Supporting Statement Part A
Programs for All-inclusive Care of the Elderly (PACE) and
Supporting Regulations in 42 CFR Part 460
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. Upon approval of a PACE application, CMS executes a 3-way program agreement with the applicant entity and the applicable State.

This information collection addresses all operational components of the PACE program, as defined in 42 CFR part 460, with the exception of the application process (460.12), which has been extracted from this currently-approved collection (OMB control number 0938-0790). We have determined that it is appropriate to separate the requirements and burden associated with the application component of the PACE program from the currently-approved collection requirements. As is, the currently approved CMS-R-244 package is lengthy and somewhat time consuming to review. We believe the change will help streamline the public and OMB's review of the application as well as the remaining requirements and burden under the CMS-R-244 package.

An OMB control number specific to the information collection associated with the application process has not been issued at this time. However, the CMS ID number for that collection is CMS-10631 and will not change.

A. Justification

1. Need and Legal Basis

Collection of this information is mandated by statute under Sections 1894 and 1934 of the Social Security Act and at 42 CFR part 460. This clearance request is for the information collected to ensure compliance with CMS requirements in the operation of PACE programs. The purpose of this PRA package is to update and revise, as necessary, burden estimates related to all requirements of an operational PACE program, with the exception of the PACE application process, which has been removed from this collection as explained in the "Background" section above. The requirements and burden associated with the application/waiver components of the PACE program are addressed in CMS-10631.

This collection involves all other responsibilities of a PO in relation to its PACE program, as required by regulation. This includes: the development and updating of a diverse array of policies and procedures, as well as other written plans specific to marketing, exchange of information and quality assessment and performance improvement; contracting activities with

appropriate providers and entities for the provision of medical services; writing and displaying an explanation of rights for PACE participants; and, providing PACE participants written information regarding grievance and appeals processes and rights to PACE participants. Additional detail regarding these requirements is provided in Section 12, below.

2. Information Users

CMS and the State Administering Agencies (SAAs) will use the information to monitor the performance of POs and ensure that all requisite regulatory requirements are satisfied in the course of PACE program operations.

3. Improved Information Technology

Since the 2002 interim final rule with comment was published, CMS has moved to technology-based methods of communicating with POs. Although CMS did not require the use of electronic information technology when PACE was first implemented, CMS now requires the use of Health Plan Management System (HPMS), beginning with the application process, and as part of the audit process and for ongoing communications.

4. Duplication of Similar Information

These information collection requirements do not duplicate similar information collections.

5. Small Businesses

The collection of information will have a minimal impact on small businesses since POs must, in addition to requirements that may be imposed by the applicable state administering agency, be able to accept substantial financial risk. Generally, state statutory licensure requirements effectively preclude small business from being licensed to bear risk needed to serve Medicare enrollees. State licensure for PACE organizations varies by State. In accordance with the CMS PACE regulations, the PACE organizations must meet any State licensure requirements. CMS does not require any specific licensure for PACE plans, but states are not prohibited from requiring licensure. Most States require PACE organizations to be licensed as adult day care, and some require home health and/or clinic licensure. A few states have developed a unique license for PACE.

6. Less Frequent Collection

Some information is collected annually, biannually or quarterly, particularly as it relates to the development of information specific to applications and program agreements or reporting of quality data. Other information relates to third party disclosure involving information imparted directly to PACE participants and could therefore vary depending on whether the information is participant-specific (e.g., communications regarding appeals) or communicated directly to all

participants (e.g., updating and displaying participant explanation of rights). If CMS were to collect this information less frequently, CMS would have limited mechanism to: (1) ensure that POs meet the regulatory requirements; and (2) properly monitor the performance of active POs.

The requirements covered by this ICR are identified below (with additional detail included in Section 12), along with the frequency of collection.

1) 460.30 Program agreement related to the application process. Requires the signature of authorized officials at the PO, CMS and SAA. This is a requirement associated with the submission of an application, i.e., to the extent a new entity submits an initial application or an active entity submits a SAE application. This requirement is rooted in statute and regulation.
2) 460.32 Program agreement updates. This requirement relates to updating documentation associated with the program agreement is one that is expected to occur periodically and most often is prompted by approval of an SAE application by an active PO. This would generally be done no more than once *annually*, as applicable. This requirement is based in statute and regulation.
3) 460.68 Program Integrity. Requires a PO 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. This requirement is specific to entities that submit an initial PACE application but could be modified over time. This requirement is based in regulation and provides protections to participants.
4) 460.70 Contracted Services. Requires that a PO contract only with entities that meet all applicable Federal and State requirements. This is primarily completed at the start of the program, but can be an ongoing activity to a certain extent. This is required by statute and further defined in regulation.
5) 460.71 Oversight of direct participant care. Requires a PO 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. This is completed at the start of the program, but could be modified or updated over time. This requirement is based in regulation and provides protections to participants.
6) 460.72 Physical environment. Requires that a PO establish, implement, and maintain a written plan to ensure that all equipment is maintained in accordance with the manufacturer's recommendations. This is completed at the start of the program, but could be updated over time. This requirement is based in regulation and provides protections to participants.
7) 460.82 Marketing. Requires that a PO prepare, update and maintain a marketing plan and a tracking system. This is completed at the start of the program, but could be updated over time. This requirement is based in regulation.
8) 460.102 Interdisciplinary team. Requires a PO to establish, implement, and maintain documented internal procedures governing the exchange of information between team members, contractors, and participants and their caregivers. This is completed at the start of the program, but could be updated over time.
9) 460.104 Participant assessment. This requirement entails documenting the reasons for an extension of the timeframe for notifying a participant (or designated representative) of its decision to approve or deny a request for a change in services. This is completed during the course of operations, as applicable, by the PO. Requirements are defined in

regulation.

10) 460.116 Explanation of rights. Requires a PO to establish, update and display the explanation of participant rights. This is completed at the start of the program, but could be updated over time. This is a quality assurance/participant safeguard that is rooted in statute and defined in regulation.
11) 460.120 Grievance process. Requires that, *upon enrollment, and at least annually thereafter,* the PO must give a participant written information on the grievance process. This is a quality assurance/participant safeguard that is rooted in statute and defined in regulation.
12) 460.122 PO's appeals process. Requires that, *upon enrollment, and at least annually thereafter,* and whenever the multidisciplinary team denies a request for services or payment, the PO must give a participant written information on the appeals process. This is a quality assurance/participant safeguard that is rooted in statute and defined in regulation.
13) 460.124 Additional appeal rights under Medicare or Medicaid. Requires a PO to 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. This is completed during in the course of operations, as necessary, by the PO. This is a quality assurance/participant safeguard that is rooted in statute and defined in regulation.
14) 460.132 Quality assessment and performance improvement plan. Requires a PACE governing body to review the plan *annually* and revise it, if necessary. This is required by statute and further expanded in regulation and is an important means for ensuring continuous quality care.
15) 460.152 Enrollment process. Requires the PO to notify CMS and the SAA and make the documentation available for review if a prospective participant is denied enrollment upon a determination that his or her health or safety would be jeopardized by living in a community setting. This is a quarterly notification.
16) 460.202 Participant health outcomes data. Requires a PO to furnish data and information pertaining to its provision of participant care. This is generally a quarterly collection. However, certain adverse events are expected to be reported on a timely, more frequent basis to assure proper monitoring and oversight.
17) 460.208 Financial statements. Requires a PO to submit financial statements. This is a quarterly collection that is based in regulation to assure proper monitoring and oversight.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

-Report information to the agency more often than quarterly;

-Prepare a written response to a collection of information in fewer than 30 days after receipt of it;

-Submit more than an original and two copies of any document;

-Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;

-Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;

-Use a statistical data classification that has not been reviewed and approved by OMB;

-Include a pledge of confidentiality that is not supported by authority established in statue or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

-Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register Notice/Outside Consultation

The 60-day notice published in the Federal Register on November 18, 2016 (81 FR 81772). No comments were received.

The 30-day notice published in the Federal Register on February 17, 2017 (82 FR 11037). A comment was received. We have attached that comment along with our response to this package. Based on that comment we have added private sector reporting burden (+ 1,155 hr) with respect to §460.32.

9. Payment/Gift to Respondent

There are no payments or gifts to respondents.

10. Confidentiality

Consistent with federal government and CMS policies, CMS will protect the confidentiality of requested information. Specifically, only information within a submitted application (or attachments thereto) that constitutes a trade secret, privileged or confidential information, (as such terms are interpreted under the Freedom of Information Act and applicable case law), and is clearly labeled as such by the Applicant, and which includes an explanation of how it meets one of the exceptions specified in 45 CFR part 5, will be protected from release by CMS under 5 U.S.C. 552(b)(4). Information not labeled as trade secret, privileged, or confidential or not including an explanation of why it meets one of the FOIA exceptions in 45 CFR part 5 will not be withheld from release under 5 U.S.C. 552(b)(4).

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs,

and other matters that are commonly considered private.

12. Burden Estimate (Total Hours & Wages)

When estimating the number of private sector respondents, we account for existing POs (rounded up to 120) plus a maximum of 10 new POs annually for a total estimated number of 130. (Note: To the extent certain requirements are applicable to service area expansion applicants, we include the concomitant burden.)

12.1. Wages

To derive average costs for private sector (PACE) entities, we used data from the U.S. Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). The following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage. We believe this occupation title is appropriate for all activities related to the information collections identified herein. The Other Healthcare Practitioners and Technical Occupations position is associated with the applicant's role in meeting operational requirements, as rooted in regulations, including those related to updating written operational policies and procedures, some of which require basic healthcare knowledge and a level of clinical expertise. In addition, this diverse category reflects basic technical knowledge and background necessary to assist with contracting activities and working with contractors to develop and implement various operational aspects of the PACE program, e.g., verifying the qualifications of new staff and developing and documenting procedures for the exchange of internal information.

Bureau of Labor Statistics (BLS) Occupation Title	BLS Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Other Healthcare Practitioners and Technical Occupations (hereinafter, "technical staff")	29-9000	29.72	29.72	59.44

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

To derive average costs for States' role, we used data from the U.S. Bureau of Labor Statistics' May 2015 National Industry-Specific Occupational Employment and Wage Estimates (NAICS 999200 - State Government, excluding schools and hospitals (http://www.bls.gov/oes/current/naics4_999200.htm#11-0000). The following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage (see discussion above).

Bureau of Labor Statistics (BLS) Occupation Title	BLS Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Occupational Health and Safety Specialists	29-9011	28.67	28.67	57.34

12.2. Burden Estimates

460.12 Application requirements. Section 460.12(a)(l) states that an individual authorized to act for the entity must submit to CMS a complete application. The burden associated with the information collection associated with the application process is captured as part of CMS-10631.

460.26 CMS evaluation of waiver requests.

Section 460.26(b) requires a PO or prospective PO 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 SAA. The burden associated with this collection is captured as part of CMS-10631.

460.30 Program agreement requirement. In summary, sections 460.30(a) and (b) state that a PO must have an agreement with CMS and the SAA to operate a PACE program under Medicare and Medicaid. Furthermore, the program agreement must be signed by an authorized official of the PO, CMS, and the SAA.

The burden associated with this requirement is the time and effort of officials at the state and the PO to review and sign the agreement. CMS estimates that the PO and State officials will each take 1 hour per agreement to complete this requirement. There will be a maximum of 10 new program agreements (for approved initial applications) for a burden of 20 hours annually (10 hours for 10 POs and 10 hours for each applicable SAA). (**See Estimate 1 and 2, respectively, in the burden summary table**).

460.32 Program agreement requirement. Section 460.32 outlines the required content of the program agreement, which is captured as part of the initial application process, and includes a number of different documentation requirements, such as certain policies and procedures.

We note that current practice is to update PO program agreements in their entirety when events that necessitate a change to the existing agreement, e.g., an approved SAE application that includes an expanded service area and/or the addition of a new PACE center, occur. This means that the burden extends beyond amending Appendix C of the agreement under these circumstances. While the expectation is that an active PO is continuously reviewing and updating its policies and procedures, including those explicitly captured and documented as part of the required content of the program agreement, we recognize the added burden associated with

efforts to update the agreement, particularly for active POs that have long-standing PACE programs. We estimate that POs, as part of the SAE process, will require, on average, an additional 15 hours to work with CMS to update the program agreement upon approval of an SAE application. We estimate the same number of burden hours associated with active POs that are replacing an existing PACE center, which generally does not require the submission of an SAE Application. We conservatively estimate that about 10 percent (or 12 of the 120 active POs will seek to replace an existing PACE center each year, for a total of 180 hours (12 POs x 15 hours). (We believe this is a fairly liberal estimate, since policies and procedures are expected to be reviewed and updated on an ongoing basis (see further discussion below), thereby minimizing the burden associated with updating program agreements.) The total annual burden associated with updating program agreements for active POs is 555 hours (25 SAE applications x 15 hours (375 hours) + 12 agreements as a result of replacement center activity x 15 hours (180 hours).

In addition, all 120 active POs are expected to regularly reassess and update, as necessary, all operational policies and procedures. CMS estimates that each PO will require approximately 5 hours annually to support this effort. Total burden for annual review of policy and procedures for active POs (120) is therefore estimated at 600 hours. Total aggregate burden associated with ongoing review and updates to operational procedures and related updates to the program agreement is **1,155 hours** (600 hours + 555 hours). (**See Estimate 1a in the burden summary table.)**

Section 460.30(c) provides that CMS may only sign program agreements with POs 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 PO and that the State is willing to enter into a PACE program agreement with the entity. CMS estimates that 3 states will take 20 hours to complete these requirements for a total annual burden of 60 hours (**see Estimate 3 in the burden summary table**). This burden is only applicable to initial applications proposing to locate a PACE program in a State that previously had not elected PACE as an optional Medicaid benefit. Given the historical experience with the PACE program, this estimate is based on an assumption that the majority of initial applications will propose to serve states (currently 32 states) with an existing SPA that accommodates the PACE benefit. (Note: Due to a recent mutual termination of a PO, one of the 32 states does not currently have an operational PO.) While do not expect many additional states to include the PACE program as part of their state plans in the near term, we conservatively estimate that up to 3 additional states will elect the PACE option, hence, a total of 60 estimated burden hours.

460.68 Program Integrity. In summary, Section 460.68(b)(l) requires POs 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. This requirement is specific only to entities that submit an initial PACE application, as active PACE programs would already have established policies and procedures. As part of the application process, an applicant entity must attest that it will comply with the requirements of Section 460.68, but the burden associated with this specific requirement is captured as part of this information collection. CMS estimates

that 10 entities annually will submit an initial PACE application and be subject to developing these policies and procedures. We estimate that each of these entities will take 3 hours to complete this requirement for a total of 30 hours (10 entities x 3 hours). (**See Estimate 4 in the burden summary table.**)

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 PO must document the disclosure. CMS estimates each PO will take 30 minutes to complete this requirement. We estimate approximately 130 POs for a total annual burden of 65 hours (**see Estimate 5 in the burden summary table**).

460.70 Contracted Services. Section 460.70(b)(1) requires that a PO contract only with entities that meet all applicable Federal and State requirements.

The application requires the applicant entity to attest that it will comply with the requirements of the applicable sections of 42 CFR part 460 related to contracted services, including 460.70. However, the burden associated with this requirement, i.e., to demonstrate that a PO has contracted only with appropriate entities, is captured as part of this information collection CMS estimates that 10 entities annually will submit an initial PACE application and be subject to contracting with entities that meet all applicable Federal and State requirements. The burden will vary by applicant, based on various factors, in particular, any enrollment limits that may be established by the State in which the PACE program will operate.

The burden associated with this requirement is the time and effort to: 1) verify that the entity meets all applicable requirements; 2) engage in contract negotiations; and, 3) execute contracts. CMS estimates that each of the 10 new applicants will require approximately 2 hours per contracted entity to conduct these activities. Assuming a PO has, on average, 100 contracted entities (e.g., individual practitioners, institutional providers and suppliers), we estimate approximately 2,000 hours overall related to contracting for new applicant entities (10 applicants x 100 contractors x 2 hours/contractor). In addition, POs that submit service area expansion (SAE) applications that are prompted by added geographic areas, the addition of a new PACE center, or a combination of the two, would be expected to entail some level of added contracting. The number of added contracted entities associated with SAEs could vary widely, but we conservatively estimate that each of the 25 SAE applicant entities annually would contract initially with 25 entities for a total annual burden of 1,250 hours (25 applicants x 25 contractors x 2 hours/contractor). The aggregate estimated burden associated with this requirement for both initial and SAE applicants is 3,250 hours annually. (**See Estimate 6 in the burden summary table.**)

The remaining burden associated with this requirement is the ongoing time associated with the PO's verification, and maintenance of the verification documentation, that any new contractors are qualified entities. CMS estimates that each active PO will spend 5 hours verifying the qualifications of new contractors. There will be approximately 130 POs for a total annual burden of 650 hours (**see Estimate 7 in the burden summary table**).

460.71 Oversight of direct participant care. In summary, section 460.7l(a) requires a PO 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 application requires the applicant entity to attest that it will comply with the requirements of 460.71. However, the burden associated with this requirement is captured as part of this information collection. CMS estimates that 10 entities annually will submit an initial PACE application and be subject to this requirement. 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 of the 10 initial applicant entities will spend 5 hours developing the program for each of the 11 required interdisciplinary team members for a total of 55 hours annually. Implementation of the program will require a minimum of two (2) hours per staff member for each of the 130 estimated active POs annually. Assuming a PO has an average staff (employees and contractors) of 150, carrying out the competency evaluation will consume 300 hours annually for a total of 39,000 hours (130 x 300 hours).

In addition, 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. Total burden for each of the 10 new POs could be as high as 375 hours annually (55 hours +300 hours+20 hours). Total burden for active POs (120) is estimated at 320 (300 hours + 20 hours). Total estimated burden for the 130 POs is 42,150 hours annually (375 hours x 10) + (320 hours x 120). (**See Estimate 8 in the burden summary table**). (Note: while we recognize that SAE applications that include new geographic areas and/or new PACE centers would present some level of additional staffing, we believe the average staff estimate of 150 adequately accounts for such fluctuations in staffing on an annual basis.)

460.72 Physical environment. Section 460.72(a)(3) states that a PO must establish, implement, and maintain a written plan to ensure that all equipment is maintained in accordance with the manufacturer's recommendations.

The application requires the applicant entity to attest that it will comply with the requirements of the Section 460.72, including ensuring that all equipment is maintained according to manufacturer's recommendations. However, the burden associated with this requirement, which includes 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, is captured as part of this information collection, and pertains to initial PACE applicant entities only. While we recognize that SAE applications submitted by active POs would be subject to this requirement, in most cases, existing policies established by the PO would apply. To the extent there would be revisions to those established policies, we believe such revisions would be nominal and therefore have not outlined the burden associated with SAE applicants. CMS estimates that annually, each initial PACE applicant (10) will need to prepare a written plan. We estimate that each applicant entity will require 2 hours to establish a written plan for an annual burden of 20 hours.

Further, we estimate that 130 active POs will require 1 hour to maintain the written plan, for a total annual burden of 130 hours. The aggregate estimated burden associated with the requirement to establish and maintain a written plan to ensure that all equipment is established

and maintained in accordance with the manufacturer's recommendations is 150 hours annually. (**See Estimate 9 in the burden summary table.**)

Section 460.72(c)(5) states that at least annually, a PO must test, evaluate, and document the effectiveness of its emergency and disaster plans. This provision has since been replaced by Section 460.84, as part of the Emergency Preparedness Regulations for PACE, effective November 16, 2016 [CMS-3178-F]. The burden associated with the new PACE-specific emergency preparedness requirements is captured as part of a separate collection approval (OMB Control No. 0938-NEW).

460.82 Marketing. Section 460.82(c) states that a PO 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. The translation of marketing materials to meet special language requirements 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, in order to effectively communicate with non-English-speaking participants being served by the PACE program.

The remaining burden associated with this requirement is the time and effort for the PO to prepare printed marketing materials. This burden is captured as part of the application requirements (see CMS-10631). Section 460.82(f) states that a PO must establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness. The application requires the applicant entity to attest that it will comply with the requirements of the Section 460.82(f); however, the burden associated with this requirement is captured in this information collection. We estimate that each of the 10 initial applicant entities would require 40 hours to establish a marketing plan, for a total of 400 hours annually.

The remaining burden associated with this requirement is the time and effort for a PO to update and maintain a marketing plan and a tracking system. CMS estimates that each PO will take 16 hours on an annual basis to comply with this requirement. There will be approximately 130 POs for a total annual burden of 2,080 hours. In aggregate, we estimate a total of 2,480 hours on an annual basis to comply with this requirement. (**See Estimate 10 in the burden summary table**).

460.102 Interdisciplinary team. Section 460.102(e) states that the PO must establish, implement, and maintain documented internal procedures governing the exchange of information between team members, contractors, and participants and their caregivers. The application requires the applicant entity to attest that it will comply with the requirements of the Section 460.102. However, the burden associated with the requirement to establish such internal procedures is captured as part of this information collection. CMS estimates that 10 entities annually will submit an initial PACE application and be subject to this requirement. We estimate that these entities will require 3 hours to establish the internal procedures for a total of 30 hours.

The remaining burden associated with this requirement is the time and effort for an active PO to update and maintain documented internal procedures governing the exchange of

information. CMS estimates that each PO will take 1 hour on an annual basis to complete this requirement. There will be approximately 130 POs for a total of 130 hours In aggregate, we estimate a total annual burden of 160 hours to establish, implement, and maintain documented internal procedures governing the exchange of information between team members, contractors, and participants and their caregivers (**see Estimate 11 in the burden summary table**).

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 PO to document the reasons for an extension. CMS estimates that on average there will be approximately 16 participants per PO 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 (16 participants x 10 minutes) x 130 POs = 346 annual hours of burden (**see Estimate 12 in the burden summary table**).

460.116 Explanation of rights. Section 460.116(c) states that the PO 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 PO 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. The translation of participant rights 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 establishing, updating and displaying these rights is subject to the PRA. The burden associated with the establishment of the explanation of rights is captured as part of the application requirements for initial PACE applicant entities (CMS-10631). CMS estimates that, on average, each active PO will take 2 hours on an annual basis to comply with these requirements. There will be approximately 130 POs for a total annual burden of 260 hours (**see Estimate 13 in the burden summary table**).

460.120 Grievance process. Section 460.120(b) states that upon enrollment, and at least annually thereafter, the PO must give a participant written information on the grievance process. The burden associated with this requirement is the time and effort for the PO to give a participant written information on the grievance process. CMS estimates that, on average, there will be 300 participants per PO receiving written information on the grievance process. Therefore, the burden associated with the disclosure of the grievance materials is (300 participants x 5 minutes) x 130 POs = 3,250 annual hours of burden (**see Estimate 14 in the burden summary table**).

Section 460.120(e) states that the PO 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 PO 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 PO receiving the additional written information on the grievance process, and 10 minutes will be devoted to each. Therefore, the burden associated with the disclosure of the additional grievance materials is (16 participants x 10 minutes) x 130 POs = 346 annual hours of burden (**see Estimate 15 in the burden summary table**).

460.122 PO'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 PO must give a participant written information on the appeals process.

The burden associated with this requirement is the time and effort for a PO to give a participant written information on the appeals process upon enrollment and at least annually thereafter. CMS estimates that, on average, there will be 300 participants per PO receiving written information on the appeals process at an estimated 5 minutes per participant. Therefore, the burden associated with the disclosure of the material outlining the appeals process is (300 participants x 5 minutes) x 130 POs = 3,250 annual hours of burden (**see Estimate 16 in the burden summary table**).

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 PO must notify CMS, the SAA, and the participant.

The burden associated with this requirement is the time and effort for a PO to notify CMS, the SAA, and the participant that the PO has made an adverse decision, estimated to be approximately 5 minutes per notification. CMS estimates that, on average, each PO will be required to notify 8 participants in writing of an adverse decision. Therefore, the burden associated with these disclosure requirements is 2 hours per plan, [(8 participant notifications x 5 minutes) + (8 CMS notifications x 5 minutes) + (8 State notifications x 5 minutes)] x 130 POs = 260 annual hours of burden for all POs (**see Estimate 17 in the burden summary table**).

460.124 Additional appeal rights under Medicare or Medicaid. Section 460.124 states that a PO 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 PO 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. It is estimated that these activities will require 1 hour per participant. CMS estimates that, on average, there will be 4 participants per PO 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 (4 participants x 1 hour) x 130 POs = 520 annual hours of burden (**see Estimate 18 in the burden summary table**).

460.132 Quality assessment and performance improvement plan. Section 460.132(a) states that the PO must have a written quality assessment and performance improvement plan. The burden associated with the development of this written plan is captured as part of the application requirements (see CMS-10631).

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 PO to document that the annual review was conducted and to revise the quality assessment and performance improvement plan, if necessary. CMS estimates that each PO will take 8 hours to complete this requirement. There will be approximately 130 POs for a total annual burden of 1,040 hours (**see Estimate 19 in the burden summary table**).

460.152 Enrollment process. Section 460.152(a)(3) states that the SAA 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 SAA to assess and maintain documentation of each potential participant assessment. The burden associated with requirement will vary by State, but CMS estimates that each SAA will take 100 hours to complete this requirement. Approximately 35 SAAs (assuming the 32 existing states that offer PACE, plus 3 additional states that may elect to offer PACE) are expected to be affected by this requirement for a total annual burden of 3,500 hours (**see Estimate 20 in the burden summary table**).

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 PO must notify CMS and the SAA and make the documentation available for review.

The burden associated with this requirement is the time and effort for the PO to notify CMS and the SAA of the action. CMS estimates that on average 25 prospective participants per PO 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 542 total annual hours (25 prospective participants x 10 minutes total) x 130 POs). (**See Estimate 21 in the burden summary table.**)

460.156 Other enrollment procedures. Section 460.156(a) states that after the participant signs the enrollment agreement, the PO 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 PO.

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.

The burden associated with item 4 (above) is the time and effort for a PO 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 PO. CMS estimates each PO will take 1 minute per new enrollee to complete this requirement. There will be approximately 130 POs and each will spend 1 hour a year for a total annual burden of 130 hours (**see Estimate 22 in the burden summary table**).

Section 460.156(b) states that the PO must submit participant information to CMS and the SAA, in accordance with established procedures.

The burden associated with this requirement is the time and effort for the PO to submit participant information to CMS and the SAA. CMS estimates that each PO will take 12 hours annually (1 hour per month) to complete this requirement. There will be approximately 130 POs for a total annual burden of 1,560 hours (**see Estimate 23 in the burden summary table**).

460.160 Continuation of enrollment. In summary, section 460.160(b) states that at least annually, the SAA 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 SAA to document the annual reevaluation. CMS estimates that each State agency will take 170 hours to complete this requirement. Approximately 35 SAAs are expected to be affected by this requirement, for a total annual burden of 5,950 hours (**see Estimate 24 in the burden summary table**).

460.164 Involuntary disenrollment. Section 460.164(e) states that before an involuntary disenrollment is effective, the SAA must review the documentation and determine in a timely manner that the PO has adequately documented acceptable grounds for disenrollment (key grounds for involuntary disenrollment include disruptive or threatening behavior, failure to pay premium and relocation outside the service area).

The burden associated with this requirement is the time and effort for the SAA to review and determine that the PO has adequately documented acceptable grounds for disenrollment. This includes any needed follow up per case, as well as providing the PO with written confirmation that the involuntary disenrollment is appropriate. CMS estimates 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. Approximately 35 State agencies are subject to this requirement, for a total annual burden of 595 hours (**see Estimate 25 in the burden summary table**).

460.190 Monitoring during trial period. Section 460.190(a) states that during the trial period, a 3-year period following initial approval, CMS, in cooperation with the SAA, will conduct

comprehensive annual reviews of the operations of a PO to ensure compliance with the requirements of these regulations.

The burden associated with this requirement is now captured as part of a separate collection specific to burden associated with PACE audits (CMS-10630, OMB No: 0938-1327). We are therefore removing the estimated 120 annual hours associated with this regulatory requirement that was previously captured as part of this information collection.

460.196 Disclosure of review results. Section 460.196(c) states that the PO 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 PO to post a notice. CMS estimates that each PO will take 5 minutes to complete this requirement. There will be approximately 130 POs for a total annual burden of 11 hours (**see Estimate 27 in the burden summary table**).

460.202 Participant health outcomes data. In summary, section 460.202(a) and (b) states that a PO must establish and maintain a health information system that collects, analyzes, integrates, and reports data necessary to measure the PO's performance, including outcomes of care furnished to participants. A PO 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 SAA.

The burden associated with this requirement is the time and effort for a PO to demonstrate the establishment of a health information system and to furnish data and information to CMS and the SAA 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 as part of the application requirements (see CMS-10631). The remaining burden associated with this section is the requirement to furnish information specified by CMS and the SAA. The burden associated with this collection is captured as part of CMS-10525, OMB control number 0938-1264.

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

The burden associated with this requirement is the time and effort for a PO to submit a certified financial statement. CMS estimates that each PO will take 4 hours to complete this requirement. There will be approximately 130 POs for a total annual burden of 520 hours (**see Estimate 28 in the burden summary table**).

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

The burden associated with this requirement is the time and effort for a PO to submit a quarterly financial statement. CMS estimates that each PO will take 16 hours (4 hours per quarter) to

complete this requirement. There will be approximately 15 POs that are affected by this trial period requirement for a total annual burden of 240 hours (**see Estimate 29 in the burden summary table**).

12.3. Burden Summary

Respondent Type: Private sector (PACE entities) at $59.44/hour.

Estimate #	**CFR Section**	**# Respondents**	**Time (hr per response)**	**# Responses (per respondent)**	**Total Annual Time (number of hours across all respondents)**	**Costs**
Reporting Requirements						
1	460.30(a) and (b)	10	1	1	10	$594
1a	460.32		5 hrs. (active PACE orgs (600 hrs. total), 15 hrs. (37 POs, including 25 SAEs and 12 with replacement center activity)	1	1,155	$68,653
4	460.68(b)(1)	10	3	1	30	$1,783
5	460.68(b)(2)	130	30 min	1	65	$3,864
6	460.70(b)(1)	35	2	1,625	3,250	$193,180
7	460.70(b)(1)	130	5	1	650	$38,636
8	460.71(a)	130	375 (initial applicants) 320 (active PACE orgs)	1	42,150	$2,505,397
9	460.72(a)(3)	130	20 (initial applicants) 130 (active PACE orgs)	1	150	$8,916
10	460.82(f)	130	40 (initial applicants 16 (active PACE orgs)	1	2,480	$147,411
11	460.102(e)	130	3 (initial applicants) 1 (active PACE orgs)	1	160	$9,510
12	460.104(c)(3)(iii)	130	10 min	16	346	$20,566
13	460.116(c)	130	2	1	260	$15,454
17	460.122(h)	130	2	24	260	$15,454
19	460.132(b)	130	8	1	1,040	$61,818

21	460.152(b)(4)	130	10 min	25	542	$32,216
22	460.156(a)	130	1 min	1	130	$7,727
23	460.156(b)	130	12	1	1,560	$92,726
28	460.208(a)(1)	130	4	1	520	$30,909
29	460.208(c)(1)	15	16	1	240	$14,266
Subtotal (Reporting)		*130*	*Varies*	*varies*	*54,998*	*$3,269,080*
Third-Party Disclosure Requirements						
14	460.120(b)	130	5 min	300	3,250	$193,180
15	460.120(e)	130	10 min	16	346	$20,566
16	460.122(b)	130	5 min	300	3,250	$193,180
18	460.124	130	2	4	520	$30,909
27	460.196(c)	130	5 min	1	11	$654
Subtotal (Third-Party Disclosures)		*130*	*Varies*	*Varies*	*7,377*	*438,489*
TOTAL		130	varies	Varies	62,375	$3,707,569

Respondent Type: States at $57.34/hour.

Estimate #	**CFR Section**	**# Respondents**	**Time (hr per response)**	**# Responses (per respondent)**	**Total Annual Time (all respondents)**	**Costs**
Reporting Requirements						
2	460.30(a) and (b)	10	1	1	10	$573
3	460.30(c)	3	20	1	60	$3,440
20	460.152(a)(3)	35	100	1	3,500	$200,690
24	460.160(b)	35	170	1	5,950	$341,173
25	460.164(e)	35	1	17	595	$34,117
TOTAL		35	varies	varies	10,115	$579,994

Respondent Types: Aggregate

Respondent Type	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)	Costs
Private sector (PACE entities)	130	Varies	Varies	98,365	62,375 hours	$3,714,702
States	35	Varies	Varies	665	10,115 hours	$579,994
TOTAL	165	varies	Varies	99,030	72,490	$4,294,696

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs associated with these ICRs.

14. Cost to Federal Government

To derive average costs, we used data from OPM's 2016 base salary for the Baltimore/Washington, D.C. region at the GS-13, step 5 level (www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/DCB_h.pdf). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Grade (Step)	Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
GS-13 (step 5)	50.04	50.04	100.08

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent.

Annualized Cost to Federal Government

CMS Staff	(85) hours x $100.08/hour	$8,507

The estimated cost associated with the assemble the program agreements, sign the agreements, coordinate any follow-on amendments, and provide the amendment to each applicable party, in accordance with 460.30, is $8,507. (Note: The cost to the government specific to the application process itself has been extracted from this collection and is now captured as part of CMS-10631. Cost to the government related to information collections related to oversight and monitoring components, such as audit and reporting, are accounted for and captured as part of other approved collections.)

15. Program or Burden Changes

Total annual burden, in aggregate, for this collection, is now estimated to be 72,490 hours. This represents an upward adjustment of +16,309 hours from the currently-approved estimate of 56,181 hours annually.

This revised total estimate, in large part, reflects an increase in active POs. The currently-approved burden specific to the PO (48,006 hours of the 56,181 total hours) accounts for 74 active PACE programs. We have revised the burden estimates upward to include all currently-

active PACE programs (about 120) plus an average of 10 new PACE programs resulting from initial applications submitted annually over the next 3 year approval cycle, for a total of 130 PACE plans. Based on public comment, we also added burden associated with POs efforts to annually reassess and update operational policies and procedures, as well as the burden associated with necessary updates to existing program agreements based in large part on SAE applications and replacement of existing PACE centers. The aggregate total annual burden associated with these activities is 1,155 hours, which was not captured previously as part of the currently-approved estimate.

In addition, we have extracted the application burden from this collection (previously estimated to be 3,775 hours). However, the new, automated application process relies to a significant extent on attestations and more limited documentation uploads and only captures the burden associated with the required uploads. We therefore are recognizing the burden associated with the development of required documentation that is not uploaded as part of the application in this collection, which also contributes to the increased estimated annual burden.

The burden associated with requirements related to 460.72(c)(5), regarding emergency preparedness and 460.202(a) and (b), regarding participant health outcomes data, is now captured as part of separate information collections, resulting in a decrease of -7,437 annual burden hours. In addition, the annual burden associated with trial period audits related to 460.190 (Monitoring during trial period) are captured as part of a separate information collection (CMS-10630, OMB No: 0938-1327). We are therefore removing the estimated 120 annual hours associated with this regulatory requirement that was previously captured as part of this information collection.

The total annual burden attributed to the states' role in this collection is now 10,115 hours, which represents an increase of 1,940 hours compared to the currently-approved collection (8,175 total annual hours). This estimate no longer includes applicable state burden (500 hours) related to the application process (460.12(a)(2)). However, while the estimated hour per response for the state's tasks associated with 460.152(a)(3), 460.160(b) and 460.164(e) remains the same, the total estimated annual burden has increased because the estimate is based on a greater number of states (35 instead of 25). (See applicable discussion in Section 12.2 above.)

16. Publication and Tabulation Dates

There is no tabulation date.

17. Expiration Date

The expiration date will be displayed.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

There are no statistical methods.