

Supporting Statement Part A
Programs for All-inclusive Care of the Elderly (PACE) and Supporting Regulations
Contained in 42 CFR 460.12-460.210
CMS-R-244, OMB 0938-0790

Background

The Programs of All-Inclusive Care for the Elderly (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. PACE programs must provide all Medicare and Medicaid covered services; financing of this model is accomplished through prospective capitation of both Medicare and Medicaid payments.

The PACE model of care includes, as core services, the provision of adult day health care and interdisciplinary team (IDT) care management, through which access to and allocation of all health services is managed. Physician, therapeutic, ancillary and social support services are furnished in the participant's residence or onsite at a PACE Center. Hospital, nursing home, home health and other specialized services are furnished in accordance with the PACE participant's needs, as determined necessary by the IDT.

Section 4801 of the Balanced Budget Act of 1997 (BBA)(Pub. L. 105-33) authorized coverage of PACE under the Medicare program by amending Title XVIII of the Social Security Act ("the Act") and 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 by amending Title XIX of the Act and adding section 1934, which directly parallels the provisions of section 1894. The regulations implementing these PACE statutory requirements are set forth in 42 CFR Part 460.

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. On December 8, 2003, the Congress enacted the MMA of 2003 (Pub. L. 108-173). Several sections of the MMA impact PACE organizations. Most notably, section 101 of the MMA affected the way in which PACE organizations are reimbursed for providing certain outpatient prescription drugs to any Part D eligible participant. As specified in sections 1894(b)(1) and 1934(b)(1) of the Act, PACE organizations shall provide all medically necessary services including prescription drugs, without any limitation or condition as to amount, duration, or scope and without application of deductibles, co-payments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid.

In 2006, CMS issued a final rule (71 FR 71244, Dec 8, 2006) that finalized both the PACE interim final rule with comment period published in the Federal Register November 24, 1999 (64

FR 66234) and the PACE interim final rule with comment period published in the Federal Register on October 1, 2002 (67 FR 61496). For a complete history of the PACE program, please see 71 FR 71244 through 71248 (Dec. 8, 2006).

4168-P would revise and update the requirements for the Programs of All-Inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs. The proposed rule addresses application and waiver procedures, sanctions, enforcement actions and termination, administrative requirements, PACE services, participant rights, quality assessment and performance improvement, participant enrollment and disenrollment, payment, federal and state monitoring, data collection, record maintenance, and reporting. The proposed changes would provide greater operational flexibility, remove redundancies and outdated information, and codify existing practice.

A. Justification

1. Need and Legal Basis

Collection of this information is mandated by statute under Sections 1894 and 1934 of the Act and at 42 CFR 460. This clearance request is for the information collected to gather data used to support approval or denial of a PACE application and to ensure compliance with CMS requirements in the operation of PACE programs.

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

Since the 2002 interim final rule with comment was published, CMS has moved to technology based methods of communicating with PACE organizations. Although CMS did not require the use of electronic information technology when PACE was first implemented, CMS currently require the use of Health Plan Management System (HPMS), beginning with the application process, and as part of the audit process and ongoing communications. . At this point, virtually all communications with PACE organizations are handled electronically.

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

Some information is collected annually, biannually or quarterly. If CMS would collect this information less frequently, CMS would have no mechanism to ensure that specific CMS requirements are being met. 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

Federal Register

Serving as the 60-day notice, the proposed rule published in the Federal Register on August 16, 2016 (81 FR 54666).

Outside Consultation

The PACE industry has offered unsolicited suggestions for improvement to the administration of the PACE program over the last few years.

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 (42 CFR Section 460.200(e)).

11. Sensitive Questions

The PACE information collection does not contain sensitive questions.

12. Burden Estimate (Total Hours & Wages)

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

This section estimates the information collection requirements of each regulatory section at 42 CFR 422.460. These estimates update and harmonize

- The already existing requirements at 42 CFR 460 (which were in previous versions of this PRA);
- The proposed provisions in proposed rule CMS-4168-P; more specifically the 21 provisions listed in Section IV of CMS-4168-P, "Information collection requirements," are estimated here; and
- The summary of total burden in Table 1.

More specifically, for each provision – whether a provision that has already appeared in 42 CFR 460 or a provision proposed in CMS-4168-P - we estimate the burden of that provision. The estimates are uniformly described by indicating

- The estimated number of applicants,
- The hourly requirements per applicant, and
- The hourly wage for technical support staff including fringe benefits based on 2015 data from the U.S. Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates for all salary estimates. We used a factor of 100% for fringe benefits.

The total burden is the product of these three numbers (divided by 3 if the burden is a one time estimate for the initial 3 years).

This layout – applicants, hourly requirements, hourly wages – is indicated by bullets in each provision and corresponds to columns in the summarizing Table 1.

460.12 Application requirements.

Section 460.12(a)(l) 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. CMS-4168-P, proposes to include in the regulations for application, the applications for Service Area Expansions (SAE).

The burden associated with this requirement is the time and effort to compile and submit application information to CMS. CMS estimates that:

- For initial applications:
 - There will be 10 applicants per year
 - Each taking 34 hours of time to complete the applications
 - The hourly wage is \$59.44
 - It follows that the total burden is $10 \times 34 \times 59.44 = \$20,210$.
- For Service Area Expansions:
 - There will be 25 applicants per year
 - Each taking 16 hours of time to complete the applications.
 - The hourly wage is 59.44
 - It follows that the total burden is $25 \times 16 \times \$59.44 = \$23,776$
- It follows that 35 entities (25 initial + 10 SAE) are expected to apply each year.

Section 460.12(b) States must provide assurance indicating that the state considers the entity to be qualified to be a PACE organization and is willing to enter into a PACE program agreement with the entity.). CMS estimates that it will take:

- 35 entities
- 20 hours each to complete the state assurance requirements
- At an hourly wage of 59.44
- It follows that the total burden is $35 \times 20 \times 59.44 = \$41,608$.

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. CMS estimates that:

- 5 States
- Will each take 8 hours to complete these requirements.
- The hourly wage is 59.44.
- It follows that the total burden for the states is $5 \times 8 \times 59.44 = \$2,378$

This estimate is based on a waiver request being submitted by a PACE organization separately from its application. 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. CMS estimates that:

- 5 entities will apply per year
- Each entity will take 20 hours to complete the requirements of this section
- The hourly wage is 59.44
- It follows that the total burden for review is $5 \times 20 \times 59.44 = \$5,944$

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. CMS estimates that organization and State officials will take 2 hours per agreement to complete this requirement.

Proposed regulation, CMS-4168-P, proposes to remove the requirement of annually including Medicaid capitation rates and instead submit methodology. It is estimated that this will reduce burden by half an hour. Thus

- There are 119 PACE organizations (PO)
- Each of which will take 1.5 hours to complete requirements
- The hourly wage is 59.44.

- It follows that the total burden is $119 \times 1.5 \times 59.44 = \$10,610$.

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. The number of states that have State Plan Amendments for the PACE program has remained steady over time. We do not expect many (if any) additional states to include the PACE program as part of their state plans in the near term. Even if they do, we do not expect that 10 or more of the remaining states would pursue this option. Therefore, there is no annual burden associated with this requirement since the number of States hosting POs has recently remained constant at 32 states. (Note: Due to a recent mutual termination of a PO, one of the 32 states does not currently have an operational PO.)

460.68 Program Integrity

Proposed regulation, CMS-4168-P, proposes in Section 460.68(a), to expand the group of individuals who should not be employed by a PO. This provision would require a one-time burden for each PO to update its written hiring policies. We estimate that

- 119 PO
- Will each take 10 hours to update their policies
- The hourly wage is 59.44
- Since this is a one-time requirement it is annualized over three years
- It follows that the total burden is $119 \times 10 \times 59.44 \div 3 = \$23,578$.

Section 460.68(b)(1) requires 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).

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. CMS estimates that

- 119 PO
- Will each take a half hour to complete this requirement.
- The hourly wage is 59.44
- It follows that the total burden is $119 \times \frac{1}{2} \times 59.44 = \$3,537$.

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. CMS estimates that:

- 119 PO
- Will each spend 5 hours verifying the qualifications of new contractors.
- There is an hourly wage of 59.44
- It follows that the total burden is $119 \times 5 \times 59.44 = \$35,367$.

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. CMS estimates that each organization will

- Initially
 - o For the IDT,
 - ✓ 5 hours are needed to develop the program for each member
 - ✓ There are 11 members
 - ✓ It follows there is a total of $5 \times 11 = 55$ hours of preparation (this figure will vary depending on processes already in place prior to issuance this rule)
 - o For PACE staff
 - ✓ Will spend 2 hours annually
 - ✓ We estimate average staff size including employees and contractors to be 150
 - ✓ It follows there is a total of $150 \times 2 = 300$ hours of preparation.
- For maintaining the program, that is, for verifying the qualifications and competency
 - o For all new staff
 - ✓ Will require a minimum of two hours per individual
 - ✓ We estimate on average, 10 new staff and contractors annually
 - ✓ It follows that we estimate $10 \times 2 = 20$ hours of maintenance annually.

Using these estimates we can estimate the initial and maintenance aggregate burden.

- For IDT staff, initially we estimate
 - o 119 PO
 - o Will spend 55 hours
 - o The hourly wage is 59.44
 - o The result is annualized over 3 years
 - o It follows that the total burden is $119 \times 55 \times 59.44 \div 3 = \$129,678$
- For other pace staff, initially, we estimate that:
 - o 119 PO
 - o Will spend 300 hours
 - o The hourly wage is 59.44

- o The result is annualized over 3 years
- o It follows that the total burden is $119 \times 300 \times 59.44 \div 3 = \$707,336$
- For maintenance of the program in future years, we estimate
 - o 119 PO
 - o Will spend 20 hours
 - o The hourly wage is 59.44
 - o It follows that the total burden is $119 \times 20 \times 59.44 = \$141,467$

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. CMS estimates that:

- 119 PO
- Will each take 1 hour to maintain the written plan.
- The hourly wage is 59.44
- It follows that the total burden is $119 \times 1 \times 59.44 = \$7,073$.

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. CMS estimates that:

- 119 PO
- Will each take ½ hour to complete this requirement.
- The hourly wage is 59.44
- It follows that the total burden is $119 \times \frac{1}{2} \times 59.44 = \$3,537$.

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. CMS estimates that:

- 119 PO

- Will each take 2 hours to prepare and update the material on an annual basis
- The hourly wage is 59.44
- It follows that the total burden is $119 \times 2 \times 59.44 = \$14,147$.

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. CMS estimates that:

- 119 PO
- Will each take 1 hour on an annual basis to complete this requirement.
- The hourly wage is 59.44.
- It follows that the total burden is $119 \times 1 \times 59.44 = \$7,073$.

Proposed regulation, CMS-4168-P, proposes to enlarge those eligible to serve as IDT members. This will require a one-time requirement for POs to update their written materials. We estimate that

- 119 PO
- Will each take 1 hour to complete these requirements
- The hourly wage is 59.44
- The resulting burden is annualized over 3 years
- It follows that the total burden is $119 \times 1 \times 59.44 \div 3 = \$2,358$.

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. CMS estimates that on average there will be approximately

- 8 participants per organization who request a reassessment and
- The team determines it needs 10 minutes (1/6 of an hour) additional time to respond to the reassessment request.
- It follows that the total time burden per PO is $8 \times 1/6 = 1.33$ hours.

Using this we can estimate the total burden.

- 119 PO
- Will each take 1.33 hour to complete this requirement
- The hourly wage is 59.44
- It follows that the total burden is $119 \times 1.33 \times 59.44 = \$9,433$.

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 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, CMS does believe the remaining burden associated with updating and displaying these rights is subject to the PRA. CMS estimates that:

- 119 PO
- Will, on average, take 8 hours on an annual basis to comply with these requirements.
- The hourly wage is 59.44
- It follows that the total burden is $119 \times 8 \times 59.44 = \$56,587$.

Proposed rule, CMS-4168-P, proposes that if a state has not established a standard for making the principal language determination, a principal language of the community is any language spoken regularly at home by at least 5 percent of the individuals in the PO's service area. . We estimate that:

- 119 PO
- Each will take a one-time effort of 5 hr. to revise the written material about participant rights
- The hourly wage is 59.44
- The resulting burden will be annualized over 3 years.
- It follows that the total burden is $119 \times 5 \times 59.44 \div 3 = \$11,789$.

Proposed rule CMS-4168-P, at Section 460.116(c)(2) proposes that the PO must display the participant rights in a prominent place in the PACE center. The proposed rule would require to add the word "PACE" before the words "participant rights" to specify that participant rights specific to PACE must be displayed. We anticipate that these changes may result in technical staff revising documents, the addition of the word "PACE" and redisplay of notices. We estimate:

- 119 PO
- Each will take a one-time effort of a half hour to complete these requirements
- The hourly wage is 59.44
- The resulting burden will be annualized over 3 years.

- It follows that the total burden is $119 \times 1/2 \times 59.44 \div 3 = \$1,179$.

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. CMS estimates that:

- On average, there will be 160 participants per organization receiving written information on the grievance process.
- It will take 1/12 of an hour, 5 minutes, to disclose materials.
- Therefore the total hourly burden is $160 \times 1/12 = 13.33$ hours.

Using this, we can estimate that:

- 119 PO
- Will take 13.33 hours each to respond to inquiries
- The hourly wage is 59.44
- It follows that the total burden is $119 \times 13.33 \times 59.44 = \$94,274$

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. CMS estimates that:

- On average, there will be 16 participants per organization receiving the additional written information on the grievance process.
- The time for communication with the participant is 1/6 hour, 10 minutes.
- Therefore the total hourly burden is $16 \times 1/6 = 1 \frac{1}{3} = 2.6672$ hour.

Using this we can estimate that

- 119 PO
- Will each take 2.6672 hour to respond to inquiries
- The hourly wage is 59.44
- Therefore the total burden is $119 \times 2.6672 \times 59.44 = \$18,866$.

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. CMS estimates that, on average:

- On average, there will be 160 participants per organization receiving written information on the appeals process.
- It will take 1/12 of an hour, 5 minutes, to disclose materials.
- Therefore the total hourly burden is $160 \times 1/12 = 13.33$ hours.

Using this we can estimate that

- 119 PO
- Will take 13.33 hours each to respond to inquiries
- The hourly wage is 59.44
- It follows that the total burden is $119 \times 13.33 \times 59.44 = \$94,274$

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. CMS estimates that, on average:

- Four participants from each organization will be involved in this process
- Notifications must be done to CMS, the State and the PO
- Each notification will take 1/12 hour or 5 minutes.
- Thus the total hourly burden is $4 \times 3 \times 1/12 = 1$ hour.

Using this we can estimate that

- 119 PO
- Will each take 1 hour to respond to inquiries
- The hourly wage is 59.44
- Therefore the total burden is $119 \times 1 \times 59.44 = \$7,073$.

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. CMS estimates that:

- On average, there will be 2 participants per organization receiving written information and assistance related to their appeal rights.
- Each participant will require 1 hour to satisfy their inquiry
- It follows that the total burden is $2 \times 1 = 2$.

Using this we can estimate that

- 119 PO
- Will each take 2 hours

- The hourly wage is 59.44
- It follows that the total burden is $119 \times 2 \times 59.44 = \$14,147$.

60.132 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. CMS estimates that:

- 119 PO
- Will each take 8 hours to complete this requirement
- The hourly wage is 59.44
- It follows that the total burden is $119 \times 8 \times 59.44 = \$56,587$.

Proposed rule, CMS-4168-P, proposes revision of §460.132(a) and (c)(3) to i) refer to quality improvement (QI) plan, ii) have a written quality improvement plan that is collaborative and interdisciplinary in nature. Because POs are already required to have a written QAPI plan, we anticipate added burden to update the plan by making it more collaborative and interdisciplinary in nature. CMS estimates that

- 119 PO
- Will each take one-time effort of 1 hour to complete this requirement.
- The hourly wage is 59.44
- It follows that the total burden is $119 \times 1 \times 59.44 \div 3 = \$2,358$.

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. CMS estimates that:

- Each of 31 State administering agencies
- Will take 100 hours to complete this requirement.
- The hourly wage is 59.44
- It follows that the total burden is $31 \times 100 \times 59.44 = \$184,264$.

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. CMS estimates that:

- On average 25 applicants per organization will be denied on an annual basis.
- The burden associated with notification is
 - 1/12 hour, 5 minutes per notification
 - To both CMS and the State agency
 - It follows that total hourly burden is 4.167 hour = 25 x 1/12 x 2

Using this we can estimate the total burden

- 119 PO
- Each will take 4.1675 hour to respond to notification needs
- The hourly wage is 59.44
- It follows that the total burden is 119 x 4.1675 x 59.44 = \$29,478.

460.154 Enrollment Agreement

Proposed regulation, CMS-4168-P, at Section 460.154 specifies the general content requirements for the enrollment agreement. Specifically, §460.154(i) states that the enrollment agreement must provide notification that enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. This proposed rule would require additional enrollment agreement language stating that if a Medicaid-only or private pay PACE participant becomes eligible for Medicare after enrollment in PACE, he or she will be disenrolled from PACE if he or she elects to obtain Medicare coverage other than from his or her PO. CMS estimates that:

- 119 PO
- Will each require a one-time burden of 1 hour to update enrollment materials
- The hourly wage is 59.44
- The burden must be annualized over three years.
- It follows that the resulting burden is 119 x 1 x 59.44 = \$2,358.

460.156 Other enrollment procedures.

Section 460.156, including the proposed revisions of CMS-4168-P, 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; and 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.

While the ICRs listed above are subject to the PRA, CMS believes 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.

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. CMS estimates that

- 119 PO
- Will each take 12 hours, 1 hour per month, to comply with this requirement
- The hourly wage is 59.44
- It follows that the total burden is $119 \times 12 \times 59.44 = \$84,880$.

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. CMS estimates that:

- 31 State agencies
- Will each take 170 hours to complete this requirement.
- The hourly wage is \$59.44
- It follows that the total burden is $31 \times 170 \times 59.44 = \$313,249$.

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. CMS estimates:

- 31 State agencies
- Will each be required to spend annually 17 hours, 17 files x 1 hour per file
- The hourly rate is 59.44
- It follows that the total burden is $31 \times 17 \times 59.44 = \$31,325$.

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. CMS estimates that:

- 119 PO
- Will each take ½ hour to complete this requirement.
- The hourly wage is 59.44
- It follows that the total burden is $119 \times \frac{1}{2} \times 59.44 = \$3,537$.

Proposed rule, CMS-4168-P, proposes amending §460.196(d) to ensure that POs make review results available for examination not just by PACE participants, but by those individuals who may be making decisions about PACE participants' care, such as family members, caregivers and authorized representatives, because we believe they should be fully aware of the PO's performance and level of compliance with statutory and regulatory requirements. CMS estimates that

- 119 PO
- Will each take a one-time effort of a ½ hour to complete this requirement.
- The hourly wage is 59.44
- The result is annualized over three years.
- It follows that the total burden is $119 \times \frac{1}{2} \times 59.44 \div 3 = \$1,179$.

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. CMS estimates that:

- 119 PO
- Will each take 100 hours (50 hours for CMS compliance+ 50 Hours for State compliance)
- The hourly wage is 59.44
- It follows that the total burden is $119 \times 100 \times 59.44 = \$707,336$.

460.208 Financial statements

Section 460.208(a)(l) 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. CMS estimates that:

- 119 PO
- Will each take 4 hours to complete this requirement.

- The hourly wage is 59.44
- It follows that the total burden is $119 \times 4 \times 59.44 = \$28,293$.

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. CMS estimates that:

- 35 PO (25 initial applications + 10 Service area expansions)
- Will each take 16 hours (4 hours per quarter) to complete this requirement
- The hourly wage is 59.44
- It follows that the total burden is $35 \times 16 \times 59.44 = \$33,286$.

All burdens are compactly summarized in Table 1.

CFR Section	Respondent Type	Source	Issue	# Respondents	Time (hr per response)	TOTAL HOURS	Hourly Wage	Annualization factor for one time burdens	Total Cost
Regulatory Citation	Sector Affected	Source of Regulatory Citation	Requirement of regulatory citation	Estimated Number of Applicants	Hourly requirement per applicant		Hourly wages for technical staff with fringe benefits	Is this an annual requirement for 1 year or an initial requirement for the first 3 years	Total Burden = # applicants x hours/requirement x hourly wage / number of years
460.12(a)(1)	Private sector (PACE)	CMS-4168-P	Initial Applications	10 ^{2a}	34 ^{2b}	340	\$59.44 ³	1	\$20,210
460.12(a)(1)	Private sector (PACE)	CMS-4168-P	Service Area Expansions	25	16 ^{2c}	400	\$59.44 ³	1	\$23,776
460.12(a)(2)	States	CMS-R-244, OMB Control #0938-0790	State Reviews	35	20	700	\$59.44 ³	1	\$41,608
460.26(b)	Private sector (PACE)	CMS-4168-P, CMS-R-244, OMB Control #0938-0790	Waiver Requests	5 ^{2d}	8	40	\$59.44 ³	1	\$2,378
460.26(b)	Private sector (PACE)	CMS-4168-P, CMS-R-244, OMB Control #0938-0790	Waiver Requests	5 ^{2d}	20	100	\$59.44 ³	1	\$5,944

460.30(a) and (b), 460.32 ^{4a}	Private sector (PACE)	CMS-4168-P, CMS-R-244, OMB Control #0938-0790	Program Agreement	119 ^{1a}	1.5 ^{4a}	179	\$59.44 ³	1	\$10,610
460.30(c)	States	CMS-R-244, OMB Control #0938-0790	Program Agreement	31 ^{1b}	20	620	\$59.44 ³	1	\$36,853
460.68(a) ^{4b}	Private sector (PACE)	CMS-4168-P	Expand individuals who can't be employed by PO	119 ^{1a}	10	1,190	\$59.44 ³	3	\$23,578
460.68(b)(2)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Program Integrity	119 ^{1a}	0.5	60	\$59.44 ³	1	\$3,537
460.70(b)(1)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Contracted Services	119 ^{1a}	5	595	\$59.44 ³	1	\$35,367
460.71(a)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Oversight of Direct Participant Care	119 ^{1a}	55	6,545	\$59.44 ³	3	\$129,678
460.71(a)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Oversight of Direct Participant Care	119 ^{1a}	300	35,700	\$59.44 ³	3	\$707,336
460.71(a)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Oversight of Direct Participant Care	119 ^{1a}	20	2,380	\$59.44 ³	1	\$141,467
460.72(a)(3)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Physical Environment	119 ^{1a}	1	119	\$59.44 ³	1	\$7,073
460.72(c)(5)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Physical Environment	119 ^{1a}	0.5	60	\$59.44 ³	1	\$3,537
460.82(c) ^{5a}	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Marketing	119 ^{1a}	2	238	\$59.44 ³	1	\$14,147
460.102(e)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	IDT	119 ^{1a}	1	119	\$59.44 ³	1	\$7,073

460.102(e)	Private sector (PACE)	CMS-4168-P	IDT, enlarge those eligible to serve as IDT members	119 ^{1a}	1	119	\$59.44 ³	3	\$2,358
460.104(c)(3)(iii)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Participant Assessment	119 ^{1a}	1.3336	159	\$59.44 ³	1	\$9,433
460.116(c)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Explanation of Rights	119 ^{1a}	8	952	\$59.44 ³	1	\$56,587
460.116(c) ^{4c}	Private sector (PACE)	CMS-4168-P	Explanation of Rights	119 ^{1a}	5	595	\$59.44 ³	3	\$11,789
460.116(c) ^{4d}	Private sector (PACE)	CMS-4168-P	Explanation of Rights	119 ^{1a}	0.5	60	\$59.44 ³	3	\$1,179
460.120(b)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Grievance Process	119 ^{1a}	13.33	1,586	\$59.44 ³	1	\$94,274
460.120(e)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Grievance Process	119 ^{1a}	2.667 ^{2e}	317	\$59.44 ³	1	\$18,866
460.122(b)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Appeals Process	119 ^{1a}	13.328	1,586	\$59.44 ³	1	\$94,274
460.122(h)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Appeals Process	119 ^{1a}	1	119	\$59.44 ³	1	\$7,071
460.124	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Additional Appeals Rights	119 ^{1a}	2	238	\$59.44 ³	1	\$14,147
460.132(b) ^{4e}	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Quality Improvement	119 ^{1a}	8	952	\$59.44 ³	1	\$56,587
460.132(b)	Private sector (PACE)	CMS-4168-P	Quality Improvement	119 ^{1a}	1	119	\$59.44 ³	3	\$2,358

460.152(a)(3)	States	CMS-R-244, OMB Control #0938-0790	Enrollment Process	31 ^{1b}	100	3,100	\$59.44 ³	1	\$184,264
460.152(b)(4)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Enrollment Process	119 ^{1a}	4.167	496	\$59.44 ³	1	\$29,478
460.1544c ^{4f}	Private sector (PACE)	CMS-4168-P	Enrollment Agreement	119 ^{1a}	1	119	\$59.44 ³	3	\$2,358
460.156(b)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Other Enrollment Procedures	119 ^{1a}	12	119	\$59.44 ³	1	\$84,880
460.160(b)	States	CMS-R-244, OMB Control #0938-0790	Continuation of Enrollment	31 ^{1b}	170	5,270	\$59.44 ³	1	\$313,249
460.164(e)	States	CMS-R-244, OMB Control #0938-0790	Involuntary Disenrollment	31	17	31	\$59.44 ³	1	\$31,325
460.196(c)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Disclosure of Review Results	119 ^{1a}	0.5	60	\$59.44 ³	1	\$3,537
460.196(c) ^{4g}	Private sector (PACE)	CMS-4168-P	Disclosure of Review Results To Family Members	119 ^{1a}	0.5 ^{2f}	60	\$59.44 ³	3	\$1,179
460.202(a) and (b)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Health Outcomes Data	119 ^{1a}	100	11,900	\$59.44 ³	1	\$707,336
460.208(a)(1)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Financial Statements	119 ^{1a}	4	476	\$59.44 ³	1	\$28,293
460.208(c)(1)	Private sector (PACE)	CMS-R-244, OMB Control #0938-0790	Financial Statements	35 ^{2g}	16	560	\$59.44 ³	1	\$33,286
Total				119	Varies	78,378	\$59.44/hr	varies	\$2,952,350

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). We intend to extract the burden related to these application requirements from the existing OMB approved PRA package as part of our effort to revise the application process. We will address the burden related to the revised application in a separate PRA package.

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 REQUIREMENT IS ADDED TO 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 REQUIREMENT 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 REQUIREMENT 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. CMS 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, CMS believes 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. CMS solicited 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 participants 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(£) 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 spend down 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)(l) 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. CMS believes 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. CMS solicited comments on this determination and request any data on the additional determination.

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), CMS believes 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(c) states that a PACE organization must have a formal process in place to gather information related to paragraphs (a) and (b) of this section, and must be able to respond in writing to a request for information from CMS within a reasonable amount of time.

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

Onsite surveys of PACE organizations are a significant cost to the federal government. CMS is taking steps, such as revising the on-site survey instrument, to reduce the overall costs associated with the monitoring and oversight of PACE organizations. CMS will be better able to assess this cost when we submitting a paperwork package for the on-site survey instrument.

15. Program or Burden Changes

This PRA package reflects changes in CMS-R-244, corrections of errors, and proposed program changes laid out in a proposed rulemaking, CMS-4168-P. The following eight changes are reflected throughout this package

- To derive average costs, we used data from the U.S. Bureau of Labor Statistics’ May 2015 National Occupational Employment and Wage Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm). In this regard, table 2 presents the mean hourly wage, the cost of fringe benefits and support costs (calculated at 100 percent of salary), and the adjusted hourly wage for the occupation code, 29-9000, “Other Healthcare Practitioners and Technical occupations,” in the occupational category 29-0000, “Healthcare Practitioners and Technical Occupations.” This code was selected since it includes PO, CMS and State staff working in healthcare but who do not have specialist or technical specialist titles.

TABLE 2: National Occupational Employment and Wage Estimates

BLS Occupation Title	BLS Occupation Code	BLS Mean Hourly Wage (\$/hr)	Fringe Benefits and Support Costs (\$/hr)	Adjusted Hourly Wage (\$/hr)
Other Technical Occupations (hereinafter, technical staff)	29-9000	29.72	29.72	59.44

- The number of PACE organizations has been updated from 74 to 119 reflecting 2016 current figures in the CMS HPMS system. Although the scope of this PRA package is for three years, we used the initial 2016 figures since they do not involve estimates.
- The number of states in which PACE organizations operate has been updated from 25 to 31 reflecting current 2016 current figures in the CMS HPMS system.
- Based on historical data for five years, the number of initial PACE applications has been updated to 25, a maximum for the five years, and the number of service area expansions has been updated to 10, a maximum for the five years. Consequently, the number of new entities annually has been updated to 35.
- Throughout the package, one-time costs have been annualized for three years. This is consistent with the scope of this PRA package. Consequently, annual figures may be added with annualized figures to produce a true estimate of cost in each of the next three years.
- Table 1, summarizing all impacts has been updated. Columns have been added to reflect whether the source of estimates is CMS-R-244 or NPRM CMS-4168-P. To improve readability, only one derived computational column, total cost, has been retained. The other columns, are raw data reflecting number of respondents, hourly wage, hours per respondent and a factor indicating annualization. When hours per respondent can be further broken down as products this information is contained in the narrative.

- The total cost column is consequently a combination of the previous four columns (product of three columns divided by the annualization factor). Consequently, errors in the previous table, when computations were not transparent, have been eliminated.
- This PRA package reflects about half a dozen line items corresponding to program changes in proposed CMS-4168-P. Furthermore, certain line items in the PRA have been eliminated or moved based on CMS-4168-P. For example, monitoring, 460.190, has been moved from the PRA section to the RIA section in CMS-4168-P and therefore has been eliminated from this PRA package; similarly, the requirement for a marketing tracking system, 460.82, is proposed to be eliminated by CMS-4168-P and is consequently eliminated from this PRA.

56,181 hours (currently approved)

22,197 hours (rule)

+8,958 (adjustments)

87,336 hours (new)

16. Publication/Tabulation

There is no tabulation date.

17. Expiration Date

The revised expiration date will be displayed on the appropriate forms.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

There are no statistical methods.