

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) approved by the Office of Management and Budget (OMB) under control number 0938-1326 (CMS-10631);
- 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); and
- The monitoring of PACE operational compliance during and after the trial period (§§460.190, 460.192), approved by OMB under control number 0938-1327 (CMS-10630).

On December 27, 2022, CMS issued a proposed rule (87 FR 79452) (CMS-4201-P, RIN 0938-AU96), which is the basis for this revised collection of information request.

As explained in further detail in sections 12 and 15 of this Supporting Statement, the proposed rule addresses various requirements, reduces administrative burden, and provides additional participant protections. The revisions streamlined service determination request extension notifications to reduce administrative burden while building in participant protections including enhanced participant rights requirements; enhanced grievance process requirements, timeframes for arranging and scheduling services, and the development of a risk tool for medical clearance, and added flexibility regarding the maintenance of medical records and communications related to participant's care, health, or safety.

While the rule proposes no changes to our State burden estimates, it proposes to revise our private sector burden estimates by 4 respondents, 23,430 responses, and 41,740 hours.

We are not proposing any changes to our PACE Manual.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Collection of this information is mandated by statute under Sections 1894 (Medicare) and 1934 (Medicaid) of the Social Security Act (hereinafter, “the Act”). Our implementing regulations are located under 42 CFR part 460 (for details, see section 12 of this Supporting Statement).

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 State Administrative Agencies (SAAs) will continue to 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 section 12 of this collection of information request, 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

The information collection requirements set out in section 12 of this document do not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

This collection of information request 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. Many 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, the provisions in this proposed rule create a net impact of savings, not cost. Consequently, this proposed rule did not include a Regulatory Flexibility Analysis (RFA), because as the Secretary certified 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 Regulatory Flexibility Act. 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. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

6. Less Frequent Collection

This collection of information request 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).

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 statute 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

Our proposed rule (CMS-4201-P; RIN 0938-AU96) published in the Federal Register on December 27, 2022 (87 FR 79452).

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 that constitutes a trade secret, privileged or

confidential information, (as such terms are interpreted under the Freedom of Information Act (FOIA) and applicable case law), and is clearly labeled as such, 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 Estimates

In this 2023 iteration, we estimate 149 PO respondents. This represents an increase of 4 PO respondents (from 145 currently approved to 149 in 2022). The number of State respondents remains unchanged at 34.

Wage Estimates

To derive average costs for both POs and public entities (the states), we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/current/oes_nat.htm). The following table presents the BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

For provisions with no changes, we believe the BLS occupation title of Other Healthcare Practitioners and Technical Occupations remains appropriate for most 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 of Other Healthcare Practitioners and Technical Occupations 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. The Compliance Officer title will be utilized to calculate burden for new provisions involving technical staff, as we believe initial implementation of new provisions will primarily require staff who specialize in examination, evaluation, and investigation of the PO's conformity with laws and regulations governing compliance.

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. Thus, for the purposes of the burden calculations below, all state administering agency (SAA) or state official wage estimates will reflect the Occupational Health and Safety Specialist adjusted hourly wage.

The remaining BLS occupation titles are for individuals who are part of the PO's IDT (e.g.,

Dietician), as that team is an integral part in providing care to participants and operating the PACE model.

BLS Occupation Title (unless indicated otherwise)	BLS Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Other Indirect Costs (\$/hr)	Adjusted Hourly Wage (\$/hr) (all occupations)	Adjusted Hourly Wage for IDT members
Compliance Officers	13-1041	36.45	36.45	72.90	
Dieticians and Nutritionists	29-1031	31.55	31.55	63.10	63.10
Passenger Vehicle Driver	53-3050	19.06	19.06	38.12	38.12
General Internal Medicine Physician (Primary Care Provider†)	29-1216	116.44	116.44	232.88	232.88
Healthcare Social Worker (Master’s-level Social Worker**)	21-1022	29.96	29.96	59.92	59.92
Home Care Coordinator* (Registered Nurse)	29-1141	39.78	39.78	79.56	79.56
Occupational Health and Safety Specialists	19-5011	37.86	37.86	75.72	
Occupational Therapists	29-1122	43.02	43.02	86.04	86.04
Other Healthcare Practitioners and Technical Occupations (hereinafter, “technical staff”)	29-9000	29.55	29.55	59.10	
Medical and Health Services Managers (PACE Center Manager*)	11-9111	57.61	57.61	115.22	115.22
Home Health and Personal Care Aides (Personal Care Attendant*)	31-1120	14.07	14.07	28.14	28.14
Physical Therapists	29-1123	44.67	44.67	89.34	89.34
Recreational Therapists	29-1125	25.91	25.91	51.82	51.82
Registered Nurse	29-1141	39.78	39.78	79.56	79.56
Average IDT wage					83.97 (923.70/11)

*Denotes the IDT role that corresponds with a particular BLS occupational title where the IDT role required per § 460.102 is not also reflected in the BLS occupational title.

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 other indirect 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.

Information Collection Requirements and Associated Burden Estimates

The following sets out requirements and burden that are unchanged by CMS-4201-P, new requirements arising from CMS-4201-P, and modifications or revisions to existing requirements arising from CMS-4201-P.

See section 15 of this Supporting Statement for a discussion of the changes to our currently approved requirements and burden estimates.

Provisions are presented in an order corresponding to the order of regulatory paragraphs in 42 CFR Part 460.

460.30 Program Agreement Requirement

Estimate #1 PACE Program Agreements: PO Burden (No Change, Annual)

The proposed rule does not change Sections 460.30(a) and (b), which 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 SAA and the PO to review and sign the agreement. CMS estimates that each PO will take one hour of technical staff labor 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 \$591 (10 hr x \$59.10/hr). The burden for SSAs is listed below.

Estimate #2 PACE Program Agreements: State Burden (No Change, Annual)

For each SSA, we estimate SAAs will incur an annual burden of 10 hours at a cost of \$757 (10 hr x \$75.72).

Estimate #3 State Plan Amendment (No Change, Annual)

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 \$4,543 (60 hr x \$75.72/hr).

460.32 Content and Terms of PACE Program Agreement

The proposed rule does not change Section 460.32, which 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. POs are also required to continuously and/or routinely review and update policies and procedures, including those explicitly captured in the program agreement.

Estimate #4 Service Area Expansion (SAE) (No Change, Annual)

We estimate that POs, as part of the SAE process, will require, on average, 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 hr) at a cost of \$31,028 (525 hr x \$59.10/hr).

Estimate #5 Replace PACE Center (No Change, Annual)

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 hr) at a cost of \$10,638 (180 hr x \$59.10/hr).

Estimate #6 Routine Review and Maintenance (No Change, Annual)

All 149 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 670.5 hours (149 POs x 4.5 hr) at a cost of \$ 39,627 (670.5 hr x \$59.10/hr).

460.63 Compliance Oversight Requirements

The proposed rule does not change Section 460.63, which 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.

Estimate #7 Self-Report of Potential Fraud or Misconduct (No Change, Annual)

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 2,980 hr (149 POs x 20 hr), at a cost of \$176,118 (2,980 hr x \$59.10/hr).

460.64 Personnel Qualifications

We propose to allow PACE organizations the option to create and implement a risk assessment tool to assist with the medical clearance process.

Estimate #8 Develop Risk Assessment Tool (New, One Time)

When applicable, we estimate there will be a one-time burden for POs to develop a risk assessment tool at 460.64(a)(5)(iii). For the development of the risk assessment tool, we estimate it would take each PO 5 hours consisting of: 4 hours of work by the compliance officer at \$72.90/hr and 1 hour of work by the PCP at \$232.88/hr. The weighted hourly wage for the compliance officer and PCP to update policies and procedures to create a risk assessment is \$104.90/hr $((4 \text{ hours} * \$72.90/\text{hr}) + (1 \text{ hour} * \$232.88)) / 5 \text{ hr}$ of aggregate burden). We estimate 248.33 hours $([149 \text{ PACE organizations} * 5 \text{ hours}] \div 3 \text{ years})$ at a cost of \$26,050 $(248.33 \text{ hours} * 104.90/\text{hr})$ for both the compliance officer and PCP roles in developing the risk assessment tool. We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires.

Estimate #9 Update Policies and Procedures (New, One Time)

We estimate there will be a one-time burden for PACE organizations associated with these new requirements to update policies and procedures related to medical clearance. We believe the compliance officer and primary care physician (PCP) would be responsible for ensuring the necessary materials are updated. For revising policies and procedures related to medical clearance, we estimate it would take 1 hour at \$72.90/hr for a compliance officer at each PACE organization to update these materials. In aggregate, we estimating an annualized burden of 49.67 hours $([149 \text{ PACE organizations} * 1\text{hr}] \div 3 \text{ years})$ at a cost of \$3,621 $(49.67 \text{ hours} * 72.90/\text{hr})$ for the development of policies and procedures. We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires.

460.68 Program Integrity

The proposed rule does not change Section 460.68, which guards against potential conflicts of interest or certain other risks individuals and organizations could present to the integrity of the PACE program.

Estimate #10 Conflict of Interest Policies and Procedures (No Change, Annual)

The proposed rule does not change Section 460.68(b)(1), which 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 10 entities will take three hours to complete this requirement for a total of 30 hours $(10 \text{ entities} * 3 \text{ hr})$ at a cost of \$1,773 $(30 \text{ hr} * 59.10/\text{hr})$.

Estimate #11 Conflict of Interest, Disclosure (No Change, Annual)

The proposed rule does not change Section 460.68(b)(2), which 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 149 POs for a total annual burden of 74.5 hours at a cost of \$4,403 (74.5 hr x \$59.10/hr).

460.70 Contracted Services

The proposed rule does not change Section 460.70(b)(1), which 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.

Estimate #12 New Applicants (No Change, Annual)

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 hr/contractor) at a cost of \$118,200 (2,000 hr x \$59.10/hr).

Estimate #13 SAE and/or New PACE Center (No Change, Annual)

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 would initially contract 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 \$103,425 (1,750 hr x \$59.10/hr).

Estimate #14 Ongoing Maintenance (No Change, Annual)

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 149 POs for a total annual burden of 745 hours (149 POs x 5 hr) at a cost of \$44,030 (745 hr x \$59.10/hr).

460.71 Oversight of Direct Participant Care

The proposed rule does not change Section 460.71 (a)(2), which 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.

Estimate #15 Competency Evaluations: Initial applications (No Change, Annual)

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 IDT members per applicant x 5 hr per IDT member) at a cost of \$46,184 (550 hr x \$83.97/hr wage rate for an IDT member).

Estimate #16 Annual Competency Evaluations: All PO staff (No Change, Annual)

Implementation of the program will require a minimum of 2 hours per staff member for each of the 149 active POs annually. Estimating an average staff (employees and contractors) of 150, carrying out the competency evaluation will take 300 hours annually per PO for a total of 44,700 hours (149 POs x 300 hours) at a cost of \$ 2,641,770 (44,700 hr x \$59.10/hr).

460.72 Physical Environment

The proposed rule does not change Section 460.72(a)(3), which 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.

Estimate #17 Written Plan for New Applicants (No Change, Annual)

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 (10 initial PACE applicants x 2 hr/ initial applicant) at a cost of \$1,182 (20 hr x \$59.10/hr).

Estimate #18 Maintain Written Plan (No Change, Annual)

We estimate that 149 active POs will require one hour to maintain the written plan, for a total annual burden of 149 hours (149 POs x 1 hr/PO) at a cost of \$8,806 (149 hr x \$59.10/hr).

460.98 Service Delivery

We are proposing to add required timeframes for arranging and scheduling services for PACE participants as specified at 460.98(b) & (c). PACE organizations are currently required to provide all necessary services to meet the needs of participants as expeditiously as the participant's health conditions require.

Estimate #19 Ongoing Documentation Costs (No Change, Annual)

CMS notes a technical change in the proposed rule: the existing section 460.98(b)(5) is being moved to 460.98(b)(4). The requirement is otherwise unchanged.

We estimate compliance officer(s) will spend 50 hours annually per PO at \$72.90/hr to document, track and monitor the provision of services across all care settings, regardless of whether services are formally incorporated into a participant's plan of care. We estimate a total annual burden of 7,450 hours at a cost of \$543,105 (149 POs * 50 hr * \$72.90/hr).

Estimate #20 Update Policies and Procedures (New, One Time)

We estimate a new, one-time burden for POs to update their policies and procedures to reflect the proposed timeframe for arranging and scheduling services at 460.98(c). We estimate that it would take the compliance officer 1 hour at \$72.90/hr to update the necessary materials. Therefore, we estimate an annualized burden of 49.67 hours ([149 PACE organizations * 1 hr] ÷ 3 years) at a cost of \$3,621 ([49.67 hr * \$72.90/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires.

460.102 Interdisciplinary Team (IDT)

Estimate #21 Information Exchange-New Applicants (No Change, Annual)

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 to establish, implement, and maintain documented internal procedures governing the exchange of information between team members, contractors, and participants and their caregivers. We estimate that these entities will require 3 hours to establish the internal procedures for a total of 30 hours (10 new entities annually x 3 hr/ new entity) at a cost of \$1,773 (30 hr x \$59.10/hr).

Estimate #22 Information Exchange-Active POs (No Change, Annual)

The remaining burden associated with this requirement in 460.102(f) is the time and effort for an active PO to update and maintain documented internal procedures governing the exchange of information. CMS estimates each PO will take one hour on an annual basis to complete this requirement. There are 149 POs for a total of 149 hours (149 POs x 1 hr/PO) at a cost of \$8,806 (149 hr x \$59.10).

460.112 Participant Rights

Section 460.112 describes specific rights that PACE participants are entitled to. POs are currently required to provide a copy the participant rights listed in § 460.112 to participants at the time of enrollment, and they are required to post a copy of the rights in the PACE center. If our proposed changes to § 460.112 are finalized, PACE organizations would be required to revise the materials they provide to participants at the time of enrollment and the posting in the PACE center to account for the new and modified requirements. The PACE organizations would also be required under this proposal to develop written templates explaining palliative care, comfort care, and end-of-life care services, which they will provide to participants to describe their treatment options.

Estimate #23 Update Participant Rights Materials (New, One Time)

We estimate a one-time burden for POs to update the participant rights included in the enrollment

information and post the new participant rights in PACE centers. We believe updating these materials would take a compliance officer 2 hours to complete at \$72.90/hr. In aggregate, we estimate an annualized burden of 99.33 hours ($[149 \text{ POs} * 2 \text{ hr}] \div 3 \text{ years}$) at a cost of \$7,241 ($99.33 \text{ hr} * \$72.90/\text{hr}$). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires.

Estimate #24 Develop Written Document of Treatment Options (New, One Time)

We estimate a one-time burden for POs to develop written templates explaining palliative care, comfort care, and end-of-life care services as specified at 460.112(c)(5). We believe the development of these materials is a one-time burden and would take a compliance officer 2 hours to complete at \$72.90/hr. In aggregate, we estimate an annualized burden of 99.33 hours ($[149 \text{ POs} * 2 \text{ hr}] \div 3 \text{ years}$) at a cost of \$7,241 ($99.33 \text{ hr} * \$72.90/\text{hr}$). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires.

Estimate #25 Provide Written Documentation of Treatment Options (New, Annual)

We are proposing to require PACE organizations to supply participants written documentation, as specified at 460.112(c)(5), explaining the different treatment options including palliative, comfort, and end-of-life care services. The tailoring of information within the written templates and providing written materials to participants as specified at proposed §460.112(c)(5), will require the services of an RN and MSW.

- Per patient, the RN is estimated to provide 1 hr of service at a cost \$79.56/hr for a total \$79.56.
- The MSW is estimated to provide 0.1667 hr (one sixth of an hour) at a cost of \$59.92 /hr for a total \$9.99 ($0.1667 * \$59.92$).
- Thus per patient, a total of 1.1667 hr ($1 \text{ hr} + 0.1667 \text{ hr}$) of service will be provided at a total cost of \$89.55 resulting in an average cost per hour of \$76.75/hr ($\$89.55/1.1667 \text{ hr}$).

We estimate the ongoing burden for proposed requirements at §460.112(c)(5) would affect 10,927 participants (20 percent of participants who are expected to need end-of-life explanations * 54,637 total PO enrollees). Therefore, to tailor and mail materials there is an annual burden of 12,749 hours ($10,927 \text{ affected participants} * 1.1667 \text{ hr}$) at a cost of \$978,486 ($12,749 \text{ hr} * \$76.75/\text{hr}$).

Estimate #26 Explanation of Treatment Options (New, Annual)

We estimate an ongoing annual burden for PACE organizations' MSW to explain treatment options to participants as specified at § 460.112(e)(2) to be 10,927 hours ($(54,637 \text{ participants enrolled in PACE as of September 2022} * 20 \text{ percent participants who require materials}) * 1 \text{ hr}$) at a cost of \$654,746 ($10,927 \text{ hr to discuss treatment options} * \$59.92/\text{hr}$).

460.116 Explanation of Rights

The proposed rule does not change Section 460.116(a) which 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 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.

Estimate #27 Explanation of (Participant) Rights (No Change, Annual)

To comply with the requirements at §460.116(a), CMS estimates that, on average, each active PO will take 2 hours per PO annually to for POs to maintain written policies and implement procedures to ensure that the participant, his or her representative, understand their rights. There are approximately 149 POs for a total annual burden of 290 hours (149 POs x 2 hours/PO) at a cost of \$ 17,612 (298 hr x \$59.10/hr).

460.120 Grievances

Estimate #28 Update Grievance Policies and Procedures (New, One Time)

We estimate a new one-time burden of 2 hours at \$72.90 hr for the PO's compliance officer to update the PO's grievance policies and procedures to reflect the proposed changes at 460.120. In aggregate, we estimate an annualized burden of 99.33 hours [(149 POs * 2 hr) ÷ 3 years] at a cost of \$7,241 (99.33 hr * \$72.90/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires.

Estimate #29 Grievance Process (No Change, Annual)

CMS notes a technical change in the proposed rule: the existing section 460.120(b) is being moved to 460.120(c). The following single burden estimate contributing one line item to the summary table reflects burden of requirements laid out in both paragraphs b and c of 460.121. Hence the ID, 460.120(b)&(c), reflects both the regulatory section as well as the relevant paragraphs. The requirement is otherwise unchanged.

POs must give a participant written information on the grievance process upon enrollment and annually thereafter. 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 and that for each participant, the PO will spend approximately five minutes (0.0833 hr) providing written notification on the grievance process. Therefore, the burden associated with the disclosure of the grievance materials is 3,724 hours (300 participants x 0.0833 hr x 149 POs) at a cost of \$220,088 (3,724 hr x \$59.10/hr).

Estimate #30 Update Grievance Process Notification (New, One Time)

We estimate a new one-time burden of 1 hour at \$72.90 per hour for the PO's compliance officer to revise the notification of the grievance process that is provided both upon enrollment and at least annually as specified at 460.120(c). In aggregate, we estimate an annualized burden of 49.67 hours [(149 POs * 1 hr) ÷ 3

years] at a cost of \$3,621 (49.67 hr * \$72.90/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires.

Estimate #31 Update Grievance Resolution Notification (New, One Time)

We estimate a new one-time burden of 1 hour at \$72.90 per hour for the PO's compliance officer to revise the written grievance resolution notification as specified at 460.120(i). In aggregate, we estimate an annualized burden of 49.67 hours [(149 POs * 1 hr) ÷ 3 years] at a cost of \$3,621 (49.67 hr * \$72.90/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires.

460.121 Service Determination Requests

Section 460.121(i)(2) requires POs to notify participants or their designated representatives in writing when they take an extension when processing a service determination request. We are proposing that POs may notify participants of the extension either orally or in writing.

Estimate #32 Notification for Service determination Request Extensions (Revised, Annual)

We estimate a new total annual burden for providing notification to participants when the IDT extends the timeframe for processing service determination requests, as we believe POs will primarily choose to provide oral rather than written notification if the proposed changes to 460.121(i)(2) are finalized, and we estimate oral notification to take less time (15 minutes) than written notification (1 hour). The MSW will provide notification at an hourly rate of \$59.92.

Based on the period 2019-2021 we estimate

- 2188 extension notifications annually.
- 80% of these notifications are expected to be oral, resulting in a per-notification burden of 80%*0.25 hour/oral notification = 0.20 hr.
- 20% of these notifications are expected to be in writing, resulting in a per-notification burden of 20%* 1 hour / written notification = 1 hr
- Therefore, the average per-hour notification burden is 0.4 hours, 0.2 hour each for oral and written notification.

Thus the total annual burden would be 875 hours (2188 annual extension notifications * 0.4 hr) at an aggregate cost of \$52,430 (875 hours * \$59.92/hr).

460.122 PACE Organization's Appeals Process

The proposed rule does not change 460.122(b), which states that, upon enrollment, at least annually thereafter, and whenever the interdisciplinary team denies a service determination request or request for payment, the PACE organization must give a participant written information on the appeals process.

Estimate #33 Appeals Process (No Change, Annual)

For section 460.122(b), 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 3,724 annual hours (300 participants x 0.0833 hr x 149 POs) at a cost of \$ 220,088 (3,724 hr x \$59.10/hr).

Estimate #34 Appeal Decision Notification (No Change, Annual)

For section 460.122(g)(2)(ii), the burden associated with notifying CMS and the SAA of a wholly or partially adverse determination is estimated to be approximately 1 hour per notification. Therefore, the burden associated with these disclosure requirements is 2,384 hours for all POs ((8 CMS notifications x 1 hr) + (8 state notifications x 1 hr) x 149 POs)) at a cost of \$140,894 (2,384 hr x \$59.10/hr).

460.124 Additional Appeal Rights under Medicare or Medicaid

The proposed rule does not change 460.124 which 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.

Estimate #35 Provision of Appeal Rights (No change, Annual)

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 596 annual hours (4 participants x 1 hour x 149 POs) at a cost of \$35,224 (596 hr x \$59.10/hr).

460.132 Quality Improvement (QI) Plan

The proposed rule does not change Section 460.132, which requires POs to have a written quality improvement plan that is collaborative and interdisciplinary in nature.

Estimate #36 Annual Review (No Change, Annual)

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. The burden for this requirement remains 8 hours per PO annually. There will be approximately 149 POs for a total annual burden of 1,192 hours (149 POs x 8 hr/PO) at a cost of \$70,447 (1,192 hr x \$59.10/hr).

460.152 Enrollment Process

The proposed rule does not change Section 460.152(a)(3), which 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.

Estimate #37 SAA Level of Care Assessment (No Change, Annual)

The burden associated with this requirement is the time and effort necessary for each SAA to assess potential PACE participants and maintain documentation of each 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 \$257,448 (3,400 hr x \$75.72/hr).

460.156 Other Enrollment Procedures

The proposed rule does not change Section 460.156(b) which states that the PO must submit participant information to CMS and the SAA, in accordance with established procedures.

Estimate #38 Submission of Enrollment Information to CMS and the SAA (No Change, Annual)

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 149 POs for a total annual burden of 1,788 hours (149 POs x 12 hr/PO) at a cost of \$105,671 (1,788 hr x \$59.10/hr).

460.160 Continuation of Enrollment

The proposed rule does not change Section 460.160(b), which 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.

Estimate #39 Annual Participant Evaluation (No Change, Annual)

The burden associated with this requirement is the time and effort for the SAA to document the annual reevaluation. CMS estimates that each SAA will take 170 hours to reevaluate whether a participant needs the level of care required under the State Medicaid plan for coverage of nursing facility services. Approximately 34 SAAs are expected to be affected by this requirement, for a total annual burden of 5,780 hours (34 SAAs x 170 hr/SAA) at a cost of \$437,662 (5,780 hr x \$75.72/hr).

460.164 Involuntary Disenrollment

The proposed rule does not change Section 460.164, which specifies the conditions under which a PACE participant can be involuntarily disenrolled from a PACE program.

Estimate #40 Review of Involuntary Disenrollments (No Change, Annual)

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 SAAs will be required to review 17 case files on an annual basis, at one hour each for each case file. Approximately 34 state agencies are subject to this requirement, for a total annual burden of 578 hours (34 SAAs x 17 case files x 1 hours/case file) at a cost of \$43,766 (578 hr x \$75.72/hr).

460.196 Disclosure of Review Results

The proposed rule does not change Section 460.196(c), which 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.

Estimate #41 Post Notice (No Change, Annual)

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 are approximately 149 POs for a total annual burden of 12.41 hours (149 POs x 0.0833 minutes/PO) at a cost of \$733 (12.41 hr x \$59.10/hr).

460.208 Financial Statements

The proposed rule does not change Section 460.208(a)(1), which 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.

Estimate #42 General Rule (No Change, Annual)

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 are approximately 149 POs for a total annual burden of 596 hours (149 POs x 4 hours/PO) at a cost of \$35,224 (596 hr x \$59.10 hr).

Estimate #43 Trial Period (No Change, Annual)

Section 460.208(c)(1) 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 quarterly financial statement will take four hours to prepare.. There will be approximately 15 POs affected by this trial period requirement, each one submitting 4 reports per year, with each report taking 4 hours. Thus the total annual burden is 240 hours (15 POs x 16 hr/PO) at a cost of \$14,184 (240 hr x \$59.10/hr).

460.210 Medical Records

In accordance with § 460.210(a), a PO must maintain a single, comprehensive medical record

for each participant, in accordance with accepted professional standards, that is accurately documented and available to all staff, among other requirements. The various medical record requirements include documenting recommendations for services from employees or contractors of the PO, including specialists and the reasons a recommended service is not approved or provided. In addition, PACE organizations are required to maintain all written communications received in any format (for example, emails, faxes, letters, etc.) from participants or other parties in their original form when the communications relate to a participant's care, health, or safety in the medical record. The proposed rule at 460.210(b)(6)(i) through (iii) modifies this requirement by allowing communications be stored either in the participant's medical record or outside of the medical record when certain conditions are met.

Estimate #44 Medical Record Contents - Documenting Recommendations for Services (No Change, Annual)

Section 460.210(b)(4)&(5) requires a PO to document recommendations for services from employees or contractors of the PO, including specialists, and to document the reasons a service recommended by an employee or contractor of the PO is not approved or provided. We estimate that each PO will have an ongoing burden of 52 hours annually (approximately 1 hr per week). Therefore, we estimate a total of 52 hours per organization per year, or a total of 7,748 hours (52 hr x 149 POs) at a cost of \$564,829 (7,748 hr * \$72.90/hr).

Estimate #45 Content of Medical Records – Maintaining Original Documentation (Revised, Annual)

Section 460.210(b)(6) requires PACE organizations to maintain all written communications received in any format (for example, emails, faxes, letters, etc.) from participants or other parties in their original form when the communications relate to a participant's care, health, or safety in the medical record. For this iteration, rather than utilizing the wages for the full IDT, we believe it is more appropriate to determine the cost associated with this provision using a compliance specialist. We estimate the ongoing burden to maintain original documentation of any written communication the PO receives relating to the care, health or safety of a participant, would be 100 hours per PO annually or 14,900 total hours (100 hr * 149 POs) at a cost of \$1,086,210 (14,900hr x \$72.90/hr).

Note however that the proposed rule at 460.210(b)(6)(i) through (iii) will allow communications be stored either in the participant's medical record or outside of the medical record provided certain conditions are met. To accommodate for this change, CMS estimates the following one-time burdens:

Estimate #46 Training (New, One Time)

We estimate that a PACE organization will spend 40 hours at a cost of \$2,916 (40 hr x \$72.90/hr) for a compliance specialist to establish training materials. In aggregate, we estimate a one-time burden of 5,960 hours (40 hours x 149 POs) at a cost of \$434,484 (5,960 hr. x \$72.90/hr).

We estimate an annualized burden to PACE organizations of 1,986.67 hours ([149 POs * 40 hr] ÷ 3 years) at a cost of \$144,828 (1,986.67 hr x \$72.90/hr). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires.

Estimate #47 Software Development/Updates (New, One Time)

We estimate an annualized burden to PACE organizations of 1,986.67 hours ($[149 \text{ POs} * 40 \text{ hr}] \div 3 \text{ years}$) at a cost of \$231,129 ($1,986.67 \text{ hr} * \$72.90/\text{hr}$). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires.

Estimate #48 File Cabinets (New, One Time)

We estimate that a PACE organization will spend a total of \$300 ($2 * \$150/\text{each}$) for 2 four-drawer locking file cabinets. In aggregate, we estimate a one-time cost of \$14,900 ($\$300 * 149 \text{ Pos} \div 3$).

Estimate #49 Update Policies and Procedures (New, One Time)

Lastly, we estimate an annualized burden to PACE organizations of 496.67 hours ($[149 \text{ POs} * 10 \text{ hr}] \div 3 \text{ years}$) at a cost of \$36,207 ($496.67 \text{ hr} * \$72.90/\text{hr}$). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires.

Burden Summary

PACE Organization Burden

ID	CFR Section	Brief Description	Total Annual Respondents	Total Annual Responses	Time / Response (hr)	Total Annual Time (hr)	Labor Cost (\$/hr)	Total Annual Cost	New, Change, No Change	Annual, or one time
Estimate #1	460.30(a)&(b)	New Program Agreements, PO	10	10	1	10	59.10	591	No change	Annual
Estimate #4	460.32	Service Area Expansion (SAE)	35	35	15	525	59.10	31,028	No change	Annual
Estimate #5	460.32	Replace PACE Center	12	12	15	180	59.10	10,638	No change	Annual
Estimate #6*	460.32	Routine Review and Maintenance	149	149	4.5	670.50	59.10	39,627	No change	Annual
Estimate #7	460.63(c)	Self-Report of Potential Fraud or Misconduct	149	149	20	2,980	59.10	176,118	No change	Annual
Estimate #8*	460.64(a)(5)(iii).	Develop Risk Assessment Tool	149	149	5	248.33	104.90	26,050	New	One-time
Estimate #9*	460.64	Update Policies and Procedures	149	149	1	49.67	72.90	3,621	New	One-time
Estimate #10	460.68(b)(1)	Conflict of Interest Policies and Procedures	10	10	3	30	59.10	1,773	No change	Annual
Estimate #11*	460.68(b)(2)	Conflict of Interest, Disclosure	149	149	0.5	74.50	59.10	4,403	No change	Annual
Estimate #12	460.70(b)(1)	New Applicants	10	1000	2	2,000	59.10	118,200	No change	Annual
Estimate #13	460.70(b)(1)	SAE and/or New PACE Center	35	875	2	1,750	59.10	103,425	No change	Annual
Estimate #14	460.70(b)(1)	Ongoing Maintenance Initial Application	149	149	5	745	59.10	44,030	No change	Annual
Estimate #15	460.71(a)(2)	Competency Evaluations Initial Application	10	110	5	550	83.97	46,184	No change	Annual
Estimate #16	460.71(a)(2)	Annual Competency Evaluations: All PO Staff	149	22350	2	44,700	59.10	2,641,770	No change	Annual
Estimate #17	460.72(a)(3)	Written Plan for New Applicants	10	10	2	20	59.10	1,182	No change	Annual
Estimate #18	460.72(a)(3)	Maintain Written Plan	149	149	1	149	59.10	8,806	No change	Annual
Estimate #19	460.98(b)(5)	Ongoing documentation costs	149	149	50	7,450	72.90	543,105	No change	Annual
Estimate #20*	460.98(c)	Update Policies and Procedures	149	149	1	49.67	72.90	3,621	New	One-time
Estimate #21	460.102(f)	Information Exchange - New Applicants	10	10	3	30	59.10	1,773	No change	Annual

Estimate #22	460.102(f)	Information Exchange - Active Pos	149	149	1	149	59.10	8,806	No change	Annual
Estimate #23*	460.112	Update participant right materials	149	149	2	99.33	72.90	7,241	New	One-time
Estimate #24*	460.112(c)(5)	Develop Written Documentation of Treatment Options	149	149	2	99.33	72.90	7,241	New	One-time
Estimate #25	460.112(c)(5)	Provide Written Documentation of Treatment Options	149	10927	1.1667	12,749	76.75	978,486	New	Annual
Estimate #26	460.112(e)(2)	Explanation of Treatment Options	149	10927	1	10,927	59.92	654,746	New	Annual
Estimate #27	460.116(a)	Explanation of (Participant Rights)	149	149	2	298	59.10	17,612	No change	Annual
Estimate #28*	460.120	Update Grievance Policies and Procedures	149	149	2	99.33	72.90	7,241	New	One-time
Estimate #29	460.120(b)&(c)	Grievance Process	149	44700	0.0833	3,724	59.10	220,088	No change	Annual
Estimate #30*	460.120(c)	Update Grievance Process Notification	149	149	1	49.67	72.90	3,621	New	One-time
Estimate #31*	460.120(i)	Update Grievance Resolution Notification	149	149	1	49.67	72.90	3,621	New	One-time
Estimate #32	460.121(i)(2)	Notification for Service Determination Request Extensions	149	2188	0.4	875	59.92	52,430	Revised	Annual
Estimate #33	460.122(b)	Appeals Process	149	44700	0.0833	3,724	59.10	220,088	No change	Annual
Estimate #34	460.122(g)(2)(ii)	Appeal Determination Notification	149	2384	1	2,384	59.10	140,894	No Change	Annual
Estimate #35	460.124	Provision of Appeal Rights	149	596	1	596	59.10	35,224	No change	Annual
Estimate #36	460.132(b)	Annual Review	149	149	8	1,192	59.10	70,447	No change	Annual
Estimate #38	460.156(b)	Other Enrollment Procedures	149	149	12	1,788	59.10	105,671	No change	Annual
Estimate #41*	460.196(c)	Post Notice	149	149	0.0833	12.41	59.10	733	No change	Annual
Estimate #42	460.208(a)(1)	General Rule	149	149	4	596	59.10	35,224	No change	Annual
Estimate #43	460.208(c)(1)	Trial Period	15	4	4	240	59.10	14,184	No change	Annual
Estimate #44	460.210(b)(4)&(5)	Documenting Recommendations for Services	149	149	52	7,748	72.90	564,829	No change	Annual
Estimate #45	460.210(b)(6)	Maintain Original Documentation	149	149	100	14,900	72.90	1,086,210	Revised	Annual
Estimate #46*	460.210(b)(6)(i) -- (iii)	Training	149	149	40	1,986.67	72.90	144,828	New	One-time

Estimate #47*	460.210(b)(6)(i) -- (iii)	Software Development Update	149	149	40	1,986.67	116.30	231,129	New	One-time
Estimate #48	460.210(b)(6)(i) -- (iii)	Purchase File Cabinets	149	149	NA	NA	300	14,900	New	One-time
Estimate #49*	460.210(b)(6)(i) -- (iii)	Update Policies & Procedures	149	149	10	496.67	72.90	36,207	New	One-time
		Totals	149	144722		128,981.42		8,467,646		

*When items are annualized, products are divided by 3 (e.g. 145 Pos x 5 hr work results not in 745 (145 x 5) but 145*5/3=248.333 in row with ID Estimate #8.

State Burden

ID	CFR Section	Brief Description	Total Annual Respondents	Total Annual Responses	Time / Response (hr)	Total Annual Time (hr)	Labor Cost (\$/hr)	Total Annual Cost	New, Change, No Change	Annual, or one time
Estimate #2	460.30(a)&(b)	New Program Agreements, States	10	10	1	10	75.72	757	No change	Annual
Estimate #3	460.30(c)	State Plan Amendment	3	3	20	60	75.72	4,543	No change	Annual
Estimate #37	460.152(a)(3)	Enrollment Process	34	34	100	3,400	75.72	257,448	No change	Annual
Estimate #39	460.160(b)	Continuation of Enrollment	34	34	170	5,780	75.72	437,662	No change	Annual
Estimate #40	460.164(f)	Involuntary Disenrollment	34	34	17	578	75.72	43,766	No change	Annual
		Totals	149	115		9,828		744,176		

Total Burden

Respondent Type	Total Annual Respondents	Total Annual Responses	Total Annual Time (hr)	Total Annual Cost
PACE organizations	149	144,722	128,981	8,467,646
States	34	115	9,828	744,176
TOTAL	183	144,837	138,809	9,211,822

12.4 Collection of Information Instruments and Instruction/Guidance Documents

We are not proposing any changes to the current PACE Manual at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019036>.

13. Capital Costs

There are no capital costs associated with the section 12 collection of information requirements.

14. Cost to the Federal Government

To derive average costs, we used data from OPM’s 2023 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/23Tables/html/DCB_h.aspx). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and the adjusted hourly wage.

Grade (Step)	Hourly Wage (\$/hr)	Fringe Benefits and Other Indirect Costs (\$/hr)	Adjusted Hourly Wage (\$/hr)
GS-13 (step 5)	60.83	60.83	121.66

Annualized Cost to Federal Government

CMS Staff	(85) hours x \$121.66 /hour	\$10,341
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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 \$10,341 (85 hr x \$121.66/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

On December 27, 2022, CMS issued a proposed rule (87 FR 79452) (CMS-4201-P, RIN 0938-AU96), which is the basis for this 2023 revised collection of information request. The changes are identified in the following table. So as not to be repetitive with regard to the new/revised requirements, readers can refer to section 12 (above) for such details.

In this 2023 iteration, we estimate 149 PO respondents. This represents an increase of 4 PO respondents (from 145 currently approved to 149 in 2022). The number of State respondents remains unchanged at 34. There was no change in State responses or hourly burden.

Regulatory Citation	Respondents			Responses			Time (hr)		
	Current	Proposed	Difference	Current	Proposed	Difference	Current	Proposed	Difference
460.30(a)&(b)	10	10	0	10	10	0	10	10	0
460.30(a)&(b)*	10	10	0	10	10	0	10	10	0

460.30(c)*	3	3	0	3	3	0	60	60	0
460.32	35	35	0	35	35	0	525	525	0
460.32	12	12	0	12	12	0	180	180	0
460.32#3	145	149	4	145	149	4	652.2	670.5	18.3
460.63(c)	145	149	4	145	149	4	2,900	2,980	80
460.64(a)(5)(iii).		149	149		149	149		248.33	248.33
460.64		149	149		149	149		49.67	49.67
460.68(b)(1)	10	10	0	10	10	0	30	30	0
460.68(b)(2)	145	149	4	145	149	4	72.5	74.5	2
460.70(b)(1)	10	10	0	1,000	1,000	-	2,000	2,000	0
460.70(b)(1)	35	35	0	875	875	0	1,750	1,750	0
460.70(b)(1)	145	149	4	145	149	4	725	745	20
460.71(a)(2)	10	10	0	110	110	0	550	550	0
460.71(a)(2)	145	149	4	21,750	22,350	600	43,500	44,700	1,200
460.72(a)(3)	10	10	0	10	10	0	20	20	0
460.72(a)(3)	145	149	4	145	149	4	145	149	4
460.98(b)(5)	145		-145	48.33		-48.33	2,416.67		(2,416.67)
460.98(b)(5)	145	149	4	145	149	4	7,250	7,450	200
460.98(c)		149	149		149	149		49.67	49.67
460.102(f)	10	10	0	10	10	0	30	30	0
460.102(f)#2	145	149	4	145	149	4	145	149	4
460.112	145	149	4	48.33	149	100.67	96.67	99.33	2.66
460.112(c)(5)#1		149	149		149	149		99.33	99.33
460.112(c)(5)#2		149	149		10,927	10,927		12,749	12,749
460.112(e)(2)		149	149		10,927	10,927		10,927	10,927
460.116(a)	145	149	4	145	149	4	290	298	8
460.12		149	149		149	149		99.33	99.33
460.120(b)(Current) 460.120(c) (Proposed)	145	149	4	43,500	44,700	1,200	3,623.55	3,724	100.45
460.120(c)		149	149		149	149		49.67	49.67
460.120(e)	145		-145	2,320		(2,320)	38.67		-38.67
460.120(i)		149	149		149	149		49.67	49.67
460.121(i)(2)	145	149	4	2,350	2,188	(162)	2,350	875	-1475
460.121	145		-145	48.33		-48.33	96.67		-96.67
460.122(b)	145	149	4	43,500	44,700	1,200	3,623.55	3,724	100.45
460.122(c)	145		-145	48.33		-48.33	193.33		-193.33
460.122(g)(2)(ii)	145	149	4	2320	2384	64	193.26	2384	2190.74
460.122(g)	145		-145	48.33		-48.33	48.33		-48.33
460.124	145	149	4	580	596	16	580	596	16
460.132(b)	145	149	4	145	149	4	1,160	1,192	32

460.152(a)(3)*	34	34	0	34	34	0	3,400	3,400	0
460.156(b)	145	149	4	145	149	4	1,740	1,788	48
460.160(b)*	34	34	0	34	34	0	5,780	5,780	0
460.164(f)*	34	34	0	34	34	0	578	578	0
460.196(c)	145	149	4	145	149	4	12.08	12.41	0.33
460.208(a)(1)	145	149	4	145	149	4	580	596	16
460.208(c)(1)	145	15	-130	580	4	-576	240	240	0
460.21	145		-145	48.33		-48.33	483.33		-483.33
460.210(b)(4)&(5)	145	149	4	145	149	4	7,540	7,748	208
460.210(b)(6)	145	149	4	145	149	4	1,450	14,900	13,450
460.210(b)(6)(i-iii)		149	149		149	149		1,986.67	1,986.67
460.210(b)(6)(i-iii)		149	149		149	149		1,986.67	1,986.67
460.210(b)(6)(i-iii)		149	149		149	149		NA	
460.210(b)(6)(i-iii)	145	149	4		149	149		496.67	496.67
Totals	179	183	4	121,406.98	144,837	23,430.02	97,068.81	138,809.42	41,740.61

* State respondents, responses, and burden hours did not change

16. Publication and Tabulation Dates

There is no tabulation date.

17. Expiration Date

The revised expiration date will be displayed once this package is approved.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

There has been no statistical method employed in this collection.