organization must retain records for the longest of the following periods: the period of time specified in State law; six years from the last entry date; or for medical records of disenrolled participants, six years after the date of disenrollment.

460.204 Financial recordkeeping and reporting requirements.

Section 460.204(b) states that a PACE organization must maintain an accrual accounting recordkeeping system.

460.210 Medical records.

Section 460.210(a) states that a PACE organization must maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards.

Section 460.210(c) states that the PACE organization must promptly transfer copies of medical record information between treatment facilities.

Section 460.210(d) states that all entries must be legible, clear, complete, and appropriately authenticated and dated. Authentication must include signatures or a secured

computer entry by a unique identifier of the primary author who has reviewed and approved the entry.

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 solicit comments on this determination and request any data on the additional determination.

460.16 Special consideration.

Section 460.16(b) states that an application from an entity seeking special consideration must include documentation of its formal activities.

460.60 PACE organizational structure

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

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 any new information is subject to CMS' time period for approval. CMS approves or disapproves marketing information within 45 days after receipt from the organization.

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.

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 CMS within a reasonable amount of time.

460.172 Documentation of disenrollment

Section 460.172(b) states a PACE organization must make documentation available for review by CMS and the State administering agency.

460.192 Ongoing monitoring after trial period

Section 460.192(a) states that at the conclusion of the trial period, CMS, in cooperation with the State administering agency, will continue to conduct reviews of a PACE organization, as appropriate, taking into account the performance level of the organization with respect to the quality of care provided and the organization's compliance with all requirements of this part.

460.194 Corrective action

Section 460.194(a) states that a PACE organization must take action to correct deficiencies identified during reviews.

460.200 Maintenance of records

Section 460.200(f)(2) states that if litigation, a claim, a financial management review, or an audit arising from the operation of the PACE program is started before the expiration of the retention period, specified in paragraph (f)(1) of this section, the PACE organization must retain the records until the completion of the litigation, or resolution of the claims or audit findings.

460.204 Financial recordkeeping and reporting requirements

Section 460.204(d) states that a PACE organization must permit CMS and the State administering agency to audit or inspect any books and records of original entry that pertain to the following: any aspect of services performed; reconciliation of participant's benefit liabilities; or determination of Medicare and Medicaid amounts payable.

460.208 Financial statements

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

The total burden for these ICRs is 25,848.5 hours. The cost associated with these requirements is estimated to be \$440,775. (44,077.5 hours * \$10 per hour).

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs associated with these ICRs.

14. Cost to Federal Government

There will be a significant cost to the federal government since there will be extensive onsite surveys of the PACE organizations. We will be better able to assess this cost when we submit a paperwork package for an on-site survey instrument.

15. Program or Burden Changes

This collection is being revised to reconcile changes that were made in 2002 interim final rule and reflect the changes being made to the requirements in the 2006 final rule.

These changes include a technical correction to an error made in the 2002 IFC and the PRA package. Section 460.12(a)(2) was deleted in the 2002 IFC. The associated burden was 25 States x 20 hours for an approximate total annual burden of 500 hours. The requirement was included in §460.30(c) of the 2002 IFC and the associated burden was 25 States X 20 hours for an approximate total annual burden of 500 hours. Therefore, the total annual burden hours remained the same.

In the 2006 final rule we are deleting §460.70(d) with an estimated burden of 54 entities x 0.5 hours for an approximate total annual burden of 27 hours.

We are also adding a new §460.68(b)(2) with an estimated burden of 54 entities x 0.5 hours for an approximate total annual burden of 27 hours. Therefore, the total annual burden hours remained the same.

In addition, due to a prior error in calculation of the total burden hours, the total burden hours are now reduced by a total of 246 hours.

16. Publication and Tabulation Dates

There is no tabulation date. The publication date of CMS –1201-F is November 24, 2008.

17. Expiration Date

There is no form associated with these ICRs; therefore, there is no expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

There are no statistical methods.