

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

We request reinstatement with change of this previously approved collection. The collection expired on March 31, 2024 (see OMB's March 4, 2024, Notice of Action).

## **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 April 12, 2023, CMS issued a final rule (88 FR 22120) CMS-4201-F (RIN 0938-AU96). Additionally, on April 23, 2024 (89 FR 30846), CMS issued a combined final rule CMS-4201-F3/CMS-4205-F (RINs 0938-AU96 and 0938-AV24, respectively). The final rules form the basis for this revised collection of information request.

As explained in further detail in sections 12 and 15 of this Supporting Statement, the final rules address various requirements, reduce administrative burden, and provide additional participant protections. The revisions streamline 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 rules did not change our state burden estimates, it revised our private sector burden estimates by plus 11 respondents, plus 100,516 responses, and plus 60,815 hours.

We are not proposing any changes to our most recently active 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 PACE organizations (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 that we will explain below.

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 these final rules create a net impact of savings, not cost. Consequently, the final rules 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 final 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

Serving as the 60-day notices, CMS–4201–P (RIN 0938–AU96) published in the Federal Register on December 27, 2022 (87 FR 79452) while CMS–4205–P (RIN 0938–AV24) published on November 15, 2023 (88 FR 78476).

The final rule CMS-4201-F (RIN 0938-AU96) published in the Federal Register on April 12, 2023 (88 FR 22120).

All commenters that addressed the proposed change to §460.121(i)(2) supported allowing the IDT to provide either oral or written notice of service determination request extensions.

Additionally, the combined final rule CMS-4201-F3/CMS–4205–F (RINs 0938-AU96 and 0938-AV24, respectively) published in the Federal Register on April 23, 2024 (89 FR 30448), respectively.

We received no comments specific to our proposed provisions and analysis of paperwork burden.

#### 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 iteration of the package, we estimate 156 PO respondents. This represents an increase of 7 PO respondents (from 149 in the current version pending OMB approval). 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 2023 National Occupational Employment and Wage Estimates

for all salary estimates ([https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm)). The following table presents the BLS’s mean hourly wage, our estimated cost of fringe benefits and overhead (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 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 interdisciplinary team (IDT) (e.g., Dietician), as that team is an integral part of 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	38.55	38.55	77.10	n/a
Dieticians and Nutritionists*	29-1031	34.27	34.27	68.54	68.54
Passenger Vehicle Driver*	53-3050	22.25	22.25	44.50	44.50
General Internal Medicine Physician* (Primary Care Provider (PCP)†)	29-1216	118.01	118.01	236.02	236.02
Healthcare Social Worker* (Master’s-level Social Worker**)	21-1022	32.42	32.42	64.84	64.84
Home Care Coordinator** (Registered Nurse*)	29-1141	45.42	45.42	90.84	90.84

Occupational Health and Safety Specialists*	19-5011	41.14	41.14	82.28	n/a
Occupational Therapists*	29-1122	46.54	46.54	93.08	93.08
Other Healthcare Practitioners and Technical Occupations* (hereinafter, “technical staff”)	29-9000	32.84	32.84	65.68	n/a
Medical and Health Services Managers* (PACE Center Manager**)	11-9111	64.64	64.64	129.28	129.28
Home Health and Personal Care Aides* (Personal Care Attendant**)	31-1120	16.05	16.05	32.10	32.10
Physical Therapists*	29-1123	48.29	48.29	96.58	96.58
Recreational Therapists*	29-1125	29.28	29.28	58.56	58.56
Registered Nurse*	29-1141	45.42	45.42	90.84	90.84
Mean Hourly IDT Wage					91.38 (1,005.18 / 11)

\*Denotes a BLS occupational title.

\*\*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 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.

### *Information Collection Requirements and Associated Burden Estimates*

As defined under 5 CFR 1320.3(c) of the PRA’s implementing regulations, this Supporting Statement’s “collection of information” requirements include program provisions that are unchanged, new requirements, and modifications or revisions to existing requirements arising from the following final rules: CMS-4201-F, CMS-4201-F3 and CMS-4205-F. CMS continues to include burden for costs identified in the previous regulations that would remain ongoing based on the final rule collection of information request.

Besides changes due to regulatory provisions, changes to burden estimates may occur due to 1) an increase in the number of POs, 2) a change in occupational titles as appropriate, and 3) a change in burden hours including those based on comments we received on the CMS- 4201-F, CMS-4201-F3 and CMS-4205-F PRAs as detailed in the accompanying document. The burden changes, including changes to provisions with no regulatory change, are summarized in Section 15.

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 final rules do not change §§ 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 believe the development of these materials is an annual burden and would take technical staff 10 hours to complete at \$65.68/hr. We estimate an annual burden of 10 hours at a cost of \$657 (10 hr x \$65.68/hr). The burden for SSAs is listed below.

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

We believe the development of these materials is an annual burden and would take a Health and Safety Specialist 10 hours to complete at \$82.28/hr. For each SSA, we estimate SAAs will incur an annual burden of 10 hours at a cost of \$823 (10 hr x \$82.28/hr).

#### **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. We believe the development of these materials for each state plan amendment is an annual burden and would take a Health and Safety Specialist 20 hours to complete at \$82.28/hr. 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 \$4,937 (60 hr x \$82.28/hr).

### **§ 460.32 Content and Terms of PACE Program Agreement**

The final rules do not change § 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. We believe the development of these materials is an annual burden and would take a Technical Specialist 15 hours to complete at \$65.68/hr. 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 \$34,481 (525 hr x \$65.68/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 believe the development of these materials is an annual burden and would take a Technical Specialist 15 hours to complete at \$65.68/hr. 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 \$11,882 (180 hr x \$65.68/hr).

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

All 156 active POs are expected to regularly reassess and update, as necessary, all operational policies and procedures. We believe this activity is an annual burden and would take a Technical Specialist 4.5 hours to complete at \$65.68/hr. Total burden for annual review of policy and procedures for active POs is therefore estimated at 702 hours (156 POs x 4.5 hr) at a cost of \$46,107 (702 hr x \$65.68/hr).

**§ 460.63 Compliance Oversight Requirements**

The final rules do not change § 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 that technical staff at each PO would take 20 hours annually. Therefore, the aggregate hourly burden is 3,120 hr (156 POs x 20 hr), at a cost of \$204,922 (3,120 hr x \$65.68/hr).

**§ 460.64 Personnel Qualifications**

The final rules allow PACE organizations 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 \$77.10/hr and 1 hour of work by the primary care provider (PCP) at \$236.02/hr. The weighted hourly wage for the compliance officer and PCP to update policies and procedures to create a risk assessment is \$108.88/hr  $((4 \text{ hr} * \$77.10/\text{hr}) + (1 \text{ hr} * \$236.02/\text{hr})) / 5 \text{ hr}$  of aggregate burden). We estimate 260 hours  $([156 \text{ PACE organizations} * 5 \text{ hours}] \div 3 \text{ years})$  at a cost of \$ 28,309  $(260 \text{ hours} * 108.88 /\text{hr})$  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 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 \$77.10/hr for a compliance officer at each PACE organization to update these materials. In aggregate, we estimated an annualized burden of 52 hours  $([156 \text{ PACE organizations} * 1 \text{ hr}] \div 3 \text{ years})$  at a cost of \$4,009  $(52 \text{ hours} * 77.10/\text{hr})$  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 final rules do not change § 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 final rules do 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 for each of these 10 entities it will take technical staff three hours, working at \$65.68/hr, to complete this requirement for a total of 30 hours  $(10 \text{ entities} * 3 \text{ hr})$  at a cost of \$1,970  $(30 \text{ hr} * 65.68/\text{hr})$ .

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

The final rules do not change § 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 that technical staff at each PO working at \$65.68/hr will take 30 minutes to complete this requirement. We estimate approximately 156 POs for a total annual burden of 78 hours at a cost of \$5,123 (78 hr x \$65.68/hr).

### **§ 460.70 Contracted Services**

The final rules do not change § 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. We believe each contractor would require 2 hours of work by technical staff working at \$65.68/hr. 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 \$131,360 (2,000 hr x \$65.68/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. We believe each application would require 2 hours of work by technical staff working at \$65.68/hr. 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 \$ 114,940 (1,750 hr x 65.68/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 technical staff at each active PO will spend five hours at \$65.68/hr verifying the qualifications of new contractors. There will be approximately 156 POs for a total annual burden of 780 hours (156 POs x 5 hr) at a cost of \$51,230 (780 hr x \$65.68/hr).

### **§ 460.71 Oversight of Direct Participant Care**

The final rules do not change § 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 each of 11 IDT members, working on average at \$91.38/hr, would require 5 hours of work. Therefore, total annual burden is 550 hours (10 initial applicant entities x 11 IDT members per applicant x 5 hr per IDT member) at a cost of \$50,259 (550 hr x \$91.38/hr wage rate for an IDT member).

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

Implementation of the program will require technical staff, working at \$65.68/hr, to devote a minimum of 2 hours per staff member for each of the 156 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 46,800 hours (156 POs x 300 hours) at a cost of \$3,073,824 (46,800 hr x \$65.68/hr).

**§ 460.72 Physical Environment**

The final rules do not change § 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 \$1,314 (20 hr x \$65.68/hr).

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

We believe that technical staff, working at \$65.68/hr will require 1 hour to maintain each written plan. We estimate a total annual burden of 156 hours (156 POs x 1 hr/PO) at a cost of \$10,246 (156 hr x \$65.68/hr).

**§ 460.98 Service Delivery**

We are finalizing new timeframes for arranging and scheduling services for PACE participants as specified at § 460.98(b) and (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 final rule: the existing §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 \$77.10 /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 7,800 hours (156 POs x 50 hr/PO) at a cost of \$601,380 (156 POs \* 50 hr \* \$77.10 /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 finalized timeframe for arranging and scheduling services at 460.98(c). We estimate that it would take the compliance officer 1 hour at \$77.10 /hr to update the necessary materials. Therefore, we estimate an annualized burden of 52 hours ([156 POs \* 1 hr] ÷ 3 years) at a cost of \$4,009 ([52 hr \* \$77.10 /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 for 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 technical staff working at \$65.68/hr will require 3 hours to establish the internal procedures for each application. We estimate total annual burden at 30 hours (10 new entities annually x 3 hr/entity) at a cost of \$1,970 (30 hr x \$65.68/hr).

**Estimate #22 Information Exchange for 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 that technical staff at each PO, working at \$65.68/hr, will take one hour on an annual basis to complete this requirement. There are 156 POs for a total of 156 hours (156 POs x 1 hr/PO) at a cost of \$10,246 (156 hr x \$65.68/hr).

**§ 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. We finalized our proposed changes to § 460.112 that 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. Additionally, PACE organizations must 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 \$77.10/hr. In aggregate, we estimate an annualized burden of 104 hours ( $[156 \text{ POs} * 2 \text{ hr}] \div 3 \text{ years}$ ) at a cost of \$8,018 ( $104 \text{ hr} * \$77.10/\text{hr}$ ). 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 \$77.10 /hr. In aggregate, we estimate an annualized burden of 104 hours ( $[156 \text{ POs} * 2 \text{ hr}] \div 3 \text{ years}$ ) at a cost of \$8,018 ( $104 \text{ hr} * \$77.10/\text{hr}$ ). 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 finalized our proposal 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 \$90.84/hr for a total of \$90.84.
- The MSW is estimated to provide 0.1667 hr (one sixth of an hour) at a cost of \$64.84/hr for a total \$10.81 ( $0.1667 * \$64.84$ ).
- 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 \$87.13 resulting in an average cost per hour of \$87.13/hr ( $\$90.84 + \$10.81 / 1.1667 \text{ hr}$ ).

We estimate the ongoing burden for finalized requirements at §460.112(c)(5) would affect 15,183 participants (20 percent of participants who are expected to need end-of- life explanations \*75,917 total enrolled PO participants). Therefore, to tailor and mail materials there is an annual burden of 17,714 hours ( $15,183 \text{ affected participants} * 1.1667 \text{ hr}$ ) at a cost of \$ 1,543,421 ( $17,714 \text{ hr} * \$87.13/\text{hr}$ ).

**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 15,183 hours ((75,917 total enrolled PO participants\* 20 percent participants who require materials) \* 1 hr) at a cost of \$984,466 (15,183 hr to discuss treatment options \* \$64.84/hr).

### **§ 460.116 Explanation of Rights**

The final rules do not change § 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, technical staff working at \$65.68/hr will take 2 hours per PO annually for POs to maintain written policies and implement procedures to ensure that the participant, his or her representative, understand their rights. There are approximately 156 POs for a total annual burden of 312 hours (156 POs x 2 hours/PO) at a cost of \$20,492 (312 hr x \$65.68/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 \$77.10/hr for the PO's compliance officer to update the PO's grievance policies and procedures to reflect the finalized changes at 460.120. In aggregate, we estimate an annualized burden of 104 hours [(156 POs \* 2 hr) ÷ 3 years] at a cost of \$8,018 (104 hr \* \$77.10/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 final rule: the existing section 460.120(b) is being moved to 460.120(c). The following single burden estimate contributes one line item to the summary table but reflects the burden of requirements laid out in both 460.121(b) and (c). Hence, ID "460.120(b)&(c)" in the summary table that follows 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 500 participants per PO receiving written information on the grievance process and that for each participant, the PO's compliance officer, working at \$77.10/hr, 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 6,497 hours (500 participants x 0.0833 hr x 156 POs) at a cost of \$500,950 (6,497 hr x \$77.10/hr).

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

We estimate a new one-time burden of 1 hour at \$77.10 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 52 hours [(156 POs \* 1 hr) ÷ 3 years] at a cost of \$4,009 (52 hr \* \$77.10/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 \$77.10 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 52 hours [(156 POs \* 1 hr) ÷ 3 years] at a cost of \$4,009 (52 hr \* \$77.10/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 finalized our proposal 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. We believe POs will primarily choose to provide oral rather than written notification, 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 \$64.84.

Based on the period 2019–2021 we estimate

- 2,188 extension notifications annually.
- 80% of these notifications are expected to be oral, resulting in a per-notification burden of  $80\% * 0.25 \text{ hour/oral notification} = 0.2 \text{ hr}$ .
- 20% of these notifications are expected to be in writing, resulting in a per-notification burden of  $20\% * 1 \text{ hour / written notification} = 0.2 \text{ hr}$ .
- Therefore, the average notification burden is 0.4 hours per notification.

Thus, the total annual burden would be 875 hours (2,188 annual extension notifications \* 0.4 hr) at an aggregate cost of \$56,748 (875 hours \* \$64.84/hr).

### **§ 460.122 PACE Organization's Appeals Process**

The final rules do 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 § 460.122(b), CMS estimates that, on average, there will be 500 participants per PO receiving written information on the appeals process. We estimate that a technical specialist will take five minutes per participant (0.0833 hr) to notify participants. Therefore, the burden associated with the disclosure of the material outlining the appeals process is 6,497 annual hours (500 participants x 0.0833 hr x 156 POs) at a cost of \$426,749 (6,497 hr x \$65.68/hr).

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

For § 460.122(g)(2)(ii), the burden associated for technical staff 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 2,496 hours for all POs ((8 CMS notifications x 1 hr) + (8 state notifications x 1 hr) x 156 POs)) at a cost of \$163,937 (2,496 hr x \$65.68/hr).

### **§ 460.124 Additional Appeal Rights under Medicare or Medicaid**

The final rules do 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 technical staff will require one hour per participant to perform these activities, 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 624 annual hours (4 participants x 1 hour x 156 POs) at a cost of \$40,984 (624 hr x \$65.68/hr).

### **§ 460.132 Quality Improvement (QI) Plan**

The final rules do not change § 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 the technical staff 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 156 POs for a total annual burden of 1,248 hours (156 POs x 8 hr/PO) at a cost of \$81,969 (1,248 hr x \$65.68/hr).

#### **§ 460.152 Enrollment Process**

The final rules do not change § 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 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 \$279,752 (3,400 hr x \$82.28/hr).

#### **§ 460.156 Other Enrollment Procedures**

The final rules do not change § 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 technical staff at each PO will take 12 hours annually (1 hour per month) to complete this requirement. There will be approximately 156 POs for a total annual burden of 1,872 hours (156 POs x 12 hr/PO) at a cost of \$122,953 (1,872 hr x \$65.68/hr).

#### **§ 460.160 Continuation of Enrollment**

The final rules do 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 \$475,578 (5,780 hr x \$82.28/hr).

#### **§ 460.164 Involuntary Disenrollment**

The final rules do not change § 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 SAA 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 \$47,558 (578 hr x \$82.28/hr).

#### **§ 460.196 Disclosure of Review Results**

The final rules do not change § 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 technical staff at each PO will take five minutes (0.0833) to complete this requirement. There are approximately 156 POs for a total annual burden of 13 hours (156 POs x 0.0833 minutes/PO) at a cost of \$853 (13 hr x \$65.68/hr).

#### **§ 460.198 PACE Participant Notification Requirement for PACE Organizations with Past Performance Issues or Compliance Deficiencies**

The final rule adds a new requirement which gives CMS the authority to, at its discretion, require a PO to disclose to its PACE participants or potential PACE participants, the PO's performance and contract compliance deficiencies in a manner specified by CMS.

#### **Estimate #50 General Rule (New, Annual)**

The annual burden of this requirement is expected to be minimal. In the past, CMS has only required Medicare Advantage Organizations and Part D sponsors to send these notices to enrollees when CMS sanctioned the organization, which is an extremely rare occurrence. Regarding POs, between CY 2019 and 2021, CMS sanctioned a total of 3 POs for an average of 1 per year. As a result, CMS projects that between one and two POs per year would be required

to notify participants and potential participants of their performance and contract compliance deficiencies.

The burden estimate associated with this requirement is the time and cost for a PO's compliance officer to complete and send out the template (which would be automated) at an hourly rate of \$77.10. In aggregate, we estimate it would take 2 hours (2 POs \* (1 hr)) at a cost of \$154(2 hr \* \$77.10/hr).

### **§ 460.208 Financial Statements**

The final rules do not change § 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 technical staff at each PO will take four hours to complete this requirement. There are approximately 156 POs for a total annual burden of 624 hours (156 POs x 4 hours/PO) at a cost of \$40,984 (624 hr x \$65.68 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 technical staff 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 \$15,763 (240 hr x \$65.68/hr).

### **§ 460.210 Medical Records**

Section 460.210(a) requires POs to 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 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 final rule § 460.210(b)(6)(i) through (iii) modified this requirement by allowing communications to be stored either in the participant's medical record or outside of the medical record when certain conditions are met.

#### **Estimate #44 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 compliance officers at 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 8,112 hours (52 hr x 156 POs) at a cost of \$624,435 (8,112 hr \* \$77.10/hr).

**Estimate #45** Maintain 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. Section 460.210(b)(6)(i) through (iii) allows communications to be stored either in the participant's medical record or outside of the medical record provided certain conditions are met.

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 15,600 total hours (100 hr \* 156 POs) at a cost of \$1,202,760 (15,600 hr x \$77.10/hr).

Note however that the final rule at 460.210(b)(6)(i) through (iii) now allows 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** Documentation Inside or Outside Medical Record (New, One Time)

We estimate a new one-time burden of 40 hours for the PO's compliance specialist to establish training materials. In aggregate, we estimate a one-time burden of 2080 hours [(156 POs \* 40 hr) ÷ 3 years] at a cost of \$160,368 (2080 hr \* \$77.10/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)

To implement the changes at 460.210(b)(6)(i) through (iii), we estimate an annualized burden to compliance specialists at PACE organizations of 2,080 hours [(156 POs \* 40 hr) ÷ 3 years] at a cost of \$160,368 (2,080 hr x \$77.10/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** Purchase File Cabinets (New, One Time)

To accommodate the additional storage changes allowed at 460.210(b)(6)(i) through (iii), we estimate that a PACE organization will spend a total of \$300 (2 × \$150/each) for 2 four-drawer

locking file cabinets. In aggregate, we estimate a one-time cost of \$15,600 (\$300 x 156 POs divided by 3).

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

To update the policies and procedures reflecting the changes at § 460.210(b)(6)(i-iii), we estimate an annualized burden to compliance specialists at PACE organization of 520 hours ([156 POs \* 10 hr] ÷ 3 years) at a cost of \$40,092 (520 hr x \$77.10/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**

Est. No.	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	Fre
<b>REPORTING</b>										
1	460.30(a)&(b)	New Program Agreements, PO	10	10	1	10	65.68	657	No change	A
4	460.32	Service Area Expansion (SAE)	35	35	15	525	65.68	34,482	No change	A
5	460.32	Replace PACE Center	12	12	15	180	65.68	11,822	No change	A
6	460.32	Routine Review and Maintenance	156	156	4.5	702	65.68	46,107	No change	A
7	460.63(c)	Self-Report of Potential Fraud or Misconduct	156	156	20	3,120	65.68	204,922	No change	A
8	460.64(a)(5)(iii)	Develop Risk Assessment Tool	156	156	5	260	108.88	28,309	New	C
9	460.64	Update Policies and Procedures	156	156	1	52	77.10	4,009	New	C
10	460.68(b)(1)	Conflict of Interest Policies and Procedures	156	10	3	30	65.68	1,970	No change	A
12	460.70(b)(1)	New Applicants	10	1000	2	2,000	65.68	131,360	No change	A
13	460.70(b)(1)	SAE and/or New PACE Center	35	875	2	1,750	65.68	114,940	No change	A
14	460.70(b)(1)	Ongoing Maintenance Initial Application	156	156	5	780	65.68	51,230	No change	A
15	460.71(a)(2)	Competency Evaluations Initial Application	10	110	5	550	91.38	50,259	No change	A

16	460.71(a)(2)	Annual Competency Evaluations: All PO Staff	156	23400	2	46,800	65.68	3,073,824	No change	A
17	460.72(a)(3)	Written Plan for New Applicants	10	10	2	20	65.68	1,314	No change	A
18	460.72(a)(3)	Maintain Written Plan	156	156	1	156	65.68	10,246	No change	A
19	460.98(b)(5)	Ongoing documentation costs	156	156	50	7,800	77.10	601,380	No change	A
20	460.98(c)	Update Policies and Procedures	156	156	1	52	77.10	4,009	New	C
21	460.102(f)	Information Exchange - New Applicants	10	10	3	30	65.68	1,970	No change	A
22	460.102(f)	Information Exchange - Active Pos	156	156	1	156	65.68	10,246	No change	A
23	460.112	Update participant right materials	156	156	2	104	77.10	8,018	New	C
24	460.112(c)(5)	Develop Written Documentation of Treatment Options	156	156	2	104	77.10	8,018	New	C
25	460.112(c)(5)	Provide Written Documentation of Treatment Options	156	15183	1.1667	17,714	87.13	1,543,421	New	A
27	460.116(a)	Explanation of (Participant Rights)	156	156	2	312	65.68	20,492	No change	A
28	460.120	Update Grievance Policies and Procedures	156	156	2	104	77.10	8,018	New	C
30	460.120(c)	Update Grievance Process Notification	156	156	1	52	77.10	4,009	New	C
31	460.120(i)	Update Grievance Resolution Notification	156	156	1	52	77.10	4,009	New	C
32	460.121(i)(2)	Notification for Service Determination Request Extensions	156	2188	0.40	875	64.84	56,748	Revised	A
35	460.124	Provision of Appeal Rights	156	624	1	624	65.68	40,984	No change	A

36	460.132(b)	Annual Review	156	156	8	1,248	65.68	81,969	No change	A
38	460.156(b)	Other Enrollment Procedures	156	156	12	1,872	65.68	122,953	No change	A
42	460.208(a)(1)	General Rule	156	156	4	624	65.68	40,984	No change	A
43	460.208(c)(1)	Trial Period	15	60	4	240	65.68	15,763	No change	A
44	460.210(b)(4)&(5)	Documenting Recommendations for Services	156	156	52	8,112	77.10	625,435	No change	A
45	460.210(b)(6)	Maintain Original Documentation	156	156	100	15,600	77.10	1,202,760	Revised	A
46	460.210(b)(6)(i)-(iii)	Training	156	156	40	2,080	77.10	160,368	New	C
47	460.210(b)(6)(i)-(iii)	Software Development Update	156	156	40	2,080	77.10	160,368	New	C
48	460.210(b)(6)(i)-(iii)	Purchase File Cabinets	156	156	NA	NA	300.00	15,600	New	C
49	460.210(b)(6)(i)-(iii)	Update Policies & Procedures	156	156	10	520	77.10	40,092	New	C
<i>Subtotal: Reporting</i>			156	47,271	varies	117,290	varies	8,543,065	n/a	
<b>THIRD PARTY DISCLOSURES</b>										
11	460.68(b)(2)	Conflict of Interest, Disclosure	156	156	0.5	78	65.68	5,123	No change	A
26	460.112(e)(2)	Explanation of Treatment Options	156	15183	1	15,183	64.84	984,466	New	A
29	460.120(b)&(c)	Grievance Process	156	78000	0.0833	6,497	77.10	500,950	No change	A
33	460.122(b)	Appeals Process	156	78000	0.0833	6,497	65.68	426,749	No change	A
34	460.122(g)(2)(ii)	Appeal Determination Notification	156	2496	1	2,496	65.68	163,937	No Change	A
41	460.196(c)	Post Notice	156	156	0.0833	13	65.68	853	No change	A
50	460.198	Participant Notification of Past Issues	2	2	1	2	77.10	154	New	A
<i>Subtotal: Third Party Disclosure</i>			156	173,993	varies	30,766	varies	2,082,232	n/a	
<b>TOTAL</b>			<b>156</b>	<b>221,264</b>	<b>varies</b>	<b>148,056</b>	<b>varies</b>	<b>10,625,297</b>	<b>n/a</b>	

State Burden

Est. No.	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	Fre
2	460.30(a)&(b)	New Program Agreements, States	10	10	1	10	82.28	823	No change	A
3	460.30(c)	State Plan Amendment	3	3	20	60	82.28	4,937	No change	A
37	460.152(a)(3)	Enrollment Process	34	34	100	3,400	82.28	279,752	No change	A
39	460.160(b)	Continuation of Enrollment	34	34	170	5,780	82.28	475,578	No change	A
40	460.164(f)	Involuntary Disenrollment	34	578	1	578	82.28	47,558	No change	A
<b>TOTAL</b>			<b>34</b>	<b>659</b>	<b>varies</b>	<b>9,828</b>	<b>82.28</b>	<b>808,648</b>	<b>No Change</b>	<b>A</b>

**Total Burden**

Respondent Type	Total Annual Respondents	Total Annual Responses	Total Annual Time (hr)	Total Annual C
PACE organizations	156	221,264	148,056	10,625,297
States	34	659	9,828	808,648
<b>TOTAL</b>	<b>190</b>	<b>221,923</b>	<b>157,884</b>	<b>11,433,945</b>

*12.4 Collection of Information Instruments and Instruction/Guidance Documents*

We are not proposing any changes to the most recently active 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](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)	64.06	64.06	128.12

Annualized Cost to Federal Government

CMS Staff	(85) hours x \$128.12/hr	\$10,890
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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 \$10,890 (85 hr x \$128.12/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 April 12, 2023, CMS issued a final rule (88 FR 22120) CMS-4201-F. Additionally, on April 23, 2024, CMS issued a final rule (89 FR 30846) CMS-4201-F3 and CMS-4205-F. The final rules mentioned above form the basis for this 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 2024 iteration, we estimate 156 PO respondents. This represents an increase of 7 PO respondents (from 149 in the current package pending OMB approval). The number of State respondents remains unchanged at 34.

There was no change in State responses or hourly burden.

Estimate ID	Regulatory Citation	Respondents			Responses			Time (hr)		
		Current	Proposed	Difference	Current	Proposed	Difference	Current	Proposed	Difference
1	460.30(a)&(b)	10	10	0	10	10	0	10	10	0
2	460.30(a)&(b)	10	10	0	10	10	0	10	10	0
3	460.30(c)	3	3	0	3	3	0	60	60	0
4	460.32	35	35	0	35	35	0	525	525	0
5	460.32	12	12	0	12	12	0	180	180	0
6	460.32	149	156	7	149	156	7	670.5	702	31.5
7	460.63(c)	149	156	7	149	156	7	2980	3,120	140
8	460.64(a)(5)(iii)	149	156	7	149	156	7	248.33	260	11.6

9	460.64	149	156	7	149	156	7	49.67	52	2.33
10	460.68(b)(1)	10	156	146	10	10	0	30	30	0
11	460.68(b)(2)	149	156	7	149	156	7	74.5	78	3.5
12	460.70(b)(1)	10	10	0	1000	1000	0	2000	2,000	0
13	460.70(b)(1)	35	35	0	875	875	0	1750	1,750	0
14	460.70(b)(1)	149	156	7	149	156	7	745	780	35
15	460.71(a)(2)	10	10	0	110	110	0	550	550	0
16	460.71(a)(2)	149	156	7	22350	23400	1050	44700	46,800	2100
17	460.72(a)(3)	10	10	0	10	10	0	20	20	0
18	460.72(a)(3)	149	156	7	149	156	7	149	156	7
19	460.98(b)(5)	149	156	7	149	156	7	7450	7,800	350
20	460.98(c)	149	156	7	149	156	7	49.67	52	2.33
21	460.102(f)	10	10	0	10	10	0	30	30	0
22	460.102(f)	149	156	7	149	156	7	149	156	7
23	460.112	149	156	7	149	156	7	99.33	104	4.67
24	460.112(c)(5)	149	156	7	149	156	7	99.33	104	4.67
25	460.112(c)(5)	149	156	7	10927	15183	4256	12749	17,714	4965
26	460.112(e)(2)	149	156	7	10927	15183	4256	10927	15,183	4256
27	460.116(a)	149	156	7	149	156	7	298	312	14
28	460.120	149	156	7	149	156	7	99.33	104	4.67
29	460.120(b)&(c)	149	156	7	44700	78000	33300	3724	6,497	2773
30	460.120(c)	149	156	7	149	156	7	49.67	52	2.33
31	460.120(i)	149	156	7	149	156	7	49.67	52	2.33
32	460.121(i)(2)	149	156	7	2188	2188	0	875	875	0.2
33	460.122(b)	149	156	7	44700	78000	33300	3724	6,497	2773
34	460.122(g)(2)(ii)	149	156	7	2384	2496	112	2384	2,496	112
35	460.124	149	156	7	596	624	28	596	624	28
36	460.132(b)	149	156	7	149	156	7	1192	1,248	56
37	460.152(a)(3)	34	34	0	34	34	0	3400	3,400	0
38	460.152(b)	149	156	7	149	156	7	1788	1,872	84
39	460.160(b)	34	34	0	34	34	0	5780	5,780	0
40	460.164(f)	34	34	0	34	578	544	578	578	0
41	460.196(c)	149	156	7	149	156	7	12.41	13	0.584
50	460.198	0	2	2	0	2	2	0	2	2
42	460.208(a)(1)	149	156	7	149	156	7	596	624	28
43	460.208(c)(1)	15	15	0	4	60	56	240	240	0
44	460.210(b)(4)&(5)	149	156	7	149	156	7	7748	8,112	364
45	460.210(b)(6)	149	156	7	149	156	7	14900	15,600	700
46	460.210(b)(6)(i)– (iii)	149	156	7	149	156	7	1986.67	2,080	93.3
47	460.210(b)(6)(i)– (iii)	149	156	7	149	156	7	1986.67	2,080	93.3
48	460.210(b)(6)(i)– (iii)	149	156	7	149	156	7	NA	NA	NA

49	460.210(b)(6)(i)– (iii)	149	156	7	149	156	7	496.67	520	23.3
<b>TOTAL</b>		<b>179</b>	<b>190</b>	<b>+11</b>	<b>121,407</b>	<b>221,923</b>	<b>+100,516</b>	<b>97,069</b>	<b>157,884</b>	<b>+60,8</b>

\* 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 collection of information request is approved by OMB.

**18. Certification Statement**

There are no exceptions to the certification statement.

**B. Collection of Information Employing Statistical Methods**

There are no statistical methods employed in this collection.