Responses to 60-day Comments Received Federal Register Notice on Revised CMS-10631, OMB 0938-1326:

The PACE Organization Application Process in 42 CFR Part 460

CMS received one comment letter on October 8, 2024, regarding the 60-day notice on the the PACE Organization Application Process in 42 CFR Part 460 (CMS-10631, OMB 0938-1326) documents.

The commenter provided feedback regarding several PACE application requirements and processes. The commenter provided several suggestions that were out of scope for this Federal Register (FR) notice, including, suggested changes to the limited application opportunities and the number of application submissions allowed under our process, changes to operational procedures associated with application withdrawals, changes to the state readiness review process, and operational changes within Health Plan Management System (HPMS). We thank the commenter for their feedback. We have provided responses to comments applicable to the documents under review in this FR notice.

COMMENTS

Comment: The commenter discussed their concerns that the updated burden estimate in the Supporting Statement of this FR notice did not account for PACE applications currently under review with CMS, because previously submitted attestations would need to be updated once the updated application is available for applicants.

Response: CMS will communicate with applicants should they need to update existing application documentation based on the updated regulations. CMS does believe the updates change the burden estimate provided in the FR notice.

<u>Comment</u>: The commenter suggested that CMS eliminate the requirement that PACE organizations submit an application when they are adding new PACE center sites under existing service areas. The commenter said this would save resources for PACE organizations and CMS.

Response: CMS's regulatory requirements, under 42 CFR 460.12(a)(1), require PACE organizations to submit complete applications in the form and manner and under the timeframes specified by CMS, that demonstrate that the organization meets all requirements.

Comment: The commenter noted that they believe CMS has significantly underestimated the number of initial applications CMS will receive in future years and provided their own estimates of anticipated growth.

Response: We thank the commenter for sharing their estimates of anticipated program growth. However, we believe our estimates are appropriate.