

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 January 19, 2021, CMS issued a final PACE rule (86 FR 6132) (CMS-4190-F2, RIN 0938-AT97), which is the basis for this 2022 revised collection of information request.

### **Summary of the Final Rule, CMS-4190-F2**

As explained in further detail in sections 12 and 15 of this Supporting Statement, the final rule addresses various requirements, reduces administrative burden, and provides additional participant protections. The revisions streamlined service determination requests and reduced administrative burden while building in participant protections including enhanced notification requirements; enhanced appeal requirements to ensure appeals are appropriately processed and that participants receive sufficient notification of the appeal decision; added requirements to ensure services are sufficiently documented, tracked and monitored; increased requirements regarding documentation that must be stored within a participant's medical record; and ensured that participants are guaranteed specific rights related to the Medicare complaint process, long term care treatment, and the right to see specialists.

## **A. Justification**

### **1. Circumstances Making the Collection of Information Necessary**

Collection of this information is mandated by statute under Sections 1894 and 1934 of the Act and at 42 CFR part 460. This clearance request is for the information collected to ensure compliance with CMS requirements in the operation of PACE programs.

## 2. Purpose and Use of Information Collection

Information addressed is based on regulatory requirements associated with active POs and is related to the operational aspects of a PACE program. CMS and the SAAs will 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 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 final rule create a net impact of savings, not cost. Consequently, this final 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 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

Our proposed rule (CMS-4190-P; RIN 0938-AT97) published in the Federal Register on February 18, 2020 (85 FR 9002). PRA-related comments were received and have been responded to in our January 19, 2021 (86 FR 5864) final rule (CMS-4190-F2; RIN 0938-AT97).

Neither of the rule packages were submitted to OMB. To correct this oversight, we are using the standard non-rule PRA process which includes the publication of 60- and 30-day Federal Register notices.

This package does not have any reporting instructions beyond what was published in the rule and codified in the CFR.

The 60-day notice published in the Federal Register on August 5, 2022 (87 FR 48030). Comments must be received by October 4, 2022

#### 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 2022 iteration, we estimate 145 PO respondents. This represents an increase of 11 PO respondents (from 134 currently approved to 145 in 2022). The number of State respondents remains unchanged at 34.

##### *12.1. 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](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 overhead (calculated at 100 percent of salary), and our adjusted hourly wage.

| Occupation or IDT Title  | BLS Occupation Code | Mean Hourly Wage (\$/hr) | Fringe Benefits and Overhead (\$/hr) | Adjusted Hourly Wage (\$/hr) |
|--|---------------------|--------------------------|--------------------------------------|------------------------------|
| Compliance Officers*   | 13-1041             | 36.45                    | 36.45                                | 72.90                        |
| Dietitians and Nutritionists*  | 29-1031             | 31.55                    | 31.55                                | 63.10                        |
| Passenger Vehicle Driver*  | 53-3050             | 19.06                    | 19.06                                | 38.12                        |
| General Internal Medicine Physician* (Primary Care Provider†)                              | 29-1216             | 116.44                   | 116.44                               | 232.88                       |
| Healthcare Social Worker* (Masters of Social Work†)  | 21-1022             | 29.96                    | 29.96                                | 59.92                        |
| Home Care Coordinator†<br>Registered Nurse*  | 29-1141             | 39.78                    | 39.78                                | 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                        |
| 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                       |
| Home Health and Personal Care Aides* (Personal Care Attendant†)                            | 31-1120             | 14.07                    | 14.07                                | 28.14                        |
| Physical Therapists*   | 29-1123             | 44.67                    | 44.67                                | 89.84                        |
| Recreational Therapists*   | 29-1125             | 25.91                    | 25.91                                | 51.82                        |
| Registered Nurses*   | 29-1141             | 39.78                    | 39.78                                | 79.56                        |

\*Denotes a BLS occupational title.

†Denotes an IDT member occupational title.

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.

| Occupation Title                                     | Adjusted Average Hourly Rate for a single IDT member | Full IDT Hourly Rate (Cost of all 11 disciplines working concurrently per hour) |
|--|--|---|
| 11 IDT Disciplines (as listed in the previous table) | \$84.02/hr   | \$924.20/hr   |

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

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

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 by the PACE final rule, new requirements arising from the PACE final rule, and modifications of existing requirements arising from the PACE final rule. 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. The following provisions include new requirements and burden: 460.98, 460.112, 460.121, 460.122, and 460.210. The following provision includes revised requirements and burden: 460.122. We further clarify that burden estimates for all provisions are modified throughout due to some combination of the following factors since the OMB approval for CMS-R-244 in December 2020: i) changes in occupations performing the labor; ii) changes in labor wages; and iii) changes in the number of POs. Therefore, if a regulatory section is designated as unchanged from the currently approved CMS-R-244 collection of information request, burden estimates for this request for collection of information would still increase based on these cost factors.

As mentioned in Section 1, the classification of each provision corresponds to the regulatory paragraphs. We have sought where possible to clearly indicate the associated regulatory section and indicated the provision type, i.e., no change, new, and/or revised as a result of the PACE final rule. To achieve clarity the following conventions are noted:

- Consistency of Summary Table and Narrative sections: The same classification is used in both the Section 12.2 Narrative and Section 12.3 Summary Table.

- Key Subtotals: While we do not provide additional tables, key subtotals are indicated by stakeholder (POs, third party disclosure, and states), and type of regulatory source, for example, no change, PACE final rule (new), and/or PACE final rule (revised).
- Identification of provisions: As mentioned in Section 1, to provide a clear outline of each provision, the following identification system is used: The Summary Table lists provisions sequentially by regulatory section order; regulatory paragraphs (or descriptions) for each section are identified by a unique title or paragraph description, and are included in both the Summary Table and Narrative sections. Additionally, the Summary Table lists provisions in the same order in which they appear in the Narrative section.
- The net changes in burden for new and revised requirements are shown below. See section 15 for a detailed description of the net change in burden for each of the requirements.

### **460.30 Program Agreement Requirement**

#### **PACE Program Agreements: PO & SSA Burden (No Change)**

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

#### **State Plan Amendment (No Change)**

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 final 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. In addition, POs are required to continuously and/or routinely review and update policies and procedures, including those explicitly captured in the program agreement.

#### Service Area Expansion (SAE) (No Change)

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).

#### PACE Replacement Center (No Change)

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).

#### Routine Review and Maintenance (No Change)

All 145 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 652.5 hours (145 POs x 4.5 hr) at a cost of \$38,563 (652.5 hr x \$59.10/hr).

### **460.63 Compliance Oversight Requirements**

The final 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.

#### Self-Report of Potential Fraud or Misconduct (No Change)

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 2,900 hr (145 POs x 20 hr), at a cost of \$171,390 (2,900 hr x \$59.10/hr).

### **460.68 Program Integrity**

The final 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.

#### Conflict of Interest Policies and Procedures (No Change)

The final 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 entities x 3 hr) at a cost of \$1,773 (30 hr x \$59.10/hr).

#### Conflict of Interest Disclosure (No Change)

The final 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 145 POs for a total annual burden of 72.5 hours at a cost of \$4,285 (72.5 hr x \$59.10/hr). In the absence of more specific data, we maximally assume that each PO adds at least one board member annually.

### **460.70 Contracted Services**

The final 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.

#### New Applicants (No Change)

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).

#### SAE and/or New PACE Center (No Change)

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).

#### Ongoing Maintenance (No Change)

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 145 POs for a total annual burden of 725 hours (145 POs x 5 hr) at a cost of \$42,848 (725 hr x \$59.10 hr).

#### **460.71 Oversight of Direct Participant Care (No change)**

The final 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.

##### **Competency Evaluations: Initial applications (No Change)**

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 \$46,211 (550 hr x \$84.02/hr wage rate for an IDT member).

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

Implementation of the program will require a minimum of 2 hours per staff member for each of the 145 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 43,500 hours (145 POs x 300 hours) at a cost of \$2,570,850 (43,500 hr x \$59.10/hr).

#### **460.72 Physical Environment (No change)**

The final 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.

##### **Written Plan for New Applicants (No Change)**

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).

##### **Maintain Written Plan (No Change)**

We estimate that 145 active POs will require one hour to maintain the written plan, for a total

annual burden of 145 hours (145 POs x 1 hr/PO) at a cost of \$8,570 (145 hr x \$59.10/hr).

#### **460.98 Service Delivery (New)**

The final rule at § 460.98(b)(5) added a new requirement for POs 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.

##### **Policies and Procedures (New)**

We estimate a new, one-time burden of 50 hours at \$72.90/hr for technical staff, in this case, Compliance or Quality Officer(s), at each PO to develop the necessary procedures and written materials. In aggregate, we estimate an annualized burden of 2,416.67 hours ( $[145 \text{ PO} \times 50 \text{ hr}] \div 3 \text{ years}$ ) at an annualized cost of \$176,175 ( $2,416.67 \text{ hr} \times \$72.90/\text{hr}$ ) for developing the necessary procedures and written materials to document, track, and monitor the provision of services. We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires.

##### **Ongoing Documentation Costs (New)**

We also estimate this provision would result in increased ongoing costs to POs. We estimate a new burden of 50 hours annually per PO at \$72.90/hr for Compliance Officer(s) to complete these activities. We estimate a total aggregate annual cost at \$528,525 ( $145 \text{ POs} \times 50 \text{ hr} \times \$72.90/\text{hr}$ ).

#### **460.102 Interdisciplinary Team (IDT) (No change)**

Section 460.102 sets forth the requirements for the PACE Interdisciplinary Team.

##### **Information Exchange-New Applicants (No Change)**

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 ( $10 \text{ new entities annually} \times 3 \text{ hr/ new entity}$ ) at a cost of \$1,773 ( $30 \text{ hr} \times \$59.10/\text{hr}$ ).

##### **Information Exchange-Active POs (No Change)**

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 145 POs for a total of 145 hours ( $145 \text{ POs} \times 1 \text{ hr/PO}$ ) at a cost of \$8,570

(145 hr x \$59.10).

#### **460.112 Participant Rights (New)**

Section 460.112 describes specific rights that PACE participants are entitled to. We finalized participant rights to include three new distinct rights, specifically, the participant's right to have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines, the right to call 1-800-MEDICARE with questions or concerns regarding the program, and the right to receive necessary care in all care settings, up to and including placement in a long-term care facility when the PACE organization can no longer maintain the participant safely in the community. The PACE organization is currently required to provide a copy of this set of participant rights to participants at the time of enrollment, and they are required to post a copy of the rights in the center. Under these proposals, the PACE organization would be required to revise the current participant rights to account for the three new requirements.

We estimate a new one-time burden of 2 hours at \$72.90 hr for the PO's technical staff to update the participant rights information included in the enrollment information and post the new participant rights in the center. In aggregate, we estimate an annualized burden of 96.67 hours ( $[145 \text{ PO} \times 2 \text{ hr}] \div 3 \text{ years}$ ) at an annualized cost of \$7,047 ( $96.67 \text{ hr} \times \$72.90/\text{hr}$ ). We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires.

#### **460.116 Explanation of Rights (No Change)**

The final 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.

#### **Explanation of (Participant) Rights (No Change)**

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 145 POs for a total annual burden of 290 hours ( $145 \text{ POs} \times 2 \text{ hours/PO}$ ) at a cost of \$17,139 ( $290 \text{ hr} \times \$59.10/\text{hr}$ ).

#### **460.120 Grievances (No Change)**

460.120 sets forth the requirements for the PACE grievance process.

#### **Grievance Process (No Change)**

Section 460.120(b) states that upon enrollment, and at least annually thereafter, the PO must give a participant written information on the grievance process. The burden associated with this requirement is the time and effort for the PO to give a participant written information on the grievance process.

CMS estimates that, on average, there will be 300 participants per PO receiving written information on the grievance process 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 3,624 hours (300 participants x 0.0833 hr x 145 POs) at a cost of \$214,178 (3,624 hr x \$59.10/hr).

#### Additional Written Information (No Change)

Section 460.120(e) states that the PO must discuss with, and provide to the participant, in writing, the specific steps, including timeframes for response, that will be taken to resolve the participant's grievance.

The burden associated with this requirement is the time and effort for the PO to discuss with, and provide to the participant, in writing, the specific steps, including timeframes for response, that will be taken to resolve the participant's grievance. CMS estimates that, on average, there will be 16 participants per PO receiving the additional written information on the grievance process, and it will take 10 minutes (0.1667 hr) to provide each participant with the information. In sum, the burden associated with the disclosure of the additional grievance materials is 39 annual hours (16 participants x 0.1667 hr x 145 POs) at a cost of \$2,304 (39 hr x \$59.10/hr).

### **460.121 Service Determination Requests (New)**

Section 460.104(d)(2) currently states the requirements for processing service determination requests (that is, requests from participants or their designated representatives to initiate, eliminate, or continue a service). The final rule moved service determination request processing requirements from the Participant Assessment section 460.104(d)(2) to a new section, 460.121, specific to service determination requests and modified the requirements to reduce burden on POs while ensuring appropriate participant protections are in place.

We finalized a new requirement at §460.121(i)(2) that requires POs to notify participants or their designated representatives when they take an extension when processing a service determination request. We expect most POs would develop a template letter to notify the appropriate parties in these situations. We are also clarifying requirements regarding the content of denial notifications following the determination of a service determination request, which would require POs to update their denial notification letter templates.

Changes to service determination request requirements include:

#### Written Notification for Service determination request Extensions (New)

Under the new section 460.121(i)(2) of this final rule, POs must provide written notification to

participants whenever they extend the processing timeframe for service determination requests.

Consequently, the new total annual burden for providing written notification to participants when the IDT extends the timeframe for processing service determination requests in accordance with 460.121(i)(2) is 2,350 hours (705 requests per 1,000 enrollees x 53,549 projected enrollment for 2022-2024 x 6.22 percent of requests that require extensions x 1 hour to process each service determination request extension) at a cost of \$140,812 (2,350 hr x \$59.92/hr for a Master's-level Social Worker (MSW) to process them).

#### SDR Extension and Denial Notification Template Letters (New)

For the new requirements in 460.121(i)(2), =

We estimate a new one-time burden of 2 hours at \$72.90/hr for the Compliance Officer (Quality Improvement Coordinator) to create and revise the extension notification and denial notification for each PO. In aggregate, we estimate an annualized burden of 96.67 hours ( $[145 \text{ PO} \times 2 \text{ hr}] \div 3 \text{ years}$ ) at an annualized cost of \$7,047 (96.67 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.

#### **460.122 PACE Organization's Appeals Process (Revised and New)**

The final rule revises the PO appeal process in 460.122 with additional requirements. Specifically, POs must develop and distribute written materials that will explain the PACE requirements to the third-party reviewers that are responsible for making appeal determinations and that POs revise their current appeal notification materials.

##### Appeals Process (No Change)

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 3,624 annual hours (300 participants x 0.0833 hr x 145 POs) at a cost of \$214,178 (3,624 hr x \$59.10/hr).

##### Appeal Decision Notification (Revised)

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 five minutes per notification (0.0833 hr). Therefore, the burden associated with these disclosure requirements is 193.26 hours for all POs ((8 CMS notifications x 0.0833 hr) + (8 state notifications x 0.0833 hr) x 145 POs) at a cost of \$11,421.67 (193.26 hr x \$59.10/hr).

##### Update Appeal Decision Notification Template (New)

For the revision of the written appeal notices in 460.122(g), we estimate it will take 1 hour at \$72.90/hr for a Compliance Officer (Quality Improvement Coordinator) at each PO to revise the

current notices. In aggregate, we estimate an annualized burden of 48.33 hours ( $[145 \text{ PO} \times 1 \text{ hr}] \div 3 \text{ years}$ ) at an annualized cost of \$3,524 ( $48.33 \text{ hr} \times \$72.90/\text{hr}$ ) for the revision of written appeal notices. We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires.

#### Distribution of Appeal Materials to 3<sup>rd</sup> Party Reviewers (New)

For the development and distribution of materials to the third party reviewers as required in 460.122(c), we estimate a new one-time burden of 4 hours at \$72.90/hr for a Compliance Officer (Quality Improvement Coordinator) at each PO to create and distribute these materials (3 hours to create and 1 hour to distribute). In aggregate, we estimate an annualized burden of 193.33 hours ( $[145 \text{ PO} \times 4 \text{ hr}] \div 3 \text{ years}$ ) at an annualized cost of \$14,094 ( $193.33 \text{ hr} \times \$72.90/\text{hr}$ ) for the distribution of 3<sup>rd</sup> party appeals reviewers. We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires.

### **460.124 Additional Appeal Rights under Medicare or Medicaid (No Change)**

Section 460.124 states that a PO must inform a participant, in writing, of his or her appeal rights under Medicare or Medicaid, or both, assist the participant in filing Medicare and Medicaid appeals, and forward the appeal to the appropriate external entity. The final rule revises 460.124 to ensure POs provide additional detail about the appeals process to participants and to improve consistency in the administration of the appeals process among POs; however, this change does not impact the burden estimate.

#### Provision of Appeal Rights (No change)

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 580 annual hours ( $4 \text{ participants} \times 1 \text{ hour} \times 145 \text{ POs}$ ) at a cost of \$34,278 ( $580 \text{ hr} \times \$59.10/\text{hr}$ ).

### **460.132 Quality Improvement (QI) Plan (No Change)**

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

#### Annual Review (No Change)

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 145 POs for a total annual burden of 1,160 hours ( $145 \text{ POs} \times 8 \text{ hr/PO}$ ) at a cost of

\$68,556 (1,160 hr x \$59.10/hr).

#### **460.152 Enrollment Process (No Change)**

The final 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.

##### **SAA Level of Care Assessment (No Change)**

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 (No Change)**

The final 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.

##### **Submission of Enrollment Information to CMS and the SAA (No Change)**

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 145 POs for a total annual burden of 1,740 hours (145 POs x 12 hr/PO) at a cost of \$102,834 (1,728 hr x \$59.10/hr).

#### **460.160 Continuation of Enrollment (No Change)**

The final 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.

##### **Annual Participant Evaluation (No Change)**

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 (No change)**

The final rule does not change Section 460.164, which specifies the conditions under which a



PACE participant can be involuntarily disenrolled from a PACE program.

#### Review of Involuntary Disenrollments (No Change)

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 (No Change)**

The final 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.

#### Post Notice (No Change)

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 145 POs for a total annual burden of 12 hours (145 POs x 0.0833 minutes/PO) at a cost of \$709 (12.08 hr x \$59.10/hr).

#### **460.208 Financial Statements (No Change)**

The final 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.

#### General Rule (No Change)

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 145 POs for a total annual burden of 580 hours (145 POs x 4 hours/PO) at a cost of \$34,278 (580 hr x \$59.10 hr).

#### Trial Period (No Change)

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 PO will take 16 hours (four hours per quarter) to submit a quarterly financial statement. There will be approximately 15 POs affected by this trial period requirement for a total annual burden of 240 hours (15 POs x 16 hr/PO) at a cost of \$14,184 (240 hr x \$59.10/hr).

#### **460.210 Medical Records (New)**

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 final rule revises 460.210 to better address how recommendations for care and treatment, decisions regarding those recommendations, and communications relating to a participant's care, health or safety should be documented in the medical record.

#### Revision of Policies and Procedures (New)

In aggregate, we estimate an annualized burden of 483.33 hours ( $[145 \text{ PO} \times 10 \text{ hr}] \div 3 \text{ years}$ ) at an annualized cost of \$35,235 ( $483.33 \text{ hr} \times \$72.90/\text{hr}$ ) for a Compliance Officer to revise materials and lead training. We are annualizing the one-time estimate since we do not anticipate any additional burden after OMB's 3-year approval period expires.

#### Medical Record Contents - Keeping Original Documentation (New)

This final rule requires PO organizations to maintain original documentation or an unaltered electronic copy of any written communication the PO receives relating to the care, health or safety of a participant. For this requirement, any IDT occupation may be involved. Therefore, to determine the cost associated with this provision, we took the wages for the full IDT (\$924.20) and divided it by the 11 occupations included in the IDT to determine an average wage of \$84.02/hr ( $\$924.20/\text{hr} / 11 \text{ occupations}$ ).

We estimate that the new, 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 10 hours per PO annually or 1,450 total hours ( $10 \text{ hr} \times 145 \text{ POs}$ ) at a cost of \$121,829 ( $1,450 \text{ hr} \times \$84.02/\text{hr}$ ).

#### Medical Record Contents - Documenting Recommendations (New)

The final rule requires a PO to document recommendations for services from employees or contractors of the PO, including specialists and require POs to document the reasons a service recommended by an employee or contractor of the PO is not approved or provided. We estimated that each PO will have new, ongoing burden of 52 hours annually (approximately 1 hr per week) to implement this part of the regulation. Therefore, we estimate a total of 52 hours per organization per year, or a total of 7,540 hours ( $52 \text{ hr} \times 145 \text{ POs}$ ) at a cost of \$633,511 ( $7,540 \text{ hr} \times \$84.02/\text{hr}$ ).

### *12.3. Burden Summary*

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

The total burdens by provision are not included in either the summary table or narrative since

some regulatory sections have provisions with burden to different sectors or from different sources (no change, new, revised, etc.). However, grand totals and subtotals are included at the bottom of the table by sectors (total hour and dollars) and include the total burden for POs, third party disclosures, and the states. Subtotals by source are also listed at the conclusion of the table. We believe that one table with clear entries and subtotals is sufficient to capture these statistics and provides a clearer interpretation of the burden estimates.

Burden Summary Table (Listed Sequentially by CFR Section)

| CFR Section        | Regulatory Section Description              | Paragraph Description (if applicable)        | Total Annual Respondents | Total Annual Responses | Time/Response (hr) | Total Annual Time (hr) | Labor Cost (\$/hr) | Total Annual Cost | Respondent Type | Action Type: 1) No change 2) New or 3) Revised | Response Frequency (annual or 1 <sup>st</sup> year divided by 3 for one-time burden) |
|--------------------|---|--|--------------------------|------------------------|--------------------|------------------------|--------------------|-------------------|-----------------|--|--|
| 460.30 (a) and (b) | Program Agreement Requirement               | New Program Agreements : PO Burden           | 10                       | 10                     | 1                  | 10                     | 59.10              | 591               | POs             | No change                                      | Annual   |
| 460.30 (a) and (b) | Program Agreement Requirement               | New Program Agreements : SSA Burden          | 10                       | 10                     | 1                  | 10                     | 75.72              | 757               | States          | No change                                      | Annual   |
| 460.30 (c)         | Program Agreement Requirement               | State Plan Amendment                         | 3                        | 3                      | 20                 | 60                     | 75.72              | 4,543             | States          | No change                                      | Annual   |
| 460.32             | Content and Terms of PACE Program Agreement | Service Area Expansion (SAE)                 | 35                       | 35                     | 15                 | 525                    | 59.10              | 31,028            | POs             | No change                                      | Annual   |
| 460.32             | Content and Terms of PACE Program Agreement | PACE Replacement Center                      | 12                       | 12                     | 15                 | 180                    | 59.10              | 10,638            | POs             | No change                                      | Annual   |
| 460.32             | Content and Terms of PACE Program Agreement | Routine Review and Maintenance               | 145                      | 145                    | 4.5                | 652.20                 | 59.10              | 38,563            | POs             | No change                                      | Annual   |
| 460.63(c)          | Compliance Oversight Requirements           | Self-Report of Potential Fraud or Misconduct | 145                      | 145                    | 20                 | 2,900                  | 59.10              | 171,390           | POs             | No change                                      | Annual   |
| 460.68 (b)(1)      | Program Integrity                           | Conflict of Interest Policies and Procedures | 10                       | 10                     | 3                  | 30                     | 59.10              | 1,773             | POs             | No change                                      | Annual   |
| 460.68 (b)(2)      | Program Integrity                           | Conflict of Interest Disclosure              | 145                      | 145                    | 0.5                | 72.5                   | 59.10              | 4,285             | POs             | No change                                      | Annual   |
| 460.70 (b)(1)      | Contracted Services                         | New Applicants                               | 10                       | 1,000                  | 2                  | 2,000                  | 59.10              | 118,200           | POs             | No change                                      | Annual   |

| CFR Section   | Regulatory Section Description       | Paragraph Description (if applicable)         | Total Annual Respondents | Total Annual Responses | Time/Response (hr) | Total Annual Time (hr) | Labor Cost (\$/hr) | Total Annual Cost | Respondent Type | Action Type: 1) No change 2) New or 3) Revised | Response Frequency (annual or 1 <sup>st</sup> year divided by 3 for one-time burden) |
|---------------|--------------------------------------|---|--------------------------|------------------------|--------------------|------------------------|--------------------|-------------------|-----------------|--|--|
| 460.70 (b)(1) | Contracted Services                  | SAE and/or New PACE Center                    | 35                       | 875                    | 2                  | 1,750                  | 59.10              | 103,425           | POs             | No change                                      | Annual   |
| 460.70 (b)(1) | Contracted Services                  | Ongoing Maintenance                           | 145                      | 145                    | 5                  | 725                    | 59.10              | 42,848            | POs             | No change                                      | Annual   |
| 460.71 (a)(2) | Oversight of Direct Participant Care | Competency Evaluations : Initial applications | 10                       | 110                    | 5                  | 550                    | 84.02              | 46,211            | POs             | No change                                      | Annual   |
| 460.71 (a)(2) | Oversight of Direct Participant Care | Annual Competency Evaluations : All PO staff  | 145                      | 21,750                 | 2                  | 43,500                 | 59.10              | 2,570,850         | POs             | No change                                      | Annual   |
| 460.72 (a)(3) | Physical Environment                 | Written Plan for New Applicants               | 10                       | 10                     | 2                  | 20                     | 59.10              | 1,182             | POs             | No change                                      | Annual   |
| 460.72 (a)(3) | Physical Environment                 | Maintain Written Plan                         | 145                      | 145                    | 1                  | 145                    | 59.10              | 8,570             | POs             | No change                                      | Annual   |
| 460.98(b)(5)  | Service Delivery                     | Policies and Procedures                       | 145                      | 48.33                  | 50                 | 2,416.67               | 72.90              | 176,175           | POs             | New  | One-time   |
| 460.98(b)(5)  | Service Delivery                     | Ongoing documentation costs                   | 145                      | 145                    | 50                 | 7,250                  | 72.90              | 528,525           | POs             | New  | Annual   |
| 460.102 (f)   | Interdisciplinary Team (IDT)         | Information Exchange - New Applicants         | 10                       | 10                     | 3                  | 30                     | 59.10              | 1,773             | POs             | No change                                      | Annual   |
| 460.102 (f)   | Interdisciplinary Team (IDT)         | Information Exchange - Active Pos             | 145                      | 145                    | 1                  | 145                    | 59.10              | 8,570             | POs             | No change                                      | Annual   |
| 460.112       | Specific Participant Rights          | Update participant rights                     | 145                      | 48.33                  | 2                  | 96.67                  | 72.90              | 7,047             | POs             | New  | One-time   |
| 460.116 (a)   | Explanation of Rights                | Explanation of (Participant) Rights           | 145                      | 145                    | 2                  | 290                    | 59.10              | 17,139            | POs             | No change                                      | Annual   |
| 460.120 (b)   | Grievances                           | Grievance Process                             | 145                      | 43,500                 | 0.0833             | 3,623.55               | 59.10              | 214,178           | POs             | No change                                      | Annual   |
| 460.120(e)    | Grievances                           | Additional Written Information                | 145                      | 2,230                  | 0.1667             | 38.67                  | 59.10              | 2,304             | POs             | No change                                      | Annual   |
| 460.121       | Service determination requests       | Notification of Extension                     | 145                      | 2,350                  | 1                  | 2,350                  | 59.92              | 140,812           | POs             | New  | Annual   |

| CFR Section    | Regulatory Section Description                      | Paragraph Description (if applicable)                               | Total Annual Respondents | Total Annual Responses | Time/Response (hr) | Total Annual Time (hr) | Labor Cost (\$/hr) | Total Annual Cost | Respondent Type | Action Type: 1) No change 2) New or 3) Revised | Response Frequency (annual or 1 <sup>st</sup> year divided by 3 for one-time burden) |
|----------------|---|---|--------------------------|------------------------|--------------------|------------------------|--------------------|-------------------|-----------------|--|--|
| 460.121        | Service determination requests                      | Denial and Extension Template Letters                               | 145                      | 48.33                  | 2                  | 96.67                  | 72.90              | 7,047             | POs             | New  | One-time   |
| 460.122 (b)    | PO Appeals Process                                  | Appeals Process   | 145                      | 43,500                 | 0.0833             | 3,623.55               | 59.10              | 214,178           | POs             | No change                                      | Annual   |
| 460.122(c)     | PO Appeals Process                                  | Distribution of Appeals Materials to 3 <sup>rd</sup> party reviewer | 145                      | 48.33                  | 4                  | 193.33                 | 72.90              | 14,094            | POs             | New  | One-time   |
| 460.122 (g)    | PO Appeals Process                                  | Appeal Determination Notification                                   | 145                      | 2,320                  | 0.0833             | 193.26                 | 59.10              | 11,421.67         | POs             | Revised  | Annual   |
| 460.122(g)     | PO Appeals Process                                  | Update Appeal Decision Notification Template                        | 145                      | 48.33                  | 1                  | 48.33                  | 72.90              | 3,524             | POs             | New  | One-time   |
| 460.124        | Additional Appeal Rights under Medicare or Medicaid | Provision of Appeal Rights  | 145                      | 580                    | 1                  | 580                    | 59.10              | 34,278            | POs             | No change                                      | Annual   |
| 460.132 (b)    | Quality Improvement (QI) Plan                       | Annual Review   | 145                      | 145                    | 8                  | 1,160                  | 59.10              | 68,556            | POs             | No change                                      | Annual   |
| 460.152 (a)(3) | Enrollment Process                                  |   | 34                       | 34                     | 100                | 3,400                  | 75.72              | 257,448           | States          | No change                                      | Annual   |
| 460.156 (b)    | Other Enrollment Procedures                         |   | 145                      | 145                    | 12                 | 1,740                  | 59.10              | 102,834           | POs             | No change                                      | Annual   |
| 460.160 (b)    | Continuation of Enrollment                          |   | 34                       | 34                     | 170                | 5,780                  | 75.72              | 437,662           | States          | No change                                      | Annual   |
| 460.164 (f)    | Involuntary Disenrollment                           |   | 34                       | 34                     | 17                 | 578                    | 75.72              | 43,766            | States          | No change                                      | Annual   |
| 460.196 (c)    | Disclosure of Review Results                        | Post Notice   | 145                      | 145                    | 0.0833             | 12.08                  | 59.10              | 709               | POs             | No change                                      | Annual   |
| 460.208 (a)(1) | Financial Statements                                | General Rule  | 145                      | 145                    | 4                  | 580                    | 59.10              | 34,278            | POs             | No change                                      | Annual   |
| 460.208 (c)(1) | Financial Statements                                | Trial Period  | 145                      | 580                    | 4                  | 240                    | 59.10              | 14,184            | POs             | No change                                      | Annual   |
| 460.210        | Medical Records                                     | Revision of Policies and Procedures                                 | 145                      | 48.33                  | 10                 | 483.33                 | 72.90              | 35,235            | POs             | New  | One-time   |
| 460.210        | Medical Records                                     | Maintenance of Original Documentation                               | 145                      | 145                    | 10                 | 1,450                  | 84.02              | 121,829           | POs             | New  | Annual   |

| CFR Section | Regulatory Section Description | Paragraph Description (if applicable) | Total Annual Respondents | Total Annual Responses | Time/Response (hr) | Total Annual Time (hr) | Labor Cost (\$/hr) | Total Annual Cost | Respondent Type | Action Type: 1) No change 2) New or 3) Revised | Response Frequency (annual or 1 <sup>st</sup> year divided by 3 for one-time burden) |
|-------------|--------------------------------|---------------------------------------|--------------------------|------------------------|--------------------|------------------------|--------------------|-------------------|-----------------|--|--|
| 460.210     | Medical Records                | Documentation of Recommendations      | 145                      | 145                    | 52                 | 7,540                  | 84.02              | 633,511           | POs             | New  | Annual   |
| TOTAL       |                                |                                       | 179                      | 121,407                | Varies             | 97,069                 | Varies             | 6,285,862         |                 |  |  |

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

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

#### 13. Capital Costs

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 2022 base salary for the Baltimore/Washington, D.C. region at the GS-13, step 5 level ([https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/DCB\\_h.pdf](https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/DCB_h.pdf)). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

| Grade (Step)   | Hourly Wage (\$/hr) | Fringe Benefits and Overhead (\$/hr) | Adjusted Hourly Wage (\$/hr) |
|----------------|---------------------|--------------------------------------|------------------------------|
| GS-13 (step 5) | 58.01               | 58.01                                | 116.02                       |

#### Annualized Cost to Federal Government

|           |                            |            |
|-----------|----------------------------|------------|
| CMS Staff | (85) hours x \$116.02/hour | \$9,861.70 |
|-----------|----------------------------|------------|

The estimated cost associated with assembling PACE program agreements, signing the agreements, coordinating any follow-on amendments, and providing the amendment to each applicable party by CMS staff is estimated to require 85 hours annually, at an estimated cost of \$9,861.70 (85 hr x \$116.02/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

In this 2022 iteration, we propose the following changes as a result of our January 19, 2021 (86 FR 6132) final rule (CMS-4190-F2, RIN 0938-AT97).

| CFR Section  | Regulatory Section Description | Paragraph Description (if applicable)                               | Total Annual Respondents | Total Annual Responses | Time/Response (hr) | Total Annual Time (hr) | Labor Cost (\$/hr) | Total Annual Cost | Respondent Type | Action Type: 1) No change 2) New or 3) Revised | Response Frequency (annual or 1 <sup>st</sup> year divided by 3 for one-time burden) |
|--------------|--------------------------------|---|--------------------------|------------------------|--------------------|------------------------|--------------------|-------------------|-----------------|--|--|
| 460.98(b)(5) | Service Delivery               | Policies and Procedures   | 145                      | 48.33                  | 50                 | 2,416.67               | 72.90              | 176,175           | POs             | New  | One-time   |
| 460.98(b)(5) | Service Delivery               | Ongoing documentation costs   | 145                      | 145                    | 50                 | 7,250                  | 72.90              | 528,525           | POs             | New  | Annual   |
| 460.112      | Specific Participant Rights    | Update participant rights   | 145                      | 48.33                  | 2                  | 96.67                  | 72.90              | 7,047             | POs             | New  | One-time   |
| 460.121      | Service determination requests | Notification of Extension   | 145                      | 2,350                  | 1                  | 2,350                  | 59.92              | 140,812           | POs             | New  | Annual   |
| 460.121      | Service determination requests | Denial and Extension Template Letters                               | 145                      | 48.33                  | 2                  | 96.67                  | 72.90              | 7,047             | POs             | New  | One-time   |
| 460.122(c)   | PO Appeals Process             | Distribution of Appeals Materials to 3 <sup>rd</sup> party reviewer | 145                      | 48.33                  | 4                  | 193.33                 | 72.90              | 14,094            | POs             | New  | One-time   |
| 460.122 (g)  | PO Appeals Process             | Appeal Determination Notification                                   | 145                      | 2,320                  | 0.0833             | 193.26                 | 59.10              | 11,421.67         | POs             | Revised  | Annual   |
| 460.122(g)   | PO Appeals Process             | Update Appeal Decision Notification Template                        | 145                      | 48.33                  | 1                  | 48.33                  | 72.90              | 3,524             | POs             | New  | One-time   |
| 460.210      | Medical Records                | Revision of Policies and Procedures                                 | 145                      | 48.33                  | 10                 | 483.33                 | 72.90              | 35,235            | POs             | New  | One-time   |
| 460.210      | Medical Records                | Maintenance of Original Documentation                               | 145                      | 145                    | 10                 | 1,450                  | 84.02              | 121,829           | POs             | New  | Annual   |
| 460.210      | Medical Records                | Documentation of Recommendations                                    | 145                      | 145                    | 52                 | 7,540                  | 84.02              | 633,511           | POs             | New  | Annual   |
| TOTAL        |                                |   | 145                      | 5,395                  | varies             | 22,118.25              | varies             | 1,679,220         | n/a             | varies   | n/a  |

We have also increased the number of PO respondents from 134 to 145 for our currently approved requirements (see section 12 for requirement details) and removed provisions with burden that no longer applies.

#### Change in Burden Summary Table (Listed Sequentially by CFR Section)

| CFR Section          | Total Respondents  |          |        | Total Annual Responses |          |        | Time Per Response (hr)<br>Change | Total Annual Time (hr) |          |          |
|----------------------|--------------------|----------|--------|------------------------|----------|--------|----------------------------------|------------------------|----------|----------|
|                      | Currently Approved | Proposed | Change | Currently Approved     | Proposed | Change |                                  | Currently Approved     | Proposed | Change   |
| 460                  | 134                | 0        | -134   | 44.67                  | 0        | -44.67 | Removed                          | 44.7                   | 0        | -44.7    |
| 460.30(a) and (b)*   | 10                 | 10       | 0      | 10                     | 10       | 0      | No change                        | 10                     | 10       | 0        |
| 460.30 (a) and (b)** | 10                 | 10       | 0      | 10                     | 10       | 0      | No change                        | 10                     | 10       | 0        |
| 460.30(c)*           | 3                  | 3        | 0      | 3                      | 3        | 0      | No change                        | 60                     | 60       | 0        |
| 460.32*              | 35                 | 35       | 0      | 35                     | 35       | 0      | No change                        | 525                    | 525      | 0        |
| 460.32**             | 12                 | 12       | 0      | 12                     | 12       | 0      | No change                        | 180                    | 180      | 0        |
| 460.32***            | 134                | 145      | 11     | 134                    | 145      | 11     | No change                        | 603                    | 652.2    | 49.2     |
| 460.63(c)            | 134                | 145      | 11     | 134                    | 145      | 11     | No change                        | 2,680                  | 2,900    | 220      |
| 460.63               | 134                | 0        | -134   | 44.67                  | 0        | -44.67 | Removed                          | 670                    | 0        | -670     |
| 460.68(a)            | 134                | 0        | -134   | 44.67                  | 0        | -44.67 | Removed                          | 446.7                  | 0        | -446.7   |
| 460.68(b)(1)         | 10                 | 10       | 0      | 10                     | 10       | 0      | No change                        | 30                     | 30       | 0        |
| 460.68(b)(2)         | 134                | 145      | 11     | 134                    | 145      | 11     | No change                        | 67                     | 72.5     | 5.5      |
| 460.70(b)(1)*        | 10                 | 10       | 0      | 1,000                  | 1,000    | 0      | No change                        | 2,000                  | 2,000    | 0        |
| 460.70(b)(1)**       | 35                 | 35       | 0      | 875                    | 875      | 0      | No change                        | 1,750                  | 1750     | 0.00     |
| 460.70(b)(1)***      | 134                | 145      | 11     | 134                    | 145      | 11     | No change                        | 670                    | 725      | 55       |
| 460.71(a)(2)         | 10                 | 10       | 0      | 110                    | 110      | 0      | No change                        | 550.0                  | 550      | 0        |
| 460.71(a)(2)         | 134                | 145      | 11     | 20,100                 | 21,750   | 1650   | No change                        | 40,200                 | 43,500   | 3,300    |
| 460.72(a)(3)*        | 10                 | 10       | 0      | 10                     | 10       | 0      | No change                        | 20                     | 20       | 0        |
| 460.72(a)(3)**       | 134                | 145      | 11     | 134                    | 145      | 11     | No change                        | 134                    | 145      | 11       |
| 460.82(c)            | 134                | 0        | -134   | 44.67                  | 0        | -44.67 | Removed                          | 223.3                  | 0        | -223.3   |
| 460.98(b)(5)*        | 0                  | 145      | 145    | 0                      | 48.33    | 48.33  | 50                               | 0.0                    | 2,416.67 | 2,416.67 |
| 460.98(b)(5)**       | 0                  | 145      | 145    | 0                      | 145      | 145    | 50                               | 0.0                    | 7,250    | 7,250    |



|                       |     |     |         |        |        |        |           |       |          |         |
|-----------------------|-----|-----|---------|--------|--------|--------|-----------|-------|----------|---------|
| 460.102(c)(i)(iv)     | 134 | 0   | 134.00  | 44.67  | 0      | -44.67 | Removed   | 44.7  | 0.00     | -44.70  |
| 460.102(f)*           | 10  | 10  | 0       | 10     | 10     | 0      | No change | 30    | 30       | 0       |
| 460.102(f)**          | 134 | 145 | 11      | 134    | 145    | 11     | No change | 134   | 145      | 11      |
| 460.104(d)(2)(iii)    | 134 | 0   | -134    | 2,144  | 0      | -2,144 | Removed   | 357   | 0.00     | -357    |
| 460.112               | 0   | 145 | 145     | 0      | 48.33  | 48.33  | 2         | 0     | 96.67    | 96.67   |
| 460.116(a)            | 134 | 145 | 11      | 134    | 145    | 11     | No change | 268   | 290      | 22      |
| 460.116(c)(1)         | 134 | 0   | -134    | 44.67  | 0      | -44.67 | Removed   | 223.3 | 0.00     | -223.3  |
| 460.116(c)(2)         | 134 | 0   | -134    | 44.67  | 0      | -44.67 | Removed   | 22.3  | 0.00     | -22.3   |
| 460.120(b)            | 134 | 145 | 11      | 40,200 | 43,500 | 3,300  | No change | 3,349 | 3,623.55 | 274.55  |
| 460.120(e)            | 134 | 145 | 11      | 2,144  | 2,320  | 176    | No change | 357   | 38.67    | -318.33 |
| 460.121*              | 0   | 145 | 145     | 0      | 2,350  | 2,350  | 1         | 0     | 2,350    | 2,350   |
| 460.121**             | 0   | 145 | 145     | 0      | 48.33  | 48.33  | 2         | 0.0   | 96.67    | 96.67   |
| 460.122(b)            | 134 | 145 | 11.00   | 40,200 | 43,500 | 3,300  | No change | 3349  | 3,623.55 | 274.55  |
| 460.122(c)            | 0   | 145 | 145     | 0      | 48.33  | 48.33  | 4         | 0     | 193.33   | 193.33  |
| 460.122(g)*           | 0   | 145 | 145     | 0      | 2,320  | 2,320  | 0.0833    | 0.0   | 193.26   | 193.26  |
| 460.122(g)**          | 0   | 145 | 145     | 0      | 48.33  | 48.33  | 1         | 0.0   | 48.33    | 48.33   |
| 460.122(h)            | 134 | 0   | -134.00 | 3,216  | 0      | -3216  | Removed   | 268   | 0        | -268    |
| 460.124               | 134 | 145 | 11      | 536    | 580    | 44     | No change | 536   | 580      | 44      |
| 460.132(a) and (c)(3) | 134 | 0   | -134    | 44.67  | 0      | -44.67 | Removed   | 44.7  | 0        | -44.7   |
| 460.132(b)            | 134 | 145 | 11      | 134    | 145    | 11     | No change | 1,072 | 1,160    | 88      |
| 460.152(a)(3)         | 34  | 34  | 0       | 34     | 34     | 0      | No change | 3,400 | 3,400    | 0       |
| 460.154               | 134 | 0   | -134    | 44.67  | 0      | -44.67 | Removed   | 44.7  | 0        | -44.7   |
| 460.156(b)            | 134 | 145 | 11      | 134    | 145    | 11     | No change | 1,608 | 1,740    | 132     |
| 460.160(b)            | 34  | 34  | 0       | 34     | 34     | 0      | No change | 5,780 | 5,780    | 0       |
| 460.164(f)            | 34  | 34  | 0       | 34     | 34     | 0      | No change | 578   | 578      | 0       |
| 460.196(c)            | 134 | 145 | 11      | 134    | 145    | 11     | No change | 11    | 12.08    | 1.08    |
| 460.196(d)            | 134 | 0   | -134    | 44.67  | 0      | -44.67 | Removed   | 22.3  | 0        | -22.3   |
| 460.208(a)(1)         | 134 | 145 | 11      | 134    | 145    | 11     | No change | 536   | 580      | 44      |

|               |     |     |     |          |         |       |           |        |        |        |
|---------------|-----|-----|-----|----------|---------|-------|-----------|--------|--------|--------|
| 460.208(c)(1) | 15  | 145 | 130 | 60       | 580     | 520   | No change | 240    | 240    | 0      |
| 460.210*      | 0   | 145 | 145 | 0        | 48.33   | 48.33 | 10        | 0      | 483.33 | 483.33 |
| 460.210**     | 0   | 145 | 145 | 0        | 145     | 145   | 10        | 0      | 1,450  | 1,450  |
| 460.210***    | 0   | 145 | 145 | 0        | 145     | 145   | 52        | 0      | 7,540  | 7,540  |
| Total         | 168 | 179 | 11  | 112,708* | 121,407 | 8,699 | varies    | 73,149 | 97,069 | 23,920 |

\*112,708 is the corrected number of currently approved responses. The actual figure that was approved in OMB's December 10, 2020, Notice of Action is 78,219 total responses, but that figure is not supported or explained in the active package or Supporting Statement. This 2022 iteration corrects that baseline by plus 34,489 responses (112,708 corrected responses - 78,219 currently approved responses). In this regard, the 2022 change should be 8,699 responses but, when considering the error and our effort to correct, the change is plus 43,188 responses (34,489 responses + 8,699 responses).

We also adjusted our burden estimates for all provisions according to current BLS wage figures and changes in the number of POs since the OMB approval for CMS-R-244 in December 2020.

| Occupational Title  | Occupational Code             | Former Adjusted Wages  | New Adjusted Wages |
|---|-------------------------------|------------------------|--------------------|
| Compliance Officers   | 13-1041                       | No previous equivalent | 72.90              |
| Dieticians and Nutritionists  | 29-1031                       | 59.94                  | 63.10              |
| Passenger Vehicle Driver  | 53-3050<br>(formerly 53-3058) | 31.94                  | 38.12              |
| General Internal Medicine Physician (Primary Care Provider)                               | 29-1216                       | 193.70                 | 232.88             |
| Healthcare Social Worker (Masters of Social Work)   | 21-1022                       | 57.02                  | 59.92              |
| Home Care Coordinator (Registered Nurse)  | 29-1141                       | 74.48                  | 79.56              |
| Occupational Health and Safety Specialists  | 19-5011                       | 73.36                  | 75.72              |
| Occupational Therapists   | 29-1122                       | 82.90                  | 86.04              |
| Other Healthcare Practitioners and Technical Occupations (hereinafter, "technical staff") | 29-9000                       | 54.44                  | 59.10              |
| Medical and Health Services Managers (PACE Center Manager)                                | 11-9111                       | 110.74                 | 115.22             |
| Home Health and   | 31-1120                       | 25.42                  | 28.14              |

|  |         |       |       |
|--|---------|-------|-------|
| Personal Care Aides<br>(Personal Care Attendant) |         |       |       |
| Physical Therapists                              | 29-1123 | 86.70 | 89.84 |
| Recreational Therapists                          | 29-1125 | 49.16 | 51.82 |
| Registered Nurses                                | 29-1141 | 74.48 | 79.56 |

#### 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.