

PACE Organization Application Process in 42 CFR Part 460
CMS-10631, OMB 0938-1326
Public Comments Based on 60-Day Public Notice

CMS received 2 sets of comments subsequent to publication of the 60-day notice that outlined the information collection and burden associated with the PACE application process in 42 CFR Part 460. Comments were submitted by a PACE professional association and an integrated healthcare system that includes ownership of a PACE organization. The 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. One commenter expressed general support for the modified approach outlined in the notice that requires SAE applicants to respond to the same attestation and upload requirements as initial applicants in order to facilitate efforts to update the PACE organization's program agreement upon approval of the expansion application.

There were also a number of comments specific to the collection instrument, which primarily included a number of corrections to regulatory provisions cited within certain attestations. In addition, both commenters expressed concerns about the estimated burden associated with completion of the collection instrument. Based on the comments, and after additional consideration of the modified application approach and the linkage to the program agreement update, CMS has reconsidered the original burden estimates. Details regarding the comments submitted, and CMS's response, are provided below.

Commenter One

Comment 1

The commenter urges CMS to expand the application submission period beyond 1 day per quarter or otherwise requests that applicants be accepted on a continual basis, particularly for SAE application. According to the commenter, the current submission timeframe does not give any deference to PACE organizations and the complex State Administering Agency and licensing requirements that must be met and do not necessarily correspond to end of quarter timeframes. Additionally, the submission period does not promote efficient operations or prioritizes PACE participant needs and access to comprehensive services.

Response

This comment is technically outside the scope of the information collection, which addresses updates to the application instrument, and not the timing of application submission, which has been a quarterly process for some time. That said, per statutory requirements, CMS is subject to a designated timeframe for the review of applications. Therefore, it is critical that the process recognize CMS's need to effectively manage staff resources and track the review status of applications. The quarterly submission requirements allows CMS to efficiently address applications that are submitted. The one day a quarter application date enables CMS to manage and review multiple applications submitted within the same timeframe, which promotes a fair and consistent review. CMS believes the quarterly process provides adequate opportunity for applicant entities to plan and prepare for the submission of an application which takes advance lead time and, for applications that involve a new PACE center, rarely include the completed state readiness review upon initial submission of the application. Therefore, CMS

does not believe the required submission timelines unduly constrain the business operations of applicant entities and their ability to submit applications on a more timely basis.

CMS Action

No change, per the rationale provided.

Comment 2

The commenter recommends that, rather than require a complete SAE application similar to an initial application) when a new PACE center is being sought, there should be an expedited application process that includes streamlined documentation and timeframes, per the current requirements of SAE applicants. The commenter is concerned that additional attestations and documentation will not only delay the submission process, but delay CMS' review period. The commenter maintains that the process requirements would ultimately result in further delay in access to services and care for PACE participants.

Response

The PACE center is the central feature of an application, for both initial and expansion applications that include a new center. As such, it is critical that CMS and the SAA ensure that applicants meet all designated requirements with regard to the center site and operations of the center. We note that applications that only include a new PACE center and not a geographic expansion are only subject to a 45-day review and not the full 90-day review. It is CMS's intention to respond to the application within that time period; the additional attestations documentation are not expected to delay CMS's review. On the contrary, the added requirements and documentation is expected to ensure that the PO continues to meet all designated requirements and, importantly, facilitate approval of the application and execution of the updated program agreement.

CMS Action

No change

Comment 3

The comment disagrees with CMS's requirement that a PACE organization submit an SAE application in order to add a new PACE center or replace a current site. The commenter maintains that, when new centers are involved, there should be an expedited application process, with streamlined documentation and timeframes.

Response

This is outside the scope of this information collection process. PACE application requirements were addressed in a proposed PACE rule (CMS-4168-P). This comment will be addressed as part of the final PACE rule.

CMS Action

No action

Comment 4

The commenter disagrees with the burden associated with an SAE application, which is estimated to be approximately half the burden of an initial application. The commenter urges CMS to revisit the calculations, accounting for stakeholder input.

Response

After further consideration, CMS agrees that the burden should be adjusted upward.

CMS Action

CMS has revised the burden associated with both initial and expansion PACE applications. The burden now recognizes the effort associated with the attestation requirements for both types of applicants as well as additional document templates that are to be uploaded to support the assembly of the program agreement.

Comment 5

The application states that CMS will only approve applications from potential PACE organizations that satisfy federal requirements as determined based on review of the application and have met the requirements of a state readiness review. The commenter requests that CMS grant provisional/conditional approval pending state/local licensing decisions. This recommendation is based on the commenter's experience, which included a substantial gap between receipt of verbal approval and the executed document.

Response

CMS will not expect anything less than a fully completed readiness review report to be submitted as part of an application or as part of the response to a request for additional information. The applicant is responsible for resolving all remaining issues prior to submitting the response. CMS defers to the SAA regarding the readiness review report and when the SAA determines that it is complete and ready for submission to CMS.

CMS Action

No further action in terms of this information collection is necessary. However, CMS has noted the concerns of the commenter and will be sure to address these concerns with its state administering agency partners.

Commenter Two

Comment 1

The commenter recommends elimination of the requirement for submission of an SAE application for POs seeking to open an additional PACE center in an existing, approved service area. The rationale is that this scenario involves only experienced POs that have demonstrated their ability to comply with PACE requirements and, furthermore, because the addition of a PACE center within an existing service area adds capacity and can only enhance beneficiaries' access to PACE center services, the commenter maintains that CMS need not be concerned that access to care for the eligible population will be negatively impacted.

As an alternative to requiring a SAE application, the commenter recommends that a PACE organization be allowed to open a new PACE center within an existing service area after providing CMS with appropriate notice. Such notice would be given a minimum of 60 days in advance of opening the PACE center and include the center's location, an assurance from the SAA of its support for the new center and willingness to amend the PACE organization's program agreement, and an attestation of financial solvency (with supporting documentation, if needed) as evidence of the program's financial capacity. Subsequently, prior to the new PACE center's opening, the PACE organization would provide CMS with the completed state readiness review confirming that the center meets all on-site review criteria.

Response

This recommendation was provided with respect to the application process in response to the proposed PACE rule (CMS– 4168– P) in October 2016. This comment will be addressed as part of the final PACE rule.

CMS Action

No change to existing application submission requirements.

Comment 2

The commenter recommends that PACE applicants be allowed to submit PACE applications continuously throughout the year rather than limit submission of applications to a single day per calendar quarter.

Response

This comment is technically outside the scope of the information collection, which addresses updates to the application instrument, and not the timing of application submission, which has been a quarterly process for some time. That said, per statutory requirements, CMS is subject to a designated timeframe for the review of applications. Therefore, it is critical that the process recognize CMS's need to effectively manage staff resources and track the review status of applications. The quarterly submission requirements allows CMS to efficiently address applications that are submitted. The one day a quarter application date enables CMS to manage and review multiple applications submitted within the same timeframe, which promotes a fair and consistent review. CMS believes the quarterly process provides adequate opportunity for applicant entities to plan and prepare for the submission of an application which takes advance lead time and, for applications that involve a new PACE center, rarely include the completed state readiness review upon initial submission of the application. Therefore, CMS does not believe the required submission timelines unduly constrain the business operations of applicant entities and their ability to submit applications on a more timely basis.

CMS Action

No change, per the rationale provided.

Comment 3

The commenter understands the modified approach to have SAE applicants respond to the same attestations and upload the same documentation required of initial PACE applicants in order to facilitate efforts to update PACE organizations' program agreements and agrees it is better to request this information as part of the application itself rather than to request it as additional information much later in the application review process. However, the commenter is hopeful that that CMS will not be requesting additional information related to documents that are submitted as part of the SAE application but were previously approved.

Response

CMS appreciates the expressed support of this approach. The purpose of the proposed modified process is to enable CMS to review all documentation to support efforts to update the program agreement, which would be required regardless upon approval of an SAE application. The intention is to use the application process to capture all relevant documentation, which we intend to review as we would documents submitted as part of an initial application in order to ensure that all established PACE requirements, including policies and procedures captured as part of this process, adhere to current regulations and guidance.

CMS Action

No change

Comment 4

The commenter requests clarification regarding expectations with respect to applicant submission of marketing materials. The commenter's understanding is that CMS need only new or revised marketing materials related to the SAE application. The commenter would not understand the rationale for resubmit previously-approved marketing materials.

Response

The commenter is correct. SAE applicants are only expected to submit new or revised marketing material related. Previously-approved material does not need to be resubmitted. Note that the marketing material is captured and tracked through a separate PACE marketing module.

CMS Action

CMS has clarified this as part of application instructions. In addition, CMS has added instructions regarding the timing of the marketing material, which is consistent with the guidance detailed in the PACE Marketing Guidelines. The added note specific to the "Marketing" section now states the following (with clarifying 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."

Comment 5

In general, the estimates of the number of hours it will take an applicant to complete the initial application process are low, most notably the 28 hours for preparation of all the documentation required to be uploaded inclusive of marketing materials, financial documentation, numerous policies and procedures, etc.

Response

After further consideration, CMS agrees that the burden should be adjusted upward.

CMS Action

CMS has revised the burden associated with both initial and expansion PACE applications. The burden now recognizes the effort associated with the attestation requirements for both types of

applicants as well as additional document templates that are to be uploaded to support the assembly of the program agreement.

Comment 6

Referring to the Table of Contents on p. 2 of the application, “3.5 Marketing” is missing.

Response

The Table of Contents has been modified to include the marketing section.

Comment 7

Referring to Section 3.3 Governing Body on p. 13, we believe the regulatory reference in A.2. should be §460.62(b).

Response

We agree.

CMS Action

CMS has made the suggested change.

Comment 8

Referring to Section 3.3 Governing Body on 13, we believe the regulatory reference in A.3. should be to §460.62(c).

Response

We agree.

CMS Action

CMS has made the suggested change.

Comment 9

Referring to Section 3.8 Appeals, on p. 24, it is not clear to us why there are references to §460.104(d)(2)(ii) and §460.1.04(d)(iii) in A.10 and A.11. These requirements relate to the service delivery request process, not the appeals process.

Response:

The regulatory citations do, in fact, relate to the service requests but also the appeals process, which is why §460.104 is referenced as part of this application section. Therefore, reference to the regulatory provisions in §460.104 will be retained.

CMS Action

None

Comment 10

Referring to Section 3.17 Interdisciplinary Team, in A.2. on p. 38, “Personal care attendant” should be “Personal care attendant or representative.”

Response

We agree.

CMS Action

CMS has made the suggested change.

Comment 11

Referring to Section 3.18 Participant Assessment, on p. 40, we believe the regulatory reference in A.1.should be §460.104(a)(4).

Response

We agree

CMS Action

CMS has made the suggested change.

Comment 12

Referring to Section 3.18 Participant Assessment, on p. 40, we believe the regulatory reference in A.2.should be §460.104(a)(2).

Response

We agree that the regulatory provision cited needs to be modified, but the correct citation, based on the language of the attestation, should be §460.104(a) to capture the requirements in §460.104(a)(1), §460.104(a)(2) and §460.104(a)(3).

CMS Action

We have made this change to the citation to appropriately reference the requirements in §460.104(a) that are reflected in the attestation.

Comment 13

Referring to Section 3.22 Emergency and Disaster Preparedness, on p. 45, this section does not reference CMS' new emergency preparedness requirements in §460.84.

Response

We agree this needs to be added.

CMS Action

We have added the following attestation:

“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.

Comment 14

Referring to Section 3.23 Transportation Services, on p. 46, we believe the regulatory reference in A.3.should be §460.76(b)(2).

Response

We agree.

CMS Action

CMS has made the suggested change.

Comment 15

Referring to Section 3.28 Quality Assessment Performance Improvement Program (QAPI), on p. 51, the header in the chart in section A refers to “Medical Records” rather than “QAPI.”

Response

We agree.

CMS Action

CMS has made the suggested change.

Comment 16

Referring to the State Readiness Review Report, under I.E., the reference to the 2000 edition of the LSC is outdated.

Response

We agree reference to the LSC document is outdated and needs to be addressed.

CMS Action

We have modified this part of the report to reference the “*latest*” edition of the LSC.

Comment 17

Referring to the State Readiness Review Report, under VIII., we ask CMS to consider a modification to the requirement that the PACE organization have evidence of all required licenses at the time of the SRR, particularly those related to the PACE center. While this would be the goal, there are instances in which the center is complete, but the state’s licensing entities have not yet signed off on related licenses, thereby holding up the SRR, submission of the applicant’s response to the request for additional information, and approval of the application. Alternatively, we ask that CMS accept the SRR with licenses pending and assurance that the licenses will be approved before the PACE organization is operational.

Response

CMS will not expect anything less than a fully completed readiness review report to be submitted as part of an application or as part of the response to a request for additional information. The applicant is responsible for resolving all remaining issues prior to submitting the response. CMS defers to the SAA regarding the readiness review report and when the SAA determines that it is complete and ready for submission to CMS.

CMS Action

No further action in terms of this information collection is necessary. However, CMS has noted the concerns of the commenter and will be sure to address these concerns with its state administering agency partners.