

**2016 High Level Summary of Change or Crosswalk of Changes for
PRA Package (CMS-10631) Electronic PACE Application (for Both Initial and Service
Area Expansion Applications)**

Revision/Clarification	Purpose of the Revision/Clarification	2016 PACE Application Section	Level of Applicant Burden <i>I = Increases burden D – Decreases burden N – No Change</i>
1. PACE application will be submitted through CMS’ Health Plan Management System.	In the application process, technology is used in the collection, processing, and storage of the data. Applicants must submit the entire PACE application and supporting documentation through the CMS HPMS. The substantial technical change is that the application submission is 100% web based and attestation driven. When compared to the paper application, there are fewer required documents.	N/A	D
2. Adding section 3.29 “State Attestations” to the electronic PACE application. An upload is required.	The purpose of this section is to ensure that the state is willing to enter into a PACE program agreement with the applying entity, and that it has processes in place to ensure compliance with its obligations under the program (42 CFR §460.12 (b)).	3.29	D –Although this section was added to the application, a decrease in burden is being identified because the application is 100% electronic

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PRA Package (CMS-XXXXX) Electronic PACE Application (for Both Initial and Service
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Revision/Clarification	Purpose of the Revision/Clarification	2016 PACE Application Section	Level of Applicant Burden <i>I = Increases burden D – Decreases burden N – No Change</i>
3. Adding section 3.31 “Application Attestation” to the electronic PACE application. An upload is required.	Applicants are required to submit an attestation about the information and statements in their application.	3.31	D – Although this section was added to the application, a decrease in burden is being identified because the application is 100% electronic
4. Added section 3.32 “State Readiness Review” to the electronic PACE application.	Applicants are required to submit a State Readiness Review of their PACE center.	3.32	D – Although this section was added to the application, a decrease in burden is being identified because the application is 100% electronic
5. Addressed typographical issues	To maintain a consistent, proper format and provide clarity	Certain miscellaneous sections	N

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6. Added the State Assurance Signature Pages to the Table of Contents.	The State Assurance Signature Pages were inadvertently not included in the Table of Contents (Section 4.3).	Table of Contents	N
7. Deleted addresses and phone numbers for the CMS Regional Office contacts.	This information can change over time. The more timely information is included at the website link, which is provided.	Section 1.2	N

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<p>8. Deleted attestation No. 3, which stated:</p> <p>“Applicant is licensed under state law as a risk-bearing entity eligible to offer health insurance or health benefits in at least one state in the RPPO region, and if not licensed in all states, the applicant has applied for additional state licenses for the remaining states in the RPPO regions. In addition, the scope of the license or authority allows the applicant to offer the type of MA plan that it intends to offer in the state or states.</p> <p>Replaced this attestation with the following:</p> <p>“Applicant agrees to appoint a participant representative to act as a liaison between the governing body and Participant Advisory Committee, to present participant issues to the governing body and to ensure community representation (42 CFR §460.62(b)(1)).</p>	<p>The original language was erroneously included. The revised language corresponds to the regulatory requirement and represents the correct language included in the current electronic application.</p>	<p>Section 3.3.A.3.</p>	<p>N</p>
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9. Changed the regulatory citation from 42 CFR 460.6(b) to 42 CFR 460.60(b).	Revised to include correct regulatory citation.	Section 3.3.B	N
10. Clarify why the applicant is asked to attest that its employees or agents will not use various prohibited marketing practices, including “unsolicited door-to-door marketing,” which was not included in the current version of the application.	Due to a formatting issue, this prohibited marketing practice did not appear in the attestation, as was intended. This prohibited practice is explicitly cited in the regulation; therefore, it is appropriate to include as part of the attestation. In addition, the applicable regulatory citation for the 5 identified prohibited marketing practices was added (42 CFR 460.82 (e)(1-5)).	Section 3.5.A.6	N

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11. Numbering of identified requirements is off.	Separated out existing attestation language by adding No. 4 to properly reflect the regulatory requirements. No change otherwise to existing language.	Sections 3.16.A.3 and 3.16.A.4	N
12. Changed the attestation to say: “Applicant ensures that staff knows how to use the emergency equipment” instead of “Applicant ensures that all staff knows how to use the emergency equipment.”	Revised to align with the regulatory language at 42 CFR 460.72 (c)(4).	Section 3.22.A.2	N

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13. Changed the regulatory citation from 42 CFR 460.50(1)(2) to 42 CFR 460.50(d)(1)(2).	Revised to include correct regulatory citation.	Section 3.25.A.1	N
14. Changed the regulatory citation from 42 CFR 460.52(1) to 42 CFR 460.52(a)(1).	Revised to include correct regulatory citation	Section 3.25.A.2	N

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15. Changed the regulatory citation from 42 CFR 460.52(2-4)) to 42 CFR 460.52(a)(2-4).	Revised to include correct regulatory citation	Section 3.25.A.3	N
16. Slightly modified and combined the last 2 bulleted requirements and changed the identified regulatory citation from 42 CFR 460,200(f)(i-iii) to 42 CFR 460.200(f)(1-2).	Revised to more accurately reflect the regulatory requirements and proper regulatory citation.	Section 3.26.A.5	N

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17. Modified the introductory statement of the Quality Assessment and Performance Improvement Program (QAPI) section.	Revised to accurately represent the purpose of the QAPI section and provide the correct regulatory citation. The introductory statement inadvertently referenced the purpose of the “Maintenance of Records & Reporting Data” and not the QAPI, as was intended.	Section 3.28	N

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<p>18. Added the following attestation:</p> <p>“A. In HPMS, complete the table below:</p> <p>1. Applicant has assurance from the SAA of the State in which the program is located indicating that the State considers the entity to be qualified to be a PACE organization and is willing to enter into a PACE program agreement with the entity.”</p>	<p>This attestation was inadvertently excluded. The attestation language corresponds to the regulatory requirement.</p>	<p>Section 3.29.A.</p>	<p>D – Although this section was added to the application, a decrease in burden is being identified because the application is 100% electronic</p>

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<p>19. Deleted attestation No. 1, which stated:</p> <p>“Applicant agrees to do the following as specified in 42 CFR §460.130(a-c):</p> <ul style="list-style-type: none"> • Develop, implement, maintain and evaluate a QAPI program; • Reflect the full range of services furnished by the PACE organization; and • Take action resulting in improvements in its performance in all types of care.” <p>Replaced this attestation with the following:</p> <p>“Applicant is requesting specific modifications or waivers of certain regulatory provisions as part of this application as permitted under Section 903 of the Benefits Improvement and Protection Act (BIPA) of 2000.”</p>	<p>The original language was erroneously included. The revised language corresponds to the regulatory requirement and reflects the correct language included in the current electronic application.</p>	<p>Section 3.30.A.1</p>	<p>N</p>
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<p>20. Added a new attestation as follows:</p> <p>“Applicant ensures that specific modifications or waivers of certain regulatory provisions as part of this application have been submitted to the SAA for review and approval, as specified in 42 CFR 460.(a)(2).”</p>	<p>This attestation was inadvertently excluded. The attestation language corresponds to the regulatory requirement.</p>	<p>Section 3.30.A.2</p>	<p>D – Although this section was added to the application, a decrease in burden is being identified because the application is 100% electronic</p>
<p>21. Deleted the words “Misc. Comments.”</p>	<p>These words were erroneously included.</p>	<p>Immediately preceding Section 4.3: “State Assurance Signature Pages”</p>	<p>N</p>

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22. Deleted reference PACE in relation to other Medicare Advantage plans in the introductory paragraph and the “County Rates” discussion. Specifically, the word “other” was deleted.	The word “other” Medicare Advantage plans, in this context, implies that PACE is a form of MA plan, and it is not.	Section 4.4	N
<p>The following are revisions made to the application subsequent to the publication of the initial 30-day Federal Register notice on May 2, 2016 (81 FR 26234)</p>			

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23. Updated the Table of Contents	Modified to reflect revision to the title of Section 4.4, which is now “Medicare and State Medicaid Capitation Payment” (added the word “Medicare” to reflect the description of the Medicare aspect of the capitation payment discussion)	Table of Contents (Section 4.4)	N
24. Revised the overview section.	Modified to provide greater clarity by including only most pertinent background information.	Section 1.1 (overview)	D (less information to review)
25. Deleted information related to regional office contacts.	Revision made because CMS Central Office staff provides technical support and responds to questions during the application process.	Section 1.2 (Technical Support)	N
26. Minor revisions to the discussion about HPMS.	To more accurately describe the role of HPMS specific to PACE and included appropriate reference the program agreement.	Section 1.3 (A) and (B)	N

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27. Deleted information regarding the listserv.	Not necessary to include for a user accessing HPMS for purposes of application.	Section 1.3 (D)	D (less information to review at time of application)
28. Deleted all but first paragraph regarding appeal information.	Redundant information, as information regarding appeal rights and process is provided as part of direct communications to applicants in the event the application is denied.	Section 1.5	D (less information to review at time of application)
29. Deleted reference to 2016 for purposes of the application.	To avoid confusion, particularly in the event the application is not revised annually.	Cover Sheet and Section 2.1	N
30. Deleted the sentence: “CMS will only accept submissions using this current 2016 version of the MA application.”	This is no longer needed with the transition to an automated process. (We note that the reference to MA was incorrect; this should have referred to the PACE application).	Section 2.1 (“Instructions” overview)	N

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<p>31. Added “N/A” as an option for responding to certain attestations, as follows:</p> <p>“In preparing a response to the prompts throughout this application, the applicant must mark “Yes” or “No” or “<i>N/A</i>” in sections organized with that format.</p>	<p>To inform the applicant that “N/A” is another option for responding to certain attestations.</p>	<p>Section 2.1 (“Instructions” overview)</p>	<p>N</p>

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<p>32. Deleted the following language: “Failure to meet the requirements represented in this application and to operate a PACE plan consistent with the applicable statutes, regulations, and the PACE program agreement, and other CMS guidance could result in the suspension of plan marketing and enrollment. If these issues are not corrected in a timely manner, the applicant will be disqualified from participation in the PACE program, as applicable.”</p>	<p>Deleted because the language does not relate to an application but, rather, is specific to an operational PACE program.</p>	<p>Section 2.1 (“Instructions” overview)</p>	<p>D (less information to review)</p>

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33. Added 2 columns to the chart to reflect required uploads specific to both initial applications and SAE applications (and correctly identified attestations required of SAE applicants).	To provide greater clarity regarding upload requirements specific to each type of application.	Section 2.3 (Chart 1)	N
34. In conjunction with No. 27 above, changed title to reflect the additional information (now “Chart of Required Attestations and Uploads”)	To appropriately reflect the additional information now included.	Section 2.3 (Chart 1)	N
35. Added “x (as applicable)” to the Column titled “Upload Required (Initial)” to denote that a waiver upload applies, as applicable, to an initial application.	Added to reflect that initial applicants may or may not upload waiver information. (This only applies to applications that are requesting a waiver(s).)	Section 2.3 (Chart 1)	N

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36. Modifications to the description of the Part D Prescription drug Benefit Instructions.	Revisions made to provide greater clarity in terms of the Part D application vis-à-vis this PACE application.	Section 2.5	N
37. Deleted attestation No. 3 as follows: “Applicant's defined geographic service area does not duplicate a service area covered by another PACE program agreement (42 CFR §460.22(a)(b)).” Similarly, the following language was deleted as part of the upload discussion: “If the geographic service area includes an area covered by another PO, identify the duplicate area.”	This is not an appropriate attestation for a PACE applicant. The SAA determines whether an entity may apply to be a PO in a geographic area that is covered by another PO; the applicant would not necessarily be in a position to attest to this or have direct knowledge of duplicate geographic service areas. (Note: see language that was added to the State Assurances Signature Pages to address the issue of geographic service area.	Section 3.1 (Service Area)	D

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<p>38. Added the following attestation (No. 7):</p> <p>“For any change in organizational structure that includes a Change of Ownership, the applicant agrees to abide by the general provisions described in the MA regulations at 42 CFR 422.550.”</p>	<p>Necessary as a follow-on to the previous attestation, which addressed the required time period for notification of a change in organizational structure. This information was addressed in recent guidance to PACE organizations.</p>	<p>Section 3.2</p>	<p>D – Although this section was added to the application, a decrease in burden is being identified because the application is 100% electronic</p>
<p>39. Deleted reference to the Board of Directors and replaced “consumer representatives(s)” with PACE participant representative(s).</p>	<p>To focus on the requirement for information specific to governing body members, per regulatory language.</p>	<p>Section 3.3(B)</p>	<p>N</p>
<p>40. Deleted certain references to “upload” and replaced with “provide”.</p>	<p>To be clear that certain financial requirements are ongoing and not necessarily specific to the application requirement alone.</p>	<p>Section 3.4.A.3 and Section 3.4.A.5</p>	<p>N</p>

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41. Added attestation No. 6 to align with the required upload (if applicable). And modified somewhat the sequence of both the attestations and follow-on upload information. Also edited some of the fiscal soundness requirements and combined certain uploads.	Modifications made to align with the structure of other Attestation sections. Edits made to provide greater clarity regarding current fiscal requirements.	Section 3.4	N (net overall effect)
42. Deleted the previously-referenced regulatory citations (42 CFR §460.98 and §460.102) and replaced them with the following 42 CFR §460.92 and §460.96).	The previously-referenced citations were incorrect. Revised to correctly identify the applicable regulatory citations.	Section 3.14 (purpose statement)	N
43. Minor edits to introductory statement.	To reflect the purpose of the section.	Section 3.16	N
44. Minor edits to introductory statement.	To reflect the purpose of the section.	Section 3.17	N

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<p>45. Modified attestation No. 4 by replacing the “2000” edition of the National Fire Protection Association's Life Safety Code with “current” edition, as follows:</p> <p>“Applicant ensures the PACE center meets the occupancy provisions of the current edition of the National Fire Protection Association's Life Safety Code that apply to the type of setting in which the center is located.</p>	<p>To ensure that the most recent edition of the National Fire Protection Association's Life Safety Code is referenced and applies.</p>	<p>Section 3.21</p>	<p>N</p>

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<p>46. Revised original attestation No. 2 which stated: “Applicant ensures that staff knows how to use the emergency equipment. Every site must have available and ready for immediate use the emergency equipment.”</p> <p>Replaced this attestation with the following:</p> <p>“Applicant ensures that staff who know how to use the emergency equipment are on the premises of every center at all times and are immediately available to use the emergency equipment.”</p>	<p>Revision made to provide greater clarity and better align with the regulatory language.</p>	<p>Section 3.22.A.2</p>	<p>N</p>

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<p>47. Revised original attestation No. 5 which stated:</p> <p>“Applicant agrees to provide for emergency services, inpatient and outpatient settings by a qualified emergency services provider, or one of its contract providers, either in or out of the PO's service area in order to evaluate or stabilize an emergency medical condition as specified in 42 CFR § 460.100(a)(1)(2).”</p> <p>Replaced this attestation with the following:</p> <p>“Applicant agrees to provide for emergency services, both inpatient and outpatient settings, by a qualified emergency services provider other than the PO or one of its contract providers, either in or out of the PO's service area, in order to evaluate or stabilize an emergency medical condition as specified in 42 CFR §460.100(b).”</p>	<p>Revision made to more closely track the regulatory language and correct the regulatory citation.</p>	<p>Section 3.22.A.5</p>	<p>N</p>
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<p>48. Made minor edits to the following attestation:</p> <p>“Applicant agrees that the transportation system has been modified to accommodate the proposed service area/site expansion.”</p>	<p>To correct minor typographical issues.</p>	<p>Section 3.23.A.7</p>	<p>N</p>

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<p>49. Revised original attestation No. 5 which stated:</p> <p>“Each meal must meet the following requirements consistent with the requirements of 42 CFR §460.78 (a): be prepared by methods that conserve nutritive value, flavor and appearance; be prepared in a form designed to meet individual needs; and be prepared and served at the proper temperature.”</p> <p>Replaced this attestation with the following:</p> <p>“Applicant agrees to provide meals that meet the following requirements consistent with 42 CFR §460.78 (a): be prepared by methods, . . .”</p>	<p>Modified to reflect an attestation statement, in line with other attestations.</p>	<p>Section 3.24.A.5</p>	<p>N</p>

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<p>50. Revised original overall purpose statement:</p> <p>“The purpose of this section is to ensure that all PACE applicants take appropriate actions to improve performance, including the establishment and operation of a QAPI in accordance with 42 CFR Section 460.130.”</p> <p>Replaced this attestation with the following:</p> <p>“The purpose of this section is to ensure that all PACE applicants take appropriate actions to improve performance, including the establishment and operation of a QAPI in accordance with 42 CFR Section 460, Subpart H, 460.200 and 460.202.”</p>	<p>The previous regulatory citation was not all-inclusive. Language modified to capture all requirements as part of Subpart H instead of citing each applicable section of the subpart.</p>	<p>Section 3.28</p>	<p>N</p>

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51. Deleted the word “provide” and replaced with “upload.”	To reflect that the document is to be uploaded.	Section 3.28(B)	N
52. Deleted reference to SAA “approval” of applicant waiver requests.	To be clear that the SAA is not required to approve waiver requests but, rather, to review such requests and provide any concerns regarding the requests.	Section 3.30.A.2	N
53. Corrected the regulatory requirement cited (i.e., 42 CFR 460.26(a)(2)).	The regulatory citation was not completely and accurately cited previously.	Section 3.30.A.2	N
54. Slight modification to the introductory statement and included a column to provide the applicant with the option to respond “N/A” to the attestations.	Waivers are not required of applicants in every case.	Section 3.30 (attestation table)	N

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55. Minor edits	To provide better clarity in terms of required information.	Section 4.1.2 and Section 4.1.3	N
<p>56. Replaced the “Subordinated Debt” attestation language previously included with the following:</p> <p>“If the applicant has a subordinated debt arrangement, the applicant must complete the “PACE Organization Attestation of Subordinated Debt Arrangement” form located at https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/FSRR.html. This completed form may be uploaded as part of the fiscal soundness part of the application (see section 3.4).</p>	To align with updated information. Entails a similar attestation (i.e., sign-off on part of a PACE organization official).	Section 4.2	I (only a slight added burden to capture the appropriate form from a separate web link)

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<p>57. Added to the statement in the “State Assurances and Signature Pages” Section: “and operate in the proposed geographic service area” as follows:</p> <p>“State certifies that the entity described in this application is qualified to be a PACE provider and operate in the proposed geographic service area.”</p>	<p>Added to denote that the State in which the PACE applicant intends to operate its program is aware of the geographic service area that the applicant proposes to serve, including any area that may duplicate an area already served by an active PO (it is up to the State whether to allow multiple POs to serve the same geographic area).</p>	<p>Section 4.3</p>	<p>N</p>
<p>58. Updated the discussion of the Medicare capitation payment methodology discussion.</p>	<p>To provide added clarity and reflect current approach and information.</p>	<p>Section 4.4</p>	<p>N</p>