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.

PACE Application

CMS recently automated the application process for PACE applications; 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 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.

Information Collection – Context

This information collection is specific to the application process associated with the PACE program, as defined above. The collection specific to the PACE application process was recently approved by OMB (OMB 0938-1326) for a 3-year period, and expires March 31, 2020; this reflects a process that is now automated for initial as well as SAE applications. However, CMS has reconsidered its approach to the application process specific to SAEs and therefore, in addition to certain minor tweaks, is making modifications to the application and the requirements for application submission.

The number of SAE applications submitted to CMS for approval has increased over time, and 35 SAE applications, on average, are now expected to be submitted annually.

Details regarding the revisions, as well as the rationale for those changes, are provided below in sections 1, 8, and 15 of this Supporting Statement.

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 is located.

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, an application also must be submitted by a PO that seeks to expand its service area and/or add a new PACE center. There are 3 specific scenarios that 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 service (i.e., PACE Center) sites;
(2) a PO seeks to open another physical (PACE center) service site in the existing geographic service area; and
(3) a PO seeks to expand its geographic service area and open another PACE center site in the expanded area.

The purpose of this PRA package is to update the application. 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 PACE organization, 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.

With this in mind, the most significant revision is a new requirement to have SAE applicants respond to the same attestations and upload the same documentation required of initial PACE applicants. (The current SAE application requires a smaller number of both attestations and uploads.) This approach provides added assurance and evidence that an active PACE organization (PO) is qualified to expand its PACE program. Furthermore, and equally important, the modified application approach greatly facilitates the amended program agreement which accompanies approval of an SAE application. Based on documentation required of and obtained through the SAE application process, the amended agreement reflects not only the expanded geographic service area and/or new PACE center site(s) applicable to a SAE application, but also any updates to operational policies and procedures and any SAA-based information required of a PO's program agreement. For many long-standing POs that may not have had updates to their program agreement for some time, the current content, particularly as it relates to operational policies and procedures at both the PO and SAA levels, could be dated. The SAE application process is a key opportunity to amend the documentation for incorporation within the program agreement.

As part of the application process, 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, which, once approved, is incorporated within the initial or amended program agreement, as applicable.

As part of the revised application, as stated above, CMS requires SAE applicants to submit all the updated and required content of a program agreement, which serves as the binding contract between CMS, the PO and the SAA. Such documentation was previously required of initial applicants only; SAE applicants only previously required to submit a subset of such documentation and CMS had to work offline with applicants to receive the remaining updates to information required as part of the program agreement but only currently captured through the automated process specific to *initial* PACE applications. This was not an efficient approach to updating the program agreement for any party to the agreement (i.e., CMS, the SAA or the PO).

The revised process also includes the addition of document upload templates for both initial and SAE applicants (See Sections 8 and 15, below) that reference the title and specific appendix in the program agreement. This change will facilitate assembly of the amended program agreement upon approval of both initial and SAE PACE applications and provide a means to capture information consistently and in accordance with the structure of the program agreement, which includes required information presented in designated appendices. We note that, while there is an understanding that the modified requirements specific to the SAE application results in some additional burden, stakeholders recognize that this is a more efficient process and are generally supportive of the approach.

2. Information Users

The information will be collected from applicants that: (1) apply for the first time; and (2) want to expand their 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.

Participation in the PACE program is 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, 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 will 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 those existing PO 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

Generally, state licensure requirements preclude small businesses from being licensed to bear the level of risk needed to serve Medicare enrollees.

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.

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

CMS has not had any outside consultations regarding the proposed modifications to the application, with the exception of the SRR tool, which reflects modifications based on SAA review. However, based on the 60-day Federal Register notice (September 5, 2017; 82 FR 41966), as well as further internal review, a number of modifications have been made to the application tool subsequent to that notice, some of which have prompted a reconsideration of estimated burden associated with the development and submission of the application, as discussed below.

CMS received comments from two entities in response to the 60-day notice. Comments were submitted by a PACE professional association and an integrated healthcare system

that includes ownership of a PACE organization. These commenters made recommendations regarding the general requirements of the application process, including the timing of the submission process and limiting the circumstances that would prompt a service area expansion (SAE) application. Such comments are outside the scope of this information collection but will be addressed as part of the PACE final rule (CMS-4168-P). One commenter requested clarification regarding the types of marketing material that is to be submitted separately for review and approval. The commenters also pointed out a number of regulatory citations inaccurately referenced in certain attestations that applicants need to address as part of the application. The citations were modified as appropriate. Those particular modifications did not, however, result in any change to the previously-estimated burden. The commenters indicated that they believe the burden estimated by CMS for the development and completion of an application (both initial and expansion) are low, and CMS has increased the burden estimates as discussed in detail below.

In addition, based on internal agency review, the following modifications were made to the application subsequent to publication of the 60-day notice:

- The attestation specific to SAE applicants regarding the trial period (previously the second attestation in the Section 3.4.2 (Fiscal Soundness)) was moved to its own unique section (Section 3.0 - Administrative Requirements – Trial Period (SAE applicants only)) and the following statement was added: "The purpose of this section is to ensure that SAE applicants have successfully completed the first trial period audit in order to be able to proceed with the submission of a SAE application." This change did not result in added burden, since there was no change to the same requirement initially presented in a different section; it was simply moved to its own section.

- A number of document upload templates were added in order to facilitate updates to the program agreement as part of an approved application, as described in Section 1 above. This was a factor in revising the burden estimates upward.

- Added, for clarification purposes, that the PACE center location needs to be included as part of the service area upload requirement (Section 3.1, Service Area). This was simply a clarification; there was no impact on the estimated burden.

As described in greater detail below, in response to comments received and further reconsideration of the requirements, CMS has increased the estimated burden to develop and submit an electronic PACE application.

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)." Additional information regarding these changes may be found in Section 15, below.

9. Payment/Gift to Respondent

There are no payments or gifts associated with this collection.

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 2016 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	29-9011	34.85	34.85	69.70
Other Healthcare Practitioners and Technical Occupations	29-9000	30.41	30.41	60.82

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 Other Healthcare Practitioners and Technical Occupations position 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, which may require basic healthcare knowledge.

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 a SAE application via the new automated process is outlined below.

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 2 burden hours was estimate 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 new requirement to upload the same documentation as required of initial applications (with the exception of the waiver request which, if applicable, is typically

submitted in conjunction with an initial application, and 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 would now be captured as part of the application and is required content for the program agreement. CMS had previously estimated that an SAE application would require approximately 18 hours per application, which represented an increase in the original estimate by 2 hours to accommodate the additional attestation and upload requirements previously only required of initial PACE applicants. These estimates were based on an internal assessment of the application materials.

However, based on feedback received from external stakeholders in response to the 60-day notice, we have reconsidered our initial burden estimates somewhat, as discussed below.

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

Attestation Topic	**Section #**	**Initial**	**SAE**	**Upload(s) Required (Initial)**	**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)
Marketing	3.5	X	X	X	X
Explanation of Rights	3.6	X	X	X	X
Grievance	3.7	X	X	X	X
Appeals	3.8	X	X	X	X
Enrollment	3.9	X	X	X	X

Disenrollment	3.10	X	X	X	X
Personnel Compliance	3.11	X	X		
Program Integrity	3.12	X	X		
Contracted Services	3.13	X	X		
Required Services	3.14	X	X		
Service Delivery	3.15	X	X		
Infection Control	3.16	X	X		
Interdisciplinary Team	3.17	X	X		
Participant Assessment	3.18	X	X		
Plan of Care	3.19	X	X		
Restraints	3.20	X	X		
Physical Environment	3.21	X	X		
Emergency and Disaster Preparedness	3.22	X	X		
Transportation Services	3.23	X	X		
Dietary Services	3.24	X	X		
Termination	3.25	X	X	X	X
Maintenance of Records & Reporting Data	3.26	X	X		
Medical Records	3.27	X	X		
Quality Assessment Performance Improvement Program (QAPI)	3.28	X	X	X	X
State Attestations	3.29	X	X	X	X
Waivers	3.30	X	X	X (as applicable)	
Application Attestations	3.31	X	X	X	X
SRR*	3.32	X	X (as applicable)	X	X (as applicable)

*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 past 3 years, CMS has received less than 10 initial applications on an annual basis; however, this number has grown. In terms of SAEs, CMS is receiving an increasing number of applications (15 in 2016 and 25 in 2017), and this number will likely grow as POs expand their service area and/or add PACE centers)

Therefore, CMS has revised the number of SAE applications expected in future years, to 35 instead of 25, for a total of 45 applications, including initial applications (10). The 45 applications estimated to be submitted annually amount to 2,550 total annual hours (see Table 1) at a cost of approximately $155.091 (2,550 hr x $60.82/hr) for other healthcare practitioners and technical 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)	15 Hours	15 Hours	675 hours (150 hr + 525 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	80 Hours	50 Hours	130 Hours
Annual Burden hours	**800 Hours (80 hr x 10 applications) (Estimate # 1, see burden summary table)**	**1,750 Hours (50 hr x 35 applications) (Estimate # 2, see burden summary table)**	**2,550 Hours**

Based on external input, as well as additional internal consideration, CMS is revising its initial aggregate estimate of 34 hours to be devoted to the development and submission of an initial application. (This included approximately 2 hours necessary to adequately review and understand the application instructions, with the remaining 32 hours based on an average of approximately 2 hours for the preparation of each required document upload (originally based on 14 total documents, including waiver requests, as applicable, but exclusive of the SRR, which is produced by the state (see burden associated with that effort below)), and all application attestations, for a total effort of 28 hours. (Note: Applicants are expected to submit their marketing materials to the HPMS PACE marketing module. However, the burden associated with this effort is captured as part of this information collection, as the marketing documentation is a required part of the application itself.)

CMS is revising its burden estimate to better account for both upload and attestation requirements, which is particularly important for SAE applicants who will now be subject to essentially the same attestation requirements as initial PACE applicants. For initial applicants, CMS estimates that, on average, 2 hours will be required to prepare each document required as part of the application process. However, this estimate no longer accounts for the burden associated with the attestation aspect of the application which, as addressed below, is now distinct from the document upload requirements. With the addition of new template documents, there will be up to 30 distinct documents that initial applicants will need to prepare (factoring in waiver requests that may or may not apply). CMS notes that the substantive part of the documentation is already required as part of

the application; some of the additional upload documentation simply reflects information that has been parsed out to align with the program agreement structure. As a result, CMS has revised its estimate upward, to 60 hours associated with the development and upload of documents (30 documents x 2 hrs = 60 hrs).

CMS continues to maintain that 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. The burden for this is captured as part of the currently-approved PACE program ICR (CMS-R-244 (OMB 0938-0790). Therefore, the burden associated with an SAE applicant providing added upload documentation as part of the application process is simply the effort to identify and upload requested documentation (and including the header requirements within the template upload documents as addressed in this section).

SAE applicants would be required to upload up to 26 documents (which includes 3 documents that are not required but, if requested, would be uploaded in order provide evidence of fiscal soundness). As a result, CMS has revised its estimate upward, to 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. We believe this burden estimate is more than generous, as it accounts for a number of template documents that merely requires the applicant to incorporate, as part of existing information, the required title and reference to the program agreement appendix as described in detail in Section 15.

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, marketing material and the QAPI, 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 applicants may have consultant expertise assisting with 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 is now separately accounting 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 175 attestations required of both initial and SAE applicants. This results in approximately 15 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.

Although two external commenters indicated that the original burden estimates were too low, we only received one comment that provided an actual estimate based on experience while acknowledging that the estimates are dependent on the type of application and other circumstances. CMS believes its revised approach to estimating burden reasonably reflects the time and effort associated with the application process, and appropriately accommodates input from commenters.

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 2 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 being conducted annually 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. 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 $78,822.72 (1,296 hr x $60.82/hr) for other healthcare practitioners and technical 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, in accordance with section 460.12(b)(1) that 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. We note that, based on SAA review, we have made minor modifications to the SRR tool, largely to clarify language, where applicable, and to ensure standard terminology.

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 $60,220.80 (864 hr x $69.70/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 $135,496.80 (1,944 hr x $69.70/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 $30,110.40 (432 hr x $69.70/hr) for an occupational health and safety specialist.

The total overall estimated burden on the part of the State is approximately 3,240 hours **(Estimate # 9, see burden summary table)** at a cost of $225,828 (3,240 hr x $69.70/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 that the request be submitted through the SAA.

This requirement generally applies to initial applications only (Section 3.30 of the application). It is rare for a SAE (regardless of type) to include a waiver request, as any existing waiver would generally apply to that SAE application. Waiver requests largely relate 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). The burden to the applicant associated with this requirement is the time and effort to develop and submit a waiver request. Although a maximum of 10 initial applications can be expected annually, not all are expected to include waiver requests. CMS estimates that a maximum of 5 applicants will submit waiver requests per year. While the amount of time and effort could vary by State/applicant, CMS estimates that approximately one-half of entities submitting initial applications (5) will request a waiver. CMS estimates that 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 $6,082.00 (100 hr x $60.82/hr) for other healthcare practitioners and technical 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 $2,788.00 (40 hr x $69.70/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.

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	80	800
460.12(a)(1) (Estimate # 2)	45	35 (SAE applications	50	1,750
460.26(b) (Estimate # 3)	10	5 (1/2 of initial applicants)	20	100
460.12(b)(1) (Estimate # 4)	27	27	48	1,296
Total Overall	**45**	**varies (see above)**	**varies (see above)**	**3,946**

Private 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 (PACE) Burden	45	varies (see above)	varies (see above)	3,946
State Burden	27	varies (see above)	varies (see above)	3,280
TOTAL	**72**	**Varies**	**Varies**	**7,226**

12.4 Information Collection Attachments

- PACE Organization Application

Attached to this ICR is the paper form that reflects the electronic submission requirements for both the initial and SAE applications. Screen shots are currently unavailable due to the contractor's production schedule. When ready, the screen shots will be made available as a non-substantive change.

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/salary-tables/18Tables/pdf/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)	52.66	52.66	105.32
GS-14 (step 5)	62.23	62.23	124.46

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 $52.66. 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 now 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 $105.32/hr x 45 applications	$18,957.60
CMS Reviewer Staff/ Regional Office (Account Manager) Reviewer Staff	(30) hours x $105.32/hr. x 45 (initial and SAE applications)	$142,182.00
Regional Office Supervisor	(2) hours x $124.46/hr. x 45 (Initial and SAE applications)	$11,201.40
Total		$172,341.00

The estimated cost for the review, and evaluation of each PACE application is approximately $3,829.80 ($172,341.00/45 applications).

15. Program or Burden Changes

As addressed above, as part of Section B.1. ("Justification"), the most significant proposed revision is a new requirement to have SAE applicants respond to the same attestations and upload the same documentation required of initial PACE applicants. This approach is different from current requirements specific to the automated SAE application, which require a significantly smaller number of both attestations and uploads than initial applications. The SAE application process is a prime opportunity for current, active PACE organizations submitting SAE applications to submit all updated information and documentation that is required content of a program agreement, in accordance with §460.30, which serves as the binding contract between CMS, the PO and the SAA. This modified approach provides an efficient means for capturing updated information in a consistent manner and facilitating approval of the amended program agreement upon approval of the SAE application.

In addition, we are proposing other modifications to the current application, largely based on early experience and feedback from the recently-instituted automation of both initial and SAE applications. Other modifications include: inclusion of additional language to clarify certain instructions regarding the application process and specific requirements; correcting regulatory citations, where applicable; distinguishing expectations in terms of the financial documentation requirements by type of application; the addition of an attestation specific to SAE applicants that addresses the first trial audit period; and, a minor modification to the SRR tool. Specific modifications, along with the rationale for those changes, are included in the accompanying summary of change document.

The changes, and burden associated with those changes, account for the use of improved information technology. Specifically, the PACE application is now 100 percent electronic for both initial and SAE applications. The automated approach, as indicated elsewhere in this supporting statement, relies heavily on "Yes" / "No" attestation responses from the applicant which, in effect, provides an affirmative declaration that specific, explicit regulatory requirements will be met upon execution of the 3-way program agreement and throughout ongoing operations of the approved PACE program. These attestations replace what had been a requirement to provide a significant amount of written information in support of the identified topic area of the application (see the chart

in Section 12.2 above for specific attestation topics within the application).

As addressed in Sections 8 and 12 above, the following modifications to the application were made subsequent to the 60-day notice period, based on internal CMS review.

- The attestation specific to SAE applicants regarding the trial period (previously the second attestation in the Section 3.4.2 (Fiscal Soundness)) was moved to its own unique section (Section 3.0 - Administrative Requirements – Trial Period (SAE applicants only) and the following statement added: "The purpose of this section is to ensure that SAE applicants have successfully completed the first trial period audit in order to be able to proceed with the submission of a SAE application." This modification does not change the burden estimates because it simply moved the same information from one section to another. The purpose of this change was that the attestation did not specifically relate to the fiscal soundness section or was appropriate for any of the other defined sections of the application. Therefore, a decision was made to create section 3.0 as a basic administrative requirement. This will be the first attestation that a PO that seeks to initiate an SAE application would address; a PO would not be able to proceed with the completion and submission of the application unless it could respond to the attestation in the affirmative.

- A number of document upload templates were added in order to facilitate updates to the program agreement as part of an approved SAE application. These templates merely provide, in addition to the required upload information, a header that includes the title of the information and references the specific appendix in the program agreement to which that material applies. For example:

  EXPLANATION OF RIGHTS
  [Appendix D of Program Agreement]

  These template documents will be incorporated within the program agreement as required appendices. As discussed in detail in Section 12.2 above, CMS has revised the original burden estimates to account for the added template documents required and in consideration of comments submitted in response to the 60-day notice.

- Section 3.1 (Service Area): CMS added language to the document upload description to clarify that the address of the PACE center facility site is to be included, as this is a central element of the application.

CMS also made a number of modifications that did not result in changes to the burden currently approved for this collection, in response to external comment on the 60-day notice. This includes the following:

- Section 3.5 (Marketing): Added this section to the Table of Contents. (It was inadvertently not included initially.)

- Section 3.5 (Marketing): Added language to the existing "Note" included within this section to emphasize that SAE applicants need only submit new or revised marketing material to the HPMS PACE Marketing Module for review, per comment submitted in response to the 60-day notice. CMS has also added instructions regarding the timing of the marketing material, which is consistent with the guidance detailed in the PACE Marketing Guidelines and some clarifying language to address questions previously raised to CMS by PACE applicants. The complete revised note is as follows (added language in bold italics):

  "NOTE: Marketing materials for both initial and SAE applications are captured separately, via the HPMS PACE marketing module. Applicants must submit marketing materials to the HPMS marketing module for CMS/state review and approval ***within 5 days of the submission of the application.*** (Note: Initial applicants must first hit the "Final Submit" button for the application itself, at which point the contract will be made available in the HPMS marketing module. ***The action of hitting the final submit button for an application submittal does not preclude the PO from submitting marketing materials.***) After the application is submitted, CMS will communicate the name of the CMS and state marketing reviewers to the applicant and the applicant may then submit all marketing materials associated with its marketing plan via the HPMS marketing module. When submitting the materials, initial and SAE applicants must include the contract number and "Initial Application" or "SAE Application" in the comments field of the marketing submission (e.g., Hxxxx initial application). ***Note that SAE applicants need only submit new or revised marketing material to the HPMS PACE Marketing Module for review.*** Initial PACE applicants may not begin marketing until they have been approved and have received a copy of their program agreement signed by all parties; SAE applicants may not begin marketing in the expanded geographic area, as applicable, until the SAE has been approved and the PO has received the amended program agreement, accompanied by an approval letter from CMS."

CMS also modified regulatory citations referenced in a number of attestations now required of both initial *and* expansion applications, as follows:

- Section 3.3 (Governing Body): the correct regulatory citation in attestation 2 and 3 is §460.62(b) and §460.62(b), respectively.

- Section 3.17 (Interdisciplinary Team): the correct in regulatory citation in attestation 2, "Personal care attendant" should be "Personal care attendant or representative."

- Section 3.18 (Participant Assessment): the regulatory reference in attestation 2 should be §460.104(a)(2). In addition, CMS also added §460.104(a)(2) and §460.104(a)(3), which are also applicable to this particular attestation.

- Section 3.22 (Emergency and Disaster Preparedness): the correct reference to CMS' new emergency preparedness requirements is §460.84. CMS replaced the first 3 attestations in Section 3.22 (Emergency and Disaster Preparedness) with a single attestation that addresses requirements in §460.84, which have replaced requirements originally in §460.72 (which has since been removed), as follows:

  > "Applicant agrees to comply with all applicable Federal, State and local emergency preparedness requirements. This includes establishing and maintaining an emergency preparedness program that meets all requirements as specified in 42 CFR §460.84."

  This attestation replaces current attestations 1-3, which related to provisions reflected in §460.72, and are now included in §460.84 and captured as part of the broad-based attestation above that is now included in the application.

- Section 3.23 (Transportation Services): the regulatory reference in attestation 3 was changed to §460.76(b)(2).

- Section 3.28 (Quality Assessment Performance Improvement Program (QAPI)): Changed to correctly reflect QAPI instead of "Medical Records."

- SRR Report. Modified the reference to the 2000 edition of the LSC as part of I.E. to "the "latest" edition.

With the proposed changes to the application, we now estimate the total burden associated with the submission of 45 applications (initial and SAE applications combined), representing 10 more SAE applications than originally estimated, to be 2,550 hours in total annually. This 2,550 hour estimate represents an increase of 1,810 hours overall to account for the added time for both initial and SAE applicants to respond to attestations and upload the same documentation, including additional template documents. On average, CMS now estimates 80 hours and 50 hours to develop and submit an initial and SAE application, respectively. This represents an increase in the currently-approved burden of 34 and 18 hours to develop and submit an initial and SAE application, respectively.

With the additional SAE applications anticipated and estimating that approximately one-half of those applications (5) will include a new PACE center site, we now expect an increase in estimated PO burden to support the SRR. We have increased the currently-approved estimate (1,056) by 240 hours to accommodate the 5 additional SRRs that will need to be conducted, for a revised estimate of 1,296 hours.

The estimated state burden associated with the SRR effort has been increased by 600 hours, which reflects the burden associated with the additional SAE applications expected annually (a total of 35 SAE applications, instead of 25, as originally estimated). There is no change to the currently-approved burden associated with waiver requests associated with the PO and the state.

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 # Responses	Newly-estimated Response	Change in Estimated Number of Responses	Currently-approved Time Estimate (hr)	Newly-estimated Hours	Change in Estimated Hours
Application Requirements (POs)	35	45	+10	740	2,550	+1,810
Support of SRR (POs)	22	27	+5	1,056	1,296	+240
SRR (States)	22	27	+5	2,640	3,240	+600
Waiver Requests (POs)	5	5	No Change	100	100	No Change
Waiver Requests (States)	5	5	No Change	40	40	No Change
Total Burden	89	109		4,576	7,079	+2,503

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.