Supporting Statement - A
The PACE Organization Application Process in 42 CFR Part 460
(CMS-10631, OMB 0938-1326)

Background

Program Overview

The Programs of All-Inclusive Care for the Elderly (PACE) consist of pre-paid, capitated plans that provide comprehensive health care services to frail, older adults in the community who are eligible for nursing home care according to State standards. PACE organizations (PO) must provide all Medicare and Medicaid covered services; financing of this model is accomplished through prospective capitation of both Medicare and Medicaid payments. Upon approval of a PACE application, CMS executes a 3-way program agreement with the applicant entity and the applicable State Administering Agency (SAA). CMS regulations at 42 CFR 460.98(b)(2) require a PO to provide PACE services in at least the PACE center, the home, and inpatient facilities. The PACE center is the focal point for the delivery of PACE services; the center is where the interdisciplinary team (IDT) is located, services are provided, and socialization occurs with staff that is consistent and familiar to participants.

Significant Legislative and Regulatory History

Section 4801 of the Balanced Budget Act of 1997 authorized coverage of PACE under the Medicare program by amending title XVIII of Social Security Act (the Act) to add section 1894 of the Act, which addresses Medicare payments and coverage of benefits under PACE. Section 4802 of the BBA authorized the establishment of PACE as a State option under Medicaid by amending title XIX of the Act and adding section 1934 of the Act, which directly parallels the provisions of section 1894 of the Act.

More recently, CMS recently issued a final PACE rule (CMS-4168-F (0938-AR60, 84 FR 25610)), effective August 2, 2019, which updates and modernizes the PACE program. This final rule codifies CMS' existing practice of relying on automated review systems for processing initial applications to become a PO and expansion applications for existing POs. In addition, the final rule modifies the PACE regulations to eliminate the need for POs to request waivers for a number of the most commonly waived provisions. This latter change is expected to improve efficiency for POs, State administering agencies, and CMS.

CMS Subsequently finalized a PACE rule (CMS-4190-F2 (86 FR 5864), applicable January 1, 2022. This rule largely impacts the participant rights aspect of the application by adding 3 new distinct rights as well as requirements related to participant appeals. The rule also includes new service determination request provisions, which enable PACE participants to request initiation of a service, modification of an existing service or continuation of a service that a PACE organization recommends to be discontinued or reduced.

PACE Application

Beginning in 2017, all PACE applications, both initial and service area expansion (SAE) applications, are submitted electronically, via the Health Plan Management System (HPMS). The automated applications are now largely attestation-based, and require more limited documentation submissions.

State Readiness Review (SRR)

As part of the application process, the applicable SAA is responsible for conducting a SRR at the applicant's PACE center site to ensure that the PACE center meets the State's regulatory requirements in terms of the physical site, including environmental assessments and staffing, among other things. Applicants are required to submit documentation of the completed readiness review to CMS as part of initial PACE applications as well as for service area expansion applications that include a new PACE center site (see information below under A.1 regarding types of expansion applications).

Information Collection – Context

This information collection is specific to the application process associated with the PACE program, as defined above. This collection is currently approved by OMB (OMB 0938-1326) for a 3-year period, and expires on April 30, 2023 However, as discussed above, CMS recently issued a final PACE rule (CMS-4190-F2), which adds some new requirements and modifies existing regulatory provisions and requirements. As a result, new attestations have been added and others associated with the application are no longer applicable and need to be removed or updated to reflect updated regulatory requirements. We are also making minor tweaks to certain document upload requirements for clarification purposes based on experience reviewing applications.

Information regarding the revisions, as well as the rationale for those changes, are provided below in sections 1, 8, and 15 of this Supporting Statement and are detailed in a separate Summary of Changes document.

A. Justification

1. Need and Legal Basis

Collection of this information is mandated by statute under sections 1894(f) and 1934(f) of the Act and at 42 CFR part 460, subpart B, which addresses the PO application and waiver process. In general, PACE services are provided through a PO. An entity wishing to become a PO must submit an application to CMS that describes how the entity meets all the requirements in the PACE program. An entity's application must be accompanied by an assurance from the SAA of the State in which the PO wishes to operate its PACE program. CMS accepts applications on a designated date four times per year (i.e., on a quarterly basis, generally the last Friday of March, June, September and December).

Initial application requirements for the PACE program are currently set forth in 42 CFR 460.12 and in the PACE Manual, Ch. 17. As with initial applications, a PO that seeks to expand its service area and/or add a new PACE center also must submit an application. Three specific scenarios would prompt the submission of an SAE application (see PACE Manual, Ch. 17, Sections 20.4 through 20.7):

(1) A PO seeks to expand its geographic service area without additional PACE center sites;
(2) A PO seeks to open another physical PACE center site to serve participants who reside in the existing geographic service area; and
(3) A PO seeks to expand its geographic service area **and** open another PACE center site.

The purpose of this PRA package is to update the application to reflect, in large part, updates as required based on the most recent final PACE rule (CMS-4190-F2). Both the attestations and uploads included in the PACE application are rooted in statute and regulation, as they are tied to the required program agreement. Sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Social Security Act define a PACE program agreement as an agreement consistent with the statute and regulations promulgated to carry out the sections, among the POs, the Secretary and a State Administering Agency for the operation of a PACE program. Regulations at 42 CFR Part 460 address requirements of the PACE program including the application and program agreement. The current regulations are very prescriptive and explicit with regard to the content of the program agreement (see Section 460.32 of the PACE regulations) and the application process is the means for which these detailed and substantive requirements are satisfied. Therefore, it is important that the attestations and upload documents are consistent with established regulatory requirements.

As part of the application process, various CMS subject matter experts review the required documentation submitted to ensure the information aligns with current regulatory requirements. Any inconsistencies between the documentation provided via the application process and established regulatory requirements are addressed as part of a request for additional information (RAI). Applicants then have the opportunity to submit revised documentation consistent with regulatory requirements in response to the RAI. Upon application approval, the final documentation is incorporated within the initial or amended program agreement, as applicable.

2. Information Users

The information will be collected from applicants that: (1) apply for the first time; and (2) existing POs that want to expand their approved service area. The information collected will be used by CMS to ensure that applicants meet CMS requirements and support the approval or denial of a PACE application.

Entities that seek to offer a PACE program do so voluntary; only applicants that are interested in participating in the program will submit an initial application. Note that applicants that wish to become a PO must also submit a Part D application (0938-0936),

which is separate from the initial PACE application. The Part D application for new POs can be found at:
http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance.html

3. Improved Information Technology

In the application process, technology is used to collect, process and store the data. The application submission is 100 percent electronic. Specifically, applicants must submit the entire application and supporting documentation through the HPMS. Initial and SAE applicants need to download templates from HPMS and upload the completed documents into HPMS for review by CMS staff.

4. Duplication of Similar Information

The PACE application is the only standardized mechanism available to record data from organizations interested in becoming a new PO or existing POs that want to expand their service area and/or add a new PACE center. The application does not duplicate any information currently collected.

5. Small Business

This collection will not impact small businesses or other small entities.

6. Less Frequent Collection

PACE application information is only collected under specific circumstances, as outlined above. This is the sole mechanism for CMS to ensure that applicants meet specified CMS requirements and support a determination of PACE application approval or denial. Less frequent collection for both active PACE organizations as well as those that seek to qualify to offer PACE programs would result in less opportunity to submit service area expansion and initial applications, respectively.

7. Special Circumstances

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

-Report information to the agency more often than quarterly;

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

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

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

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

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

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

8. Federal Register Notice/Outside Consultation

The 60-day notice was published in the Federal Register on 01/18/2022 (87 FR 2613). One set of comments was submitted during this comment period. In addition to recommendations regarding the application process, which are outside the scope of this information collection, the specific comments were largely editorial in nature. Some of the comments impact the paper copy application, not the electronic application to which this information collection applies. Additional detail regarding all comments made in response to the 60-day notice, and CMS' responses, are addressed as part of the response to comment document.

The 30-day notice was published in the Federal Register on 04/29/2022 (87 FR 25489).

CMS has not had any outside consultations regarding the proposed modifications to the application. However, the proposed modifications are consistent with and supported by the newly-issued PACE rule ((CMS-4190-F2 (86 FR 5864). All changes to the PACE application are addressed in a separate document titled, "High Level Summary of Change or Crosswalk of Changes for PRA Package (OMB Control No. 0938-1326 Electronic PACE Application (for Both Initial and Service Area Expansion Applications)."

9. Payment/Gift to Respondent

There are no payments or gifts associated with this collection, but participating in this collection provides the respondent entity the ability to qualify to participate in the PACE program.

10. Confidentiality

Consistent with Federal government and CMS policies, CMS will protect the confidentiality of the requested proprietary information. Specifically, only information

within a submitted application (or attachments thereto) that constitutes a trade secret, privileged or confidential information, (as such terms are interpreted under the Freedom of Information Act and applicable case law), and is clearly labeled as such by the applicant, and which includes an explanation of how it meets one of the expectations 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 or more of the FOIA exceptions in 45 CFR part 5 will not be withheld from release under 5 U.S.C. 552(b)(4).

11. Sensitive Questions

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

12. Burden Estimate (Total Hours & Wages)

12.1 Wages

To derive average costs for private sector entities to prepare and submit PACE applications, CMS used data from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). 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.

Bureau of Labor Statistics (BLS) Occupation Title	**BLS Occupation Code**	**Mean Hourly Wage ($/hr)**	**Fringe Benefits and Overhead ($/hr)**	**Adjusted Hourly Wage ($/hr)**
Occupational Health and Safety Specialists	19-5011	$37.55	$37.55	$75.10
Management Analysts	13-1111	$46.91	$46.91	$93.82

CMS believes these two positions are reasonable and relevant to the applicant or the SAA staffer(s) associated with the identified activity related to the application process, as applicable. The Occupational Health and Safety Specialist position is associated with the role of the SAA in conducting the State readiness reviews and review of waivers. The description includes State government positions and includes activities such as reviewing, evaluating, and analyzing work environments and conducting inspections and enforcing adherence to laws and regulations governing the health and safety of individuals. All of these activities align with the SRR role. The Management Analyst position, which includes program analyst positions, is largely associated with the applicant's role in meeting stated regulatory requirements, including those related to the preparation of operational policies and procedures, development of waiver requests, which largely relate

to the composition and requirements of the Individualized Care Team, and responding to SRR questions.

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

12.2 Burden Estimates

The anticipated burden associated with the submission of both an initial application as well as an SAE application is outlined below. Although some changes were made to the application tool, overall, the changes were nominal, related primarily to some added attestations applicants are required to respond to or minor language changes to attestations. The most significant modification and only impact on existing estimated burden is the addition of attestations an applicant must read and respond to by clicking on the appropriate radio button to agree that a specific regulatory requirement will be met. Seven attestations were added to the application related to a newly-added section to the regulation i.e., service determination process (§460.121). Additional attestations were also added, resulting in an estimated added hour overall for applicants to review and click on the radio button agreeing to each attestation. The number of attestations associated with the most recent updated PACE rule resulted in an increase of required attestations, from approximately 175 to about 190. Therefore, instead of 15 hours associated with this part of the application (approximately 5 minutes per attestation, we now estimate 16 hours to complete all attestations associated with the application (190 x 5min / 60). There are no new document upload requirements.

Application Requirements (§460.12)

Section 460.12(a)(l) states that in order for CMS to determine whether an entity qualifies as a PO, an individual authorized to act for the entity must submit to CMS a complete application that describes how the entity meets all requirements in this part.

Both initial PACE program applications, as well as applications for proposed SAEs of existing PACE programs, are submitted via an automated process, as described above. CMS originally estimated that respondent burden for completion and submission of an *initial* PACE application as part of the new automated/electronic process, which includes the development and uploading of a number of supporting documents representing diverse operational aspects of the proposed program, to be 34 hours per application. This estimate recognized that an initial application requires the development and upload of documentation that incorporates substantive detail related to a diverse array of operational policies and procedures. The estimate accounted for the review of application instructions and approximately two burden hours was estimated to reflect *both* the document upload requirements and responses to associated attestations within the automated application.

CMS estimated that respondent burden for completion of a PACE SAE application would require appreciably less development.

Even with the requirement to upload the same documentation as required of initial applications (with the exception of the fiscal soundness section, which includes different attestation requirements for initial and SAE applicants and no required upload, although an applicant may be asked to provide specific information as part of a request for additional information), CMS estimated that the burden associated an SAE application is approximately half the burden of an initial application. The basis for this is that an active SAE applicant should, at any given time, have current and up-to-date information on hand, and this includes ongoing operational policies and procedures, current governing body member information and other documentation that is now be captured as part of the application and is required content for the program agreement.

The chart below outlines the attestation and upload requirements for each type of application.

Attestation Topic	Section #	Initial	SAE	Upload(s) Required	Upload(s) Required (SAE)
Service Area	3.1	X	X	X	X
Legal Entity and Organizational Structure	3.2	X	X	X	X
Governing Body	3.3	X	X	X	X
Fiscal Soundness	3.4	X	X	X	X (not an upfront requirement; however, certain uploads may be requested as part of a request for additional information only if deemed necessary by CMS reviewers)
Attestation Topic	**Section #**	**Initial**	**SAE**	**Upload(s) Required**	**Upload(s) Required (SAE)**
Marketing*	3.5	X	X	X	X

Explanation of Rights	3.6	X	X	X	X
Grievance	3.7	X	X	X	X
Service Determination Process	3.8	X	X		
Appeals	3.9	X	X	X	X
Enrollment	3.10	X	X	X	X
Disenrollment	3.11	X	X	X	X
Personnel Compliance	3.12	X	X		
Program Integrity	3.13	X	X		
Contracted Services	3.14	X	X		
Required Services	3.15	X	X		
Service Delivery	3.16	X	X		
Infection Control	3.17	X	X		
Interdisciplinary Team	3.18	X	X		
Participant Assessment	3.19	X	X		
Plan of Care	3.20	X	X		
Attestation Topic	**Section #**	**Initial**	**SAE**	**Upload(s) Required**	**Upload(s) Required (SAE)**
Restraints	3.21	X	X		
Physical Environment	3.22	X	X		
Emergency and Disaster Preparedness	3.23	X	X		
Transportation Services	3.24	X	X		
Dietary Services	3.25	X	X		
Termination	3.26	X	X	X	X
Maintenance of Records & Reporting Data	3.27	X	X		
Medical Records	3.28	X	X		
Quality Improvement	3.29	X	X	X	X
State Attestations	3.30	X	X	X	X
Waivers	3.31	X	X	X (as applicable)	X (as applicable
Application Attestations	3.32	X	X	X	X
SRR**	3.33	X	X (as applicable)	X	X (as applicable)

- PACE marketing materials are captured separately, via the CMS marketing module. ** The SRR is required but may or may not be uploaded as part of the initial submission of the application; the SRR may be uploaded after the initial application submission, subsequent to CMS's request for additional information.

In total, CMS estimates that it will receive 45 PACE applications (approximately 10 initial and 35 SAE applications) annually. Over the recent years, the number of initial applications CMS has received has varied, but on average has averaged no more than 10 initial applications on an annual basis. In terms of SAEs, CMS is receiving an increasing number of applications (15 in 2016 and 25 in 2017, 27 in 2018, 27 in 2019, and 21 in 2020). While the overall number has clearly varied, this number will likely grow as POs continue to expand their service area and/or add PACE centers.

Therefore, we believe 35 SAE applications as represented in the currently-approved information collection continues to be a reasonable annual estimate. The 45 applications estimated to be submitted annually (10 initial applications and 35 SAEs) amount to 2,595 total annual hours (see Table 1) at a cost of approximately $ 243,463 (2,595 hr x $93.82/hr) for the Management Analyst occupation. Note that this estimated overall burden captures effort necessary to meet specified regulatory requirements, including those related to the preparation of operational policies and procedures, as represented in the required uploads identified above.

Table 1: Summary of Hours Burden by Type of Application

Application/Responses	**Initial (maximum expected)**	**Service Area Expansion (maximum expected)**	**Total (aggregate)**
Expected Applications	10	35	45
Review Instructions (#of hours)	2 Hours	2 Hours	90 hours (20 hr + 70 hr)
Complete Application (# of hours to address attestations)	16 Hours	16 Hours	720 hours (160 hr + 560 hr)
Complete Application (# of hours to address document uploads)	60 Hours	30 Hours	1,650 hours (600 hr + 1,050 hr)
Discussions with SAA	3 Hours	3 Hours	135 hours (30 hr + 105 hr)
Overall # of hours per application /proposal	81 Hours	51 Hours	132 Hours
	810 Hours (81 hr x 10 applications)	**1,785 Hours (51 hr x 35 applications)**	**2,595 Hours**

Annual Burden hours	**(Estimate # 1, see burden summary table)**	**(Estimate # 2, see burden summary table)**	

For initial applicants, CMS estimates that, on average, 2 hours will be required to prepare each document required as part of the application process. There are up to 30 distinct documents that applicants will need to prepare (factoring in waiver requests that may or may not apply). CMS estimates a total of 60 hours associated with the development and upload of documents (30 documents x 2 hrs = 60 hrs).

CMS estimates the burden associated with an SAE application is approximately half the burden required of an initial application. As discussed in the section above, the basis for this is that active POs that submit SAE applications are expected to regularly reassess and update, as necessary, all documentation that supports their operations. Therefore, the expectation is that SAE applicants have current and up-to-date information on hand, and this includes ongoing operational policies and procedures and other pertinent information related to the PO's business model and operations, which is required content of the program agreement to be amended upon approval of the SAE application. This burden is part of the current PACE program ICR (CMS-R-244 (OMB 0938-0790). Therefore, the burden associated with an SAE applicant providing upload documentation as part of the application process is simply the effort to identify and upload requested documentation in the template format provided by CMS.

SAE applicants are required to upload up to 26 documents (which includes three documents that are not required but, if requested, would be uploaded in order to provide evidence of fiscal soundness). As a result, CMS estimates 30 hours associated with the development of upload documents, which represents one-half the burden associated with document preparation and submission required of initial applicants, as explained above. Furthermore, in providing an average overall estimate, CMS recognizes that the burden for the preparation of the specified documentation for an initial application will vary by applicant, but that greater effort will likely be spent on the development of a subset of required document uploads (in particular, the quality improvement plan, as well as documentation that addresses policies and procedures related, for example, to grievances, appeals and enrollment/disenrollment). CMS believes this average burden is reasonable because we are aware that many applicants utilize consultants in the application process and applicants likely have access to sample material (for example, via the National PACE Association) that can be tailored to their vision of how the unique processes would be operationalized.

In addition, CMS now separately accounts for the burden associated with attestations that will apply to both initial and SAE applications. As with other CMS-based applications, CMS estimates approximately 5 minutes for each of the approximately 190 attestations

required of both initial and SAE applicants. This results in approximately 16 (190 X 5min / 60) hours of additional burden for each application.

CMS estimates that approximately 3 additional hours will be necessary for discussions and communications with the applicable State (including coordinating the logistics of the SRR (see additional detail regarding the SRR below), providing necessary documents and addressing any requests for additional information the State may need to assess readiness) to ensure all necessary application requirements are satisfied. Note that while there may be instances in which CMS will require the applicant to respond to questions or requests to clarify information related to the application information or documentation, we are not delineating added burden related to this effort because this would be applicant-specific and could vary across applicants, though this has historically not been a significant burden. This burden is shown in the Table 1 above.

We note that the estimates above are consistent with the currently approved information collection. We have no reason to modify the estimated number of applications because the number fluctuates somewhat every year, and is based on business decisions made by applicant entities and active POs. That said, we have not had a situation in which the number of applications wildly exceeds the average number we have stated. Therefore, we believe our somewhat conservative estimates in the annual number of initial and SAE applications anticipated remain valid and appropriate. In addition, the latest updated PACE rule resulted in additional attestations (in particular, 7 additional attestations due related to the service determination process, which is new to the PACE program *(§460.121)*, a couple attestations were eliminated in their entirety. As we note elsewhere, these changes modestly changed the overall estimated time to review and respond to the additional attestations by adding an additional hour to the overall burden associated with completion of an application. We also acknowledge that language was added to certain attestations or otherwise modified somewhat to align with the updated regulation. However, we consider the overall impact on burden related to those changes to be negligible and we believe is more than accommodated within our estimates.

Support of SRR (§460.12(b)(1))

Applicable to initial applications and as well as SAE applications that include the addition of a new PACE Center.

As part of the initial application process, as well as SAE applications that include the addition of a new PACE Center, the applicable State must conduct a readiness review, referred to as a SRR. CMS estimates that two representatives of the applicant entity will spend 3 days escorting State staff during their on-site presence as part of their readiness review, as detailed below. The on-site review is expected to occur at 27 sites per year. This estimate is based on 27 SRRs conducted annually for all initial applications (10) as well as for 17 SAE applications, or about one-half of SAEs expected to include the addition of a new PACE Center, totaling 27 SRRs. This results in a total annual estimate of 1,296 hours (2 staff x 3 days x 8 hr/day x 27 sites) **(Estimate # 4, see burden summary table)** at a cost of $121,591(1,296 hr x $93.82/hr) for a Management Analyst occupation.

The SRR may be either uploaded as part of the application or subsequent to the application submission (see footnote to the attestation and upload chart above). This is in accordance with the requirement in the PACE program agreement between CMS, the State and the applicant (once approved) which states that a SRR of the applicant entity will be performed that assures, for example, that the entity has fully developed its policies and procedures, and has obtained commitments from key staff. The SRR focuses on a wide variety of areas, including the design and construction of the building, emergency preparedness, and the site's compliance with OSHA, FDA, State and local laws. The proposed PACE Center must meet State and Federal requirements at the time of the application and, for initial applicants, in accordance with section 460.12(b)(1), requires assurance that the State considers the entity to be qualified to be a PO and is willing to enter into a PACE program agreement with the entity. A SRR tool is available for States to utilize and/or modify for purposes of their review. For SAE applicants, per section 460.12(b)(2), an assurance from the State is required indicating that the State is willing to amend the PACE program agreement to include the new center site.

The States' burden is based on 27 SRRs being conducted annually, including for all initial applications (10) as well as for 17 SAE applications, or about one-half of SAEs that are expected to include the addition of a new PACE Center, for a total of 27 SRRs. (The SRR does not apply to SAEs that only include an expansion of the geographic service area and do not involve new PACE Centers.) It is estimated that two State staff will spend two days to prepare for the SRR, including the development of supporting material and coordinating logistical arrangements with the applicant for a total of 864 estimated hours (2 staff x 2 days x 8 hr/day x 27 SRRs) **(Estimate # 6, see burden summary table)** at a cost of $64,886 (864 hr x $75.10/hr) for an occupational health and safety specialist. In addition, CMS estimates that 3 State staff will spend three days at on-site (27 sites) to review the physical facility for a total of 1,944 hours (3 staff x 3 days x 8 hr/day x 27 sites) **(Estimate # 7, see burden summary table)** at a cost of $145,994 (1,944 hr x $ 75.10/hr) for an occupational health and safety specialist.

Upon completion of the SRR, the State will be responsible for preparing and submitting a report of its findings and providing an electronic copy to the applicant and, provided the applicant meets all of the criteria addressed in the readiness review, the applicant uploads the completed SRR report to HPMS as part of the application submission. It is estimated that 2 staff will spend one day preparing and completing the SRR report and reviewing any responses, as applicable, from the applicant related to outstanding areas for a total of 432 hours (2 staff x 1 day x 8 hours/day x 27) **(Estimate # 8, see burden summary table)** at a cost of $32,443 (432 hr x $75.10/hr) for an occupational health and safety specialist.

The total overall estimated burden on the part of the State is approximately 3,240 hours (864 hr + 1,944 hr + 432) **(Estimate # 9, see burden summary table)** at a cost of $243,324 (3,240 hr x $75.10/hr).

The State burden for submitting the SRR is negligible, since this requires the electronic transfer of a fully developed document.

Program Agreement Requirement (§460.30(c))

POs must be located in a State with an approved State plan amendment electing PACE as an optional benefit under its Medicaid State plan in order for CMS to sign program agreements with approved POs. This means that the State must pursue a State plan amendment that includes the PACE option. The burden for a State to develop its State Plan amendment to elect PACE as an optional Medicaid benefit and to write an assurance to CMS indicating that the State considers the entity to be qualified to be a PO and that the State is willing to enter into a PACE program agreement with the entity, in accordance with §460.12(b)(1) and (b)(2), respectively, is captured under the currently approved PACE program ICR (CMS-R-244 (OMB 0938-0790).

Evaluation of Waiver Requests (§460.26)

Section 460.26(b) requires a PO or prospective PO to submit a written request to obtain CMS approval of its request for waiver or modification of a PACE regulatory requirement to meet the needs of PACE Participants. Section 460.26(a) requires submission through the SAA.

This requirement generally applies to initial applications (Section 3.30 of the application), as any existing waiver would generally apply to an SAE application. However, there have been circumstances in which active POs may have a need to request a waiver when applying for an expansion, for example in the event a waiver only applies to a proposed new center but not the existing center. Waiver requests historically have largely related to the composition and requirements of the Individualized Care Team (e.g., requests for the inclusion of community-based Physicians and Nurse Practitioners on the Interdisciplinary Team). However, a recent updated PACE rule CMS-4168-F (0938-AR60, 84 FR 25610)), effective August 2, 2019, significantly reduced the burden associated with the preparation and submittal of waiver requests because it eliminated the need for some of the commonly requested waivers.

While CMS previously estimated that approximately one-half of initial applicants would submit a waiver request, given the removal of the need to request a number of the most common waivers necessary prior to that 2019 final rule, CMS now expects no more than 2 waiver requests from initial applicants and no more than 3 requests from active POs seeking to expand their programs. The basis for such requests would depend on unique circumstances in the locality in which the organization is operating or intends to operate. Therefore, CMS is not in a position to know what future requests might entail. While the amount of time and effort could vary by State/applicant, CMS estimates that each applicant will require 20 hours to complete the requirements associated with this section for a total annual burden of 100 hours **(Estimate # 3, see burden summary table)** at a cost of $9,382 (100 hr x $93.82/hr) for the Management Analyst occupation.

The State's burden associated with the requirement at section 460.26(a) is the time and effort for the State to review the waiver request(s) and forward the request from initial

applicants to CMS, along with a summary of any concerns or conditions associated with the applicant's waiver requests(s), as applicable. CMS estimates that 5 States will take 8 hours to complete these requirements for a total estimated annual burden of 40 hours **(Estimate # 5, see burden summary table)** at a cost of $3,004 (40 hr x $75.10/hr) for an occupational health and safety specialist. The burden can vary based on the waiver(s) requested and level of communications and scrutiny required of the State as part of its review.

Notice of CMS Determination on Waiver Requests (§460.28)

Section 460.28 addresses the timeframes for CMS determination and notification regarding approval or denial of waiver requests. This includes accounting for the need to request additional information as necessary in order to make a determination regarding the waiver request.

The need to request additional information related to a waiver request is very rare. Most often, initial waiver requests include all necessary information for CMS consideration in making a determination regarding the request. In the unusual circumstance in which additional information is necessary, it is typically for clarification purposes and is addressed directly, via email, with no need for the requesting entity to submit added documentation. Therefore, little, if any, added burden is placed on the entity requesting the waver. Therefore, we believe that the burden associated with waiver requests and outlined as part of §460.26, as captured in this information collection, adequately accounts for any such information that may be needed as addressed in §460.28.

12.3 Summary of Annual Burden Estimates

Private Sector (PACE) Burden

CFR Section	**# Respondents**	**# Responses**	**Time (hr per response)**	**Total Annual Time (all respondents)**
460.12(a)(1) (Estimate # 1)	45	10 (initial applications	81	810
460.12(a)(1) (Estimate # 2)	45	35 (SAE applications	51	1,785
460.26(b) (Estimate # 3)	45	5 (2initial and 3 SAE applicants)	20	100
460.12(b)(1) (Estimate # 4)	27	27	48	1,296
Total Overall Private	**45**	**varies (see above)**	**varies (see above)**	**3,991**

Sector (PACE) Burden				

State Burden

CFR Section	**# Respondents**	**# Responses**	**Time (hr per response)**	**Total Annual Time (all respondents)**
460.12(b)(1) (Prepare for SRR) (Estimate # 6)	27	27	32	864
460.12(b)(1) (Conduct SRR reviews (Estimate # 7)	27	27	72	1,944
460.12(b)(1) (Prepare final SRR report (Estimate # 8)	27	27	16	432
Subtotal (SRR only) (Estimate # 9)	*27*	*27*	*120*	*3,240*
460.26(a) (Review of waiver request) (Estimate # 5)	5	5	8	40
Total Overall State Burden	**27**	**varies (see above)**	**varies (see above)**	**3,280**

TOTAL BURDEN

	# Respondents	**# Responses**	**Time (hr per response)**	**Total Annual Time**
Private Sector	45	varies (see above)	varies (see above)	3,991

(PACE) Burden				
State Burden	27	varies (see above)	varies (see above)	3,280
TOTAL	**72**	**Varies**	**Varies**	**7,271**

12.4 Information Collection Attachments

- Application

Attached to this ICR is the paper form that reflects the electronic submission requirements for both the initial and SAE applications. A blank application that includes all attestations and descriptions of applicable upload documents required of each section of the application, both for initial and expansion applications, is available through the Health Plan Management System.

13. Capital Cost (Maintenance of Capital Costs)

CMS does not anticipate additional capital costs. CMS does not require the acquisition of new systems or the development of new technology to complete the application.

System requirements for submitting HPMS applicant information are minimal. Applicants will need the following access to HPMS: (1) Internet or Medicare Data Communications Network (MDCN) connectivity, (2) use of Microsoft Internet Explorer web browser (version 5.1 or higher) with 128-bits encryption and (3) a CMS-issued user ID and password with access rights to HPMS for each user within the applicant's organization who will require such access. CMS anticipates that all qualified applicants meet these system requirements and will not incur additional capital costs.

14. Cost to Federal Government

To derive average costs, CMS used data from OPM's 2018 base salary for the Baltimore/Washington, D.C. region at the GS-13 and GS-14 step 5 levels (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salarytables/pdf/2022/DCB_h.pdf). In this regard, the following table presents the hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage. (Note that regional office cost estimates may be somewhat below or above the Baltimore/Washington, D.C. region costs, depending on locality pay factors but use of this particular region ensures a solid, conservative estimate.)

Grade (Step)	Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
GS-13 (step 5)	58.01	58.01	116.02
GS-14 (step 5)	68.55	68.55	137.1

As indicated, CMS is adjusting employee hourly wage estimates by a factor of 100 percent.

CMS central office staff providing subject matter expertise across multiple components, including the Center for Medicaid and CHIP Services and the Center for Medicare, are responsible for the review of specific sections of initial and SAE PACE applications; these staff are typically at the GS-13 grade level and Health Insurance Specialist position type with an hourly wage of $58.01. Regional office staff, also typically at the GS-13 level with an Account Manager position type, are primarily responsible for the overall review of applications, but there may be some interaction with Central Office staff.

It is anticipated that the review of an SAE application will require approximately the same amount of time associated with the review of an initial application because the same uploads required for the initial application are now required of SAE applications. We note that regional office supervisor effort is included to confirm the staff review decisions specific to the application. The regional office supervisor is usually at the GS-14 grade level.

Annualized Cost to Federal Government

Systems staff (HPMS)	(4) hours x $116.02/hr x 45 applications	$20,884
CMS Reviewer Staff/ Regional Office (Account Manager) Reviewer Staff	(30) hours x $116.02/hr. x 45 (initial and SAE applications)	$156,627
Regional Office Supervisor	(2) hours x $137.1/hr. x 45 (Initial and SAE applications)	$12,339
Independent HPMS Contractor	System Design Life Cycle (all phases of requirements gathering, analysis, design, coding, testing, and maintenance)	$38,976
Total		$228,826

The estimated cost for the review and evaluation of each PACE application (inclusive of all system design life cycle and maintenance costs) is approximately $ 5,085 ($228,826/45 applications).

15. Program or Burden Changes

As addressed above, as part of Section A.1. ("Justification"), the proposed revision relates to the need to update the application to reflect provisions and requirements associated with an updated PACE rule (CMS-4190-F2), applicable January 1, 2022. This largely impacts the required attestations all applicants must agree to. Per the discussion in Section 12.2, some additional attestations were added, including 7 attestations related to a newly-added section to the regulations, i.e., service determination process. Additional attestations were also added, resulting in an estimated added hour overall for applicants to review and click on the radio button agreeing to each attestation. The number of attestations associated with the most recent updated PACE rule resulted in an increase of required attestations, from approximately 175 to about 190. Therefore, instead of 15 hours associated with this part of the application (approximately 5 minutes per attestation (~ 190 total), we now estimate 16 hours to complete all attestations associated with the application. In addition, we note that some attestation language was removed or modified to account for requirements in the latest updated regulation. We also note that there is also some increase in cost burden based on updated wages specific to the requirements at §460.12 and §460.26. Specific modifications, along with the rationale for those changes, are included in the accompanying detailed summary of change document.

With the proposed changes to the application, we do not estimate changes to the burden associated with the submission of PACE applications. We still expect approximately 45 applications (initial and SAE applications combined. However, with the added estimated burden associated with the completion of required attestations, we now estimate a total annual burden of 2,595 applicant hours to complete the application. (See Table 1.) On average, CMS estimates 81 hours and 51 hours to develop and submit an initial and SAE application, respectively.

There is no change to the currently-approved burden associated with SRRs or waiver requests associated with the PO and the State.

Based on comments provided as part of the 60-day comment period, CMS is making the following changes to the electronic application:

1) Governing Body. Section 3.3 (Attestation No. 3) – In response to the comment that the attestation should not reference "community representation" because that is not addressed in §460.62(c), CMS is modifying the attestation to better align with the regulatory provision cited, as follows:

Current Language: Applicant agrees to appoint a participant representative to act as a liaison between the governing body and Participant Advisory Committee, to present participant issues to the governing body and to ensure community representation (§460.62(c)).

New Language: Applicant agrees to appoint a participant representative to act as a liaison between the governing body and Participant Advisory Committee and present participant issues from the participant advisory committee to the governing body, per §460.62(c).

2) Marketing. Section 3.5 (Attestation No. 6) – In response to the comment that the attestation language does not fully address the regulatory requirement cited, CMS is modifying the last bullet of the attestation to better align with the regulatory provision cited, as follows:

Applicant agrees that its employees or agents will not use the following prohibited marketing practices in accordance with 42 CFR §460.82(e) (added language in italics):

- Unsolicited door-to-door marketing, *or other unsolicited means of direct contact*.

These changes do not change the estimated burden outlined in the 60-day notice.

The following table displays the burden previously approved by OMB specific to each key requirement associated with this information collection, as well as the newly- estimated burden for approval by OMB.

Task		Currently-approved Response	Change in Estimated Number of Responses	Currently-approved Time Estimate (hr)	Newly-estimated Hours	Change in Estimated Hours
Application Requirements (POs)		45	No Change	2,550	2,595	Slight increase
Support of SRR (POs)		27	No Change	1,296	1,296	No Change
SRR (States)		27	No Change	3,240	3,240	No Change
Waiver Requests (POs)		5	No Change	100	100	No Change
Waiver Requests (States)		5	No Change	40	40	No Change
Total Burden		109		7,226	7,271	N/A

16. Publication and Tabulation Dates

This information is not published or tabulated.

17. Expiration Date

The expiration date is displayed on the first page of the application.

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.