

**Crosswalk/Summary of Change Based on 60-day Comments and CMS Response for
PRA Package (CMS-10631 Electronic PACE Application)**

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<p>1. Comment from National PACE Association with support from other commenters: Commenters recommended allowing multiple expansion applications to be submitted and under review by CMS at the same time. (CMS does not allow PACE organizations to submit an expansion application if one is currently pending.)</p>	<p>Recommendation not accepted. The recommendation to allow PACE organizations to have more than one pending application at a time is outside the scope of this information collection. However, it should be noted that this recommendation has been considered by CMS and addressed through other channels.</p>	<p>N/A</p>	<p>N</p>
<p>2. Comment from PACE Southeast Michigan: Recommended further streamlining that process to allow POs to submit one application for two centers that will be opened within one year.</p>	<p>This is allowable currently as part of the application process.</p>	<p>N/A</p>	<p>N</p>

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<p>3. Comment from National PACE Association with support from other commenters: In the absence of being able to have more than one expansion application under review concurrently, commenters recommend that CM allow a PO seeking to expand its geographic service area when another application is pending to opt to establish a new contract if such application has the support of its SAA.</p>	<p>The suggestion is outside the scope of this information collection. That said, CMS notes that a single, PACE organization-specific program agreement, which serves as the binding contract between CMS, the PO and the State Administering Agency, provides the essential basis for the operations of the PO. The suggestion would result in multiple program agreements specific to a single PO and, depending on the timing of submission and review of that organization’s expansion applications, would, over time, likely result in varying program agreement information applicable to a single entity, which would be cumbersome and confusing for all parties involved.</p>	N/A	N

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<p>4. Comment from National PACE Association with support from other commenters: Commenters recommended having distinct applications specific to type of expansion application (meaning different applications that involve adding a PACE center site to the existing approved service area and those that involve only a geographic expansion).</p>	<p>Recommendation not accepted. CMS addressed the need for utilizing the same application for initial and expansion applications as part of the previous information collection cycle. In addition to serving as a qualification tool, the application process facilitates approval of the amended program agreement upon approval of the SAE application (regardless of type) and provides a means to capture information consistently.</p>	<p>N/A</p>	<p>N</p>

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<p>5. Comment from National PACE Association with support from other commenters: Commenters recommended that CMS not require expansion applications to upload documents that have not been altered in any way since CMS' approval of a previous application.</p>	<p>Recommendation not accepted. As addressed in the supporting statement, the application process is a key trigger for updating the required content of the program agreement and is a direct means for capturing the applicable documentation for that update and ensuring that the documentation provided by PACE organizations, which includes policies and procedures, satisfies regulatory requirements. CMS notes that past updates to the application were made to facilitate this process which includes, in part, requiring similar documentation to be provided by both initial and expansion applicants.</p>	<p>N/A</p>	<p>N</p>

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<p>6. Comment from UnityPoint Health: Recommended that PACE center relocations not be subject to providing all documents associated with the application process.</p>	<p>PACE organizations that relocate an existing PACE center site do not need to submit an application; there is separate replacement center guidance that includes steps to take for relocations. That said, the replacement (i.e., relocation) of a PACE center is another key trigger for updating the required content of the program agreement and is a direct means for capturing the applicable documentation for that update and ensuring that the documentation provided by PACE organizations, which includes policies and procedures, satisfies regulatory requirements.</p>	<p>N/A</p>	<p>N</p>
<p>7. Comment from PACE Southeast Michigan: Recommended that the application period be expanded to at least six times per year rather than limiting it to the current four dates per year.</p>	<p>Recommendation not accepted. Unlike the Medicare Advantage program, which has one opportunity per year to submit applications, PACE applicants have four opportunities. CMS believes this is more than adequate and plans to continue offering four quarterly application submission opportunities per year.</p>	<p>N/A</p>	<p>N</p>

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<p>8. Comment from PACE Southeast Michigan: Requested that CMS reduce the review time for center openings after State Readiness Review from 60 days to 30 days. Since there is no onsite visit by CMS to the centers, we feel that 30 days to review the approved Readiness Review is sufficient time.</p>	<p>This is outside the scope of the information collection. That said, it is not clear what the commenter refers to in terms of a 30 and 60-day time period. However, we note the SRR is only part of the RAI response and, per regulation, CMS has 45 or 90 days to review the response to the RAI (depending on type of application, which includes a SRR as applicable) before approving an application.</p>	<p>N/A</p>	<p>N</p>
<p>9. Comment from National PACE Association: Page 17, Section E, in the 3rd sentence of the Note, reference to “subordinated debt” should be “subordinated/guaranteed debt,” as follows: “If subordinated/guaranteed debit is identified by the PACE organization (legal entity), it should be included in the total PACE liabilities and the amount of subordinated/guaranteed debt must be clearly identified on the balance sheet of the financial statements and financial projections (if applicable).”</p>	<p>Comment accepted; edit made to application.</p>	<p>Section 3.4.1 (Upload Document E)</p>	<p>N</p>

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<p>10. Comment from National PACE Association: Page 20 – Should language in 4. related to principal languages of the community mirror the language in the attestation related to Explanation of Rights on p. 21? More specifically, “Applicant agrees to make marketing materials available to prospective and current participants in English and in any other principal languages of the community as determined by the State in which the PACE organization is located (in the absence of a State standard, a principal language of the community is any language that is spoken by at least 5 percent of the individuals in the PACE organization’s service area), and in Braille, if necessary.”</p>	<p>Comment accepted; edits made to application. In addition to the proposed language, we added at the end of the attestation statement the following “per 42 CFR §460.82(c) and referenced §460.82 as part of the “Purpose” statement in the Explanation of Rights section (3.6). We also added language to Section 3.6 to align with the language in Section 3.5.</p>	<p>Section 3.5 (Attestation #4) Section 3.6 (Purpose statement and Attestation #4)</p>	<p>N</p>
<p>11. Comment from National PACE Association: Page 27 – In the 10th bullet under 4., replace “they” with “the potential participant.”</p>	<p>Comment accepted; edit made to application.</p>	<p>Section 3.9 (Attestation #4)</p>	<p>N</p>
<p>12. Comment from National PACE Association: Page 27 – in the 3rd bullet under 5., replace “the written notification” with “the reason for the denial.” This would be consistent with 42 CFR §460.152(b)(3).</p>	<p>Comment accepted; edit made to application.</p>	<p>Section 3.9 (Attestation #5)</p>	<p>N</p>
<p>13. Comment from National PACE Association: Page 30 – in the 1st bullet under 3., reword as follows consistent with change due to June 3, 2019 final rule: “Participant, after a 30-day grace period, fails to pay or make satisfactory arrangements to pay, any premium due the PACE</p>	<p>Comment accepted per comment and to align with the new PACE rule; edit made to application.</p>	<p>Section 3.10 (Attestation #1)</p>	<p>N</p>

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14. Comment from National PACE Association: Page 30 – in the 3 rd bullet under 3., reword as follows: “Participant is determined to no longer meet the State Medicaid nursing facility level of care requirements and is not deemed eligible.”	This language was already included in the application. No change necessary.	Section 3.10 (Attestation #3)	N
15. Comment from National PACE Association: Page 30 – under 3. need to include language that speaks to new reasons for involuntary disenrollment as a result of June 3, 2019 final rule: (1) The participant, after a 30-day grace period, fails to pay or make satisfactory arrangements to pay any applicable Medicaid spend down liability or any amount due under the post-eligibility treatment of income process, as permitted under §§460.182 and 460.184; and (2) Participant’s caregiver engages in disruptive or threatening behavior.	Comment accepted. Language added	Section 3.10 (Attestation #3)	I (nominal: simply added an additional bullet)
16. Comment from National PACE Association: Page 30 – under 3., references to §460.164(a) and §460.164(b) should be to §460.164(b) and §460.164(c).	Comment accepted; edit made to application.	Section 3.10 (Attestation #3)	N
17. Comment from National PACE Association: Page 31 – in 4., reference to §460.164(c) should be to §460.164(d).	Comment accepted; edit made to application.	Section 3.10 (Attestation #4)	N
18. Comment from National PACE Association: Page 31 – in 5., reference to §460.164(d) should be to §460.164(e).	Comment accepted; edit made to application.	Section 3.10 (Attestation #5)	N
19. Comment from National PACE Association: Page 31 – in 6., reference to §460.164(e) should be to §460.164(f).	Comment accepted; edit made to application.	Section 3.10 (Attestation #6)	N

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20. Comment from National PACE Association: Page 31 – in 9., consistent with June 3, 2019 final rule, replace “in a timely manner” with “within 30 days.”	Comment accepted; edit made to application.	Section 3.10 (Attestation #9)	N
21. Comment from National PACE Association: Page 38 – in 3., consistent with §460.98(c), reword as follows: “Applicant agrees, at a minimum, to provide the following services <i>at each PACE center</i> as specified in 42 CFR §460.98(c):” Also, “physician” in the 1 st bullet should be replaced with “primary care provider” to reflect the change in the June 3, 2019 final rule.	Comment accepted; added the words “at each PACE center.” Also modified the bulleted statement as follows: “Primary care, including services furnished by a primary care provider as defined in §460.102(c) and nursing services;”	Section 3.15 (Attestation #3)	N (negligible change)
22. Comment from National PACE Association: Page 43 – in 1., the language in this attestation should reference initial participant assessments.	Comment accepted; edit made to application.	Section 3.18 (Attestation #1)	N

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<p>23. Comment from National PACE Association: Page 43 – in 2., June 3, 2019 final rule modified requirement for initial comprehensive assessment to require it be completed in a timely manner in order to allow for development of the initial plan of care within 30 days of the date of enrollment. Attestation should be revised to reflect this.</p>	<p>Comment accepted; edits made to application. Attestation modified as follows:</p> <p>“Applicant ensures that each participant receives an initial face-to-face assessment conducted by the following IDT members and completes the assessment in a timely manner in order to meet the requirements in 460.104(b):”</p> <p>Also made minor word changes in last bullet to align with updated rule.</p>	<p>Section 3.18 (Attestation #2)</p>	<p>N</p>
<p>24. Comment from National PACE Association: Page 44 – in 4., reference to “healthcare professionals” should be “other team members” consistent with the PACE rule.</p>	<p>Comment accepted; edit made to application.</p>	<p>Section 3.18 (Attestation #4)</p>	<p>N</p>
<p>25. Comment from National PACE Association: Page 44 – in 6., should reference to “participants/caregivers” be “participants/designated representatives”?</p>	<p>Comment accepted; edit made to application.</p>	<p>Section 3.18 (Attestation #6)</p>	<p>N</p>

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<p>26. Comment from National PACE Association: Page 44 – in 7., because unscheduled reassessments refer to both reassessments in response to changes in health status and in response to participants/designated representatives’ request for service, it is not accurate to say that “unscheduled reassessments are conducted face-to-face by the applicable IDT members specified in 42 CFR §460.104(c).” For requests for service, “the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct a reassessment.” Further, it is not necessarily the case that unscheduled reassessments related to service requests will be conducted face-to-face under the revised 42 CFR §460.104(d)(2).</p>	<p>Comments accepted; edits made to application as follows to align with updated PACE rule (Attestation #7):</p> <p>“Applicant ensures that <i>semi-annual</i> reassessments are conducted face-to-face by the applicable IDT members specified in 42 CFR §460.104(c).”</p> <p>In addition, we clarify the applicability of §460.104(d)(1) by modifying the language as follows (Attestation #8):</p> <p>“Applicant ensures that there are explicit procedures for performance of unscheduled reassessments as specified in <i>42 CFR §460.104(d)(1)</i> and §460.104(d)(2).”</p>	<p>Section 3.18 (Attestations #7 and #8)</p>	<p>N</p>

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27. Not based on comment, but CMS modified the language to provide greater clarity and to align with the updated PACE rule.	Modified language is as follows: “Applicant ensures the integration of discipline-specific assessments by the IDT into a comprehensive single plan of care for each participant <i>within 30 days of the date of enrollment consistent with the requirements of 42 CFR §460.106(a).</i> ”	Section 3.19 (Attestation #1)	N
28. Comment from National PACE Association: Page 46 – in 3., should “assessment” be “assessed”?	Comment accepted; edit made to application.	Section 3.20 (Attestation #3)	N
29. Comment from National PACE Association: Referring to page 63, in the first paragraph under Medicare and State Medicaid Capitation Payment, the second sentence should clarify that the frailty adjuster applies to payments for community-based, i.e., non-LTI, participants only.	Comment not accepted. After consult with appropriate subject matter experts, it was determined that information is adequate overall for that purpose and contains accurate information, so no change is needed at this time.	Section 4.13 (Document Upload Templates)	N
30. Comment from National PACE Association: Referring to p. 68, 2 nd to last paragraph, reference should be to 42 CFR §460.164(f)?	Comment accepted; edit made to application.	Section 4.20 (Document Upload Templates)	N

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<p>31. Comment from National PACE Association: Referring to p. 70, in 4.21 Applicant Attestation, do references to Center for Beneficiary Choices and Center for Medicaid and State Operations need to be updated?</p>	<p>Comment accepted; edit made to application.</p>	<p>Section 4.21 (Document Upload Templates)</p>	<p>N</p>
<p>32. Comments from National PACE Association: State Readiness Review (pp. 71-98):</p> <ul style="list-style-type: none"> o Should the introduction to the State Readiness Review section reference SRRs that exist in the context of expansion applications? o In general, the MET/NOT MET options in the Criteria Met column often do not line up well with the statement in the Readiness Criteria column. o Referring to p. 87, reference to “multidisciplinary” should be changed in “interdisciplinary.” o Referring to p. 91, reference to “principle language” should be “principal language.” o Referring to p. 92, reference to “multidisciplinary team” should be “interdisciplinary team.” 	<p>Comments accepted; edits and formatting corrections made to State Readiness Review tool part of application.</p>	<p>Readiness Review Report</p>	<p>N</p>