

Revision/Clarification	Purpose of the Revision/Clarification	2023 PACE Application Section	Level of Applicant Burden <i>I = Increases burden</i> <i>D – Decreases burden</i> <i>N – No Change</i>
1. Updated Table of Contents.	Changes resulted in revisions to pagination.	Table of Contents	N
2. Global change – removed reference to “42 CFR” prior to regulatory citations from attestations.	The “purpose” statement that precedes the set of attestations associated with each review area in HPMS includes the full 42 CFR, Part 460 regulatory section so it is redundant to include that reference as part of each regulatory provision citation noted.	Global change	N

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3. Revised or added information to “General Information” and “Instructions” areas (Sections 1 and 2, respectively).	To reinforce and clarify CMS expectations regarding PACE applications.	Sections 1 and 2	N (This is part of the background for the paper only; the electronic application does not include Sections 1 and 2).
4. Added a row to reflect the Service Determination Process section (3.8) specific to PACE. Modified the section number for all sections that follow.	The Service Determination Process was added per updated PACE rule [CMS-4190-F2].	2.2 (Chart 1)	N
5. Removed sentence in NOTE under Marketing section that states: “PACE organizations are no longer required to submit marketing materials as a part of their application.”	The marketing module has been established for a number of years so this statement is no longer necessary.	3.5.B (Note)	N

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<p>6. Removed “accompanied by an approval letter from CMS” from the following statement:</p> <p>“; SAE applicants may not begin marketing in the expanded geographic area, as applicable, until the SAE has been approved and the PACE organization has received the amended program agreement accompanied by an approval letter from CMS.”</p>	<p>The approval letter for an expansion application is sent to a PACE organization electronically, through HPMS. It does not accompany the updated program agreement.</p>	<p>3.5.B. (Note)</p>	<p>N</p>
<p>7. Added a sentence in the Explanation of Rights section that states:</p> <p>“Please note the PACE Participant Rights template, which may be found at: https://www.cms.gov/Medicare/Health-Plans/PACE/Overview.”</p>	<p>To provide assistance to applicants in the development of their participant rights documentation by referencing a template document available to them.</p>	<p>3.6.B (Document Upload description)</p>	<p>N</p>
<p>8. Added the Service Determination Process section and 7 associated attestations. Modified the section number for all sections that follow.</p>	<p>The Service Determination Process was added per updated PACE rule [CMS-4190-F2].</p>	<p>3.8</p>	<p>I</p>

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9. Deleted reference to 42 CFR 460.104 from the “purpose” statement.	The regulatory requirements at 460.104 are not directly applicable to this section and therefore not necessary to cite.	Section 3.9 (Purpose)	N
10. Made revisions to the bulleted language.	To align with modifications per updated PACE rule [CMS-4190-F2].	Section 3.9. (Attestation No. 1)	N
11. Made revisions to the language. The attestation now indicates that participants are to be provided “written information on the appeals process upon enrollment, at least annually thereafter and whenever the interdisciplinary team (IDT) denies a service determination request or request for payment, . . . ” (“service determination request replaces “request for services.”)	Modified to account for new requirements per updated PACE rule [CMS-4190-F2].	Section 3.9 (Attestation No. 2)	N

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<p>12. Deleted reference to appointing an appropriately credentialed impartial third party per §460.122(c)(4). The attestation now states:</p> <p>“Applicant agrees to give all parties involved in the appeal a reasonable opportunity to present evidence related to the dispute in person, and in writing as specified in §460.122(d).”</p>	<p>This is addressed in Attestation No. 1 so not necessary to include in this attestation. In addition, this requirement is distinct from providing all parties involved in the appeal a reasonable opportunity to present evidence related to the dispute per §460.122(d).</p>	<p>3.9 (Attestation No. 3)</p>	<p>N (perhaps a nominal decrease due to removal of redundant Language addressed in a separate attestation)</p>
<p>13. Reordered certain attestations. What was originally Attestations 9-11 are now NOs 6-8.</p>	<p>To provide a cleaner flow, i.e., to follow the order of the regulatory provisions.</p>	<p>Section 3.9 (Attestations 6-8)</p>	<p>N</p>

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<p>14. Modified former attestation No. 6 (now Attestation No. 9) to state: “Applicant agrees to give all parties involved in the appeal appropriate written notification of the decision to approve or deny the appeal that meets specified requirements at §460.122(g). “</p> <p>The previous attestation language about furnishing the disputed service as expeditiously as the participant’s health condition requires, is now Attestation No. 10.</p>	<p>To align with modifications per updated PACE rule [CMS-4190-F2].</p>	<p>Section 3.9 (Attestation No. 9)</p>	<p>N</p>
<p>15. Modified previous language in Attestation No. 12.</p>	<p>To capture updated regulatory requirements in §460.124 without a lot of added specificity.</p>	<p>Section 3.9 (Attestation 12)</p>	<p>N (although slightly less verbiage)</p>

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16. Deleted the word “Note” from the first document upload description (B).	Not necessary to include.	Section 3.9.B	N
17. Deleted the word “Note” from the first document upload description (C). Also made other minor edits to the language.	To eliminate unnecessary language.	Section 3.9.C	N (slightly less verbiage)

<p>18. Minor wording updates to section 3.10.A, question 4 (bullets 1 and 3):</p> <p>Applicant agrees that the intake process minimally includes the following activities for PACE staff and the potential participant, representative, and/or caregiver as specified in §460.152(a):</p> <ul style="list-style-type: none"> • Explains the PACE program, using a copy of the enrollment agreement described in §460.154; • Informs participant that PACE is the sole service provider; • Informs participant that PACE guarantees access to services, but not access to specific providers; • Provides a list of employed and most current list of contracted staff who deliver PACE services; • Discloses required monthly premium if applicable; • Discloses Medicaid spend-down obligations if applicable; • Discloses post-eligibility treatment of income if applicable; • Requires a signed release form from potential participant to allow the PACE organization to obtain medical, financial, and Medicare and Medicaid eligibility information; • Requires assessment by the SAA to determine eligibility for nursing facility services (NF) level of care coverage under the State Medicaid Plan; and • Requires assessment by the PACE staff to determine if the potential participant can be cared for appropriately in a community setting and that the individual meets all PACE eligibility criteria. 	<p>To more closely track the regulatory requirements.</p>	<p>Section 3.10 (Attestation No. 4)</p>	<p>N</p>
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<p>19. Added a Note to section 3.10.B that states:</p> <p>“Note: The policies and procedures for eligibility and enrollment must be developed in accordance with 42 CFR §460.150, §460.152, §460.154, §460.156, §460.158, and §460.160.”</p>	<p>This information should have been included per previous business specifications for the application part of HPMS.</p>	<p>Section 3.10. (Document upload B)</p>	<p>N</p>
<p>20. Added an attestation that states the following:</p> <p>“Applicant agrees that its employees or contractors do not engage in any practice that would reasonably be expected to have the effect of steering or encouraging disenrollment of participants due to a change in health status, per §460.162(c).”</p>	<p>This is an important part of the regulation that should have been included previously.</p>	<p>Section 3.11. (Attestation No. 3)</p>	<p>I</p>

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<p>21. Added the bolded language as follows:</p> <p>“Applicant agrees that involuntary disenrollment of a participant will only be initiated for any of the following reasons as specified in §460.164(b) and §460.164(c), and is effective on the first day of the next month that begins 30 days after the day the PACE organization sends notice of the disenrollment to the participant, per §460.164(a).”</p>	<p>The language is an important part of the PACE regulations and needed to be specified here.</p>	<p>Section 3.11. (Attestation No. 4)</p>	<p>N (perhaps a slight increase due to some added language)</p>
<p>22. Updated bolded language to the purpose statement of the Required Services section to the following:</p> <p>“The purpose of this section is to ensure that all PACE applicants provide a benefit package for PACE participants consistent with the requirements of §460.90, §460.92, and §460.96. “</p>	<p>Added regulation citation §460.90 at the suggestion of CMS audit staff because of instances in which PACE organizations inappropriately restrict access to services. In part, §460.90 stipulates that PACE participants are not subject to limitations or conditions relating to amount, duration, scope of Medicare and Medicaid services or cost sharing.</p>	<p>Section 3.15 (Purpose)</p>	<p>N</p>

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<p>23. Added bolded language as follows:</p> <p>“Applicant agrees to provide a PACE benefit package for all participants, regardless of the source of payment as specified in §460.92(a), that includes the following:”</p>	To explicitly reference the applicable regulatory provision.	Section 3.15 (Attestation No. 1)	N
<p>24. Added the following attestation:</p> <p>“Applicant agrees that decisions by the interdisciplinary team to provide or deny services must be based on an evaluation of the participant that takes into account (§460.92(b)):</p> <p>(1) The participant’s current medical, physical, emotional, and social needs; and</p> <p>(2) Current clinical practice guidelines and professional standards of care applicable to the particular service.”</p>	To align with modifications per updated PACE rule [CMS-4190-F2].	Section 3.15 (Attestation No. 2)	I

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<p>25. Deleted the first 2 bullets of Attestation No. 3 (formerly No. 2):</p> <ul style="list-style-type: none"> • Services not authorized by the IDT, even if a required service, unless it is an emergency service; • Inpatient private room and/or private duty nursing (unless medically necessary) and non-medical items for personal convenience (unless authorized by IDT); 	<p>Removed per updated PACE rule [CMS-4190-F2].</p>	<p>Section 3.15 (Attestation No. 3 (formerly No. 2))</p>	<p>D</p>
<p>26. Added an attestation as follows:</p> <p>“Applicant agrees to provide a benefit package in which Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost sharing do not apply, per §460.90(a).”</p>	<p>To include an important regulatory provision at §460.90 not previously specified in the application.</p>	<p>Section 3.15 (Attestation No. 4)</p>	<p>I</p>

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<p>27. Added an attestation as follows:</p> <p>“Applicant agrees that the participant, while enrolled in the PACE program, must receive Medicare and Medicaid benefits solely through the PACE organization, per §460.90(b).”</p>	<p>To include an important regulatory provision at §460.90 not previously specified in the application.</p>	<p>Section 3.15 (Attestation No. 5)</p>	<p>I</p>
<p>28. Updated the Service Delivery attestation to the following:</p> <p>“1. Applicant agrees to be responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, and must establish and implement a written plan to ensure that care is appropriately furnished, per §460.98(a).</p>	<p>To align with modified language per the updated PACE rule [CMS-4190-F2] to emphasize that the applicant agrees to be responsible for providing care that meets the needs of each participant.</p>	<p>Section 3.16 (Attestation No. 1)</p>	<p>N</p>

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<p>29. Added bolded language to Attestation No. 2 as follows:</p> <p>“Applicant agrees to provide and oversee the provision of services as specified in §460.98(b):”</p> <p>Also modified the first bullet by adding the word “furnishing, as follows:</p> <p>“• Including furnishing comprehensive medical, health, and social services that integrate acute and long-term care in accordance with §460.98(b)(1);”</p> <p>AND <i>added</i> bullets 3 and 4 as follows:</p> <p>“•Provided as expeditiously as the participant’s health condition requires, taking into account the participant’s medical, physical, emotional, and social needs; and</p> <p>• Document, track and monitor the provision of services across all care settings in order to ensure the interdisciplinary team remains alert to the participant’s medical, physical, emotional, and social needs regardless of whether services are formally incorporated into the participant's plan of care.”</p>	<p>Revisions made to address provisions of the updated PACE rule [CMS-4190-F2] at §460.98.</p>	<p>Section 3.16 (Attestation No. 2)</p>	

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<p>30. Modified the introductory statement as follows (bolded language added):</p> <p>“Applicant ensures that the IDT and individual IDT members do the following as specified in §460.102(d): “</p> <p>AND modified the 4th bullet as follows:</p> <p>Regularly inform the IDT of the medical, functional, and psychosocial condition of each participant; (instead of “Communicates regularly about, and remains alert to, . . .”</p> <p>ALSO added the 3rd and 5th bullets:</p> <p>“• Document all recommendations for care or services and the reason(s) for not approving or providing recommended care or services, if applicable, in accordance with §460.210(b).”</p> <p>• Remain alert to pertinent input from any individual with direct knowledge of or contact with the participant, including the following: (A) Other team members; (B) Participants; (C) Caregivers; (D) Employees; (E) Contractors; (F) Specialists; (G) Designated representatives; and”</p>	<p>To align with modified language per the updated PACE rule [CMS-4190-F2]</p>	<p>3.18 (Attestation No. 4)</p>	

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<p>31. Modified the language as follows:</p> <p>“Applicant agrees to establish written policies and implement procedures to safeguard the privacy of any information that identifies a particular participant consistent with the requirements for confidentiality per §460.200(e).”</p>	To more closely reflect the regulatory requirements.	Section 3.18 (Attestation No. 5)	N
<p>32. Added a section (§) to the regulatory provision cited in the introductory statement (§460.104(b)).</p>	For consistency purposes	Section 3.19 (Attestation No. 2)	N

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<p>33. Modified introductory statement as follows (bold language added):</p> <p>“Applicant ensures that the IDT conducts unscheduled reassessments per requirements at §460.104(d):”</p> <p>ALSO revised the second bullet to read as follows:</p> <p>“• In response to a service determination request the PACE organization expects to deny or partially deny, in accordance with §460.121(h).”</p>	<p>Change to introductory statement to be cleaner and to point to specific regulatory provision addressed in attestation.</p> <p>Modified bulleted language to incorporate the new service determination request requirement at §460.121 per the updated PACE rule [CMS-4190-F2].</p>	<p>Section 3.19 (Attestation No. 6)</p>	<p>N</p>

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<p>34. Deleted reference to 42 CFR §460.104(d)(2) from the following statement:</p> <p>“Applicant ensures that there are explicit procedures for performance of unscheduled reassessments as specified in 42 CFR §460.104(d)(1) and 42 CFR §460.104(d)(2).”</p>	<p>This regulatory provision was modified per the updated PACE rule [CMS-4190-F2 to indicate that unscheduled reassessments may be conducted in response to a service determination request. This specific provision is now captured separately, as part of Attestation No. 6 as well as in separate requirements that address service determination requests per §460.121.</p>	<p>Section 3.19 (Attestation No. 8)</p>	<p>N (nominal change to verbiage)</p>

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<p>35. Revised the language as follows (bolded language added): “Applicant ensures data collection, record maintenance, and report submission as required by CMS and the SAA per §460.200(a).”</p>	<p>To point to specific regulatory provision addressed in attestation.</p>	<p>3.27 (Attestation No. 1)</p>	<p>N</p>
<p>36. Revised the language as follows (bolded language added): “Applicant ensures CMS and SAA access to data and records per §460.200(b) including, but not limited to:”</p>	<p>To point to specific regulatory provision addressed in attestation.</p>	<p>3.27 (Attestation No. 2)</p>	<p>N</p>
<p>37. Added the following attestation: “Applicant ensures CMS and the SAA are able to obtain, examine or retrieve participant health outcomes data, which may include reviewing information at the PACE site or remotely, and agrees that this may entail uploading or electronically transmitting information, or sending hard copies of required information by mail, per §460.200(b)(2).”</p>	<p>To mirror the language in the updated PACE rule [CMS-4190-F2].</p>	<p>Section 3.27 (Attestation No. 3)</p>	<p>I</p>

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<p>38. Revised introductory language as follows (bolded language added):</p> <p>“Applicant ensures written policies and implementation of procedures to safeguard data, books and records against the following, as specified in §460.200(d)(1):</p>	<p>To point to specific regulatory provision addressed in attestation.</p>	<p>Section 3.27 (Attestation No. 4)</p>	<p>N</p>
<p>39. Revised introductory language as follows (bolded language added):</p> <p>“Applicant ensures confidentiality of health information, per §460.200(e), through policies and procedures that do the following:”</p>	<p>To point to specific regulatory provision addressed in attestation.</p>	<p>Section 3.27 (Attestation No. 5)</p>	<p>N</p>
<p>40. Revised introductory language as follows (bolded language added):</p> <p>“Applicant ensures retention of records, per §460.200(f), for the longest of the following periods:”</p>	<p>To point to specific regulatory provision addressed in attestation.</p>	<p>Section 3.27 (Attestation No. 6)</p>	<p>N</p>

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<p>41. Revised language as follows (bolded language added):</p> <p>“Applicant agrees to maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards, as specified in §460.210(a).”</p>	<p>To point to specific regulatory provision addressed in attestation.</p>	<p>3.28 (Attestation No. 1)</p>	<p>N</p>
<p>42. Added the following attestation:</p> <p>“Applicant ensures that the medical record contains, at a minimum, all required components specified in §460.210(b).”</p>	<p>Added to address added requirements language in the updated PACE rule [CMS-4190-F2].</p>	<p>3.28 (Attestation No. 3)</p>	<p>I</p>

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<p>43. Revised language as follows (bolded language added):</p> <p>“Applicant agrees to promptly transfer copies of pertinent medical record information between treatment facilities, per §460.210(c).”</p>	<p>Language modified to align with language in the regulatory provision.</p>	<p>3.28 (Attestation No. 4)</p>	<p>N</p>
<p>44. Revised language as follows (bolded language added):</p> <p>“Applicant's medical records are appropriately authenticated, per §460.210(d), by ensuring the following:</p> <ul style="list-style-type: none"> • All entries are legible, clear, complete, and appropriately authenticated and dated; and, . . .” 	<p>To point to specific regulatory provision addressed in attestation.</p> <p>Replaced “must have” with “are” in bulleted language to better follow the introductory statement.</p>	<p>3.28 (Attestation No. 5)</p>	<p>N</p>

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<p>45. Revised language as follows (bolded language added):</p> <p>“The purpose of this section is to ensure that the state is willing to enter into a PACE program agreement with the applying entity, or, as applicable, is willing to amend the program agreement with a PACE organization applying to expand its service area and/or add a PACE center site, and that it has processes in place to ensure compliance with its obligations under the program at 42 CFR §460.12 (b).”</p>	<p>The reference to the regulatory citation was originally a parenthetical. Modified to incorporate as part of the purpose statement by deleting the open and close parens and adding the word “at”.</p>	<p>Section 3.30 (Purpose Statement)</p>	<p>N</p>
<p>46. Revised language as follows (bolded language added):</p> <p>“In the documents section upload a description of the state’s process for enrollment of participants into the state system, per §460.182(d), including the criteria for deemed continued eligibility for PACE in accordance with 460.160(b)(3).”</p>	<p>To point to specific regulatory provision addressed in attestation.</p>	<p>Section 3.30 (Upload document E)</p>	<p>N</p>

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<p>47. Revised language as follows (bolded language added):</p> <p>“In the documents section upload a description of the state’s process to oversee the applicant’s administration of the SAA’s criteria for determining if a potential PACE enrollee is safe to live in the community at the time of enrollment, per §460.150(c) and §460.152(b).”</p>	<p>To specify that the criteria are designated by the State Administering Agency (SAA). The regulatory citations are included to point to specific regulatory provisions addressed in the attestation.</p>	<p>Section 3.29 (Upload document F)</p>	<p>N</p>
<p>48. Revised language as follows (bolded language added):</p> <p>“In the documents section upload a description of the state’s process for disenrollment of participants from the state’s system, per §460.182(d), as well as the process for prior review of involuntary disenrollments in accordance with §460.164(f).”</p>	<p>Language added to point to specific regulatory provisions addressed in the attestation and to specifically reference the requirement at §460.164(f).</p>	<p>Section 3.29.H</p>	<p>N</p>

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<p>49. Added a statement to the instructions for the Explanation of Rights upload (bolded language added):</p> <p>“(Instruction: Include a description of the Participant Bill of Rights. This must be consistent with the requirements at 42 CFR §460.110, §460.112, §460.116, and §460.118. Refer to the PACE Participant Rights template document, which includes current requirements, at: <a 338="" 481="" 551"="" 671="" href="https://www.cms.gov/Medicare/Health-Plans/PACE/Overview.”)”</p> </td> <td data-bbox="> <p>To provide additional instruction to the applicant by pointing to a template document that provides current requirements.</p> </p>	<p>Section 4.4</p>	<p>N</p>	
<p>50. Modified the instructions for the Additional Appeals Rights section (bolded language added):</p> <p>“(Instructions: Describe policies and procedures regarding (deleted <i>“informing”</i>) participants’ (deleted <i>“of their”</i>) additional appeals rights under Medicare and/or Medicaid. Note: This process must be developed in accordance with 42 CFR §460.124, including the process for filing any further appeals, and should specify whether the timeframes for responding to appeals are calendar days or business days.)”</p>	<p>To clearly state that we want a PACE applicant’s policy on additional appeal rights and not just the policy for informing participants. Last part added to provide important instruction to applicants.</p>	<p>Section 4.11</p>	<p>N</p>

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<p>51. Modified language in the State Attestations/Assurances Signatures Pages document to state the following (bolded language added):</p> <p>Service area specific to this application (deleted “<i>by county or zip codes, as applicable</i>”). (Include name of each applicable county and specify either full or partial for each. If partial, list all applicable zip codes specific to that county. For expansion applications, only enter the new service area being added.) _____</p> <p>(Deleted “(if an expansion application, only enter the new service area being added.)”</p>	<p>To provide added clarity to applicants and states in completing this required form.</p>	<p>4.20</p>	<p>N</p>