Supporting Statement Part A
Programs of All-Inclusive Care for 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 three-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 and waiver processes (§§460.12, 460.26 and 460.28), which is approved by OMB under control number 0938-1326 (CMS-10631, expiration date December 31, 2021) and;
- The PACE Quality Data monitoring and reporting requirements (§§460.130(d), 460.200(b)(1), 460.200(c) and 460.202), approved by OMB under control number 0938-1264 (CMS-10525, expiration date June 30, 2020).

This revised Paperwork Reduction Act (PRA) package includes changes made to the PACE program as a result of the PACE Final Rule, CMS-4168-F, published June 3, 2019, as well as previously approved requirements. The revisions to this PRA are extensive due to factors including the PACE Final Rule provisions, intricate and/or in some cases nuanced changes to existing provisions, and complex and numerical errors in the existing PRA approval. To clarify and eliminate ambiguities, CMS revised this package to streamline, reflect changes to existing COI activities, and eliminate ambiguous, extraneous and/or duplicative information. Consequently, this PRA package has been reconstructed and is being submitted as a standalone package. Section 15 provides a summary comparison of this revised PRA package with the current PRA.

In addition to substantive changes, this PRA package has been revised, streamlined, and reorganized in the following ways:

i) Identifies the associated regulatory citation in the Section 12.2 narrative and the Section 12.3 summary table;
ii) Separately discussing the burden impact of each provision, under unique headers, and assigning each provision its own line item in the summary table;
iii) To assist in obtaining key subtotals, identifying provisions according to the group of stakeholders impacted and the nature of the regulatory source;
iv) Establishing three groups of affected stakeholders: PACE Organizations (POs), third party disclosures, and states; and
v) Identifying three types of regulatory sources: “existing,” “PACE Final Rule (New),” and “PACE Final Rule Modification.” The term “existing” refers to current

provisions which were continued. The term "PACE Final Rule (New)" refers to new provisions introduced in the PACE Final Rule, 84 FR 25610, June 3, 2019. The term "PACE Final Rule Modification" refers to existing provisions that were modified by the PACE Final Rule.

Summary of the PACE Final Rule, CMS-4168-F

The PACE Final rule addressed various operational requirements, providing for greater flexibility, removing redundancies and outdated information, and codifying existing practice. A summary of the PACE Final Rule provisions is below:

Global Change for Quality Improvement (QI): Terminology Change (Part 460)
The final rule replaces all references to "quality assessment and performance improvement" with the term "quality improvement."

Content and Terms of PACE Program Agreement (§460.32)
Sections 460.32 and 460.180(b) require that PACE program agreements specify the methodology used to calculate the Medicare capitation rate. CMS amended §460.32(a)(12) by requiring that the program agreement include the Medicaid capitation rates or the Medicaid payment rate methodology.

Governing Body (§460.62)
Section 460.62(a)(7) requires that a PO's governing body be able to administer a quality improvement program as described in §460.130.

Compliance Oversight Requirements (§460.63)
Section 460.63 requires POs to have a compliance oversight program for responding to compliance issues, investigating potential compliance problems, and correcting non-compliance and fraud, waste and abuse.

Personnel Qualifications for Staff with Direct Participant Contact (§460.64(a)(3))
Section 460.64(a)(3) now allows POs to hire employees or contractors with less than 1 year of experience working with a frail or elderly population as long as they meet all other qualification requirements under §460.64(a) and receive appropriate training.

Program Integrity (§460.68(a))
Section §460.68(a)(3) enables POs to determine whether an individual's contact with participants would pose a potential risk because the individual has been convicted of criminal offenses related to physical, sexual, drug, or alcohol abuse or use, rather than entirely prohibiting the hiring of such individuals. §460.68(a)(4) prevents POs from employing or contracting with individuals or organizations who have been found guilty of abusing, neglecting, or mistreating individuals by a court of law. §460.68(a)(5) prevents POs from employing individuals or contracting with organizations or individuals who have been convicted of any of the crimes listed in section

1128(a) of the Act.

Marketing (§460.82)
Section 460.82(e)(4) allows the use of non-employed agents/brokers, provided they are appropriately trained, to market PACE programs. In addition, the scope of prohibited marketing practices was expanded to include additional means of marketing through unsolicited contact. Lastly, the requirement at §460.82(f) that POs establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a tracking system was removed.

Interdisciplinary Team (IDT) (§460.102)
Section 460.102(c)(1) allows primary care to be furnished by a "primary care provider" rather than a "primary care physician." Section 460.102(b) allows one individual to fulfill two separate roles on an IDT when the individual meets applicable state licensure requirements and is qualified to fill each role. The requirement that members of the IDT must serve primarily PACE participants has been eliminated.

Participant reassessment (§460.104)
In §460.104(b), if the IDT determines from its assessment that certain services do not need to be included in the participant's care plan, the IDT must document in the care plan the reasons why such services are not needed. CMS removed the requirement in §460.104(c)(2) requiring annual reassessments by the physical therapist, occupational therapist, dietician, and home care coordinator. §460.104(d)(2) now specifies that the appropriate members of the IDT may use remote technologies to conduct unscheduled reassessments when a participant or his or her caregiver or designated representative makes a request to initiate, eliminate, or continue a particular service, and the service request will likely be deemed necessary to improve or maintain the participant's overall health status.

Plan of Care (§460.106)
Section 460.106(a) now requires that the IDT develop the plan of care within 30 days of the participant's enrollment date. In §460.106(b), the following new care plan requirements were added, i.e. the plan of care must: (1) utilize the most appropriate interventions for each of the participant's care needs that advances the participant toward the measurable goals and desired outcomes; (2) identify each intervention and how it will be implemented; and (3) identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes.

Explanation of Rights (§460.116)
Section 460.116(c)(1) requires 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.

Quality Improvement General Rule (§460.130)
Section 460.140 was removed and consolidated within §460.130 in an effort to combine all the general rules for quality improvement under subpart H.

Quality Improvement (QI) Plan (§460.132)
CMS revised §460.132(a) and (c)(3) by referring to a quality improvement (QI) plan and removed all references to "assessment and performance," and, specified that POs must have a written QI plan that is collaborative and interdisciplinary in nature.

Enrollment Agreement (§460.154)
Section 460.154(i) adds new 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 their PO.

Other Enrollment Procedures (§460.156)
Section 460.156(a) outlines the items that POs are required to provide to PACE participants upon enrollment, including a membership card. The PACE Final Rule eliminated the requirement that POs provide participants with stickers for their Medicare and Medicaid cards, and instead are required to include the PO's phone number on the participant's PO membership card.

Involuntary Disenrollment (§460.164)
Section 460.164(b)(3) now permits involuntary disenrollment in situations where the participant's caregiver engages in disruptive or threatening behavior.

Disclosure of Review Results (§460.196)
CMS amended §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.

Maintenance of Records and Reporting of Data (§460.200)
In Sections 460.200(f)(ii) and (iii), CMS changed the medical record retention requirement from six years to 10 years.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Collection of this information is mandated by statute under Sections 1894 and 1934 of the 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.

In addition, this revision request updates the burden estimates associated with the requirements of an operational PACE program, which are outlined in Section 12.

2. Purpose and Use of Information Collection

Information addressed is based on regulatory requirements associated with active POs and is related to the operational aspects of a PACE program. CMS and the 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. Use of Improved Information Technology and Burden Reduction

CMS requires the use of the Health Plan Management System (HPMS) for all initial communications, including the application phase, as well as ongoing communications. POs will continue to utilize HPMS to comply with the requirements outlined in this PRA, as well as other IT applications, such as electronic mailboxes and their internal systems to communicate with and submit necessary information and/or documents to CMS and the states.

4. Duplication of Efforts

These information collection requirements do not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

This collection of information will not have significant impact on small businesses. There are several reasons for this.

First, 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 POs varies by state. In accordance with the CMS PACE regulations, the POs 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 POs 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.

Additionally, as noted in Final Rule 84 FR 25,610 (June 3, 2019), the Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has significant impact on a substantial number of entities. However, the final rule has a net impact of savings, not cost, and consequently, this Final Rule did not prepare an analysis for the RFA because it determined, and the Secretary certifies, that the changes of this regulation would not have a significant economic impact, nor net additional costs requiring possible regulatory relief, on a substantial number of small entities.

Thirdly: Section 1102(b) of the Act requires a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. As previously explained, this Final Rule will allow for increased staffing flexibility among POs; therefore, we are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

6. Less Frequent Collection

This PRA includes various aspects of an operational PACE program and requires information to be collected from POs at various intervals, including annually, quarterly, a one-time occurrence, or on an as needed basis. Some of the intervals are driven by regulation, and others are dependent on individual circumstances, (e.g., the need to update a Program Agreement due to the addition of a new PACE center).

Note that some of the requirements relate to third party disclosures and involve information given directly to PACE participants. The frequency for these disclosures vary depending on whether the information is participant-specific (e.g., appeal rights for denials of PACE services) or items communicated more broadly to all participants (e.g., updating and displaying participant rights). If CMS were to collect or require 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.

Section 12 provides a sequential discussion by regulatory paragraphs, and identifies the status of each provision (i.e., existing provision, new provision due to the Pace Final Rule, or a modification to an existing provision by the Pace Final Rule). We defer discussion on this until Section 12 since some of the provisions contain a mix of existing, new, and/or modifications to existing requirements.

1) 460. Global Change for Quality Assessment and Performance Improvement. (QI) Terminology Change. The Final Rule requires that all references to the terms "quality assessment and performance improvement" be replaced with the term "quality improvement."
2) 460.30 Program agreement related to the application process. Requires the signature of authorized officials at the PO, CMS and SAA. This requirement is 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.
3) 460.32 Content and Terms of PACE Program Agreement. 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.
4) 460.63 Compliance Oversight Program. Requirements. Requires POs to have a compliance oversight program for responding to compliance issues, investigating potential compliance problems, and correcting noncompliance and fraud, waste and abuse.
5) 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. The PACE Final Rule added provisions regarding the hiring of individuals who have been convicted of certain criminal offenses.
6) 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.
7) 460.71 Oversight of direct participant care. Requires a PO to develop a competency

evaluation program to ensure that employees and/or contractors providing direct participant care have the skills, knowledge, and ability to perform the duties associated with their positions.

8) 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.
9) 460.82 Marketing. The Final Rule now allows the use of non-employed agents/brokers, provided they are appropriately trained, to market PACE programs. The scope of prohibited marketing practices has been expanded to include additional means of marketing through unsolicited contact. In addition, the updated rule removed the requirement that POs establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a tracking system.
10) 460.102 Interdisciplinary team (IDT). 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 done at the start of the program, but could be updated over time. The PACE Final Rule now allows primary care to be furnished by a "primary care provider" rather than a "primary care physician," and, one individual may now fulfill two separate roles on the IDT provided the individual meets applicable state licensure requirements and is qualified to fill each role.
11) 460.104 Participant reassessment. 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. Also, the PACE Final Rule now requires that if the IDT determines from its assessment that certain services do not need to be included in the participant's care plan the reasons why such services are not needed. In addition, the IDT may use remote technologies to conduct unscheduled reassessments when a participant or his or her caregiver or designated representative makes a request to initiate, eliminate or continue a particular service, and the service request will likely be deemed necessary to improve or maintain the participant's overall health status.
12) 460.106 Plan of care. Requires that a participant's plan of care be developed by the IDT within 30 days of the participant's date of enrollment. In addition, there are three new requirements regarding the content of the plan of care, and pertain to participant interventions, goals, implementation, determining progress and desired outcomes.
13) 460.116 Explanation of rights. Requires a PO to establish, update and display the explanation of participant rights. This is done at the start of the program, but could be updated over time. The PACE Final Rule now requires 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 five percent of the individuals in the PO's service area.
14) 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.
15) 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.
16) 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 the course of operations, as necessary, by the PO.

17) 460.132 Quality improvement (QI) plan. Requires a PACE governing body to review the quality improvement plan annually and revise as needed. The PACE Final Rule now requires that POs have a written quality improvement plan that is collaborative and interdisciplinary in nature.
18) 460.154 Enrollment Agreement. Requires that the enrollment agreement provide notification that enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. The PACE Final Rule added new 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 their PO.
19) 460.156 Other Enrollment Procedures. Requires that POs provide participants with certain items upon enrollment, including a membership card. The PACE Final Rule eliminated the requirement that POs provide participants with stickers for their Medicare and Medicaid cards, and instead are required to include the PO's phone number on the participant's PO membership card. In addition, Section 460.156(b) states that the PO must submit participant information to CMS and the SAA in accordance with established procedures.
20) 460.164(b)(3) Involuntary Disenrollment. The PACE Final Rule now permits involuntary disenrollment in situations where the participant's caregiver engages in disruptive or threatening behavior.
21) 460.196 Disclosure of Review Results. The PACE Final Rule now requires 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.
22) 460.208 Financial statements. Requires a PO to submit financial statements, which assures 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

Serving as the 60-day notice, the CMS-4168-P proposed rule (RIN 0938-AR60) published in the Federal Register on August 16, 2016 (81 FR 54666). No PRA-related comments were received.

The CMS-4168-F final rule published in the Federal Register on June 3, 2019 (84 FR 25610).

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 PO respondents, due to the time lapse from when the final PACE Final Rule, CMS-4168-F was released, we now account for 134 POs. To the extent certain

requirements are applicable to service area expansion (SAE) applicants, we include that burden as well using current estimates of 35 SAEs per year.

12.1. Wages

To derive average costs for both POs and public entities (the states), we used data from the U.S. Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/current/oes_nat.htm#29-0000). This data is the most current. The following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

We believe the BLS occupation title (Other Healthcare Practitioners and Technical Occupations) is appropriate for all activities related to the information collections identified herein for POs. The position is associated with the applicant's role in meeting regulatory and operational requirements, including those related to updating written operational policies and procedures, some of which require basic healthcare knowledge and a level of clinical expertise. This diverse category reflects basic technical knowledge and background necessary to assist with contracting activities and working with PACE staff (both employed and contracted) to develop and implement various operational aspects of the PACE program.

We believe the BLS occupation title (Occupational Health and Safety Specialist) is appropriate for all activities related to the information collections identified herein for state entities. The position is associated with the applicant's role in reviewing, evaluating and analyzing PACE environmental, operational and other program requirements, and assisting POs in complying with these requirements.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Other Healthcare Practitioners and Technical Occupations (hereinafter, "technical staff")	29-9000	27.22	27.22	54.44
Occupational Health and Safety Specialists	19-5011	36.68	36.68	73.36

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, because both fringe benefits and overhead costs vary significantly from employer to employer. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

12.2. Information Collection Requirements and Associated Burden Estimates

The COI activities requirements in this PRA package include provisions that already exist in the program, new requirements arising from the PACE Final Rule, and modifications of existing

requirements arising from the PACE Final Rule. We further clarify that burden estimates for all provisions are modified throughout due to some combination of: i) changes in labor wages; ii) changes in the number of POs; and iii) changes in other estimates such as the number of service area expansions per year.

As mentioned in Section 1, the classification of each provision corresponds to the regulatory paragraphs. We have sought where possible to clearly indicate the associated regulatory section and indicated the provision type, i.e., existing, new, and/or modified as a result of the PACE Final Rule. To achieve clarity the following conventions are noted:

- Consistency of Summary Table and Narrative sections: The same classification is used in both the Section 12.2 Narrative and Section 12.3 Summary Table.
- Source of error and confusion: As noted above, we are revising several numerical errors from the existing package and adding additional burden hours through new, existing and/or modified COI requirements.
- Key Subtotals: While we do not provide additional tables, key subtotals are indicated by stakeholder (POs, third party disclosure, and states), and type of regulatory source, for example, existing, PACE Final Rule (New), and/or PACE Final Rule Modification.
- Identification of provisions: As aforementioned in Section 1, to provide a clear outline of each provision, the following identification system is used: The Summary Table lists provisions sequentially by regulatory section order; regulatory paragraphs (or descriptions) for each section are identified by a unique title or paragraph description, and are included in both the Summary Table and Narrative sections. Additionally, the Summary Table lists provisions in the same order in which they appear in the Narrative section.

These changes are intended to increase readability and public comprehension, avoid substantive or mathematical errors, and ensure accuracy in future PRA packages.

460 Global Quality Improvement (QI) Terminology Change *(Pace Final Rule (New))*

The final rule replaces all references to "quality assessment and performance improvement" with the term "quality improvement" in §§460.32(a)(9), 460.60(c), 460.62(a)(7), 460.70(b)(1)(iii), 460.120(f), 460.122(i), 460.130(a), 460.132(a) and (c)(3), 460.134(a), 460.136(a), (b), (c), (c)(1) and (c)(2) 460.138(b), and 460.172(c). The change also affects the heading for subpart H and the section headings for §§460.132, 460.134, and 460.136.

The burden associated with this includes a one-time burden estimate of 1 hour at $54.44/hr for technical staff to replace or amend existing written materials with the updated term. In aggregate, we estimate an annualized burden of 44.7 hours ([134 PO x 1 hour] ÷ 3 years) at an annualized cost of $2,433 (*44.7 hr. x $54.44/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires.

460.30 Program Agreement Requirement

New Program Agreements: PO & SSA Burden (Existing)
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. In addition, an authorized official of the PO, CMS, and the SAA must sign the program agreement.

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 each PO will take one hour per agreement to complete this requirement. We estimate there will be a maximum of 10 new program agreements annually.

There is burden to both POs and SSAs. For POs we estimate an annual burden of 10 hours at a cost of $544 (10 hr x $54.44/hr). For each SSA, we estimate state Officials will incur an annual burden of 10 hours at a cost of $734 (10 hr x $73.36).

State Plan Amendment (Existing)

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. This burden is only applicable to initial applications proposing to locate a PACE program in a state that has not yet elected PACE as an optional Medicaid benefit**.**
We estimate there will be three states incurring this burden annually. 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 it considers the entity to qualify to be a PO. The state must also be willing to enter into a PACE program agreement with the entity. CMS estimates that three states will take 20 hours to complete these requirements for a total annual burden of 60 hours (3 states x 20 hr/state) at a cost of $4,402 (60 hr x $73.36/hr).

460.32 Content and Terms of PACE Program Agreement

Section 460.32 outlines the required content of the program agreement. POs are required to update PO program agreements in their entirety when events that necessitate a change to the existing agreement occur, such as an approved Service Area Expansion (SAE) application, which includes an expanded service area and/or the addition of a new PACE center. In addition, POs are required to continuously and/or routinely review and update policies and procedures, including those explicitly captured in the program agreement.

Service Area Expansion (SAE) (Existing)
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. Throughout this PRA, we estimate 35 SAEs annually.

The annual burden associated with updating program agreements as part of the SAE process is 525 hours (35 SAE applications x 15 hours) at a cost of $ 28,581 (525 hr x $54.44/hr).

PACE Replacement Center (Existing)
We estimate 15 burden hours associated with active POs that are replacing an existing PACE center. We conservatively estimate that approximately 12 POs will seek to replace an existing

PACE center each year, for a total of 180 hours (12 POs x 15 hours) at a cost of $9,799 (180 hr x $54.44/hr.

Routine Review and Maintenance (Existing)
All 134 active POs are expected to regularly reassess and update, as necessary, all operational policies and procedures. CMS estimates that each PO will require approximately 4.5 hours annually to support this effort. Total burden for annual review of policy and procedures for active POs is therefore estimated at 603 hours (134 POs x 4.5 hr) at a cost of $32,827(603 hr x $54.44/hr).

460.63 Compliance Oversight Requirements

The final rule created a new section, requiring POs to have a compliance oversight program for responding to compliance issues, investigating potential compliance problems, and correcting non-compliance and fraud, waste and abuse.

Policies and Procedures (PACE Final Rule (New))
For each PO, we estimate a one-time burden of 15 hours at $54.44/hr for technical staff to create written training materials and written procedures for the expansion of a PO's existing system of responding to and correcting non-compliance (that the PO previously established in its role as a Part D plan sponsor) to prospectively encompass all of its PACE operations. In aggregate, we estimate an annualized burden of 670 hours ([134 PO x 15 hour] ÷ 3) at a cost of $ 36,475 (670 hr. x $54.44/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's three-year approval period expires.

Self-Report of Potential Fraud or Misconduct (PACE Final Rule (New))
To estimate the annual burden of self-reporting potential fraud or misconduct to CMS and the SAA as required by § 460.63(c), we estimate each PO would take 20 hours annually. Therefore, the aggregate hourly burden is 2,680 hr. (134 POs x 20 hours), at an aggregate cost of $145,899 (2,680 hr. x $54.44 /hr).

460.68 Program Integrity

Section 460.68 guards against potential conflicts of interest or certain other risks individuals and organizations could present to the integrity of the PACE program. Final rule amendments to §460.68(a) added three new requirements:

- §460.68(a)(3) requires POs to determine whether an individual's contact with participants would pose a potential risk because the individual has been convicted of criminal offenses related to physical, sexual, drug, or alcohol abuse or use, rather than entirely prohibiting the hiring of such individuals.

- §460.68(a)(4) prohibits POs from employing or contracting with individuals or organizations who have been found guilty of abusing, neglecting, or mistreating individuals by a court of law or who have had a finding entered into the state nurse aide registry concerning abuse, neglect, mistreatment of residents, or misappropriation of their property.

- §460.68(a)(5) added a new restriction that prevents POs from employing individuals or contracting with organizations or individuals who have been convicted of any of the crimes listed in section 1128(a) of the Act.

We describe the burden associated with these requirements below:

Program Integrity Policies and Procedures (PACE Final Rule (New))
We anticipate that these changes may result in POs revising their written policies and procedures related to the hiring of individuals with criminal histories and revising their employment applications. We estimate a one-time burden of 10 hr at $54.44/hr for technical staff to make these revisions to the written policies and procedures. In aggregate, we estimate an annualized burden of 446.7hours ([134 POs x 10 hr]/3 yr) at a cost of $24,318 (446.7 hr x $54.44/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's three-year approval period expires.

Conflict of Interest Policies and Procedures (Existing)
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. 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 three hours to complete this requirement for a total of 30 hours (10 entities x 3 hours) at a cost of $1633 (30 hr x 54.44/hr).

Conflict of Interest Disclosure (Existing)
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 134 POs for a total annual burden of 67 hours at a cost of $3,647 (67 hr x $54.44/hr). In the absence of more specific data, we maximally assume that each PO adds at least one board member annually.

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 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.

New Applicants (Existing)
CMS estimates that each of the 10 new applicants will require approximately two 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) at a cost of $ 108,880 (2,000 hr x $54.44/hr).

SAE and/or New PACE Center (Existing)
In addition, POs that submit SAE applications, add a new PACE center, or a combination of the two, would be expected to have a need for additional contracting. The number of added contracted entities associated with SAEs could vary widely, but we conservatively estimate that each of the 35 SAE applicant entities annually would contract initially with 25 entities for a total annual burden of 1,750 hours (35 applicants x 25 contractors x 2 hours/contractor) at a cost of $ 95,270 (1,750 hr x 54.44/hr.

Ongoing Maintenance (Existing)
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 five hours verifying the qualifications of new contractors. There will be approximately 134 POs for a total annual burden of 670 hours at a cost of $ 36,475 (670 hr x $54.44/hr).

460.71 Oversight of Direct Participant Care

Section 460.7l (a)(2) 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.

Competency Evaluations: Initial applications (Existing)
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 and document the results. CMS estimates a burden of 550 hours (10 initial applicant entities x 11 interdisciplinary team members per applicant x 5 hours per interdisciplinary team member) at a cost of $ 29,942 (550 hr x $54.44/hr).

Annual Competency Evaluations: All PO staff (Existing)
Implementation of the program will require a minimum of two (2) hours per staff member for each of the 134 active POs annually. Estimating an average staff (employees and contractors) of 150, carrying out the competency evaluation will consume 300 hours annually for a total of 40,200 hours (134 POs x 300 hours [40,200] at a cost of $2,188,488 (40,200 hr x $54.44/hr).

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.

Written Plan for New Applicants (Existing)
The burden associated with this requirement includes the time and effort for new PACE applicants to establish and maintain a written plan to ensure that all equipment is maintained in accordance with the manufacturer's recommendations. CMS estimates that annually, each initial PACE applicant (10) will need to prepare a written plan. We estimate that each applicant entity

will require two hours to establish a written plan for an annual burden of 20 hours at a cost of $1,089 (20 hr x $54.44/hr).

Maintain Written Plan (Existing)
We estimate that 134 active POs will require one hour to maintain the written plan, for a total annual burden of 134 hours at a cost of $7,295 (134 hr x $54.44/hr).

460.82 Marketing

Revise Policies and Procedures (PACE Final Rule (New))
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 final rule at § 460.82(e)(4)(i) and (ii) now allows the use of non-employed agents/brokers, provided they are appropriately trained, to market PACE programs. The final rule also expands the scope of prohibited marketing practices to include additional means of marketing through unsolicited contact.

The burden associated with these provisions is the one-time burden of updating marketing policies and materials. We however do not anticipate for example additional training for non-employed agents/brokers since the already existing training in place would be applicable to them. The change includes who may take the training, not the training itself.

We estimate a one-time burden of five hours at $54.44/hr for technical staff to revise the written marketing policies and materials. In aggregate, we estimate an annualized burden of 223.3 hours ([134 POs x 5 hr]/3 yr) at a cost of $12,156 (223.3 hr x $54.44/hr).

Removal of Requirement for a Documented Marketing Plan
The final rule removed §460.82(f), which required that POs establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness. Therefore, we estimate a burden reduction related to removing the requirements for the marketing plan and the tracking system. Note that we did not list this in the summary table because the former burden of creating a marketing plan was removed, resulting in zero hours of work for the marketing plan.

460.102 Interdisciplinary Team (IDT)

The final rule at § 460.102(c)(1)(i-iv) now allows primary care to be furnished by a “primary care provider” rather than a “primary care physician.” The PO must revise or develop policies and procedures for the oversight of its primary care providers.

The final rule also permits a PO to have one individual fulfill two separate roles on an IDT when

the individual meets applicable state licensure requirements and is qualified to fill each role and able to provide appropriate care to meet the participant's needs. Lastly, CMS has eliminated the requirement that members of the IDT must serve primarily PACE participants.

Update Policies and Procedures (PACE Final Rule Modification)
We estimate a one-time burden of one hour at $54.44/hr for technical staff to update their PO's policy and procedures. In aggregate, we estimate an annualized burden of 44.7 hours ([134 POs x 1 hr]/3 yr) at a cost of $2,433 (44.7 hr x $54.44/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB' 3-year approval period expires.

Information Exchange-New Applicants (Existing)
Section 460.102(f) 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. 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 at a cost of $1633 (30 hr x $54.44/hr).

Information Exchange-Active POs (Existing)
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 one hour on an annual basis to complete this requirement. There will be approximately 134 POs for a total of 134 hours at a cost of $7,295.

460.104 Participant Assessment

Documenting Services Not Needed (PACE Final Rule (New))
Section 460.104 sets forth the requirements for PACE participant assessments. CMS now requires that if the IDT determines from its assessment that certain services do not need to be included in the participant's care plan. In the final rule, revisions to §460.104(b) now require that the IDT must document in the care plan the reasons why such services are not needed and are not included in the plan.

As both the development of and updates to the care plan are a typical responsibility for the IDT we believe that any burden associated with this would be incurred by persons in their normal course of business.

In addition, we removed the requirement in §460.104(c)(2) requiring annual reassessments by the physical therapist, occupational therapist, dietician, and home care coordinator.

Participant Reassessment and Remote Technology (PACE Final Rule Modification)
CMS also revised §460.104(d)(2) to specify that the appropriate members of the IDT may use remote technologies to conduct unscheduled reassessments when a participant or his or her caregiver or designated representative makes a request to initiate, eliminate or continue a particular service, and the IDT determines that the use of remote technology is appropriate and the service request will likely be deemed necessary to improve or maintain the participant's

overall health status and the participant or his or her designated representative agrees to the use of remote technology.

While these requirements involve a collection of information, we believe that the burden associated with these 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.

Participant Reassessment (Existing)

Section 460.104(d)(2)(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, approximately 16 participants per PO will request a reassessment, and the team determines the additional time needed to respond to the reassessment request. We estimate that each reassessment will take 10 minutes (0.0167 hr). Therefore, the burden associated with this requirement is 357 annual hours (16 participants x 0.0167 x 134 POs) at a cost of $19435 (357 hr x $54.44/hr).

***460.106 Plan of Care** (PACE Final Rule Modification)*

Section 460.106(a) requires that a participant's plan of care be developed by the IDT promptly. This final rule amends this requirement by specifying that the IDT must develop the plan of care within 30 days of the participant's date of enrollment. In addition, CMS finalized the following three new requirements pertaining to the content of the plan of care at §460.106(b):

(1) The plan must utilize the most appropriate interventions for each of the participant's care needs that advances the participant toward the measurable goals and desired outcomes;
(2) The plan must identify each intervention and how it will be implemented; and
(3) The plan must identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes.

While these requirements involve a collection of information, we believe that the burden associated with these requirements is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

460.116 Explanation of Rights

Section 460.116(a) requires that POs have written policies and procedures to ensure that the participant, his or her representative, if any, understand their rights as a PACE participant. This provision is interpreted to mean 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 burden associated with establishing, updating and displaying these rights is subject to the PRA.

Note: 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.

Explanation of (Participant) Rights (Existing)
CMS estimates that, on average, each active PO will take two hours on an annual basis to comply with the requirements at §460.116(a). There will be approximately 134 POs for a total annual burden of 268 hours at a cost of $14,590 (268 hr x $54.44/hr).

Revise Explanation of Rights (PACE Final Rule Modification)
The final rule at § 460.116(c)(1) now requires 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 five percent of the individuals in the PO's service area.

We anticipate that these changes may result in technical staff revising documents. We estimate a one-time burden of 5 hours at $54.44/hr for technical staff to revise the written material about participant rights. In aggregate, we estimate an annualized burden of 223.3 hours ([134 POs x 5 hr]/3 yr) at a cost of $12,156 (223.3/hr x $54.44/hr).

Redisplay "Participant Rights" as "PACE Participant Rights" (PACE Final Rule Modification)
Section 460.116(c)(2) states that the PO must display the participant rights in a prominent place in the PACE center. The final rule requires POs to add the word "PACE" before the words "participant rights," and must therefore be displayed as "PACE Participant Rights."

We anticipate that these changes may result in technical staff revising documents. Since the only change is the addition of the word "PACE" and redisplay of notices, we estimate a one-time burden of 0.5 hour at $54.44.02/hr for technical staff to revise the notices. In aggregate, we estimate an annualized burden of 22.3 hours ([134 POs x 0.5 hr]/3 yr) at a cost of $1,214 (22.3 hr x $54.44/hr). We are annualizing the one-time estimates since we do not anticipate any additional burden after OMB's three-year approval period expires.

460.120 Grievances

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.

Grievance Process (Existing)
CMS estimates that, on average, there will be 300 participants per PO receiving written

information on the grievance process. We estimate that for each participant approximately five minutes (0.0833 hr) will be spent. Therefore, the burden associated with the disclosure of the grievance materials is 3,349 annual hours (300 participants x 0.0833 x 134 POs) at a cost of $182,320 (3,349 hr x $54.44/hr).

Additional Written Information (Existing)
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 (0.1667 hr) will be devoted to each. Therefore, the burden associated with the disclosure of the additional grievance materials is 357 annual hours (16 participants x 0.01667 x 134 POs) at a cost of $19,435 (357 hr x $54.44/hr).

460.122 PO 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.

Appeals Process (Existing)
CMS estimates that, on average, there will be 300 participants per PO receiving written information on the appeals process at an estimated five minutes per participant (0.0833 hr). Therefore, the burden associated with the disclosure of the material outlining the appeals process is 3,349 annual hours (300 participants x 0.0833 x 134 POs) at a cost of $182,320 (3,349/hr x $54.44/hr).

Appeal Determination Notification (Existing)
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, and is estimated to be approximately five minutes per notification (0.0833 hr). CMS estimates that, on average, each PO will be required to notify eight participants in writing of an adverse decision. Therefore, the burden associated with these disclosure requirements is 268 hours for all POs (8 participant notifications x 0.0833 hr) + (8 CMS notifications x 0.0833 hr) + (8 State notifications x 0.0833 hr)] x 134 POs) at a cost of $14,590 (268 hr x $54.44/hr).

460.124 Additional Appeal Rights under Medicare or Medicaid *(Existing)*

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. CMS estimates that these activities will require one hour per participant, and on average, there will be four participants per PO receiving written information and assistance related to their appeal rights. Therefore, the burden associated with this requirement is 536 annual hours (4 participants x 1 hour x 134 POs) at a cost of $ $29,180 (536 hr x $54.44/hr).

460.132 Quality Improvement (QI) Plan

Section 460.132(a) states that the PO must have a written quality improvement plan that is collaborative and interdisciplinary in nature.

Update QI Plan (PACE Final Rule Modification)
In the final rule, CMS revised §460.132(a) and (c)(3) by referring to a quality improvement (QI) plan, and removed all references to "assessment and performance," and now requires that POs have a written quality improvement plan that is collaborative and interdisciplinary in nature. Because POs are already required to have a written QI plan, we anticipate added burden to update the plan by making it more collaborative and interdisciplinary in nature.

We estimate a one-time burden of one hour at $54.44/hr to update material. In aggregate, we estimate an annualized burden of 44.7 hours ([134 POs x 1 hr]/3 yr) at a cost of $ 2,433 (44.7 hr x $54.44/hr) to update QI plans. We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's three-year approval period expires.

Annual Review (Existing)
Section 460.132(b) states that the PACE governing body must review the quality improvement 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 plan, if necessary. CMS estimates that each PO will take eight hours to complete this requirement. There will be approximately 134 POs for a total annual burden of 1072 hours at a cost of $ 58,360 (1072 hr x $54.44/hr).

***460.152 Enrollment Process** (Existing)*

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 34 SAAs (assuming the 31 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 3,400 hours at a cost of $249,424 (3,400 hr x $73.36/hr).

460.154 Enrollment Agreement *(PACE Final Rule Modification)*

Section 460.154 specifies the general content requirements for the enrollment agreement. The PACE Final Rule at §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. CMS now requires 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.

We estimate a one-time burden of one hour at $54.44/hr to update enrollment materials. In aggregate, we estimate an annualized burden of 44.7 hr ([134 POs x 1 hr]/3 yr) at a cost of $2,433 (44.7 hr x $54.44/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's three-year approval period expires.

460.156 Other Enrollment Procedures *(Existing)*

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 134 POs for a total annual burden of 1,608 hours at a cost of $87,540 (1,608 hr x $54.44/hr).

460.160 Continuation of Enrollment *(Existing)*

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 34 SAAs are expected to be affected by this requirement, for a total annual burden of 5,780 hours at a cost of $424,021 (5,780 hr x $73.36/hr).

460.164 Involuntary Disenrollment *(PACE Final Rule Modification)*

Section 460.164 specifies the conditions under which a PACE participant can be involuntarily disenrolled from a PACE program. The PACE Final Rule at § 460.164 (c)(2) now permits involuntary disenrollment in situations where the participant's caregiver engages in disruptive or

threatening behavior, which is defined as exhibiting behavior that jeopardizes the participant's health or safety, or the safety of the caregiver or others.

Section 460.164(f) 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. 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. CMS estimates that each state agency will be required to review 17 case files on an annual basis, at one hour each, for a total of 17 hours. Approximately 34 state agencies are subject to this requirement, for a total annual burden of 578 hours at a cost of $42,402 (578 hr x $73.36/hr).

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.

Post Notice (Existing)
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 five minutes (0.0833) to complete this requirement. There will be approximately 134 POs for a total annual burden of 11 hours at a cost of $599 (11 hr x $54.44/hr).

Update Notice (PACE Final Rule Modification)
The final rule amends §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.

We anticipate that these changes may result in technical staff redisplaying documents. We estimate a one-time burden of 0.5 hour at $54.44/hr for technical staff to redisplay the review results. In aggregate, we estimate an annualized burden of 22.3 hours ([134 POs x 0.5 hr]/ 3 yr) at a cost of $1,214 (22.3 hr x $54.44/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's three-year approval period expires.

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.

General Rule (Existing)
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 four hours to complete this requirement. There will be approximately 134 POs for a total annual burden of 536 hours at a cost of $29,180 (536 hr x $54.44/hr).

Trial Period (Existing)

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 (four 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 at a cost of $13,066 (240 hr x $54.44/hr).

12.3. Burden Summary

This section presents a summary table of all hour and dollar burdens listed sequentially by CFR section, and aligns with the narrative in Section 12.2. Each provision is uniquely identified by the regulatory section number, and if applicable, a brief description of the specific COI function/activity for that section using the same identifiers utilized in the Section 12.2 narrative.

The total burdens by provision are not included in either the summary table or narrative since some regulatory sections have provisions with burden to different sectors or from different sources (existing, PACE Final Rule, modification, etc.). However, grand totals and subtotals are included at the bottom of the table by sectors (total hour and dollars) and include the total burden for POs, third party disclosures, and the states. Subtotals (total hours and dollars) by source are also listed at the conclusion of the table. We believe that one table with clear entries and subtotals is sufficient to capture these statistics and provides a more clear interpretation of the burden estimates.

Summary Table: All Hour and Dollar Burdens Listed Sequentially by CFR Section

CFR Section	Regulatory Section Description	Paragraph Description (if applicable)	Number of Respondents	Number of Responses	Hr/ response	Total hr	Wages/ hr	Total Wages	Sector	1) Existing Provision 2) PACE Final Rule (New) or 3) PACE Final Rule Modification	Annual or 1st year divided by 3
460	Global Quality Improvement (QI) Terminology Change		134	1	1	44.7	54.44	2,433	POs	PACE Final Rule (New)	First Year cost divided by 3 years
460.30 (a) and (b)	Program Agreement Requirement	New Program Agreements: PO Burden	10	1	1	10	54.44	544	POs	Existing	Annual

460.30 (a) and (b)	Program Agreement Requirement	New Program Agreements: SSA Burden	10	1	1	10	73.36	734	States	Existing	Annual
460.30 (c)	Program Agreement Requirement	State Plan Amendment	3	1	20	60	73.36	4,402	States	Existing	Annual
460.32	Content and Terms of PACE Program Agreement	Service Area Expansion (SAE)	35	1	15	525	54.44	28,581	POs	Existing	Annual
460.32	Content and Terms of PACE Program Agreement	PACE Replacement Center	12	1	15	180	54.44	9,799	POs	Existing	Annual
460.32	Content and Terms of PACE Program Agreement	Routine Review and Maintenance	134	1	4.5	603	54.44	32,827	POs	PACE Final Rule (New)	Annual
460.63	Compliance Oversight Requirements	Policies and Procedures	134	1	15	670	54.44	36,475	POs	PACE Final Rule (New)	First Year cost divided by 3 years
460.63	Compliance Oversight Requirements	Self-Report of Potential Fraud or Misconduct	134	1	20	2680	54.44	145,899	POs	PACE Final Rule (New)	Annual
460.68 (a)	Program Integrity	Program Integrity Polices/Procedures	134	1	10	446.7	54.44	24,318	POs	PACE Final Rule (New)	First Year cost divided by 3 years
460.68 (b)(1)	Program Integrity	Conflict of Interest Policies and Procedures	10	1	3	30	54.44	1,633	POs	Existing	Annual
460.68 (b)(2)	Program Integrity	Conflict of Interest Disclosure	134	1	0.5	67	54.44	3,647	POs	Existing	Annual
460.70 (b)(1)	Contracted Services	New Applicants	10	100	2	2000	54.44	108,880	POs	Existing	Annual
460.70 (b)(1)	Contracted Services	SAE and/or New PACE Center	35	25	2	1750	54.44	95,270	POs	Existing	Annual
460.70 (b)(1)	Contracted Services	Ongoing Maintenance	134	1	5	670	54.44	36,475	POs	Existing	Annual
460.71 (a)(2)	Oversight of Direct Participant Care	Competency Evaluations: Initial applications	10	11	5	550	54.44	29,942	POs	Existing	Annual
460.71 (a)(2)	Oversight of Direct Participant Care	Annual Competency Evaluations: All PO staff	134	150	2	40200	54.44	2,188,488	POs	Existing	Annual

460.72 (a)(3)	Physical Environment	Written Plan for New Applicants	10	1	2	20	54.44	1,089	POs	Existing	Annual
460.72 (a)(3)	Physical Environment	Maintain Written Plan	134	1	1	134	54.44	7,295	POs	Existing	Annual
460.82 (c)	Marketing	Revise Policies and Procedures	134	1	5	223.3	54.44	12,156	POs	PACE Final Rule (New)	First Year cost divided by 3 years
460.102 (c)(i) - (iv)	Interdisciplinary Team (IDT)	Update Policies and Procedures	134	1	1	44.7	54.44	2,433	POs	PACE Final Rule Modification	First Year cost divided by 3 years
460.102 (f)	Interdisciplinary Team (IDT)	Information Exchange - New Applicants	10	1	3	30	54.44	1,633	POs	Existing	Annual
460.102 (f)	Interdisciplinary Team (IDT)	Information Exchange - Active POs	134	1	1	134	54.44	7,295	POs	Existing	Annual
460.104 (d) (2)(iii)	Participant reassessment		134	16	0.1667	357	54.44	19,435	POs	Existing	Annual
460.116 (a)	Explanation of Rights	Explanation of (Participant) Rights	134	1	2	268	54.44	14,590	POs	Existing	Annual
460.116 (c)(1)	Explanation of Rights	Revise Explanation of Rights	134	1	5	223.3	54.44	12,156	POs	PACE Final Rule Modification	First Year cost divided by 3 years
460.116 (c)(2)	Explanation of Rights	Redisplay “Participant Rights” as “PACE Participant Rights”	134	1	0.5	22.3	54.44	1,214	POs	PACE Final Rule Modification	First Year cost divided by 3 years
460.120 (b)	Grievances	Grievance Process	134	300	0.0833	3349	54.44	182,320	3rd Party Disclosure	Existing	Annual
460.120 (e)	Grievances	Additional Written Information	134	16	0.1667	357	54.44	19,435	3rd Party Disclosure	Existing	Annual
460.122 (b)	PO Appeals Process	Appeals Process	134	300	0.0833	3349	54.44	182,320	3rd Party Disclosure	Existing	Annual
460.122 (h)	PO Appeals Process	Appeal Determination Notification	134	24	0.0833	268	54.44	14,590	POs	Existing	Annual
460.124	Additional Appeal Rights under Medicare or Medicaid		134	4	1	536	54.44	29,180	3rd Party Disclosure	Existing	Annual

460.132 (a) and (c)(3)	Quality Improvement (QI) Plan	Update QI	134	1	1	44.7	54.44	2,433	POs	PACE Final Rule Modification	First Year cost divided by 3 years
460.132 (b)	Quality Improvement (QI) Plan	Annual Review	134	1	8	1072	54.44	58,360	POs	Existing	Annual
460.152 (a) (3)	Enrollment Process		34	1	100	3400	73.36	249,424	States	Existing	Annual
460.154	Enrollment Agreement		134	1	1	44.7	54.44	2,433	POs	PACE Final Rule Modification	First Year cost divided by 3 years
460.156 (b)	Other Enrollment Procedures		134	1	12	1608	54.44	87,540	POs	PACE Final Rule Modification	Annual
460.160 (b)	Continuation of Enrollment		34	1	170	5780	73.36	424,021	States	Existing	Annual
460.164 (f)	Involuntary Disenrollment		34	1	17	578	73.36	42,402	States	PACE Final Rule Modification	Annual
460.196 (c)	Disclosure of Review Results	Post Notice	134	1	0.0833	11	54.44	599	3rd Party Disclosure	Existing	Annual
460.196 (d)	Disclosure of Review Results	Update Notice	134	1	0.5	22.3	54.44	1,214	POs	PACE Final Rule (New)	First Year cost divided by 3 years
460.208 (a) (1)	Financial Statements	General Rule	134	1	4	536	54.44	29,180	POs	Existing	Annual
460.208 (c) (1)	Financial Statements	Trial Period	15	4	4	240	54.44	13,066	POs	Existing	Annual
Totals		Aggregate	*168*	*Varies*	*Varies*	73148.7	*Varies*	4,168,160			
Subtotals by Source		Existing				65,893		3,762,227			
Subtotals by Source		PACE Final Rule (New)				4,690		255,322			
Subtotals by Source		PACE Final Rule Modification				2,566		150,611			
Subtotals by Sector		POs				55,719		3,033,323			
Subtotals by Sector		3rd Party Disclosure				7,602		413,854			
Subtotals by Sector		States				9,828		720,983			

12.4 Collection of Information Instruments and Instruction/Guidance Documents

Guidance documents include the CMS PACE Manual at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019036.

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 2020 base salary for the Baltimore/Washington, D.C. region at the GS-13, step 5 level (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/DCB.pdf). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

Grade (Step)	Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
GS-13 (step 5)	55.75	55.75	111.50

Annualized Cost to Federal Government

CMS Staff	(85) hours x $111.50/hour	$9,478

The estimated cost associated with assembling PACE program agreements, signing the agreements, coordinating any follow-on amendments, and providing the amendment to each applicable party by CMS staff is estimated to require 85 hours annually, at an estimated cost of $9,478 (85 hr x $111.50/hr).

The cost to the government specific to the PACE application process is captured as part of CMS-10631. In addition, 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 and Burden Changes

15.1 Overview of Program and Burden Changes

As noted above, the current active package has several numerical errors and combines new, existing and/or modified COI requirements. Therefore, this PRA package has been significantly revised and is being submitted as a standalone package. In addition, due to the complexities of combining new, existing and modified requirements, and in light of the various numerical errors in the existing PRA, making accurate and/or logical comparisons between this PRA and the active PRA was difficult. Nevertheless, to the best of our efforts, a reconstruction of a numerically correct version of the current active package was made and facilitated summary level comparisons. The following points should be noted:

- For existing provisions, changes in burden arose because of some combination of the following factors: i) the number of POs increased; ii) labor costs changed (in some cases

decreasing) due to the different years when the PRA packages were written; and iii) various other estimates (for example, the number of SAEs) per year changed.

- The PACE Final Rule created new requirements with new burdens, removed some of the former requirements (e.g., marketing plans) which decreased burden, and modified some of the existing provisions. A summary of the changes brought about by the PACE Final Rule are located in in both the Section 12.2 narrative and Section 12.3 summary table.
- As noted above and as indicated in the Summary Table, the total annual burden is (when rounded) 73,000 hours at a cost of $4.1 million. This burden is allocated to the POs, states, and third party disclosures in the approximate proportions of 75 percent, 15 percent and 10 percent (when percentages are rounded to the nearest five percent). The burden is allocated to existing provisions and the PACE Rule provisions in the approximate proportions of 90 percent and 10 percent (of the 10 percent of burden arising from the PACE rule, six percent arises from completely new provisions and four percent arising from modifications to existing provisions).
- A reconstruction of a numerically accurate version of the current active document shows that approximately:
    - Total dollar burden overall is reduced by about two percent while total hour burden is increased by about two percent
    - For POs and third party disclosures, the dollar burden was reduced by 6 percent, while dollar burden for states increased 24 percent.
    - For POs and third party disclosures, the hour burden increased by about three percent while for the states, hour burden decreased three percent.
- We also note that the PACE Final Rule removed §460.82(f), which required that POs establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness. Therefore, in the Final Rule, we estimated a burden reduction related to removing the requirements for the marketing plan and the tracking system of 1340 hours (134 POs * 10 hours of work formerly needed to create the marketing program) and a consequent savings of $72,950 (1340 hours reduced * $54.44/hr).

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.