

Revision/Clarification	Purpose of the Revision/Clarification	Level of Applicant Burden I = Increases burden D = Decreases
<p>1. Referring to the Supporting Statement Part A on p. 3, <u>5. Small Businesses</u>, it states that PACE organizations “must possess an insurance license.” PACE organizations are subject to fiscal soundness requirements under 42 CFR 460.80 and additional requirements that may be imposed by their state administering agencies. They are not, however, subject to a federal requirement to possess an insurance license.</p>	<p>Discussion revised in response to the comment. We deleted language that PACE organizations must possess an insurance license. We included the following clarifying language (in italics):</p> <p>The collection of information will have a minimal impact on small businesses since POs must, <i>in addition to requirements that may be imposed by the applicable state administering agency</i>, 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. <i>State licensure for PACE organizations varies by State. In accordance with the CMS PACE regulations, the PACE organizations must meet any State licensure requirements. CMS does not require any specific licensure for PACE plans, but states are not prohibited from requiring licensure. Most States require PACE organizations to be licensed as adult day care, and some require home health and/or clinic licensure. A few states have developed a unique license for PACE.</i></p>	<p>No change to burden</p>

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<p>2. In general, although we do not dispute the necessity of the activities included in this collection, we believe that many of the burden estimates are low and inadequately reflect the efforts necessary to perform many operational requirements of PACE organizations. As an example, the estimates, where applicable, reflect the time required to develop initial program agreements, policies and procedures, contracts, competency evaluation programs, etc. However, they do not in some cases appear to reflect the time that is required to review and update these materials over time; in others, the amount of time allocated for such activities is very minimal.</p>	<p>We agree that the burden associated with the current practice of updating program agreements, as well as the expectation that active POs reassess and review existing operational policies and procedures, should be explicitly reflected. We have therefore added to the burden initially captured as part of the program agreement requirement (Section 460.30).</p> <p>We note, however, that other burden estimates remain the same. They are consistent with the existing approved collection and, absent direct input from active POs regarding the burden requirements, we have no basis to increase the existing estimates.</p>	<p>I</p>

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<p>3. Page 5 of the Supporting Statement Part A, 460.26 CMS evaluation of waiver requests, states that the burden associated with waiver requests are captured as part of CMS-10631. We understand this in the context of waiver requests submitted in conjunction with applications but it appears that neither CMS-10631 nor CMS-R-244 captures the burden associated with waiver requests submitted outside the application process. We would like to take this opportunity to suggest that the burden to PACE organizations, states and CMS related to waivers would be reduced substantially if CMS were to finalize the proposed rule for PACE that was published in the Federal Register on August 16, 2016. The proposed changes to current regulatory requirements would undoubtedly reduce the need for operational waivers moving forward.</p>	<p>We believe we have adequately captured the burden of the waiver requests as part of the CMS-10631 collection. Further, we agree that the overall burden associated with waiver requests is likely to be greatly reduced should the rule be finalized as proposed.</p>	<p>No change to burden</p>

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<p>4. Referring to pp. 13-14 of the Supporting Statement Part A, <i>460.190 Monitoring during trial period</i>, CMS estimates the burden associated with a comprehensive annual review to be eight hours for a PACE organization undergoing a trial period audit. The audit requirements being implemented beginning 2017 include, but are not limited to, submission of seven data universes. We do not believe that eight hours is nearly enough to reflect the amount of time this process requires of PACE organizations. In addition, we are unclear as to how the data collection requirements in CMS-R-244 relate to those in CMS-10630 and, further, why requirements under 460.190, but not 460.192, are included in CMS-R-244.</p>	<p>We are removing the burden associated with this requirement from this information collection, as the burden associated with trial period PACE audits is captured as part of another collection (CMS-10630, OMB No: 0938-1327).</p>	<p>D</p>