

Section in Current CMS-10630 (11/27/2019)	Original Language	Clarification or Change	Revised Language
Appeals1P651P661P681P73 Participant Impact Tab Column G	If the answer to this question is No the PO may enter NA in fields I-O.	Technical Clarification	If the answer to this question is No the PO may enter NA in fields H-O.
Assessment1P491P501P82 Instructions Tab Instructions Section	Annual/Semiannual Assessments:	Technical Clarification	Semiannual Assessments:
Assessment1P491P501P82 Participant Impact Tab Column F	Did the participant experience a change in their health or psychosocial status during the audit review period that?	Technical Clarification	Did the participant experience a change in their health or psychosocial status during the audit review period that required a change in status assessment?
Assessment1P491P501P82 Participant Impact Tab Column AD	Optional: Please note, you do not have to complete this column. If there are any mitigating factors that you would like CMS to consider related to a specific participant, please enter the information in this column.	Technical Clarification	General Information: This information is to be completed for all Impact Analyses Optional: Please note, you do not have to complete this column. If there are any mitigating factors that you would like CMS to consider related to a specific participant, please enter the information in this column.
Attachment1PACEAudit ProcessDataRequest Universe Preparation & Submission Purpose	To evaluate PACE organizations (PO's)' compliance with regulatory requirements in the following four areas related to the Programs of All-Inclusive Care for the Elderly (PACE).	Typographical Error	To evaluate PACE organizations' (POs)' compliance with regulatory requirements in the following four areas related to the Programs of All-Inclusive Care for the Elderly (PACE).
Attachment1PACEAudit ProcessDataRequest Universe Preparation & Submission 2.2.1 Documentation	The PO's Quality Assessment and Performance Improvement (QAPI) plan(s) that were in use during the data collection period;	Technical Clarification	The PO's Quality Improvement (QI) plan(s) that were in use during the data collection period;

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AttachmentIPACEAudit ProcessDataRequest Universe Preparation & Submission 2.3 Documentation	NOTE: Organizations must submit the information identified in Attachment IV in writing but do not need to submit the information using the excel template Attachment IV and may submit the information in another format so long as all requested information is included.	Added additional language to clarify data entry requirements based on comments.	NOTE: Organizations must submit the information identified in Attachment IV in writing but do not need to submit the information using the excel template Attachment IV and may submit the information in another format so long as all requested information is included. Requests for observation data will typically be limited to participants assigned to an IDT at the center are CMS auditors are conducting the onsite portion of the audit. However, CMS reserves the right to request data for participants from other PACE centers, as needed, to ensure all of the observations can be completed. For example, if medication administration or wound care is not being provided at the center where the onsite audit is conducted, CMS auditors may request data from other PACE centers in order to determine whether observations may be completed at an alternative site. The audit team will identify the subset of participants for whom information must be provided.
AttachmentIPACEAudit ProcessDataRequest Audit Elements IV Quality Assessment 1. Quality Assessment Review	Quality Assessment Review: CMS will conduct an interview and review data/documentation with the PO's staff responsible for the development and implementation of the quality assessment and performance improvement program.	Technical Clarification	Quality Assessment Review: CMS will conduct an interview and review data/documentation with the PO's staff responsible for the development and implementation of the quality improvement program.
AttachmentIPACEAudit ProcessDataRequest Audit Elements IV Quality Assessment 2. Review Quality Assessment and Performance Improvement Documentation	2. Review Quality Assessment and Performance Improvement Documentation: CMS will review relevant documentation and information related to the PO's quality assessment and performance improvement program.	Technical Clarification	2. Review Quality Improvement Documentation: CMS will review relevant documentation and information related to the PO's quality improvement program.

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<p>AttachmentIPACEAudit ProcessDataRequest</p> <p>Audit Elements</p> <p>IV Quality Assessment</p> <p>2. Review Quality Assessment and Performance Improvement Documentation</p>	<p>Documentation that staff members and contractors are involved in the development and implementation of the QAPI program</p>	<p>Technical Clarification</p>	<p>Documentation that staff members and contractors are involved in the development and implementation of the QI program</p>
<p>AttachmentIPACEAudit ProcessDataRequest</p> <p>Audit Elements</p> <p>IV Quality Assessment</p> <p>3.1. Did the PO develop and/or implement an effective, data driven quality assessment and performance improvement program?</p>	<p>3.1. Did the PO develop and/or implement an effective, data driven quality assessment and performance improvement program?</p>	<p>Technical Clarification</p>	<p>3.1. Did the PO develop and/or implement an effective, data driven quality improvement program?</p>
<p>AttachmentIPACEAudit ProcessDataRequest</p> <p>Audit Elements</p> <p>IV Quality Assessment</p> <p>3.2. Did the PO ensure that the appropriate staff were involved in the development and implementation of QAPI activities and did the PO appropriately disseminate information related to the QAPI activities?</p>	<p>3.2. Did the PO ensure that the appropriate staff were involved in the development and implementation of QAPI activities and did the PO appropriately disseminate information related to the QAPI activities?</p>	<p>Technical Clarification</p>	<p>3.2. Did the PO ensure that the appropriate staff were involved in the development and implementation of QI activities and did the PO appropriately disseminate information related to the QI activities?</p>

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<p>AttachmentIPACEAudit ProcessDataRequest</p> <p>Appendix A</p> <p>Table 5: List of Participant Medical Records (LOPMR) Record Layout</p>	<p>None</p>	<p>Added additional language to clarify data entry requirements based on comments.</p>	<ul style="list-style-type: none"> • PACE organizations may use any and all information available to them when populating these fields, including participant medical records, claims data, and any other participant-specific information the PACE organization may maintain.
<p>AttachmentIPACEAudit ProcessDataRequest</p> <p>Appendix A</p> <p>Table 5: List of Participant Medical Records (LOPMR) Record Layout</p> <p>Row L</p> <p>Description Column</p>	<p>Were any ER visits or hospitalizations (admission or observation) a result of hypoglycemia, hyperglycemia, or decreased oxygen saturation?</p> <p>Enter Y if the participant went to the ER or was admitted to the hospital (or observed at the hospital) for one of these reasons.</p> <p>Enter N if the participant did not go to the ER or was not admitted to the hospital (or observed at the hospital) for one of these reasons.</p>	<p>Added additional language to clarify data entry requirements based on comments.</p>	<p>Were any ER visits or hospitalizations (admission or observation) a result of hypoglycemia, hyperglycemia, or decreased oxygen saturation?</p> <p>Enter Y if the participant went to the ER or was admitted to the hospital (or observed at the hospital) with a primary or secondary diagnosis of hypoglycemia, hyperglycemia, or decreased oxygen saturation.</p> <p>Enter N if the participant did not go to the ER or was not admitted to the hospital (or observed at the hospital) with a primary or secondary diagnosis of hypoglycemia, hyperglycemia, or decreased oxygen saturation.</p>
<p>AttachmentIPACEAudit ProcessDataRequest</p> <p>Appendix A</p> <p>Table 5: List of Participant Medical Records (LOPMR) Record Layout</p> <p>Row N</p> <p>Description Column</p>	<p>Enter Y if the participant was in a SNF or NF at the time that the universe is completed.</p> <p>Enter N if the participant was not in a SNF or NF at the time that the universe is completed.</p>	<p>Added additional language to clarify data entry requirements based on comments.</p>	<p>Enter Y if the participant was in a SNF or NF at the time that the universe is completed.</p> <p>Enter N if the participant was not in a SNF or NF at the time that the universe is completed. Enter N if the participant was disenrolled (voluntarily, involuntarily or deceased) at the time the universe is completed.</p>

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<p>AttachmentIPACEAudit ProcessDataRequest</p> <p>Appendix A</p> <p>Table 5: List of Participant Medical Records (LOPMR) Record Layout</p> <p>Row AB</p> <p>Description Column</p>	<p>Enter the frequency that the participant attends the PACE center at the time the universe is completed. For example, 5 days per week, 2 times per month, etc.</p>	<p>Added additional language to clarify data entry requirements based on comments.</p>	<p>Enter the frequency that the participant attends the PACE center at the time the universe is completed. For example, 5 days per week, 2 times per month, etc. Enter 0 if the participant was disenrolled (voluntarily, involuntarily or deceased) at the time the universe is completed.</p>
<p>AttachmentIIPACESupplemental Questions</p> <p>Instructions Tab</p> <p>Instructions Section</p>	<p>PACE organizations may upload also grievance and service delivery request policies pertaining to the questions in the PACE Supplemental Questions tab.</p>	<p>Technical Clarification</p>	<p>PACE organizations may also upload grievance and service delivery request policies pertaining to the questions in the PACE Supplemental Questions tab.</p>
<p>AttachmentIIIPre-AuditIssueSummary</p> <p>Pre-Audit Issue Summary Tab</p> <p>Column E</p>	<p>Was the non-compliance disclosed to the CMS account manager prior to the date of the Audit Engagement Letter prior to the date of the Audit Engagement Letter?</p> <p>Yes/No</p>	<p>Technical Clarification</p>	<p>Was the non-compliance disclosed to the CMS account manager prior to the date of the Audit Engagement Letter?</p> <p>Yes/No</p>
<p>AttachmentIVOnsiteObs PartList</p> <p>Instructions Tab</p> <p>Instructions Section</p>	<p>Enter responses to each question in Onsite Observation Participant List tab of this document.</p>	<p>Modified location of pre-existing instructions</p>	<p>Enter responses to each question in Onsite Observation Participant List tab of this document. Organizations have the option of submitting the information using this excel template or may submit the information in another format the organization can provide. If certain information is not available on the first day of audit, please discuss this with the audit lead prior to submitting.</p>

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AttachmentIVOnsiteObsPartList Instructions Tab Due Date Section	Organizations must submit all of the information identified on tab 2 (OnsiteObsParticipantList) of this template via HPMS on the first day of the onsite audit. Organizations have the option of submitting the information using this excel template or may submit the information in another format the organization can provide. If certain information is not available on the first day of audit, please discuss this with the audit lead prior to submitting.	Modified location of pre-existing instructions	Organizations must submit all of the information identified on tab 2 (OnsiteObsParticipantList) of this template via HPMS on the first day of the onsite audit.
AttachmentIVOnsiteObsPartList Instructions Tab Instructions Section	- Participants who are scheduled to have medications administer by an employee or contracted employee in the PACE center or participant's home on the week of the onsite audit;	Technical Clarification	- Participants who are scheduled to have medications administered by an employee or contracted employee in the PACE center or participant's home on the week of the onsite audit;
AttachmentIVOnsiteObsPartList OnsiteObsParticipantList Tab Column K	Which days will wound care performed? M/T/W/Th/F Enter NA if the participant does not receive wound care from PO staff. List all days that wound care will be performed.	Technical Clarification	Which days will wound care be performed? M/T/W/Th/F Enter NA if the participant does not receive wound care from PO staff. List all days that wound care will be performed.
AttachmentIVOnsiteObsPartList OnsiteObsParticipantList Tab Column N	Which days will home care be provided? M/T/W/Th/F Enter NA if the participant does not receive wound care from PO staff. List all days that apply.	Technical Clarification	Which days will home care be provided? M/T/W/Th/F Enter NA if the participant does not receive home care. List all days that apply.
AttachmentVAuditSurvey Audit Activities Section Questions 2-5	Clinical Appropriateness and Care Planning	Technical Clarification	Provision of Services

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AttachmentVAuditSurvey Audit Activities Section Questions 2-5	Onsite	Technical Clarification	Removed
CMS10630Supporting StatementAPACE Justification Section 12.4: Information Collection Instruments and Instruction/Guidance Documents	Clinical Appropriateness and Care Planning Impact Analysis Template	Technical Clarification	Provision of Services Impact Analysis Template
CMS10630Supporting StatementAPACE Justification Section 15: Program Burden Changes	Additionally, since publishing this package for the 60-day comment period, a new regulation has gone into effect which allows CMS to conduct ongoing audits using a risk assessment.	Added regulation in response to comments.	Additionally, since publishing this package for the 60-day comment period, a new regulation has gone into effect which allows CMS to conduct ongoing audits using a risk assessment (see the Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE) Final Rule published in the Federal Register on June 3, 2019 (84 FR 25610)).
EmergencyCare1P07 Participant Impact Tab Row 1 Instructions Columns G-P	Emergency Notification Information: This is to be completed for all participants during the Impact Analysis review period.	Instruction Clarification	Emergency Notification Information: This is to be completed for all selected participants.
EmergencyCare1P07 Participant Impact Tab Row 1 Instructions Columns V-W	Billing Information: If requested, these questions must be completed for all participants during the Impact Analysis review period.	Instruction Clarification	Billing Information: If requested, these questions must be completed for all selected participants.
EmergencyCare1P07 Participant Impact Tab Row 1 Instructions	Additional Information: This is to be completed for all participants during the Impact Analysis review period.	Instruction Clarification	Additional Information: This is to be completed for all selected participants.

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Columns X-Z			
Effectuation1P021P111P30 Participant Impact Tab Column E	Date of Disenrollment Enter NA if the participant is still enrolled.	Technical Clarification	Date of Disenrollment MM/DD/YYYY Enter NA if the participant is still enrolled.
Effectuation1P021P111P30 Participant Impact Tab Column M	What evidence/documentation does the PO have that demonstrates the service was approved? Enter NA if the service was not provided to the participant.	Technical Clarification	What evidence/documentation does the PO have that demonstrates the service was provided? Enter NA if the service was not provided to the participant.
EmergencyCare1P07 Participant Impact Tab Column N	Time of assessment. Enter NA if the participant did not contact the PO before utilizing emergency services.	Technical Clarification	Time of assessment. HH:MM AM/PM Enter NA if the participant did not contact the PO before utilizing emergency services.
EmergencyCare1P07 Participant Impact Tab Column P	Did staff or contractors from the PO: • Instruct the participant and/or caregiver that prior authorization was needed before to going to the ER or calling 911; or • Instruct the participant and/or caregiver that approval was needed before to going to the ER or calling 911; or • Instruct the participant and/or caregiver not to go to the ER or call 911? (Yes/No) Enter NA if the participant did not contact the PO before utilizing emergency services.	Technical Clarification	Did staff or contractors from the PO: • Instruct the participant and/or caregiver that prior authorization was needed before going to the ER or calling 911; or • Instruct the participant and/or caregiver that approval was needed before going to the ER or calling 911; or • Instruct the participant and/or caregiver not to go to the ER or call 911? (Yes/No) Enter NA if the participant did not contact the PO before utilizing emergency services.
Grievances1P311P751P77 Instructions Tab Instructions Section	• Review the selected medical records to determine if the participant was informed of the grievance process at the time of enrollment and on at least annually basis.	Technical Clarification	• Review the selected medical records to determine if the participant was informed of the grievance process at the time of enrollment and on at least an annual basis.
Grievances1P311P751P77 Participant Impact Tab Column E	Date of Disenrollment Enter NA if the participant is still enrolled.	Technical Clarification	Date of Disenrollment MM/DD/YYYY Enter NA if the participant is still enrolled.

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Grievances1P311P751P77 Participant Impact Tab Column Q	Is their documentation that the complaint was processed as a grievance in accordance the PO's grievance policies? (Yes/No)	Technical Clarification	Is there documentation that the complaint was processed as a grievance in accordance the PO's grievance policies? (Yes/No)
Grievances1P311P751P77 Participant Impact Tab Column W	Is their documentation that the participant was informed of the grievance process, in writing, upon enrollment? (Yes/No)	Technical Clarification	Is there documentation that the participant was informed of the grievance process, in writing, upon enrollment? (Yes/No)
Grievances1P311P751P77 Participant Impact Tab Column X	Is their documentation that the participant was informed of the grievance process, in writing, on an annual basis? (Yes/No)	Technical Clarification	Is there documentation that the participant was informed of the grievance process, in writing, on an annual basis? (Yes/No)
Grievances1P311P751P77 Participant Impact Tab Column X	Enter NA if the participant was not disenrolled before the grievance process was reviewed or if the participant was newly enrolled.	Technical Clarification	Enter NA if the participant was disenrolled before the grievance process was reviewed or if the participant was newly enrolled.
HomeCare1P02 Participant Impact Tab Column F	During the Audit Review Period a. Did the IDT determine home care was necessary; b. Did a provider order home care; or c. Was home care included in the care plan? If the PO enters Yes to any of the above enter yes in this column. Enter No if home care services were not determined necessary, approved or ordered. (Yes/No) If No is entered, the organization may enter NA in all remaining fields.	Technical Clarification	During the Audit Review Period a. Did the IDT determine home care was necessary; b. Did a provider order home care; or c. Was home care included in the care plan? Enter Yes if any of the above are true. Enter No if home care services were not determined necessary, approved or ordered. If No is entered, the organization may enter NA in all remaining fields.
HomeCare1P02 Participant Impact Tab Column G	If the answer to column F is Yes, please indicate whether the home care was: a. Determined necessary by the IDT; b. Approved as part of a service delivery request; c. Approved a part of an appeal; d. Ordered by a provider?	Technical Clarification	If the answer to column F is Yes, please indicate whether the home care was: a. Determined necessary by the IDT; b. Approved as part of a service delivery request; c. Approved as part of an appeal; d. Ordered by a provider?

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Personnel Participant Impact Tab Column F	Date of Termination MM/DD/YYYY	Technical Clarification	Date of Termination MM/DD/YYYY Enter NA if employee was not terminated during audit review period.
Personnel Participant Impact Tab Column G	Type of Employment	Technical Clarification	Type of Employment Enter contract, Full-time, Part-time, Volunteer, or Other.
Personnel Participant Impact Tab Column H	Direct Participant Contact	Technical Clarification	Direct Participant Contact (Yes/No)
Personnel Participant Impact Tab Column I	License	Technical Clarification	License (Yes/No)
Personnel Participant Impact Tab Column T	Is there documentation that the staff member was evaluated by a PCP, NP, or PA, and determined to be free of communicable prior to engaging in direct participant contact? (Yes/No)	Technical Clarification	Is there documentation that the staff member was evaluated by a PCP, NP, or PA, and determined to be free of communicable diseases prior to engaging in direct participant contact? (Yes/No)
Personnel Participant Impact Tab Column V	Date the driver was provided training on handling the special needs of the participants. MM/DD/YYYY Enter Not Completed if the individual was never provided training. If the auditor did not select Driver Specific Training on the instructions tab the PO may enter NA in fields V-W.	Technical Clarification	Date the driver was provided training on handling the special needs of the participants. MM/DD/YYYY Enter Not Completed if the individual was never provided training. If the auditor did not select Driver Specific Training on the instructions tab the PO may enter NA in fields V-X.
SDRIdentification1P76 Participant Impact Tab Column F	Did the participant or their representative request to initiate, eliminate, or continue a particular item or service during the audit review period? (Yes/No)	Technical Clarification	Did the participant or their representative request to initiate, eliminate, or continue a particular item or service during the audit review period? (Yes/No)

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	In No, please enter NA in all remaining columns.		If No, please enter NA in all remaining columns.
SDRIdentification1P76 Participant Impact Tab Column G	Enter the date he participant or their representative requested to initiate, eliminate, or continue a particular item or service. MM/DD/YYYY	Technical Clarification	Enter the date the participant or their representative requested to initiate, eliminate, or continue a particular item or service. MM/DD/YYYY
SDRIdentification1P76 Participant Impact Tab Column H	Is their documentation that the request was processed as a service delivery request? (Yes/No)	Technical Clarification	Is there documentation that the request was processed as a service delivery request? (Yes/No)
SDRs1P601P611P85 Participant Impact Tab Column E	Date of Disenrollment Enter NA if the participant is still enrolled.	Technical Clarification	Date of Disenrollment MM/DD/YYYY Enter NA if the participant is still enrolled.
SrvcRestrict1P90 Participant Impact Tab Column J	If the service was requested or determined necessary by the IDT, what was the request or recommendation? (Example: participant requested overnight home care)	Technical Clarification	If the service was requested or determined necessary by the IDT, what was the request or determination? (Example: participant requested overnight home care)
SrvcRestrict1P90 Participant Impact Tab Column L	Describe why the limitation that was applied.	Technical Clarification	Describe why the limitation was applied.
WoundCare1P02 Instructions Tab Scope	All participants enrolled during the audit review period.	Technical Clarification	<ul style="list-style-type: none"> • The scope of this Impact Analysis is limited to 50% of the participants enrolled during the audit review period who were not included in the provision of services sample selection. • The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.
WoundCare1P02 Instructions Tab Scope	<ul style="list-style-type: none"> • Review all relevant participant documentation during the audit review period to determine if each participant had one or more wounds. • Respond to the questions in the participant impact tab. 	Technical Clarification	<ul style="list-style-type: none"> • Review only the participant medical records selected by the auditor. The selected participants are identified in the Participant Impact tab. • Review the selected medical records to determine if the participants had wounds that required wound care.

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	<ul style="list-style-type: none"> • The participant impact tab must include all participants who were enrolled in the PACE organization during the audit review period. This includes new enrollees and participants who were existing enrollees at the start of the audit review period. • The review timeframe is the audit review period. Errors noted before or after the audit review period should not be included. • After completing the Impact Analysis, if any changes need to be made to the Root Cause Analysis, please update the changes in the RCA tab. 		<ul style="list-style-type: none"> • Respond to the questions in the participant impact tab. • The review timeframe is the audit review period. Errors noted before or after the audit review period should not be included. • After completing the Impact Analysis, if any changes need to be made to the Root Cause Analysis, please update the changes in the RCA tab.