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

While this collection is being submitted to OMB as a ‘‘New’’ package, the collection is not new. The collection is currently approved by OMB under control number 0938-0790 (CMS-R-244). Based on internal review we propose to remove the application from that package but, before doing so, we need approval of the application under a new OMB control number. This will avoid lapses in OMB’s approval along with any violations of the PRA.

As is, the currently approved CMS-R-244 package is lengthy and somewhat time consuming to review. This new collection revises the existing package to include the automated PACE application, changes to the content of that application, and the process utilized by both initial applicants and active PACE organizations that seek to expand their service area. We believe the change will help streamline the public and OMB’s review of the application as well as the remaining requirements and burden under the CMS-R-244 package.

Background

A. Program Description

The Programs of All-Inclusive Care for the Elderly (PACE) is a pre-paid, capitated plan that provides comprehensive health care services to frail, older adults in the community, who are eligible for nursing home care according to State standards. PACE programs must provide all Medicare and Medicaid covered services; financing of this model is accomplished through prospective capitation of both Medicare and Medicaid payments. Upon approval of a PACE application, CMS executes a 3-way program agreement with the applicant entity and the applicable State.

CMS regulations at 42 CFR 460.98(b)(2) require a PACE Organization (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. The PACE model of care includes, as core services, the provision of adult day health care and interdisciplinary team (IDT) care management, through which access to and allocation of all health services is managed. Physician, therapeutic, ancillary and social support services are furnished in the participant’s residence or onsite at a PACE Center. Hospital, nursing home, home health and other specialized services are furnished in accordance with the PACE participant’s needs, as determined necessary by the IDT. To provide PACE participants with flexibility regarding access to quality care, CMS has allowed POs to offer some services in other settings which are referred to as an Alternative Care Settings (ACS). An ACS can be any physical location in the PO’s CMS approved existing service area other than the participant’s home, an inpatient facility, or PACE center.

B. Significant Legislative and Regulatory History

Section 4801 of the BBA 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. (Each State that elects PACE as a state option is required to have a State Administering Agency responsible for administering PACE Program Agreements in their State (the State Medicaid Agency may or may not be the State Administering Agency)). Section 4803 of the BBA addresses implementation of PACE under both Medicare and Medicaid, the effective date, timely issuance of regulations, and priority and special consideration in processing applications.

As directed by section 4803 of the BBA, an interim final rule with comment period (IFC) was published on November 24, 1999, establishing requirements for PACE under sections 1894 and 1934 of the Act (64 FR 66234). The 1999 IFC was a comprehensive rule that addressed eligibility, administrative requirements, application procedures, services, payment, participant rights, and quality assurance under PACE.

A second regulation (published on October 1, 2002 (67 FR 61496)) revised the original regulation, incorporated revisions to the original regulation, implementing Section 903 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554) by establishing a process through which PACE organizations may request waiver of certain regulatory requirements. The purpose of the waivers is to provide for reasonable flexibility in adapting the PACE model to the needs of particular organizations (such as those in rural areas).

Sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act provide for reasonable flexibility in adapting the PACE service delivery model to the needs of particular organizations and permit the Secretary, in close consultation with State Administering Agencies, to modify or waive provisions of the PACE regulations so long as any such modification or waiver is not inconsistent with and would not impair the essential elements, objections, and requirements of these sections. The regulation also provided for greater flexibility in adapting the PACE service delivery model to the needs of the particular organization and removed the requirement that PACE organizations directly employ the interdisciplinary team, the program director, and medical director and allowed for these positions to be contracted. A final rule (71 FR 71244), published on December 8, 2006 finalized both the PACE IFC published in the November 24, 1999 and the PACE IFC published in the October 1, 2002.

C. PACE Application

Until 2016, when the initial PACE application was automated (see Section B. Justification, below) an individual authorized to act for the applicant entity submitted to CMS a complete paper-based application that describes how the entity meets all

requirements of Part 460. It is the responsibility of the PACE organization and the State Administering Agency to validate the information contained in each application. An entity's application must be accompanied by an assurance from the State Administering Agency (SAA) of the State in which the program is located indicating that the State considers the entity to be qualified to be a PACE organization and is willing to enter into a PACE program agreement with the entity. PACE applications could be submitted at any time during the year, and included the following components:

-Cover Sheet with the appropriate signatures;
-Table of Contents for the Narrative part;
-Table of Contents for Documents part;
-Narrative part, with each question copied and brief and precise answers, divided into chapters;
-Documents part, arranged by chapters; this part should follow the Narrative. Materials such as marketing brochures and booklets should be inserted in envelopes in the appropriate places in the application.

CMS evaluates an application for approval as a PACE organization on the basis of the information contained in the application, information obtained through onsite visits conducted by CMS or the SAA, and information obtained by the SAA.

As stated in 42 CFR 460.20, within 90 days after an organization submits a complete application to CMS, CMS can:
(1) approve the application;
(2) deny the application and notify the entity in writing of the basis for denial and the process for requesting reconsideration of the denial; or
(3) request additional information needed to make a final determination.

It is common for PACE applications to require a request for additional information, particularly when a State Readiness Review is not complete at the time of the application submission. (We note that, while documentation of the State readiness Review is a required component of the application, it may or may not be uploaded as part of the initial submission of the application and is often uploaded subsequent to CMS's request for additional information.) Upon receipt of all of the responses to the request for additional information and the completed State Readiness Review (addressed below), CMS has an additional 90 days to either approve the application or disapprove the application and notify the entity in writing of the basis for the denial and the process for requesting reconsideration of the denial. For purposes of the 90-day time limit, the date that an application is submitted to CMS is the date on which the application is delivered to the address designated by CMS.

An application is deemed approved if CMS fails to act on the application within 90 days after the date the application is submitted by the organization or the date CMS receives all requested additional information. The time period for the review of an SAE application is similarly 90 days or 45 days, depending on the type of expansion

application submitted (see additional information in Section B. Justification, below and Guidance delineated in Chapter 17 of the PACE manual).

D. State Readiness Review

As part of the application process, the SAA is responsible for conducting a State Readiness Review at the applicant's PACE center site to ensure that the PACE center meets the regulatory requirements in terms of the physical site, which includes overall environmental assessments and staffing. Documentation of the completed readiness review must be submitted as part of the application process.

The purpose of this review is to determine the organization's readiness to administer the PACE program and enroll participants. The SRR includes a minimum set of criteria established by CMS in conjunction with the States. States are free to add any additional criteria to the State Readiness Review they deem necessary to help determine if the applicant:
(1) meets the requirements stipulated in the PACE regulation;
(2) has developed policies and procedures consistent with the PACE regulations; and
(3) has established the contracts necessary to provide all inclusive, quality care to its participants.

During the initial and expansion application processes, the second clock may not begin until all of the elements of the State Readiness Review tool are met to the satisfaction of the State and submitted to CMS.

E. Information Collection – Context

This information collection is specific to the application process associated with the PACE program, defined above. The PACE application requirements set forth at 42 CFR 460.12 have historically been part of a currently -approved information collection request (CMS-R-244, OMB 0938-0790)), which includes all other operational components of the program, as defined in 42 CFR part 460.

As indicated, we have determined that it is appropriate to separate the requirements and burden associated with the application component of the PACE program from the currently-approved collection requirements. As discussed in detail below, we are moving the PACE application from a paper format to a fully electronic, automated one, and this aspect of the PACE program could potentially be subject to more frequent change, as we may find we have to make incremental changes based on early experience and lessons learned with the automated process. (The automated application process is currently employed for initial applications but, with OMB approval, will also be required of POs that wish to expand their existing service areas.) A separate and distinct information collection specific to the PACE application will accommodate future modification of information collection requirements related to the application process and provide greater clarity and transparency overall to respondents and interested parties regarding this critical PACE component.

B. 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 State Administering Agency (SAA) of the State in which the PO is to be located.

Initial application requirements for the PACE program are currently set forth in 42 CFR 460.12 and in the PACE Manual, Ch. 17. Until recently, the submission of initial and SAE PACE applications and supporting information was in paper format. These applications are often hundreds of pages long, expensive to reproduce and transmit, and administratively inefficient, as staff reviewing different parts of the application are located in different physical locations and must receive hard copies of the material. However, beginning in 2016, initial PACE applications are being submitted via a new automated, electronic submission process.

As with initial applications, an application also must be submitted for a PO that seeks to expand its service area and/or add a new service site. There are a 3 specific scenarios that would prompt the submission of an service area expansion (SAE) application, including: 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 service site in the existing geographic service area; and, 3) a PO seeks to expand its geographic service area and open another physical site in the expanded area. For additional information regarding the circumstances in which a PO must submit an expansion application and the process to be utilized is currently provided in sub-regulatory guidance (see PACE Manual, Ch. 17, Sections 20.4 through 20.7).

The number of SAE applications submitted to CMS for approval has increased over time, and 25 SAE applications, on average, are expected to be submitted annually in the coming years. The purpose of this PRA package is to enable the submission of both initial PACE applications which, as addressed previously, is now submitted electronically as well as SAE applications, using the aforementioned automated submission process. We have successfully transitioned the Medicare Advantage application and Prescription Drug Plan (PDP) application to a fully electronic submission process, enabling a more organized and streamlined review, and would like to bring those same efficiencies to all PACE application processes.

This clearance request is for the information collected to ensure applicant compliance with CMS requirements and to gather data used to support approval or denial of either an initial PACE application or a SAE application submitted by an existing PO.

2. Information Users

The information collected will be from applicants who: (1) wish to become a new PO and (2) for existing PO who want to expand their service area. The information collected in these two types of application will be used by CMS to: (1) ensure that applicants meet CMS requirements, (2) support the determination of approval or denial of a PACE application.

Participation in the PACE program is voluntary in nature; 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 in the collection, processing and storage of the data. The application submission is 100 percent electronic. Specifically, applicants must submit the entire application and supporting documentation through CMS' Health Plan Management System (HPMS). This is the case for both initial and SAE applications. The PACE application has several sections that require applicants to respond to attestations based upon the application type (either initial PACE application or SAE). For example, when an applicant accesses HPMS to complete the process for an initial application, the applicant would be guided through the parts of the application that need to be completed by this type of applicant. Additionally, both the initial and SAE applications has documents referred to as "templates" that are forms that need to be downloaded from HPMS, completed by the applicant and uploaded into HPMS so the completed documents can be reviewed by CMS staff that perform the application review process.

An SAE application is a subset of the initial application and includes a significantly smaller number of both attestations and uploads; this reduced effort is reflected in an overall burden associated with the SAE application that is approximately one-half that of an initial application (see Section 12, below, which outlines the burden estimate for both initial and expansion applications).

4. Duplication of Similar Information

The PACE application that is accessed via HPMS contains information essential for the operation and implementation of the PACE program. It 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. Where possible, we have modified the standard application to accommodate information that is captured and resides in HPMS. Otherwise, the form does not duplicate any information currently collected.

5. Small Business

The collection of information will have a minimal impact on small businesses since applicants must possess an insurance license and be able to accept substantial financial risk. Generally, state statutory licensure requirements effectively preclude small business from being licensed to bear risk needed to serve Medicare enrollees.

6. Less Frequent Collection

PACE application information is only collected under specific circumstances, as outlined above. If this information is not collected, as appropriate, CMS will have no mechanism to: (1) ensure that applicants meet specified CMS requirements; and (2) 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

The 60-day notice published in the Federal Register on December 8, 2015 (80 FR 76193). The 30-day notice published on May 2, 2016 (81 FR 26234). Both published under CMS-R-244 (OMB 0938-0790). Based on internal review we republished the 30-day notice under a new CMS ID number (CMS-10631) and the tentative OMB control number (0938–New) as part of the notice published on September 12, 2016 (81 FR 62742). The only significant change made from the previous May 2016 notice and the September 2016 notice is the removal of this collection from 0938-0790 in order to create a new collection. We address other, nominal changes made to the application subsequent to these notices in Section 15, below ("Program or Burden Changes)." No public comments were received in response to the 30-day republication of September 2016.

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, we used data from the U.S. Bureau of Labor Statistics' May 2015 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 (calculated at 100 percent of salary), and the adjusted hourly wage.

Bureau of Labor Statistics (BLS) Occupation Title	BLS Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Occupational Health and Safety Specialists	29-9011	28.67	28.67	57.34
Other Healthcare Practitioners and Technical Occupations	29-9000	29.72	29.72	59.44

We believe these two positions are reasonable and relevant to the applicant or the State Administering Agency (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, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily 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 we believe 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, will be submitted via an automated process, as described above. CMS estimates 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 is **34 hours** per application. While an initial application requires the development and upload of documentation that incorporates substantive detail related to a diverse array of operational policies and procedures, CMS estimates that respondent burden for completion of a PACE SAE application, which is now largely attestation-based and requires appreciably less development and uploading of supporting documentation than an initial application, is approximately half the burden of an initial application, or **16 hours** per application. These estimates are based on an internal assessment of the application materials.

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

Attestation Topic	Section #	Initial	SAE	Upload Required (Initial)	Upload Required (SAE)
Service Area	3.1	X	X	X	X
Legal Entity and Organizational Structure	3.2	X		X	
Governing Body	3.3	X		X	
Fiscal Soundness	3.4	X	X	X	X
Marketing	3.5	X	X	X	X
Explanation of Rights	3.6	X		X	
Grievance	3.7	X		X	
Appeals	3.8	X		X	
Enrollment	3.9	X		X	
Disenrollment	3.10	X		X	
Personnel Compliance	3.11	X			
Program Integrity	3.12	X			
Contracted Services	3.13	X	X		
Required Services	3.14	X			
Service Delivery	3.15	X			
Infection Control	3.16	X			
Interdisciplinary Team	3.17	X			
Participant Assessment	3.18	X			
Plan of Care	3.19	X			
Restraints	3.20	X			
Physical Environment	3.21	X			
Emergency and Disaster Preparedness	3.22	X			
Transportation Services	3.23	X	X		

Dietary Services	3.24	X			
Termination	3.25	X		X	
Maintenance of Records & Reporting Data	3.26	X			
Medical Records	3.27	X			
Quality Assessment Performance Improvement Program (QAPI)	3.28	X		X	
State Attestations	3.29	X		X	X
Waivers	3.30	X		X (as applicable)	
Application Attestations	3.31	X	X	X	X
State Readiness Review*	3.32	X	X (as applicable)	X	X (as applicable)

*The State Readiness Review is required but may or may not be uploaded as part of the initial submission of the application; the State Readiness Review may be uploaded after the initial application submission, subsequent to CMS's request for additional information.

In total, CMS estimates that it will receive **35 PACE applications** (no more than **10 initial** and **25 SAE** applications) annually. (Over the past 3 years, we have received less than 10 initial applications on an annual basis; however, this number has grown and we believe the number will exceed 10 annually. In terms of SAEs, we are receiving an increasing number of applications (15 in 2016), and we believe this number will also grow as POs expand their service area and/or add PACE centers.) The 35 applications that we estimate we will receive annually amount to **740 total annual hours** (see Table 1) at a cost of **$43,985.60** (740 hr x $59.44/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	25	35
Review Instructions (#of hours)	2 Hours	2 Hours	4 Hours
Complete Application (# of hours)	32 Hours	14 Hours	46 Hours
Overall # of hours per application /proposal	34 Hours	16 Hours	50 Hours
Annual Burden hours	340 Hours	400 Hours	740 Hours

CMS estimates a total of 34 hours to be devoted to the development and submission of an initial application. Of this total, approximately 2 hours will be necessary to adequately review and understand the application instructions. The remaining 32 hours associated

with the completion of an initial application accounts for an average of approximately 2 hours for the preparation of each required document upload (14 total, including waiver requests, as applicable, but exclusive of the state readiness review, 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.)

In providing an average overall estimate, we recognize that the burden for the preparation of the specified documentation 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). We believe 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.

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. The remaining time (approximately 1 hour) is the estimated time necessary to submit the application in HPMS, which includes addressing all applicable attestations and uploading all required documents. 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.

The estimated number of hours to complete an SAE application is estimated to be less than one-half that required of initial applications, in large part because the SAE application does not require the preparation and approval of the general policies and procedures that are captured as part of an initial application because they would apply to the expanded service area.

<u>Support of State Readiness Review (§460.12(b)(1))</u>

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 State Readiness Review (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 **22 sites** per year. This estimate is based on 22 SRRs being conducted annually for all initial applications (10) as well as for 12 SAE applications, or about one-half of SAEs that are expected to include the addition of a new PACE Center, for a total of 22 SRRs. This results in a **total annual estimate of 1,056 hours** (2 staff x 3 days x 8 hr/day x 22 sites) at a cost of **$62,768.64** (1,056 hr x $59.44/hr) for other healthcare practitioners and technical occupation.

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 State Readiness Review (SRR), which may be either uploaded as part of the application (Section 3.32 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.

The States' burden is based on 22 SRRs being conducted annually, including for all initial applications (10) as well as for 12 SAE applications, or about one-half of SAEs that are expected to include the addition of a new PACE Center, for a total of 22 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 **704 estimated hours** (2 staff x 2 days x 8 hr/day x 22 SRRs) at a cost of **$40,367.36** (704 hr x $57.34/hr) for an occupational health and safety specialist. In addition, CMS estimates that 3 State staff will spend three days at on-site (22 sites) to review the physical facility for a total of **1,584 hours** (3 staff x 3 days x 8 hr/day x 22 sites) at a cost of **$90,826.56** (1,584 hr x $57.34/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

352 hours (2 staff x 1 day x 8 hours/day x 22) at a cost of **$20,183.68** (352 hr x $57.34/hr) for an occupational health and safety specialist.

The total overall estimated burden on the part of the State is approximately **2,640 hours** at a cost of **$151,377.60** (2,640 hr x $57.34/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 State administering agency.

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. We estimate that that each applicant will require **20 hours** to complete the requirements associated with this section for a total annual burden of **100 hours** at a cost of **$5,944.00** (100 hr x $59.44/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** at a cost of **$2,293.60** (40 hr x $57.34/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)	35	10 (initial applications	34	340
460.12(a)(1)	35	25 (SAE applications	16	400
460.26(b)	10	5 (1/2 of initial applicants)	20	100
460.12(b)(1)	22	22	48	1,056
Total Overall Private Sector (PACE) Burden	35	varies (see above)	varies (see above)	1,896

State Burden

CFR Section	# Respondents	# Responses	Time (hr per response)	Total Annual Time (all respondents)
460.26(a) (Review of waiver request)	5	5	8	40
460.12(b)(1) (Prepare for SRR)	22	22	32	704
460.12(b)(1) (Conduct SRR reviews	22	22	72	1,584
460.12(b)(1) (Prepare final SRR report	22	22	16	352
Subtotal (SRR only)	22	22	120	2,640
Total Overall State Burden	22	varies (see above)	varies (see above)	2,680

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 nonsubstantive change. This is expected to be later this year. The changes, if any, are expected to be minor and limited to reflect the electronic application. While not anticipated, substantive changes will be subject to the regular PRA process including the provision of 60- and 30-day comment periods.

13. Capital Cost (Maintenance of Capital Costs)

We do not anticipate additional capital costs. CMS requirements do 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, we used data from OPM's 2016 base salary for the Baltimore/Washington, D.C. region at the GS-13 and GS-14 step 5 levels (www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/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)	50.04	50.04	100.08
GS-14 (step 5)	59.13	59.13	118.26

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent.

Central Office staff across multiple components, including CMCS and CM, are responsible for the review of initial PACE applications and are typically at the GS-13 grade level and Health Insurance Specialist position type with an hourly wage of $50.04.

Regional Office staff, typically at the GS-13 level with a RO Account Manager position type, are primarily responsible for the review of SAE applications, but there may be some interaction with Central Office staff.

It is anticipated that the review of an SAE application will require a fraction of the time associated with the review of an initial application because only a small subset of uploads required for the initial application are necessary for an SAE application. The burden associated with the review includes time to review information that may be submitted as a result of a request for additional information, but is generally not a significant added burden. Note Regional Office Supervisor effort is included to confirm the RO staff review decisions specific to the SAE. The RO Supervisor is usually at the GS-14 grade level.

Annualized Cost to Federal Government

Systems staff (HPMS)	(4) hours x $100.08/hr x 35 applications	$14,011.20
CMS Reviewer Staff	(30) hours x $100.08/hr. x 10 (initial) applications	$30,024
Regional Office (Account Manager) Reviewer Staff	(10) hours x $100.08/hr. x 25 (SAE) applications	$25,020
Regional Office Supervisor	(2) hours x $118.26/hr. x 25 (SAE)	$5,913
Total		$74,968

The estimated cost for the review, and evaluation of each PACE application is approximately $2,142 ($74,968/ 35 applications).

15. Program or Burden Changes

While this collection is being submitted to OMB as a ‘‘New’’ package, the collection is not new. The collection is currently approved by OMB under control number 0938-0790 (CMS-R-244). Based on internal review we propose to remove the application from that package but, before doing so, we need approval of the application under a new OMB control number. This will avoid lapses in OMB’s approval along with any violations of the PRA.

As is, the currently approved CMS-R-244 package is lengthy and somewhat time consuming to review. We believe the change will help streamline the public and OMB’s review of the application as well as the remaining requirements and burden under the CMS-R-244 package.

The change also accounts for the use of improved information technology. Specifically, the PACE application will now be 100 percent electronic; the process for submission of both the application and supporting information was previously in paper format. These applications are often hundreds of pages long, expensive to reproduce and transmit. Automation of the application will provide for a more organized and streamlined submission and review process. 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).

Previously, in what was exclusively a paper-based process, application questions resulted in applicants submitting lengthy narrative discussions detailing how, specifically, the applicant intended to meet the specified regulatory requirements. In addition, the application required the development of substantial documentation to support application requirements. While the automated application still requires some level of uploaded documentation for both initial and SAE applications, as described in Section 12.2 above, the substantial reliance on attestations for both initial and SAE applications significantly reduces the overall burden that had been associated with an entirely paper-based process. The previously-estimated burden associated with the paper-based application process, which accounted for the time and effort to compile and submit a paper application to CMS, was 3,775 hours. This was based on an estimated 25 entities applying per year, with each entity requiring approximately 151 hours to complete the requirements. With the change to an automated process, the overall annual burden is substantially reduced; we now estimate the total burden associated with the submission of 35 applications annually to be 740 hours in total, a reduction of 3,035 hours.

The previous estimate was at a cost of $10/hour or a total of $37,750, based on 3,775 estimated hours associated with the development and submission of a paper-based application. We are now estimating a total of 740 hours for these activities, at a cost of $59.44/hour, based on current BLS data, as indicated above in Section 12. The overall result is a total cost estimate in the amount of $43,986, representing an increase over the previous estimate of 6,236 hours. While this represents an increase in cost as compared to the current estimate, the magnitude of the increase is the result of a significantly higher, but more current, wage estimate than the wage used to derive the current cost estimate. In addition, the current estimate did not account for the effort of the applicant entity pursuing an initial applicant or an SAE that includes a new PACE center in supporting the SRR that is conducted by the state. It is estimated that the PACE applicant would require 1,056 hours annually, for a total cost of approximately $62,769, to support this part of the application. Total aggregate costs to the applicant are therefore estimated to be $106,755 ($43,986 + $62,769).

The changes made to the application based on public comment were largely to align the attestations with the regulatory language and address typographical issues. Subsequent to the initial 60 and 30-day notices, CMS staff made additional minor edits to the application that, while considered non-substantive modifications, were necessary to further correct or clarify the regulatory requirements. (See document that provides a detailed crosswalk of changes for this PRA package.) These revisions as whole do not change the estimated burden.

As described previously, the industry is already subject to the automated application process associated with initial PACE applications and has been made aware that we plan to similarly automate the SAE application. The proposed automation of all PACE applications has received a positive reaction from the industry, as this process will result in much less burden and a much more streamlined process overall.

16. Publication and Tabulation Dates

This information is not published or tabulated.

17. Expiration Date

CMS is not requesting an exemption from displaying the expiration date.

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.