

# PACE 2020 PRA Crosswalk

## Based on 60 Day Comments

Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
Attachment I PACE Audit Process and Data Request  Audit Purpose and General Guidelines  Purpose	<p><b>Purpose:</b> To evaluate PACE organizations' compliance with regulatory and/or manual requirements in the following four areas related to the Programs of All-Inclusive Care for the Elderly (PACE). The Centers for Medicare and Medicaid Services (CMS) will perform its audit activities using these instructions (unless otherwise noted).</p> <ul style="list-style-type: none"> <li>• Service Delivery Requests, Appeals and Grievances (SDAG);</li> <li>• Clinical Appropriateness and Care Planning (care planning, participant assessments, interdisciplinary team (IDT) requirements, medical records, participant observations, etc.);</li> <li>• Personnel Records; and</li> <li>• Quality</li> </ul>	<p>Modified text to remove PACE manual reference.</p> <p>Changed the name of the Clinical Appropriateness and Care Planning Element to Provision of Services to more accurately reflect the scope of the review.</p>	<p><b>Purpose:</b> 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). The Centers for Medicare and Medicaid Services (CMS) will perform its audit activities based on these instructions (unless otherwise noted).</p> <ul style="list-style-type: none"> <li>• Service Delivery Requests, Appeals and Grievances (SDAG);</li> <li>• Provision of Services (care planning, participant assessments, interdisciplinary team (IDT) requirements, medical records, participant observations, etc.);</li> <li>• Personnel Records; and</li> <li>• Quality</li> </ul>	No change
Attachment I PACE Audit Process and Data Request  Audit Purpose and General Guidelines  Audit Review	<p><b>Audit Review:</b> During the audit, CMS will review data and documentation collected prior to the audit fieldwork, as well as conduct real-time observations of participants and equipment. CMS reserves the right to examine all relevant documentation or information related to our audit, and may expand our collection of information in order to evaluate participant impact or outcomes.</p>	<p>Modified text to more accurately reflect CMS' expectations regarding access to documentation during the audit.</p>	<p><b>Audit Review:</b> During the audit, CMS will review data and documentation collected prior to and during the audit fieldwork, as well as conduct real-time observations of participants and equipment. CMS reserves the right to access all relevant documentation or information related to our audit, and may expand our collection of information in order to evaluate participant impact or outcomes.</p>	No change
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<p>Attachment I PACE Audit Process and Data Request</p> <p>Audit Purpose and General Guidelines</p> <p>Responding to Documentation Requests</p>	<p><b>Responding to Documentation Requests:</b> The PACE organization (PO) is expected to present any supporting documentation requested during the audit and upload the supporting documentation, as requested, to the Health Plan Management System (HPMS) using the designated file names as indicated in the Document Request Log (DRL). Documents must be uploaded within the timeframes specified by the CMS Audit Team. Additionally, some elements or sample review may be done remotely and organizations are expected to provide full case files or medical records to CMS upon request.</p>	<p>Modified text to more accurately reflect CMS' expectations regarding access to documentation during the audit.</p>	<p><b>Responding to Documentation Requests:</b> The PACE organization (PO) is expected to allow access to any supporting documentation requested during the audit and upload the supporting documentation, as requested, to the Health Plan Management System (HPMS) using the designated file names as indicated in the Document Request Log (DRL). Documentation requests may include requests for portions of the medical record, or the full medical record when warranted. Documents must be uploaded within the timeframes specified by the CMS Audit Team. Additionally, some elements or sample review may be done remotely and organizations will be expected to provide full case files to CMS upon request.</p>	<p>Increase - low</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Audit Purpose and General Guidelines</p> <p>Issues of Non-Compliance Disclosed Prior to Notification of the Audit</p>	<p><b>Issues of Non-Compliance Disclosed Prior to Notification of the Audit:</b> POs will be asked to provide a list of all issues of non-compliance disclosed to CMS <u>prior</u> to the date the audit engagement letter is issued.</p> <p>Issues identified by CMS or the SAA through ongoing monitoring or other account management and oversight activities during the audit year are not considered disclosed. POs should exclude Level I and Level II data already reported to CMS and any data that is not relevant to the audit elements included in this document.</p> <p>POs must provide a description of each disclosed issue and the status of correction using the Pre-Audit Issue Summary template (Attachment III). Attachment III is due 5 business days after the audit engagement letter is issued. The PO's Account Manager will review Attachment III to validate that disclosed issues were reported to CMS prior to receipt of the audit engagement letter.</p> <p>When CMS determines that a disclosed issue was promptly identified, corrected, and the risk to participants has been mitigated, CMS will not apply the Immediate Corrective Action Required condition classification to that condition. CMS may require organizations to submit a completed root cause analysis and/or impact analysis for any disclosed issue of noncompliance.</p>	<p>Change Level II data to PACE Quality data to align with changes to HPMS.</p>	<p><b>Issues of Non-Compliance Disclosed Prior to Notification of the Audit:</b> POs will be asked to provide a list of all issues of non-compliance disclosed to CMS <u>prior</u> to the date the audit engagement letter is issued.</p> <p>Issues identified by CMS or the SAA through ongoing monitoring or other account management and oversight activities during the audit year are not considered disclosed. POs should exclude PACE Quality data already reported to CMS and any data that is not relevant to the audit elements included in this document.</p> <p>POs must provide a description of each disclosed issue and the status of correction using the Pre-Audit Issue Summary template (Attachment III). Attachment III is due 5 business days after the audit engagement letter is issued. The PO's Account Manager will review Attachment III to validate that disclosed issues were reported to CMS prior to receipt of the audit engagement letter.</p> <p>When CMS determines that a disclosed issue was promptly identified, corrected, and the risk to participants has been mitigated, CMS will not apply the Immediate Corrective Action Required condition classification to that condition. CMS may require organizations to submit a completed root cause analysis and/or impact analysis for any disclosed issue of noncompliance.</p>	<p>No change</p>

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<p>Attachment I PACE Audit Process and Data Request</p> <p>Audit Purpose and General Guidelines</p> <p>Root Cause Analysis/Impact Analysis</p>	<p><b>Root Cause Analysis/Impact Analysis:</b> Root Cause Analyses and/or Impact Analyses must be submitted by the PO when they are requested by the CMS audit team. Each Root Cause Analysis describes the nature of the problem and a description of why the non-compliance occurred. When necessary, CMS will also request an Impact Analysis. Each Impact Analysis must identify all participants subject to or impacted by the issues of non-compliance generally from the beginning of the data collection period through the audit exit conference. However, in some circumstances, CMS may modify the review scope as determined necessary. POs will have up to 10 business days to complete the requested Impact Analysis templates. CMS may validate the accuracy of the Impact Analysis submission(s). In the event an Impact Analysis cannot be produced, is incomplete, or is determined by means of validation to be inaccurate, CMS will report that the scope of noncompliance cannot be determined and impacted an unknown number of participants within the PO.</p>	<p>Modified Impact Analysis language to reflect changes in the methodology.</p> <p>Added language to clarify that validation of Impact Analyses may require the submission of additional case files.</p>	<p><b>Root Cause Analysis/Impact Analysis:</b> Root Cause Analyses and/or Impact Analyses must be submitted by the PO when they are requested by the CMS audit team. Each Root Cause Analysis describes the nature of the problem and a description of why the non-compliance occurred. When necessary, CMS will also request an Impact Analysis. For each Impact Analysis, CMS will identify the participants that must be reviewed by the organization. The PACE organization must then identify which of those participants were subject to or impacted by the issues of non-compliance generally from the beginning of the data collection period through the audit exit conference. However, in some circumstances, CMS may modify the review scope as determined necessary. POs will have up to 10 business days to complete the requested Impact Analysis templates. CMS may validate the accuracy of the Impact Analysis submission(s) and may require the organization to submit additional case files or provide access to participant medical records. In the event an Impact Analysis cannot be produced, is incomplete, or is determined by means of validation to be inaccurate, CMS will report that the scope of noncompliance cannot be determined and impacted an unknown number of participants within the PO.</p>	<p>Decrease - high</p> <p>Increase - low</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Audit Purpose and General Guidelines</p> <p>Informing the PO of the results</p>	<p><b>Informing PO of Results:</b> CMS will provide daily updates regarding potential conditions identified during the audit. The CMS Audit Team will do its best to be as timely and transparent as possible when communicating potential conditions. A preliminary summary of conditions identified during the audit will also be presented during the exit conference. Following the exit conference the PO will receive a Draft Audit Report. Once the Draft Audit Report is issued, POs will have 10 business days from the date of issuance to comment on conditions identified in the report. If the PO submits comments, CMS will review and respond to each comment before issuing a Final Audit Report.</p>	<p>Added additional language to more accurately reflect CMS' expectation that the PO will be informed of, and has the ability to ask questions about, audit findings throughout the course of the audit. Clarification was requested by commenters and does not represent a change in our current practice.</p>	<p><b>Informing PO of Results:</b> CMS will provide daily updates regarding potential conditions identified during the audit. The CMS Audit Team will be as timely and transparent as possible when communicating potential conditions. A preliminary summary of conditions identified during the audit will also be presented during the exit conference. POs will have an opportunity to ask questions and discuss potential findings during the daily updates and the exit conference. Following the exit conference the PO will receive a Draft Audit Report. Once the Draft Audit Report is issued, POs will have 10 business days from the date of issuance to comment on conditions identified in the report. If the PO submits comments, CMS will review and respond to each comment before issuing a Final Audit Report.</p>	<p>No change</p>

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Attachment I PACE Audit Process and Data Request  Universe Preparation & Submission  Documentation and Data Submission Timeframes	<b>Documentation and Data Submission Timeframes:</b> Universes and documentation collected prior to and during the audit are used to determine PO compliance with the PACE regulatory and manual requirements within the four identified audit elements. Documentation and universes must be submitted in the timeframes indicated below.	Modified text to remove PACE manual reference.	<b>Documentation and Data Submission Timeframes:</b> Universes and documentation collected prior to and during the audit are used to determine PO compliance with the PACE regulatory requirements within the four identified audit elements. Documentation and universes must be submitted in the timeframes indicated below.	No change
Attachment I PACE Audit Process and Data Request  Universe Preparation & Submission  Documentation and Data Submission Timeframes  Documentation and Data Universes due within 20 business days of the audit engagement letter:  Documentation	<b>Documentation:</b> <ul style="list-style-type: none"> <li>The PO's Quality Assessment and Performance Improvement (QAPI) plan(s) that were in use during the data collection period;</li> <li>Participant Advisory Committee (PAC) minutes for the data collection period; and</li> <li>A current organization chart including staff names and titles.</li> </ul>	Removed the requirement to provide an organization chart based on comments.	<b>Documentation:</b> <ul style="list-style-type: none"> <li>The PO's Quality Assessment and Performance Improvement (QAPI) plan(s) that were in use during the data collection period;</li> <li>Participant Advisory Committee (PAC) minutes for the data collection period</li> </ul>	Decrease - moderate
Attachment I PACE Audit Process and Data Request  Universe Preparation & Submission  Documentation and Data Submission Timeframes  Documentation due the first day of the onsite portion of audit fieldwork	<b>Documentation due the first day of the onsite portion of audit fieldwork:</b> The PO will submit the following documentation when auditors arrive onsite for the audit fieldwork.  <ul style="list-style-type: none"> <li>Completed Onsite Observation Participant List (Attachment IV).</li> </ul>	Modified the requirements for onsite observation participant lists based on comments to provide POs flexibility in how the information is provided.	<b>Documentation due the first day of the onsite portion of audit fieldwork:</b> The PO will submit the following documentation when auditors arrive onsite for the audit fieldwork.  <ul style="list-style-type: none"> <li>Completed Onsite Observation Participant List (Attachment IV).</li> </ul> <p><b>NOTE:</b> 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.</p>	Decrease - moderate

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Attachment I PACE Audit Process and Data Request  Universe Preparation & Submission  Pulling and Submitting Universes	For the participant medical record universe, POs must include all participants who were enrolled at any point during the data collection period. This includes participants who were enrolled prior to or during the data collection period, regardless of whether or not they are still enrolled (e.g., disenrolled or expired). POs do not need to submit medical records for each participant, only the information identified in Appendix A, Table 5.	Added text based on comments to clarify that CMS does not expect participant medical records to be submitted at the time universes are submitted.	For the participant medical record universe, POs must include all participants who were enrolled at any point during the data collection period. This includes participants who were enrolled prior to or during the data collection period, regardless of whether or not they are still enrolled (e.g., disenrolled or expired). POs do not need to submit medical records with the universes for each participant, only the information identified in Appendix A, Table 5.	No change
Attachment I PACE Audit Process and Data Request  Universe Preparation & Submission  CMS Analysis of Universes  Table 2, AR Record Layout	<ul style="list-style-type: none"> <li>Notification is provided to the participant no later than 30 days from the date of receipt for standard appeals.</li> <li>Notification is provided to the participant no later than 72 hours from receipt of a request for an expedited appeals.</li> <li>Notification is provided to the participant no later than 17 days from receipt of a request for an expedited appeals for which an extension is taken.</li> </ul>	Modified language to include “representative” consistent with regulatory language.	<ul style="list-style-type: none"> <li>Notification is provided to the participant/representative no later than 30 days from the date of receipt for a standard appeal.</li> <li>Notification is provided to the participant/representative no later than 72 hours from receipt of a request for an expedited appeal.</li> <li>Notification is provided to the participant/representative no later than 17 days from receipt of a request for an expedited appeal for which an extension is taken.</li> </ul>	No change
Attachment I PACE Audit Process and Data Request  Universe Preparation & Submission  Selecting Samples	<b>Selecting Samples:</b> Auditors will review the universes collected from the PO and select samples in accordance with the instructions noted below. For elements done via desk review (e.g., the Service Delivery Request, Appeals, and Grievance (SDAG) element and/or Personnel), samples will be provided to the PO 2 business days before the review of each element. Onsite observations conducted as part of the Clinical Appropriateness and Care Planning element will be selected from the Onsite Observation Participant List (Attachment IV) on the first day of the onsite audit. Medical record samples for the Clinical Appropriateness and Care Planning Element will be provided to the PO 1 hour prior to the start of the review of medical records.	Changed name of the Clinical Appropriateness and Care Planning element and related text to Provision of Services. Additionally, text was updated based on PO comments to provide additional information regarding CMS’ expectations for medical record access.	<b>Selecting Samples:</b> Auditors will review the universes collected from the PO and select samples in accordance with the instructions noted below. For elements done via desk review (e.g., the Service Delivery Request, Appeals, and Grievance (SDAG) element and/or Personnel), samples will be provided to the PO two business days before the review of each element. Onsite observations conducted as part of the Provision of Services element will be selected from the Onsite Observation Participant List (Attachment IV) on the first day of the onsite audit. Medical record samples for the Provision of Services Element will be provided for informational purposes to the PO one hour prior to the start of the review of medical records. The PO is not expected to upload any medical record documentation within the one hour timeframe following receipt of the samples. PACE organizations are required to allow CMS immediate access to the medical records for each sample within that time.	No change

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<p>Attachment I PACE Audit Process and Data Request</p> <p>Audit Elements</p> <p>Service Delivery Requests, Appeals and Grievances (SDAG)</p> <p>Select Sample Cases</p>	<p><b>Select Sample Cases:</b> CMS will select 40 targeted sample cases. When selecting sample cases, CMS will attempt to ensure that the sample set is representative of various types of service requests, appeals and grievances. CMS will use all universes, documentation, and available information in order to target samples for review. The SDAG sample set will include:</p> <ul style="list-style-type: none"> <li>• 10 denied service delivery requests</li> <li>• 10 approved service delivery requests</li> <li>• 5 denied appeals</li> <li>• 5 approved appeals</li> <li>• 10 grievances</li> </ul> <p>CMS reserves the right to adjust the number of service delivery requests, appeals or grievance samples if the number of entries in a given universe is less than the number of required samples and/or if CMS needs to further investigate participant impact.</p>	<p>Added language to clarify how sample selections may be adjusted in the event that there are not enough samples in a given sample type and to clarify that CMS may add additional samples if there is a need to investigate noncompliance</p>	<p><b>Select Sample Cases:</b> CMS will select 40 targeted sample cases. When selecting sample cases, CMS will attempt to ensure that the sample set is representative of various types of service requests, appeals and grievances. CMS will use all universes, documentation, and available information in order to target samples for review. The SDAG sample set will include:</p> <ul style="list-style-type: none"> <li>• 10 denied service delivery requests</li> <li>• 10 approved service delivery requests</li> <li>• 5 denied appeals</li> <li>• 5 approved appeals</li> <li>• 10 grievances</li> </ul> <p>CMS reserves the right to adjust the number of service delivery requests, appeals or grievance samples if the number of entries in a given universe is less than the number of required samples. For example, if a PO does not have 5 approved appeals, CMS may add additional denied appeals or additional approved service delivery requests to make up the total number of samples. Additionally, CMS may add additional samples or case review in order to further investigate potential noncompliance or participant impact.</p>	<p>No change</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Audit Elements</p> <p>Service Delivery Requests, Appeals and Grievances (SDAG)</p> <p>Review Sample Cases Documentation</p>	<p><b>Review Sample Case Documentation:</b> CMS will review all sample case file documentation to determine compliance with regulatory and manual requirements including: identifying the request, processing the request, notifying participants timely and appropriately, and providing any approved services. The PO will need to provide the following documents via HPMS during the audit:</p>	<p>Modified text to remove PACE manual reference.</p>	<p><b>Review Sample Case Documentation:</b> CMS will review all sample case file documentation to determine compliance with regulatory requirements including: identifying the request, processing the request, notifying participants timely and appropriately, and providing any approved services. The PO will need to provide the following documents via HPMS during the audit:</p>	<p>No change</p>

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<p>Attachment I PACE Audit Process and Data Request</p> <p>Audit Elements</p> <p>Service Delivery Requests, Appeals and Grievances (SDAG)</p> <p>Review Sample Cases Documentation</p> <p>For service delivery requests:</p>	<ul style="list-style-type: none"> <li>Documentation of the IDT’s decision to approve or deny the request based on assessment(s) conducted by the IDT, in response to the request</li> <li>For service delivery request approvals: If oral notification was provided, medical record notes and/or documentation of notification to the participant/participant representative If written notification was provided, a copy of the written notification provided to the participant/participant representative</li> </ul>	<p>Modified text to more accurately reflect regulatory language and regulatory requirements.</p>	<ul style="list-style-type: none"> <li>Documentation of the IDT’s decision to approve or deny the request based on assessment(s) conducted in response to the request by the IDT</li> <li>For service delivery request approvals: If oral notification was provided, medical record notes and/or documentation of notification to the participant/designated representative If written notification was provided, a copy of the written notification provided to the participant/designated representative</li> </ul>	<p>No change</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Audit Elements</p> <p>Service Delivery Requests, Appeals and Grievances (SDAG)</p> <p>Review Sample Cases Documentation</p> <p>For appeals:</p>	<ul style="list-style-type: none"> <li>For approvals, documentation that the service and/or item was provided, including an annotation in the participant’s medical record</li> </ul>	<p>Modified language to align with section 2.1 and to clarify that documentation may come from multiple sources within the medical record.</p>	<ul style="list-style-type: none"> <li>For approvals, documentation that the service and/or item was provided, including an annotation in the participant’s medical record (e.g., an annotation in the participant’s medical record, assessments, progress notes)</li> </ul>	<p>No change</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Audit Elements</p> <p>Provision of Services</p>	<p>Clinical Appropriateness &amp; Care Planning</p>	<p>Changed the name of the Clinical Appropriateness and Care Planning Element to Provision of Services to more accurately reflect the scope of the review.</p>	<p>Provision of Services</p>	<p>No change</p>

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<p>Attachment I PACE Audit Process and Data Request</p> <p>Audit Elements</p> <p>Provision of Services</p> <p>Select Sample Cases</p>	<p><u>Medical Record Review:</u> CMS will select 15 targeted medical records that appear clinically significant. When selecting sample cases, CMS will attempt to ensure that the sample set is representative of various types of medical, functional, and social needs (e.g., hospitalizations, wound care, dialysis, social needs, home bound, skilled nursing care). CMS will use all universes, documentation, and available information in order to target participant samples for review. CMS may review additional medical records as needed in order to appropriately investigate potential compliance issues discovered during the review of audit elements.</p>	<p>Changed the number of medical record samples from 15 to 30 in order to reduce the need for Impact Analyses in some circumstances.</p> <p>Modified language regarding the scope of the review to clarify that CMS expanded the number of records reviewed, if necessary, when non-compliance is identified.</p> <p>Added additional language to clarify that the need for medical record access may be continued following the onsite portion of the audit.</p>	<p><u>Medical Record Review:</u> CMS will select 30 targeted medical records that appear clinically significant. When selecting sample cases, CMS will attempt to ensure that the sample set is representative of various types of medical, functional, and social needs (e.g., hospitalizations, wound care, dialysis, social needs, home bound, skilled nursing care). CMS will use all universes, documentation, and available information in order to target participant samples for review. CMS may expand the scope of review or add medical records as needed in order to appropriately investigate potential compliance issues discovered during the review of audit elements. Additionally, CMS may require access to medical records following the audit fieldwork to validate impact analyses or other submitted information.</p>	<p>Change in the number of samples: Decrease - high</p> <p>Modification of scope language: No Change</p> <p>Continuing Medical Record Access: Increase - low</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Audit Elements</p> <p>Provision of Services</p> <p>Review Sample Case Documentation</p>	<p>CMS will review participant medical records and conduct participant observations to determine compliance with regulatory and manual requirements including: provision of required services, coordination and management of participant care, completion of required assessments, and the development and review of participant care plans.</p>	<p>Modified text to remove PACE manual reference.</p>	<p>CMS will review participant medical records and conduct participant observations to determine compliance with regulatory requirements including: provision of required services, coordination and management of participant care, completion of required assessments, and the development and review of participant care plans.</p>	<p>No Change</p>

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Attachment I PACE Audit Process and Data Request  Audit Elements  Provision of Services  Review Sample Case Documentation  Medical Record Review	<ul style="list-style-type: none"> <li>All documentation related to participant assessments: <ul style="list-style-type: none"> <li>Initial comprehensive assessments</li> <li>Annual, semi-annual, and unscheduled assessments</li> </ul> </li> <li>Documentation that assessments were completed as required</li> <li>IDT progress notes, evaluations, or other documentation related to initial, semiannual, annual, and unscheduled assessments</li> <li>Documentation related to assessment outcomes, changes in care plans, participant outcomes, etc.</li> </ul>	Updated requirement to reflect PACE regulatory changes effective 08/02/2019.	<ul style="list-style-type: none"> <li>All documentation related to participant assessments: <ul style="list-style-type: none"> <li>Initial comprehensive assessments</li> <li>Semi-annual and unscheduled assessments</li> </ul> </li> <li>Documentation that assessments were completed as required</li> <li>IDT progress notes, evaluations, or other documentation related to initial, semiannual, and unscheduled assessments</li> <li>Documentation related to assessment outcomes, changes in care plans, participant outcomes, etc.</li> </ul>	No change
Attachment I PACE Audit Process and Data Request  Audit Elements  Provision of Services  Apply Compliance Standards	3.3.1 Did the PO perform assessments as required (initial, annual, semi-annual, or more frequently when necessary)?	Updated requirement to reflect PACE regulatory changes effective 08/02/2019.	3.3.1 Did the PO perform assessments as required (initial, semi-annual, or more frequently when necessary)?	No change
Attachment I PACE Audit Process and Data Request  Audit Elements  Provision of Services  Sample Case Results	<b>Sample Case Results:</b> CMS will test each of the 15 medical records, 5 participant observations, and emergency equipment and vehicle inspections. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. <b>NOTE:</b> Cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may have a single condition or multiple conditions of non-compliance.	Updated to reflect the change in the number of medical record samples.	<b>Sample Case Results:</b> CMS will test each of the 30 medical records, 5 participant observations, and emergency equipment and vehicle inspections. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. <b>NOTE:</b> Cases and conditions may have a oneto-one or a one-to-many relationship. For example, one case may have a single condition or multiple conditions of non-compliance.	No change
Attachment I PACE Audit Process and Data Request  Audit Elements  Personnel Records  Select Sample Cases	<b>Select Sample Cases:</b> CMS will select 10 targeted personnel records. CMS will attempt to ensure that the sample set is representative of various types of employees, including part-time, full-time, contract, volunteers, etc.	Modified language regarding the scope of the review to clarify that CMS may expand the number of records reviewed, if necessary, when non-compliance is identified.	<b>Select Sample Cases:</b> CMS will select 10 targeted personnel records. CMS will attempt to ensure that the sample set is representative of various types of employees, including part-time, full-time, contract, volunteers, etc. Additionally, CMS may add additional samples or case review in order to further investigate potential non-compliance or participant impact.	Increase - low

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Attachment I PACE Audit Process and Data Request  Audit Elements  Personnel Records  Review Sample Case Documentation	<b>Review Sample Case Documentation:</b> CMS will review all sample case file documentation to determine compliance with regulatory and manual requirements. The PO must provide CMS auditors unrestricted access to these records and may be required to upload copies and/or screenshots of the following documents during and/or after the audit:	Modified text to remove PACE manual reference.	<b>Review Sample Case Documentation:</b> CMS will review all sample case file documentation to determine compliance with regulatory requirements. The PO must provide CMS auditors unrestricted access to these records and may be required to upload copies and/or screenshots of the following documents during and/or after the audit:	No change
Attachment I PACE Audit Process and Data Request  Appendix  Appendix A - Programs of AllInclusive Care for the Elderly (PACE) Record Layouts	Please use a comma (,) with no spaces to separate multiple values within one field if there is more than one piece of information for a specific field (e.g., PCP, RN, MSW). Do not include any leading or trailing spaces.	Added additional instructions reminding POs that no fields may be left blank. This is a reminder of the current expectation based on comments and not a change from to the current process.	Please use a comma (,) with no spaces to separate multiple values within one field if there is more than one piece of information for a specific field (e.g., PCP, RN, MSW). Do not include any leading or trailing spaces and do not leave any fields blank.	No change
Attachment I PACE Audit Process and Data Request  Appendix  Table 1: Service Delivery Requests (SDR) Record Layout	<u>Include</u> all requests <u>processed</u> by the PO as service delivery requests under 42 CFR 460.104(d)(2).	Modified language to remove the regulatory citation.	<u>Include</u> all requests <u>processed</u> by the PO as service delivery requests.	No change
Attachment I PACE Audit Process and Data Request  Appendix  Table 1: Service Delivery Requests (SDR) Record Layout  Row H  Description Column	Enter the date(s) the IDT member(s) completed required assessments in response to the service delivery request.  If more than one assessment was completed, enter all dates separated by a comma.  Submit in MM/DD/YYYY format (e.g., 01/01/2020).  Enter NA if an assessment was not completed or if the assessment was not completed in response to the service delivery request (e.g., do not include semiannual or annual assessments if they were not done in response to the requested service).	Updated requirement to reflect PACE regulatory changes effective 08/02/2019.	Enter the date(s) the IDT member(s) completed required assessments in response to the service delivery request.  If more than one assessment was completed, enter all dates separated by a comma.  Submit in MM/DD/YYYY format (e.g., 01/01/2020).  Enter NA if an assessment was not completed or if the assessment(s) was not completed in response to the service delivery request (e.g., do not include semi-annual assessments if they were not done in response to the requested service).	No change

Section in Current CMS-10630	Original Language	Clarification or	Revised Language	Burden
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<b>(04/16/2019)</b>		<b>Change</b>		
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 1: Service Delivery Requests (SDR) Record Layout</p> <p>Row J</p> <p>Description Column</p>	<p>Enter Y if the assessment was completed and was conducted in-person.</p> <p>Enter N if the assessment was completed but was not conducted in-person.</p> <p>Enter NA if no assessment was completed or was not completed in response to the service delivery request.</p>	<p>Modified the data entry requirement to align with the regulatory requirement.</p>	<p>Enter Y if any assessment or assessments were completed and were conducted in-person.</p> <p>Enter N if assessments were completed but none of the assessments were conducted in-person.</p> <p>Enter NA if no assessment was completed or was not completed in response to the service delivery request.</p>	<p>No change</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 1: Service Delivery Requests (SDR) Record Layout</p> <p>Row K</p> <p>Description Column</p>	<p>Valid fields include: Approved, Denied or Partially Approved/Denied.</p> <p>Enter approved if all of the requested services and/or items were approved as requested.</p> <p>Enter denied if all of the requested services and/or items were denied.</p> <p>Enter partially approved/denied if the request was not fully approved as requested and/or the PO provided a modified or alternative service to the participant.</p>	<p>Modified the data entry requirement to allow POs to enter withdrawn based on comments.</p>	<p>Valid fields include: Approved, Denied, Partially Approved/Denied, or Withdrawn.</p> <p>Enter approved if all of the requested services and/or items were approved as requested.</p> <p>Enter denied if all of the requested services and/or items were denied.</p> <p>Enter partially approved/denied if the request was not fully approved as requested and/or the PO provided a modified or alternative service to the participant.</p> <p>Enter withdrawn if the participant and/or the designated representative requested to withdraw the service delivery request prior to the organization rendering a decision.</p>	<p>No change</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 1: Service Delivery Requests (SDR) Record Layout</p> <p>Row L</p> <p>Description Column</p>	<p>If the request was denied or partially denied, please enter a brief explanation of why the request was denied.</p>	<p>Added additional language to clarify data entry requirements based on comments.</p>	<p>If the request was denied or partially denied, please enter a brief explanation of why the request was denied.</p> <p>Enter NA if the request was approved or withdrawn.</p>	<p>No change</p>

<b>Section in Current CMS-10630 (04/16/2019)</b>	<b>Original Language</b>	<b>Clarification or Change</b>	<b>Revised Language</b>	<b>Burden</b>
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Attachment I PACE Audit Process and Data Request  Appendix  Table 1: Service Delivery Requests (SDR) Record Layout  Row P  Description Column	Enter the date that the approved service or item was provided to the participant. Please enter a date for any request that was partially or fully approved.  Submit in MM/DD/YYYY format (e.g., 01/01/2020).  Enter NA if the request was denied or if there was no documentation of the effectuation (provision) of the service.	Added additional language to clarify data entry requirements based on comments.	Enter the date that the approved service or item was provided to the participant. Please enter a date for any request that was partially or fully approved.  Submit in MM/DD/YYYY format (e.g., 01/01/2020).  Enter NA if the request was denied, withdrawn or if there was no documentation of the effectuation (provision) of the service.	No change
Attachment I PACE Audit Process and Data Request  Appendix  Table 2: Appeal Requests (AR) Record Layout  Row D  Description Column	Indicate if the request was submitted by the participant or designated representative (which may include a caregiver, family member, POA, legal guardian, etc.).	Modified the data entry requirement to align with the regulatory requirement.	Indicate if the request was submitted by the participant, caregiver or family.	No change
Attachment I PACE Audit Process and Data Request  Appendix  Table 2: Appeal Requests (AR) Record Layout  Row D  Example Column	designated representative	Modified the data entry requirement to align with the regulatory requirement.	Caregiver	No change
Attachment I PACE Audit Process and Data Request  Appendix  Table 2: Appeal Requests (AR) Record Layout  Row I  Field Name Column	Category of the Appeal	Modified title to align with PACE Quality Monitoring language based on comments.	Category of the Appeal/Appeal Type	No change

Section in Current CMS-10630	Original Language	Clarification or	Revised Language	Burden
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<b>(04/16/2019)</b>		<b>Change</b>		
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 2: Appeal Requests (AR) Record Layout</p> <p>Row I</p> <p>Description Column</p>	<p>Provide the category or type of appeal request. Examples include: home care, center attendance, glasses, hearing aids, respite, specialist consultations, medication, etc.</p>	<p>Modified valid field entries to align with PACE Quality Monitoring language based on comments.</p>	<p>Provide the category or type of appeal request. Valid fields include: Decreased Center Attendance, Denial of Enrollment, Dentures, Durable Medical Equipment, Glasses, Hearing Aid, Home Modification(s), Increased Center Attendance, Increased Home Care, Involuntary Disenrollment, Medical Procedure, Medical Supplies, Nursing Facility Placement - Long Term, Nursing Facility Placement – Respite, Nursing Facility Placement - Short Term, Specialist Consultation or Visit, Surgical Procedure, Transportation, or Other</p>	<p>No change</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 2: Appeal Requests (AR) Record Layout</p> <p>Row J</p> <p>Field Name Column</p>	<p>Description of the Appeal</p>	<p>Modified title to align with PACE Quality Monitoring language based on comments.</p>	<p>Description of the Appeal/Specific Issue</p>	<p>No change</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 2: Appeal Requests (AR) Record Layout</p> <p>Row K</p> <p>Description Column</p>	<p>Valid fields include: Approved, Denied or Partially Approved/Denied.</p> <p>Enter approved if all of the requested services and/or items were approved as requested.</p> <p>Enter denied if all of the requested services and/or items were denied.</p> <p>Enter partially approved/denied if the request was not fully approved as requested and/or the PO provided a modified or alternative service to the participant.</p>	<p>Modified the data entry requirement to allow POs to enter withdrawn based on comments.</p>	<p>Valid fields include: Approved, Denied, Partially Approved/Denied or Withdrawn.</p> <p>Enter approved if all of the requested services and/or items were approved as requested.</p> <p>Enter denied if all of the requested services and/or items were denied.</p> <p>Enter partially approved/denied if the request was not fully approved as requested and/or the PO provided a modified or alternative service to the participant.</p> <p>Enter withdrawn if the participant and/or designated representative requested to withdraw the appeal prior to a decision being rendered.</p>	<p>No change</p>

<b>Section in Current CMS-10630 (04/16/2019)</b>	<b>Original Language</b>	<b>Clarification or Change</b>	<b>Revised Language</b>	<b>Burden</b>
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<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 2: Appeal Requests (AR) Record Layout</p> <p>Row L</p> <p>Description Column</p>	<p>If the appeal was denied or partially denied, please enter a brief explanation of why the request was denied.</p>	<p>Added additional language to clarify data entry requirements based on comments.</p>	<p>If the appeal was denied or partially denied, please enter a brief explanation of why the request was denied.</p> <p>Enter NA if the appeal was approved or withdrawn.</p>	<p>No change</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 2: Appeal Requests (AR) Record Layout</p> <p>Row M</p> <p>Description Column</p>	<p>Enter the date the PO provided written notification to the participant or designated representative, of the third-party's decision to approve or deny the appeal.</p> <p>Submit in MM/DD/YYYY format (e.g., 01/01/2020).</p> <p>Enter NA if written notification was not provided or not documented.</p>	<p>Modified data entry options to clarify who may be considered a representative.</p>	<p>Enter the date the PO provided written notification to the participant or other representative (e.g. family or caregiver), of the third-party's decision to approve or deny the appeal.</p> <p>Submit in MM/DD/YYYY format (e.g., 01/01/2020).</p> <p>Enter NA if written notification was not provided or not documented.</p>	<p>No change</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 2: Appeal Requests (AR) Record Layout</p> <p>Row N</p> <p>Description Column</p>	<p>This column only applies to expedited appeals. Enter the time the PO provided written notification to the participant or participant representative, of the third-party's decision to approve or deny the appeal.</p> <p>Submit in HH:MM format (e.g., 23:59).</p> <p>Enter NA if the appeal was not expedited (i.e., was processed as a standard appeal) or if written notification was not provided.</p>	<p>Modified data entry options to clarify who may be considered a representative.</p>	<p>This column only applies to expedited appeals. Enter the time the PO provided written notification to the participant or other representative (e.g. family or caregiver), of the third-party's decision to approve or deny the appeal.</p> <p>Submit in HH:MM format (e.g., 23:59).</p> <p>Enter NA if the appeal was not expedited (i.e., was processed as a standard appeal) or if written notification was not provided.</p>	<p>No change</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 3: Grievance Requests (GR) Record Layout</p> <p>Row D</p> <p>Description Column</p>	<p>Indicate if the grievance was submitted by the participant or caregiver. The term caregiver may include family members, POA, legal guardians, other caregivers, etc.</p>	<p>Modified title to align with PACE Quality Monitoring language based on comments.</p>	<p>Indicate if the grievance was submitted by the participant, caregiver or family.</p>	<p>No change</p>

Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 3: Grievance Requests (GR) Record Layout</p> <p>Row F</p> <p>Field Name Column</p>	<p>Category of the Grievance</p>	<p>Modified title to align with PACE Quality Monitoring language based on comments.</p>	<p>Category of the Grievance/Grievance Type</p>	<p>No change</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 3: Grievance Requests (GR) Record Layout</p> <p>Row F</p> <p>Description Column</p>	<p>Provide the category or type of grievance. Examples include: Personnel or staffing issue, service delivery, dietary, transportation, home care, etc.</p>	<p>Modified valid field entries to align with PACE Quality Monitoring language based on comments.</p>	<p>Provide the category or type of grievance. Valid fields include: Activities, Communication, Contracted Specialist, Contracted Facility (Hospital, SNF, etc.), Dietary, Disenrollment, Enrollment, Home Care, Marketing, Medical Care, Medication, PACE Services, Supplies, Transportation, or Other</p>	<p>No change</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 3: Grievance Requests (GR) Record Layout</p> <p>Row F</p> <p>Description Column</p>	<p>specialist services</p>	<p>Modified example to align with revised entry options.</p>	<p>Home Care</p>	<p>No change</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 3: Grievance Requests (GR) Record Layout</p> <p>Row G</p>	<p>Category of the Grievance</p>	<p>Modified field name to better align with PACE quality monitoring data entry name based on comments.</p>	<p>Category of the Grievance/Grievance Type</p>	<p>No change</p>

Filed Name Column				
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Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 3: Grievance Requests (GR) Record Layout</p> <p>Row I</p> <p>Description Column</p>	<p>Date notification of the grievance resolution was provided by the PO to the participant and/or caregiver. If both oral and written notification was provided, enter the first notification date. Submit in MM/DD/YYYY format (e.g., 01/01/2020).</p> <p>Enter NA if the grievance was not resolved or if no notification of the resolution was made.</p>	<p>Added additional language to clarify data entry requirements based on comments.</p>	<p>Date notification of the grievance resolution was provided by the PO to the participant and/or caregiver. If both oral and written notification was provided, enter the first notification date. Submit in MM/DD/YYYY format (e.g., 01/01/2020).</p> <p>Enter NA if the grievance was not resolved or if no notification of the grievance resolution was made.</p> <p>Enter NNR if the participant, family or caregiver specifically requested not to receive notification about the grievance resolution.</p>	<p>No change</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 5: List of Participant Medical Records (LOPMR) Record Layout</p> <p>Additional Row</p>	<p>This row did not exist in the initial Attachment I PACE Audit Process and Data Request submission</p>	<p>MBI row added to allow CMS to correlate participant data with other data collected by CMS.</p>	<p>Field Name: Medicare Beneficiary Identifier</p> <p>Description: If the participant has Medicare, enter the Medicare Beneficiary Identifier.</p> <p>Enter NA if the participant is not a Medicare participant.</p>	<p>Increase - low</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 5: List of Participant Medical Records (LOPMR) Record Layout</p> <p>Number of Emergency Room Visits</p>	<p>Enter the number of emergency room visits that occurred during the data collection period. Include ER visits that resulted in an observation or hospitalization.</p>	<p>Modified language to improve clarity.</p>	<p>Enter the number of emergency room visits that occurred during the data collection period. Include ER visits that resulted in a hospital admission or observation.</p>	<p>No change</p>
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 5: List of Participant Medical Records (LOPMR) Record Layout</p>	<p>This row did not exist in the initial Attachment I PACE Audit Process and Data Request submission</p>	<p>Replace multiple rows: AP Low Blood Glucose Level, AQ High Blood Glucose Level, and AR Oxygen Saturation Level based on comments.</p>	<p>Field Name: Hospitalization/ Emergency Room Reason</p> <p>Description: Was the ER visit or hospitalization (admission or observation) as a result of hypoglycemia or 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>Decrease - high</p>



Additional Row			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.	
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Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
Attachment I PACE Audit Process and Data Request  Appendix  Table 5: List of Participant Medical Records (LOPMR) Record Layout  Additional Row	This row did not exist in the initial Attachment I PACE Audit Process and Data Request submission	Replaced row AO Significant Weight Gain.	Field Name: CHF Exacerbation  Description: Enter Y if the participant was diagnosed with a CHF exacerbation during the data collection period.  Enter N if the participant was not diagnosed with a CHF exacerbation or the participant did not have a diagnosis of CHF during the data collection period.	Decrease - moderate
Attachment I PACE Audit Process and Data Request  Appendix  Table 5: List of Participant Medical Records (LOPMR) Record Layout  Row V	Field Name: Currently Receiving Home Care  Description: Enter skilled if the participant was receiving either skilled home care or a combination of skilled and unskilled home care at the time that the universe is completed.  Enter unskilled if the participant is currently receiving unskilled home care only at the time that the universe is completed.  Enter NA if the participant is not currently receiving home care.	Removed based on comments.	Removed	Decrease - moderate
Attachment I PACE Audit Process and Data Request  Appendix  Table 5: List of Participant Medical Records (LOPMR) Record Layout  Row W  Description Column	Enter Y if an employee/contracted employee dispensed medication to the participant in the participant's home and/or the PACE center at any time during the data collection period.  Enter N if an employee/contracted employee did not dispense medication to the participant in the participant's home and/or the PACE center at any time during the data collection period. Prompting/medication reminders are not considered medication administration assistance.	Modified language to more accurately characterize the service provided by the PO based on comments.	Enter Y if an employee/contracted employee administered medication to the participant in the participant's home and/or the PACE center at any time during the data collection period.  Enter N if an employee/contracted employee did not administer medication to the participant in the participant's home and/or the PACE center at any time during the data collection period. Prompting/medication reminders are not considered medication administration assistance.	No change

Attachment I PACE Audit Process and Data Request  Appendix  Table 5: List of Participant Medical Records (LOPMR) Record Layout  Row X	Field Name: Specialist Ordered Medications  Description: Did any specialist prescribe a medication for the participant during the data collection period, regardless of whether the medication was provided to the participant?  If Yes, enter the name of each medication.  If No, enter N.	Removed based on comments.	Removed	Decrease - high
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<b>Section in Current CMS-10630 (04/16/2019)</b>	<b>Original Language</b>	<b>Clarification or Change</b>	<b>Revised Language</b>	<b>Burden</b>
Attachment I PACE Audit Process and Data Request  Appendix  Table 5: List of Participant Medical Records (LOPMR) Record Layout  Row Y	Field Name: Delivery of Specialist Ordered Medications  Description: Were all medications prescribed by a specialist provided to the participant?  If Yes, enter Y.  If No, enter the name of each medication that was not provided.  Enter NA, if no prescriptions were prescribed by a specialist during the data collection period.	Removed based on comments.	Removed	Decrease - high
Attachment I PACE Audit Process and Data Request  Appendix  Table 5: List of Participant Medical Records (LOPMR) Record Layout  Row Z	Field Name: Specialist Recommended Medications  Description: Did any specialist recommend a medication for the participant during the data collection period, regardless of whether the medication was prescribed and/or provided to the participant?  If Yes, enter the name of each medication.  If No, enter N.	Removed based on comments.	Removed	Decrease - high
Attachment I PACE Audit Process and Data Request  Appendix  Table 5: List of Participant Medical Records (LOPMR) Record Layout	Field Name: Delivery of Specialist Recommended Medications  Description: Were all medications recommended by a specialist prescribed and/or provided to the participant?  If Yes, enter Y.	Removed based on comments.	Removed	Decrease - high

Row AA	<p>If No, enter the name of each medication that was not prescribed and/or provided.</p> <p>Enter NA, if no medications were recommended by a specialist during the data collection period.</p>			
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 5: List of Participant Medical Records (LOPMR) Record Layout</p> <p>Row AB</p>	<p>Field Name: Participant Pain</p> <p>Description: Did the participant report pain at any time during the data collection period?</p> <p>Enter Y if the participant reported pain at any point during the data collection period.</p> <p>Enter N if the participant did not report pain at any point during the data collection period.</p>	Removed based on comments.	Removed	Decrease - moderate

Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 5: List of Participant Medical Records (LOPMR) Record Layout</p> <p>Row AE</p>	<p>Did the PO limit the participant's access to opioid medications at any time during the data collection period?</p> <p>Enter Y if any limitations were placed on opioid medications.</p> <p>Enter N if there were no limitations placed on opioid medications.</p>	Removed based on comments.	Removed	Decrease - moderate
<p>Attachment I PACE Audit Process and Data Request</p> <p>Appendix</p> <p>Table 5: List of Participant Medical Records (LOPMR) Record Layout</p> <p>Row AH</p> <p>Field Name Column</p>	Number of Falls reported as a Level II event	Modified language to align with PACE Quality Monitoring language based on comments.	Number of Falls Reported in PACE Quality data	No change

Attachment I PACE Audit Process and Data Request  Appendix  Table 5: List of Participant Medical Records (LOPMR) Record Layout  Row AH  Description Column	Enter the number of falls the participant had that were reported as a Level II event during the data collection period.	Modified language to align with PACE Quality Monitoring language based on comments.	Enter the number of falls the participant had that were reported in the PACE Quality Data during the data collection period.	No change
Attachment I PACE Audit Process and Data Request  Appendix  Table 5: List of Participant Medical Records (LOPMR) Record Layout  Row AL  Description Column	Enter Y if the participant was routinely incontinent during the data collection period.  Enter N if the participant was not incontinent or had acute/transient incontinence during the data collection period.	Clarified conditions for data requirement based on comments.	Enter Y if the participant was routinely incontinent during the data collection period.  Enter N if the participant was not routinely incontinent or had acute/transient incontinence during the data collection period.	No change

<b>Section in Current CMS-10630 (04/16/2019)</b>	<b>Original Language</b>	<b>Clarification or Change</b>	<b>Revised Language</b>	<b>Burden</b>
Attachment I PACE Audit Process and Data Request  Appendix  Table 5: List of Participant Medical Records (LOPMR) Record Layout  Row AN  Description Column	Enter Y if the participant lost more than 2 pounds in 24 hours or 5 pounds in 7 days at any point during the data collection period.  Enter N if the participant did not lose more than 2 pounds in 24 hours or 5 pounds in 7 days at any point during the data collection period.	Modified the data requirements to align with those commonly used by PACE Organizations based on comments.	Enter Y if the participant had a weight loss of more than 5% within a 30 day period or 10% within a 180-day period.  Enter N if the participant did not have a weight loss of more than 5% within a 30 day period or 10% within a 180-day period.	Decrease - moderate
Attachment I PACE Audit Process and Data Request  Appendix  Table 5: List of Participant	Field Name: Significant Weight Gain  Description: Enter Y if the participant gained more than 2 pounds in 24 hours or 5 pounds in 7 days at any point during the data collection period.	Replaced with new row for CHF Exacerbation based on comments.	Removed	Decrease - moderate

Medical Records (LOPMR) Record Layout  Row AO	Enter N if the participant did not gain more than 2 pounds in 24 hours or 5 pounds in 7 days at any point during the data collection period.			
Attachment I PACE Audit Process and Data Request  Appendix  Table 5: List of Participant Medical Records (LOPMR) Record Layout  Row AP	Field Name: Low Blood Glucose Level  Description: Enter Y if the participant had a blood glucose reading less than 60 at any point during the data collection period.  Enter N if the participant did not have a blood glucose reading less than 60 at any point during the data collection period.	Replaced with new row for Hospitalization/ Emergency Room Reason based on comments.	Removed	Decrease - high
Attachment I PACE Audit Process and Data Request  Appendix  Table 5: List of Participant Medical Records (LOPMR) Record Layout  Row AQ	Field Name: High Blood Glucose Level  Description: Enter Y if the participant had a blood glucose reading greater than 400 at any point during the data collection period.  Enter N if the participant did not have a blood glucose reading greater than 400 at any point during the data collection period.	Replaced with new row for Hospitalization/ Emergency Room Reason based on comments.	Removed	Decrease - high

<b>Section in Current CMS-10630 (04/16/2019)</b>	<b>Original Language</b>	<b>Clarification or Change</b>	<b>Revised Language</b>	<b>Burden</b>
Attachment I PACE Audit Process and Data Request  Appendix  Table 5: List of Participant Medical Records (LOPMR) Record Layout  Row AR	Field Name: Oxygen Saturation Level  Description: Enter Y if the participant had an oxygen saturation level of less than 85% at any point during the data collection period.  Enter N if the participant did not have an oxygen saturation level of less than 85% at any point during the data collection period.	Replaced with new for Hospitalization/ Emergency Room Reason based on comments.	Removed	Decrease - high
Attachment I PACE Audit Process and Data Request  Appendix  Table 5: List of Participant Medical Records (LOPMR) Record Layout	If the participant required a mechanically altered diet at any point during the data collection period, enter a description of the diet (e.g., pureed, mechanical, etc.).  Enter NA if the participant did not require a mechanically altered diet at any point during the data collection period.	Removed based on comments.	Removed	Decrease - moderate

Row AS				
Attachment I PACE Audit Process and Data Request  Appendix  Table 5: List of Participant Medical Records (LOPMR) Record Layout	Enter Y if the participant required oxygen on a regular basis at any point during the data collection period.  Enter N if the participant did not require oxygen on a regular basis.	Modified language for clarity.	Enter Y if the participant required oxygen on a regular basis at any point during the data collection period.  Enter N if the participant did not require oxygen on a regular basis at any point during the data collection period.	No change
Row AU				
Attachment II PACE Supplemental Questions  Question 2	List the emergency medications (name, dosage and quantity) that your organization keeps readily available on site at all times.  Note: List drug name as written on the product label. Do not include medications that are stored in a cabinet, cart, room, etc. for convenience but are not specifically for emergency situations. This list of emergency drugs may be provided as a separate attachment labeled emergency medications.	Grammatical correction.	List the emergency medications (name, dosage and quantity) that your organization keeps readily available on site at all times.  Note: List drug name as written on the product label. Do not include medications that are stored in a cabinet, cart, room, etc. for convenience but are not specifically for emergency situations. This list of emergency drugs may be provided as a separate attachment labeled emergency medications.	No change
Attachment II PACE Supplemental Questions  Question 9	Can participants obtain prescriptions written from any prescriber including specialists? If no, explain the process of reviewing the order and rewriting the prescription.	Modified the language for clarity based on comments.	Can participants obtain prescriptions or orders written from any prescriber including specialists? This includes prescriptions or orders for medications, DME, or any other care/services applicable. If no, explain the process of reviewing recommendations for prescriptions or orders from other prescribers and how the PACE organization determines if the order or recommendation should be provided.	No change

Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
Attachment III Pre-Audit Issues Summary	No change	No change	No change	No change
Attachment IV Onsite Obs Participant List  Instructions Tab	This document must be completed and submitted to HPMS on the first day of the onsite audit.	Modified the instruction requirements based on comments.	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.	Decrease moderate

Attachment V Audit Survey Pre-Audit Activities Question 5	Question added	Added to assess PO burden based on comments.	How many hours do you estimate staff spent collecting, reviewing, and submitting data prior to the audit?	No change  Completion of the audit survey is optional.
Attachment V Audit Survey Pre-Audit Activities Question 6	Question added	Added to assess PO burden based on comments.	Was the timeframe for submitting documentation and data during the pre-audit portion of the audit adequate?	No change  Completion of the audit survey is optional.
Attachment V Audit Survey Audit Activities Question 7	Question added	Added to assess PO burden based on comments.	7. In order to complete the requested Impact Analyses:  a. How many hours do you estimate it took to complete the requested Impact Analyses?  b. How many staff members do you estimate it took to complete the requested Impact Analyses?	No change  Completion of the audit survey is optional.
Attachment V Audit Survey Audit Activities Question 9	Question added	Added to assess PO burden based on comments.	How many hours do you estimate staff spent collecting, reviewing, and submitting data prior to the audit?	No change  Completion of the audit survey is optional.
Attachment V Audit Survey Audit Activities Question 10	Question added	Added to assess PO burden based on comments.	Was the timeframe for submitting documentation and data during the pre-audit portion of the audit adequate?	No change  Completion of the audit survey is optional.

<b>Section in Current CMS-10630 (04/16/2019)</b>	<b>Original Language</b>	<b>Clarification or Change</b>	<b>Revised Language</b>	<b>Burden</b>
Attachment V Audit Survey Post-Audit Activities Question 5	Question added	Added to assess PO burden based on comments.	How many hours do you estimate staff spent collecting, reviewing, and submitting data prior to the audit?	No change  Completion of the audit survey is optional.

Attachment V Audit Survey Post-Audit Activities Question 6	Question added	Added to assess PO burden based on comments.	Was the timeframe for submitting documentation and data during the pre-audit portion of the audit adequate?	No change  Completion of the audit survey is optional.
Attachment V Audit Survey General Audit Questions Question 3	How would you compare the audit of your PACE organization with the audits of other PSs operated by the same parent organization? Enter NA if the PO's parent organization does not operate any other PACE organizations or if the PACE contracts do not compare audit experiences.	Grammatical correction.	How would you compare the audit of your PACE organization with the audits of other POs operated by the same parent organization? Enter NA if the PO's parent organization does not operate any other PACE organizations or if the PACE contracts do not compare audit experiences.	No change
Attachment V Audit Survey General Audit Questions Question 5	Question added	Added to assess audit consistency based on comments.	If you feel that your audit experience was different than other PACE organizations operated by the different parent organization, please explain how they were different:	No change  Completion of the audit survey is optional.
AlertIDT1P14 Instructions Tab Scope	All participants enrolled during the audit review period.	Modified the scope of the review based on comments.	<ul style="list-style-type: none"> <li>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.</li> <li>The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.</li> </ul>	Decrease - high

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AlertIDT1P14 Instructions Tab Instructions	<ul style="list-style-type: none"> <li>Review all participant medical record documentation during the audit review period to determine if the IDT did not remain alert to any pertinent input from other team members, participants, and caregivers.</li> <li>Respond to the questions in the participant impact tab.</li> <li>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.</li> <li>The review timeframe is the audit review period. Errors noted prior to the audit review period should not be included.</li> <li>After completing the Impact Analysis, if any changes need to be made to the Root Cause Analysis,</li> </ul>	Modified the instructions to reflect the change in the scope of the review based on comments.	<ul style="list-style-type: none"> <li>Review only the participant medical records selected by the auditor. The selected participants are identified in the Participant Impact tab.</li> <li>Review documentation during the audit review period identified in this tab (Instructions).</li> <li>Determine if the IDT did not remain alert to any pertinent input from other team members, participants, and caregivers.</li> <li>Respond to the questions in the participant impact tab.</li> <li>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.</li> </ul>	No change



	please update the changes in the RCA tab.			
AlertIDT1P14 Participant Impact Tab Original Column P	If the communication issue caused a delay in or failure to: assess the participant, provide necessary care and/or services, provide access to emergency care, etc., <u>please describe</u> the care and/or services that were not provided or were delayed.	Added language to clarify how to respond when the questions is not applicable based on comments.	If the communication issue caused a delay in or failure to: assess the participant, provide necessary care and/or services, provide access to emergency care, etc., <u>please describe</u> the care and/or services that were not provided or were delayed.  Enter NA if Not Applicable.	No change
AlertIDT1P14 Participant Impact Tab Original Column Q	Were the services delayed or not provided?  Enter Delayed or Not Provided	Added language to clarify how to respond when the questions is not applicable based on comments.	Were the services delayed or not provided?  Enter Delayed or Not Provided  Enter NA if Not Applicable.	No change
AlertIDT1P14 Participant Impact Tab Original Column R	If delayed, what date did the participant receive the appropriate care and/or services.  Enter Date  Enter Not Provided if the services were never provided.	Added language to clarify how to respond when the questions is not applicable based on comments.	If delayed, what date did the participant receive the appropriate care and/or services.  Enter Date  Enter Not Provided if the services were never provided. Enter NA if Not Applicable.	No change
AlertIDT1P14 Participant Impact Tab Original Column U	If yes, describe the negative outcomes.	Added language to clarify how to respond when the questions is not applicable based on comments.	If yes, describe the negative outcomes.  Enter NA if Not Applicable.	No change

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AppealExt1P71 Participant Impact Tab Original Column L	Were there any negative participant outcomes?  (Yes/No)	Removed based on comments.	Removed	Decrease - high
AppealExt1P71 Participant Impact Tab Original Column M	If yes, describe the negative outcomes.	Removed based on comments.	Removed	Decrease - moderate

<p>Appeals1P651P661P681P73</p> <p>Instructions Tab</p> <p>Scope</p>	<p>Categorizing Appeals:</p> <ul style="list-style-type: none"> <li>Review each participant's medical record who was enrolled at any point during the audit review period.</li> </ul> <p>Appeal Reviewers:</p> <ul style="list-style-type: none"> <li>Review all of the appeals processed during the audit review period.</li> </ul> <p>Presenting Evidence During Appeals:</p> <ul style="list-style-type: none"> <li>Review all of the appeals processed during the audit review period.</li> </ul> <p>Medicaid and Medicare Appeal Rights</p> <ul style="list-style-type: none"> <li>Review all of the appeals processed during the audit review period.</li> </ul>	<p>Modified the scope of the review based on comments.</p>	<p>Categorizing Appeals:</p> <ul style="list-style-type: none"> <li>Review all denied service delivery requests during the audit review period.</li> </ul> <p>Appeal Reviewers:</p> <ul style="list-style-type: none"> <li>Review all of the appeals processed during the audit review period.</li> </ul> <p>Presenting Evidence During Appeals:</p> <ul style="list-style-type: none"> <li>Review all of the appeals processed during the audit review period.</li> </ul> <p>Medicaid and Medicare Appeal Rights</p> <ul style="list-style-type: none"> <li>Review all of the appeals processed during the audit review period.</li> </ul>	<p>Decrease - moderate</p>
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Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
<p>Appeals1P651P661P681P73</p> <p>Instructions Tab</p> <p>Instructions</p>	<p>General:</p> <ul style="list-style-type: none"> <li>If there have been any changes to the Root Cause Analysis, since the original Root Cause Analysis was provided, please update the changes in the RCA tab.</li> <li>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.</li> </ul> <p>Categorizing Appeals:</p> <ul style="list-style-type: none"> <li>Review each participant's medical record to determine if the participant submitted an appeal.</li> </ul> <p>Appeal Reviewers:</p> <ul style="list-style-type: none"> <li>Review all of the appeals processed during the audit review period and respond to the questions in the Participant Impact tab.</li> </ul> <p>Presenting Evidence During Appeals:</p> <ul style="list-style-type: none"> <li>Review all of the appeals processed during the audit review period and respond to the questions in the Participant Impact tab.</li> </ul> <p>Medicaid and Medicare Appeal Rights</p> <ul style="list-style-type: none"> <li>Review all of the appeals processed during the audit review period and respond to the questions in the Participant Impact tab.</li> </ul>	<p>Modified the instructions to reflect the change in the scope of the review based on comments.</p>	<p>General:</p> <ul style="list-style-type: none"> <li>If there have been any changes to the Root Cause Analysis, since the original Root Cause Analysis was provided, please update the changes in the RCA tab.</li> <li>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.</li> </ul> <p>Categorizing Appeals:</p> <ul style="list-style-type: none"> <li>Review the medical record for each participant who had a service delivery request denial to determine if the participant requested an appeal.</li> <li>Respond to the questions in the Participant Impact Tab.</li> </ul> <p>Appeal Reviewers:</p> <ul style="list-style-type: none"> <li>Review all of the appeals processed during the audit review period and respond to the questions in the Participant Impact tab.</li> </ul> <p>Presenting Evidence During Appeals:</p> <ul style="list-style-type: none"> <li>Review all of the appeals processed during the audit review period and respond to the questions in the Participant Impact tab.</li> </ul> <p>Medicaid and Medicare Appeal Rights</p> <ul style="list-style-type: none"> <li>Review all of the appeals processed during the audit review period and respond to the questions in the Participant Impact tab.</li> </ul>	<p>No change</p>

Appeals1P651P661P681P73 Participant Impact Tab Original Column G	Did the participant request an appeal during the audit review period (or appeal/challenge a denied service delivery request)?  (Yes/No)	Added language to clarify how to respond when the questions is not applicable based on comments.	Did the participant request an appeal during the audit review period (or appeal/challenge a denied service delivery request)?  (Yes/No)  If the auditor did not select Categorizing Appeals on the instructions tab the PO may enter NA in fields G-O.  If the answer to this question is No the PO may enter NA in fields I-O.	No change
Appeals1P651P661P681P73 Participant Impact Tab Original Column L	If the appeal/request/challenge was resolved, date of resolution/decision.  MM/DD/YYYY	Added language to clarify how to respond when the questions is not applicable based on comments.	If the appeal/request/challenge was resolved, date of resolution/decision.  MM/DD/YYYY  Enter NA if the appeal was not resolved.	No change

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Appeals1P651P661P681P73 Participant Impact Tab Original Column N	If the participant was provided the item/service, what was the date that service was provided?  MM/DD/YYYY	Added language to clarify how to respond when the questions is not applicable based on comments.	If the participant was provided the item/service, what was the date that service was provided?  MM/DD/YYYY  Enter NA if the item/service was not provided.	No change
Appeals1P651P661P681P73 Participant Impact Tab Original Column O	What evidence is there to demonstrate that the service was received?	Added language to clarify how to respond when the questions is not applicable based on comments.	What evidence is there to demonstrate that the service was received?  Enter NA if the item/service was not provided.	No change
Appeals1P651P661P681P73 Participant Impact Tab Original Column P	Were there any negative participant outcomes as a result of the failure to appropriately categorize an appeal?  (Yes/No)	Removed based on comments.	Removed	Decrease - high
Appeals1P651P661P681P73 Participant Impact Tab Original Column Q	Were any of the appeal reviewers involved in the initial decision to deny the service delivery request?  (Yes/No)	Added language to clarify how to respond when the questions is not applicable based on comments.	Were any of the appeal reviewers involved in the initial decision to deny the service delivery request?  (Yes/No)  If the auditor did not select Appeals Reviewers on the instructions tab the PO may enter NA in fields P-W.	No change

			If the answer to this question is No the PO may enter NA in fields Q-W.	
Appeals1P651P661P681P73 Participant Impact Tab Original Column U	If approved, what date did the participant receive the service?	Added language to clarify how to respond when the questions is not applicable based on comments.	If approved, what date did the participant receive the service?  Enter NA if the appeal was denied.	No change
Appeals1P651P661P681P73 Participant Impact Tab Original Column V	If denied, did the participant/representative request a Medicare/Medicaid appeal?	Added language to clarify how to respond when the questions is not applicable based on comments.	If denied, did the participant/representative request a Medicare/Medicaid appeal?  Enter NA if the appeal was approved.	No change

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Appeals1P651P661P681P73 Participant Impact Tab Original Column W	If the participant requested another appeal, was the external appeal approved or denied?	Added language to clarify how to respond when the questions is not applicable based on comments.	If the participant requested another appeal, was the external appeal approved or denied?  Enter NA if the appeal was approved or if the participant did not request an additional appeal.	No change
Appeals1P651P661P681P73 Participant Impact Tab Original Column X	What was the date of the external Medicare/Medicaid decision?	Added language to clarify how to respond when the questions is not applicable based on comments.	What was the date of the external Medicare/Medicaid decision?  Enter NA if the appeal was approved or if the participant chose not to pursue additional appeal.	No change
Appeals1P651P661P681P73 Participant Impact Tab Original Column Y	Were there any negative participant outcomes as the result of a failure to appoint independent and/or appropriately credentialed third-party reviewers?  (Yes/No)	Removed based on comments.	Removed	Decrease - high
Appeals1P651P661P681P73 Participant Impact Tab Original Column Z	Did the PO provide written notification to the participant/participant representative that included the participant/participant representative's right to present evidence related to the dispute <u>in person</u> ?  (Yes/No)	Added language to clarify how to respond when the questions is not applicable based on comments.	Did the PO provide written notification to the participant/participant representative that included the participant/participant representative's right to present evidence related to the dispute in person?  (Yes/No)  If the auditor did not select Presenting Evidence During Appeals on the instructions tab the PO may enter NA in	No change

Appeals1P651P661P681P73 Participant Impact Tab Original Column AB	Enter the date written notification was provided to the participant/participant representative.  MM/DD/YYYY	Added language to clarify how to respond when the questions is not applicable based on comments.	fields X-AE. Enter the date written notification was provided to the participant/participant representative.  MM/DD/YYYY  Enter NA if the participant/participant representative did not receive written notification.	No change
Appeals1P651P661P681P73 Participant Impact Tab Original Column AE	Was the participant/participant representative given an opportunity to present evidence related to the dispute in person?  (Yes/No)	Added language to clarify how to respond when the questions is not applicable based on comments.	Was the participant/participant representative given an opportunity to present evidence related to the dispute in person?  (Yes/No)  Enter NA if the participant/representative did not request to present information in person.	No change

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Appeals1P651P661P681P73 Participant Impact Tab Original Column AF	Was the participant/participant representative given an opportunity to present evidence related to the dispute in writing?  (Yes/No)	Added language to clarify how to respond when the questions is not applicable based on comments.	Was the participant/participant representative given an opportunity to present evidence related to the dispute in writing?  (Yes/No)  Enter NA if the participant/representative did not request to present information in writing.	No change
Appeals1P651P661P681P73 Participant Impact Tab Original Column AG	Enter the date PO responded to the appeal.  MM/DD/YYYY	Added language to clarify how to respond when the questions is not applicable based on comments.	Enter the date PO responded to the appeal.  MM/DD/YYYY  Enter NA if there was no response to the appeal.	No change
Appeals1P651P661P681P73 Participant Impact Tab Original Column AH	Were there any negative participant outcomes as a result of the failure to provide the participant with an opportunity to provide evidence during an appeal?  (Yes/No)	Removed based on comments.	Removed	Decrease - high
Appeals1P651P661P681P73 Participant Impact Tab Original Column AI	Enter the date of the appeal decision.  MM/DD/YYYY	Added language to clarify how to respond when the questions is not applicable based on comments.	Enter the date of the appeal decision.  MM/DD/YYYY  If the auditor did not select Medicaid and Medicare Appeal Rights on the instructions tab the PO may enter NA in fields AF-AL.	No change

Appeals1P651P661P681P73 Participant Impact Tab Original Column AK	For denials, did the PO provide written notification to the participant/participant representative informing them of their appeal rights under Medicare and Medicaid?  (Yes/No)	Added language to clarify how to respond when the questions is not applicable based on comments.	For denials, did the PO provide written notification to the participant/participant representative informing them of their appeal rights under Medicare and Medicaid?  (Yes/No)  Enter NA if the service being appealed was approved.	No change
Appeals1P651P661P681P73 Participant Impact Tab Original Column AL	Did the participant/participant representative request to pursue their appeal rights under Medicare and Medicaid?  (Yes/No)	Added language to clarify how to respond when the questions is not applicable based on comments.	Did the participant/participant representative request to pursue their appeal rights under Medicare and Medicaid?  (Yes/No)  Enter NA if the service being appealed was approved.	No change

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Appeals1P651P661P681P73 Participant Impact Tab Original Column AM	Did the PO provide assistance to the participant/participant representative in choosing which appeal rights to pursue?  (Yes/No)	Added language to clarify how to respond when the questions is not applicable based on comments.	Did the PO provide assistance to the participant/participant representative in choosing which appeal rights to pursue?  (Yes/No)  Enter NA if the service being appealed was approved or if the participant/participant representative chose not to pursue additional appeals.	No change
Appeals1P651P661P681P73 Participant Impact Tab Original Column AN	Did the PO forward the appeal to the appropriate external entity?  (Yes/No)	Added language to clarify how to respond when the questions is not applicable based on comments.	Did the PO forward the appeal to the appropriate external entity?  (Yes/No)  Enter NA if the service being appealed was approved or if the participant/participant representative chose not to pursue additional appeals.	No change
Appeals1P651P661P681P73 Participant Impact Tab Original Column AO	Enter the date the appeal was forwarded to Medicare, Medicaid, or Both.  MM/DD/YYYY	Added language to clarify how to respond when the questions is not applicable based on comments.	Enter the date the appeal was forwarded to Medicare, Medicaid, or Both.  MM/DD/YYYY  Enter NA if the service being appealed was approved or if the participant/participant representative chose not to pursue additional appeals.	No change
Appeals1P651P661P681P73 Participant Impact Tab	Were there any negative participant outcomes as a result of the failure to provide Medicare and/or Medicaid appeal rights?  (Yes/No)	Removed based on comments.	Removed	Decrease - high

Original Column AP				
Appeals1P651P661P681P73	If yes, describe the negative outcomes.	Removed based on comments.	Removed	Decrease - moderate
Participant Impact Tab				
Original Column AQ				

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Assessments1P491P501P82  Instructions Tab  Scope	<p>Unscheduled Assessments:</p> <ul style="list-style-type: none"> <li>All participants enrolled during the audit review period.</li> </ul> <p>Annual/Semiannual Assessments:</p> <ul style="list-style-type: none"> <li>All participants enrolled during the audit review period.</li> </ul> <p>Initial Assessments:</p> <ul style="list-style-type: none"> <li>All participants who were newly enrolled during the audit review period.</li> </ul>	Modified the scope of the review based on comments..	<p>Unscheduled Assessments:</p> <ul style="list-style-type: none"> <li>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.</li> <li>The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.</li> </ul> <p>Semiannual Assessments:</p> <ul style="list-style-type: none"> <li>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.</li> <li>The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.</li> </ul> <p>Initial Assessments:</p> <ul style="list-style-type: none"> <li>The scope of this Impact Analysis is limited to 50% of the participants newly enrolled during the audit review period who were not included in the provision of services sample selection.</li> <li>The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.</li> </ul>	Decrease - high

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<p>Assessments1P491P501P82</p> <p>Instructions Tab</p> <p>Instructions</p>	<p>General:</p> <ul style="list-style-type: none"> <li>Once done the participant impact tab, if there have been any changes to the Root Cause Analysis, since the original Root Cause Analysis was provided, please update the changes in the RCA tab.</li> <li>The review timeframe is the audit review period. Errors noted prior to the audit review period should not be included.</li> </ul> <p>Unscheduled Assessments:</p> <ul style="list-style-type: none"> <li>Review the medical records for all participants during the audit review period in order to determine:             <ol style="list-style-type: none"> <li>If the participant had a change in status; and</li> <li>If all required IDT members completed assessments as required.</li> </ol> </li> </ul> <p>Annual/Semiannual Assessments:</p> <ul style="list-style-type: none"> <li>Review the medical records for all participants during the audit review period in order to determine if all required IDT members completed assessments as required.</li> </ul> <p>Initial Assessments:</p> <ul style="list-style-type: none"> <li>Review the medical records for all participants who were newly enrolled during the audit review period in order to determine if all required IDT members completed assessments as required.</li> </ul>	<p>Modified the instructions to reflect the change in the scope of the review based on comments.</p>	<p>General:</p> <ul style="list-style-type: none"> <li>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.</li> <li>The review timeframe is the audit review period. Errors noted prior to the audit review period should not be included.</li> </ul> <p>Unscheduled Assessments:</p> <ul style="list-style-type: none"> <li>Review only the participant medical records selected by the auditor. The selected participants are identified in the Participant Impact tab.</li> <li>Review the selected medical records to determine:             <ol style="list-style-type: none"> <li>If the participant had a change in status; and</li> <li>If all required IDT members completed assessments as required.</li> </ol> </li> </ul> <p>Annual/Semiannual Assessments:</p> <ul style="list-style-type: none"> <li>Review only the participant medical records selected by the auditor. The selected participants are identified in the Participant Impact tab.</li> <li>Review the selected medical records to determine if all required IDT members completed assessments as required.</li> </ul> <p>Initial Assessments:</p> <ul style="list-style-type: none"> <li>Review only the participant medical records selected by the auditor. The selected participants are identified in the Participant Impact tab.</li> <li>Review the selected medical records to determine if all required IDT members completed assessments as required.</li> </ul>	<p>No change</p>
<p>Assessments1P491P501P82</p> <p>Participant Impact Tab</p> <p>Original Column F</p>	<p>Did the participant experience a change in their health or psychosocial status during the audit review period that?</p> <p>(Yes/No)</p>	<p>Added language to clarify how to respond when the questions is not applicable based on comments.</p>	<p>Did the participant experience a change in their health or psychosocial status during the audit review period that?</p> <p>(Yes/No)</p> <p>If the auditor did not select Unscheduled Assessments on the instructions tab the PO may enter NA in fields F-M.</p> <p>If the answer to this question is No the PO may enter NA in fields G-M.</p>	<p>No change</p>

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Assessments1P491P501P82 Participant Impact Tab Original Column H	Is there documentation that assessments were completed by all required IDT members?  (Yes/No)	Revised for clarity based on comments.	Is there documentation that assessments were completed by all required IDT members (at a minimum this includes: PCP, RN and MSW, and any other discipline determined to be actively involved in the care plan) in response to the change in condition?  (Yes/No)	No change
Assessments1P491P501P82 Participant Impact Tab Original Column I	Enter the IDT members who completed assessments.	Removed based on comments.	Removed	Decrease - moderate
Assessments1P491P501P82 Participant Impact Tab Original Column J	Enter the IDT members who did not complete assessments.	Revised for clarity based on comments.	Enter the IDT members who did <u>not</u> complete assessments.  Enter NA if the participant received all required assessments.	No change
Assessments1P491P501P82 Participant Impact Tab Original Column N	Identify the assessments that were <u>not</u> completed inperson.  (PCP, RN, etc)	Revised for clarity based on comments.	Identify the assessments that were <u>not</u> completed inperson.  (PCP, RN, etc.)  Enter NA if participant had all assessments completed in person.	No change
Assessments1P491P501P82 Participant Impact Tab Original Column Q	Should the participant have had a Semi-annual Assessment during the audit review period?  (Yes/No)	Revised based on regulatory changes effective 08/02/2019 and added language to clarify how to respond when the questions is not applicable based on comments.	Should the participant have had a Semi-annual Assessment during the audit review period?  (Yes/No)  If the auditor did not select Semiannual Assessments on the instructions tab the PO may enter NA in fields N-W.  If the answer to this question is No the PO may enter NA in fields O-W.	Decrease - low
Assessments1P491P501P82 Participant Impact Tab Original Column R	What type of assessments should the participant have had during the audit review period?  (Annual, Semi-Annual, or Both)	Removed based on regulatory changes effective 08/02/2019.	Removed	Decrease - low
Assessments1P491P501P82 Participant Impact Tab	Did the participant have an Annual or Semi-annual Assessment completed during the audit review period?  (Yes/No)	Revised based on regulatory changes effective 08/02/2019.	Did the participant have a Semi-annual Assessment completed during the audit review period?  (Yes/No)	Decrease - low

Original Column S				
Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
Assessments1P491P501P82 Participant Impact Tab Original Column T	Enter the type of assessment completed.  Enter each type of assessment on a new row (annual on one, semi-annual on another).  (annual/semi-annual)	Removed based on regulatory changes effective 08/02/2019.	Removed	Decrease - low
Assessments1P491P501P82 Participant Impact Tab Original Column U	Which disciplines were actively involved in the development or implementation of the participant's plan of care, at the time of assessment?  Identify all disciplines that apply.	Revised based on regulatory changes effective 08/02/2019.	For participants that should have had a semi-annual assessment completed, which disciplines were actively involved in the development or implementation of the participant's plan of care, at the time of assessment?  Identify all disciplines that apply.	No change
Assessments1P491P501P82 Participant Impact Tab Original Column V	List the IDT members who <u>completed</u> assessments.	Removed to reduce burden based on comments.	Removed	Decrease - low
Assessments1P491P501P82 Participant Impact Tab Original Column W	List the IDT members who <u>DID NOT</u> complete assessments.	Revised based on regulatory changes effective 08/02/2019.	List the IDT members who <u>DID NOT</u> complete assessments (at a minimum the required disciplines include PCP, RN, MSW and any disciplines identified in the previous column).  Enter NA if the participant received all required semiannual assessments.	No change
Assessments1P491P501P82 Participant Impact Tab Original Column Y	Identify the assessments that were not completed inperson.  (PCP, RN, etc)	Revised for clarity based on comments.	Identify the assessments that were not completed inperson.  (PCP, RN, etc.)  Enter NA if all assessments were completed in person.	No change
Assessments1P491P501P82 Participant Impact Tab Original Column AD	Did any negative outcomes occur as a result of the failure to conduct in-person annual or semiannual assessments?  (Yes/No)	Removed based on comments.	Removed	Decrease - high

Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
Assessments1P491P501P82 Participant Impact Tab Original Column AE	Did the required IDT members complete assessments?  (Yes/No)	Added language to clarify the required IDT disciplines and added language to clarify how to respond when the questions is not applicable based on comments.	Did the required IDT members complete all initial assessments (at a minimum this includes PCP, RN, MSW, RD, HCC, RT/AC, PT and OT)?  (Yes/No)  If the auditor did not select Initial Assessments on the instructions tab the PO may enter NA in fields X-AC.  If the answer to this question is Yes the PO may enter NA in fields Y-AC.	No change
Assessments1P491P501P82 Participant Impact Tab Original Column AF	List the IDT members who <u>completed</u> assessments.	Removed based on comments.	Removed	Decrease - low
Assessments1P491P501P82 Participant Impact Tab Original Column AI	Identify any assessments not completed in-person.  (RN, MSW, etc)	Added language to clarify how to respond when the questions is not applicable based on comments.	Identify any assessments not completed in-person.  (RN, MSW, etc.)  Enter NA if all assessments were completed in person.	No change
Assessments1P491P501P82 Participant Impact Tab Original Column AL	Did any negative outcomes occur as a result of the failure to conduct in-person initial assessments?  (Yes/No)	Removed based on comments.	Removed	Decrease -high
Assessments1P491P501P82 Participant Impact Tab Original Column AM	If yes, describe the negative outcomes.	Removed based on comments.	Removed	Decrease - moderate
CarePlanContent1P84	Impact Analysis Template	Removed based on comments.	Removed	Decrease - high
CarePlanPartCGInvolvement1P20	Impact Analysis Template	Removed based on comments.	Removed	Decrease - high
CDC1P25	Impact Analysis Template	Removed based on comments.	Removed	Decrease - high
CenterSrvcs1P01	Impact Analysis Template	Removed based on comments.	Removed	Decrease - high
Effectuation1P021P111P30	Date the service delivery request was received by IDT.	Added language to clarify how to	Date the service delivery request was received by IDT.	No change

Participant Impact Tab Original Column G	MM/DD/YYYY	respond when the questions is not applicable based on comments.	MM/DD/YYYY If the auditor did not select Provision of services following an approved service delivery request on the instructions tab the PO may enter NA in fields G-N.	
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Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
Effectuation1P021P111P30 Participant Impact Tab Original Column H	Date the service delivery request was approved by the IDT.  MM/DD/YYYY	Removed based on comments.	Removed	Decrease - high
Effectuation1P021P111P30 Participant Impact Tab Original Column I	Date oral/written notification was provided to the participant/participant representative. If oral and written notification were provided, enter the earliest date.  MM/DD/YYYY	Revised for clarity based on comments.	Date oral/written notification of the approval was provided to the participant/participant representative. If oral and written notification were provided, enter the earliest date.  MM/DD/YYYY  Enter NA is notification was not rendered to the participant.	No change
Effectuation1P021P111P30 Participant Impact Tab Original Column K	If modified or partial approval, what was the approved service?	Revised for clarity based on comments.	If modified or partial approval, what was the approved service?  Enter NA if approved in full.	No change
Effectuation1P021P111P30 Participant Impact Tab Original Column N	What evidence/documentation does the PO have that demonstrates the service was approved?	Revised for clarity based on comments.	What evidence/documentation does the PO have that demonstrates the service was approved?  Enter NA if the service was not provided to the participant.	No change
Effectuation1P021P111P30 Participant Impact Tab Original Column P	Was the participant enrolled in Medicaid? This includes participants who are Medicaid only and dual eligible.  (Yes/No)	Added language to clarify how to respond when the questions is not applicable based on comments.	Was the participant enrolled in Medicaid? This includes participants who are Medicaid only and dual eligible.  (Yes/No)  If the auditor did not select Provision of services to Medicaid participants during an appeal on the instructions tab the PO may enter NA in fields O-X.  If the answer to this question is No the PO may enter NA in fields P-X.	No change
Effectuation1P021P111P30	Was the PO proposing to terminate or reduce services currently being furnished to the participant?	Revised for clarity based on comments.	Was the appeal related to a termination or reduction in services that were currently being furnished to the participant?	No change

Participant Impact Tab Original Column R	(Yes/No)		(Yes/No)	
Effectuation1P021P111P30 Participant Impact Tab Original Column V	Was the service approved or denied by the third-party reviewer?	Revised for clarity based on comments.	Was the service approved, denied or partially denied by the third-party reviewer?	No change

Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
Effectuation1P021P111P30 Participant Impact Tab Original Column W	If the service was terminated and the service was approved by the third-party reviewer, enter the date that the service resumed. Enter NA if the service was denied by the third-party.  MM/DD/YYYY	Revised for clarity based on comments.	If the service was terminated and the service was approved by the third-party reviewer, enter the date that the service resumed.  MM/DD/YYYY  Enter NA if the service was denied by the third-party or the service was never terminated.	No change
Effectuation1P021P111P30 Participant Impact Tab Original Column X	What evidence or documentation does the PO have to show the service was provided?	Revised for clarity based on comments.	What evidence or documentation does the PO have to show the service was provided?  Enter NA if the service was not provided.	No change
Effectuation1P021P111P30 Participant Impact Tab Original Column Z	Date the appeal was received by IDT.  MM/DD/YYYY	Added language to clarify how to respond when the questions is not applicable based on comments.	Date the appeal was received by IDT.  MM/DD/YYYY  If the auditor did not select Provision of services following an approved appeal on the instructions tab the PO may enter NA in fields Y-AG.	No change
Effectuation1P021P111P30	Question added	Question added to provide additional clarity to Impact Analysis.	Description of the item/service being appealed.	Increase - low
Effectuation1P021P111P30 Participant Impact Tab Original Column AA	Was the service approved or denied by the third-party reviewer?	Revised for clarity based on comments.	Date the appeal was approved by any appeal entity (e.g., third party reviewer, IRE, State fair hearings, etc.).	No change
Effectuation1P021P111P30	New column	Added for clarity based on	Entity that approved the appeal.	Increase - low

Participant Impact Tab		comments.	(Third Party Reviewer, IRE, State Fair Hearings, etc.)	
Effectuation1P021P111P30 Participant Impact Tab Original Column AB	Date the appeal was approved or denied by the thirdparty reviewer.  MM/DD/YYYY	Removed based on comments.	Removed	Decrease - low
Effectuation1P021P111P30 Participant Impact Tab Original Column AC	For denied appeals, did the participant request an additional appeal hearing through Medicaid or Medicare?  (Yes/No)	Removed based on comments..	Removed	Decrease - low

Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
Effectuation1P021P111P30 Participant Impact Tab Original Column AD	If the participant request an additional appeal hearing through Medicaid or Medicare, was the service approved or denied by the Medicaid or Medicare reviewer? If the participant did not exercise their additional appeal rights, enter NA.	Removed based on comments.	Removed	Decrease - low
Effectuation1P021P111P30 Participant Impact Tab Original Column AE	If the participant request an additional appeal hearing through Medicaid or Medicare, enter the date that the decision was rendered. If the participant did not exercise their additional appeal rights, enter NA.  MM/DD/YYYY	Removed based on comments.	Removed	Decrease - low
Effectuation1P021P111P30 Participant Impact Tab Original Column AF	Was the final decision Approved, Denied, or Partially Approved/Denied?	Revised for clarity based on comments.	Was the final decision Approved or Partially Approved/Denied?	No change
Effectuation1P021P111P30 Participant Impact Tab Original Column AG	If partially approved/denied, what was the approved portion of the item or service?	Revised for clarity based on comments.	If partially approved/denied, what was the approved portion of the item or service?  Enter NA if the appeal was approved in full.	No change
Effectuation1P021P111P30 Participant Impact Tab Original Column AH	If the service was approved or partially approved by either the third-party, Medicaid, or Medicare reviewer, enter the date that the service was provided or resumed. Enter NA if the service was denied by the third-party.  MM/DD/YYYY	Revised for clarity based on comments.	If the service was approved or partially approved by either the third-party, Medicaid, or Medicare reviewer, enter the date that the service was provided or resumed.  MM/DD/YYYY  Enter Not Provided if the approved service was not provided or if there is no evidence the approved service was provided.	No change

Effectuation1P021P111P30 Participant Impact Tab Original Column AI	What evidence or documentation does the PO have to demonstrate that the approved service was provided?	Revised for clarity based on comments.	What evidence or documentation does the PO have to demonstrate that the approved service was provided?  Enter NA if the approved service was not provided.	No change
Effectuation1P021P111P30 Participant Impact Tab Original Column AK	If the participant experienced any negative outcomes, please describe the negative outcomes.	Added language to clarify how to respond when the questions is not applicable based on comments.	If the participant experienced any negative outcomes, please describe the negative outcomes.  Enter NA if there were no negative outcomes.	No change

Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
Effectuation1P021P111P30 Participant Impact Tab Original Column AL	If the participant experienced negative outcomes, did they occur, in some part, as a result of the failure to provide the item or service?  (Yes/No)	Added language to clarify how to respond when the questions is not applicable based on comments.	If the participant experienced negative outcomes, did they occur, in some part, as a result of the failure to provide the item or service?  (Yes/No)  Enter NA if there were no negative outcomes	No change
EmergencyCare1P07 Instructions Tab Scope	All participants enrolled at any point during the audit review period.	Modified the scope of the review based on comments.	<ul style="list-style-type: none"> <li>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.</li> <li>The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.</li> </ul>	Decrease - high

<p>EmergencyCare1P07</p> <p>Instructions Tab</p> <p>Instructions</p>	<ul style="list-style-type: none"> <li>Review all participant documentation during the audit review period to determine if each participant requested emergency care, reported an emergency situation, or required emergency care at any time during the audit review period.</li> <li>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.</li> <li>Read each question carefully before responding.</li> <li>Respond to the questions in the participant impact tab.</li> <li>The review timeframe is the audit review period stated above. Errors noted prior to the audit review period should not be included.</li> <li>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.</li> </ul>	<p>Modified the instructions to reflect the change in the scope of the review based on comments.</p>	<ul style="list-style-type: none"> <li>Review only the participant medical records selected by the auditor. The selected participants are identified in the Participant Impact tab.</li> <li>Read each question carefully before responding.</li> <li>Respond to the questions in the participant impact tab.</li> <li>The review timeframe is the audit review period stated above. Errors noted prior to the audit review period should not be included.</li> <li>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.</li> </ul>	<p>No change</p>
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Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
<p>EmergencyCare1P07</p> <p>Participant Impact Tab</p> <p>Original Column G</p>	<p>During the audit review period did the participant or caregiver:</p> <ul style="list-style-type: none"> <li>Utilize emergency services (regardless of whether authorization was requested);</li> <li>Request emergency services (regardless of whether the participant went to the emergency department); or</li> <li>Contact the PO or one of its contracted providers to report an emergency?</li> </ul> <p>(Yes/No)</p> <p>If the response is No in this column, the PO may enter NA in all remaining columns.</p>	<p>Revised for clarity based on comments.</p>		<p>No change</p>



EmergencyCare1P07 Participant Impact Tab Original Column H	When did the participant or caregiver: <ul style="list-style-type: none"> <li>Utilize emergency services;</li> <li>Request emergency services; or</li> <li>Contact the PO or one of its contracted providers to report an emergency?</li> </ul> MM/DD/YYYY  Use a new line for each request, report or ER visit.	Removed based on comments.	Removed	Decrease - low
EmergencyCare1P07 Participant Impact Tab Original Column I	Was this a request for Emergency services, a utilization or a report of an emergency?  (Enter Request, Report or Utilization)	Removed based on comments.	Removed	Decrease - moderate
EmergencyCare1P07 Participant Impact Tab Original Column J	Did the participant or caregiver contact the PO or one its contacted providers before utilizing emergency services?  (Yes/No)	Revised for clarity based on comments.	Did the participant contact the PO before going to the ER?  Yes/No	No change
EmergencyCare1P07 Participant Impact Tab Original Column K	If contact was made before utilizing emergency services (or to ask whether to use emergency services), who did the participant or caregiver contact (PO, oncall, contracted on-call, etc.)?	Revised for clarity based on comments.	If the participant contacted the PO before going to the ER please enter the date and time of the initial contact.  MM/DD/YYYY, HH:MM AM/PM  Enter NA if the participant did not contact the PO before utilizing emergency services.	No change

<b>Section in Current CMS-10630 (04/16/2019)</b>	<b>Original Language</b>	<b>Clarification or Change</b>	<b>Revised Language</b>	<b>Burden</b>
EmergencyCare1P07 Participant Impact Tab Original Column L	If contact was made before utilizing emergency services, describe the symptoms as reported by the participant and/or caregiver.	Revised for clarity based on comments.	Please briefly describe the concerns and/or symptoms reported by the participant and/or caregiver.  Enter NA if the participant did not contact the PO before utilizing emergency services.	No change.
EmergencyCare1P07 Participant Impact Tab Original Column M	Date of initial contact prior to utilization of emergency services.  MM/DD/YYYY  Enter NA if the participant did not contact the PO before utilizing emergency services.	Removed based on comments.	Removed	No change.

EmergencyCare1P07 Participant Impact Tab Original Column N	Time of initial contact prior to utilization of emergency services.  Enter NA if the participant did not contact the PO before utilizing emergency services.	Removed based on comments.	Removed	Decrease - moderate
EmergencyCare1P07 Participant Impact Tab Original Column P	Did PO or contracted staff assess the participant before they sought emergency treatment?  (Yes/No)  Enter NA if the participant did not contact the PO before utilizing emergency services.	Column P was divided into two questions to improve clarity based on comments..	Did staff or contractors from the PO assess the participant in response to the participant/caregiver's initial contact?  Yes/No  Enter NA if the participant did not contact the PO before utilizing emergency services.	No change
EmergencyCare1P07 Participant Impact Tab Original Column P	Did PO or contracted staff assess the participant before they sought emergency treatment?  (Yes/No)  Enter NA if the participant did not contact the PO before utilizing emergency services.	Column P was divided into two questions to improve clarity based on comments.	Was the assessment completed prior to the participant utilizing the ER?  Yes/No  Enter NA if the participant did not utilize the ER or if the participant/caregiver did not contact the PO before utilizing emergency services.	No change

Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
EmergencyCare1P07 Participant Impact Tab Original Column T	If the participant was instructed to not utilize emergency services, what was the basis for that decision?  Enter NA if the participant did not contact the PO before utilizing emergency services.	Columns T, U, and V were consolidated into a single question to improve clarity based on comments.	Did staff or contractors from the PO: <ul style="list-style-type: none"> <li>• Instruct the participant and/or caregiver that prior authorization was needed before to going to the ER or calling 911; or</li> <li>• Instruct the participant and/or caregiver that approval was needed before to going to the ER or calling 911; or</li> <li>• Instruct the participant and/or caregiver not to go to the ER or call 911?</li> </ul> Yes/No  Enter NA if the participant did not contact the PO before utilizing emergency services.	Decrease - low

EmergencyCare1P07 Participant Impact Tab Original Column U	At any point, was the participant or caregiver told that emergency services must be authorized? (This includes conversations before or after emergency services were rendered)  (Yes/No)	Columns T, U, and V were consolidated into a single question to improve clarity based on comments.	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.	Decrease - low
EmergencyCare1P07 Participant Impact Tab Original Column V	If yes, how was this information communicated to the participant or caregiver (i.e., during on-call conversation, information packet provided to participant, etc)?	Columns T, U, and V were consolidated into a single question to improve clarity based on comments.	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.	Decrease - low

Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
EmergencyCare1P07 Participant Impact Tab Original Column W	Did the participant or caregiver seek emergency care or utilize emergency care after contacting the PO or one of the POs contracted providers?  (Yes/No)	Revised for clarity based on comments.	Date/ Time the participant went to the ER.  MM/DD/YYYY, HH:MM  Enter NA if the participant did not utilize emergency services.	No change
EmergencyCare1P07 Participant Impact Tab Original Column X	Did emergency room records indicate that the participant was experiencing an emergent situation?  (Yes/No)  Enter NA if the participant did not utilize emergency services.	Revised for clarity based on comments.	Did emergency room records indicate that the participant was experiencing an emergent situation?  (Yes/No)  Enter NA if the participant did not utilize emergency services.	No change

			This question applies to all ER visits regardless of whether the participant/caregiver contacted the PO.	
EmergencyCare1P07 Participant Impact Tab Original Column Y	If emergency room records indicated that the participant experienced an emergent situation, please describe the situation.  Enter NA if the participant did not utilize emergency services.	Revised for clarity based on comments.	If emergency room records indicated that the participant experienced an emergent situation, please describe the situation.  Enter NA if the participant did not utilize emergency services.  This question applies to all ER visits regardless of whether the participant/caregiver contacted the PO.	No change
EmergencyCare1P07 Participant Impact Tab Original Column Z	If the participant DID NOT utilize emergency services, did the participant experience any serious jeopardy to their health, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part?  (Yes/No)  Enter NA if the participant did utilize emergency services.	Removed based on comments.	Removed	Decrease - moderate

Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
EmergencyCare1P07 Participant Impact Tab Original Column AA	If the participant experienced negative outcomes, did they occur, in some part, as a result of the failure to seek emergency care?  (Yes/No)	Revised for clarity based on comments.	Did the participant experience any negative outcomes after being instructed: <ul style="list-style-type: none"> <li>That prior authorization was needed before to going to the ER or calling 911; or</li> <li>That approval was needed before to going to the ER or calling 911; or</li> <li>Not to go to the ER or call 911?</li> </ul> (Yes/No)  Enter NA if none of the above are applicable.	No change
EmergencyCare1P07 Participant Impact Tab Original Column AB	If yes, describe the negative outcomes.	Added language to clarify how to respond when the questions is not applicable based on comments.	If yes, describe the negative outcomes.  Enter NA if the participant did not experience any negative outcomes.	No change

EmergencyCare1P07 Participant Impact Tab	Question added	Added to simplify the Impact Analysis based on comments.	If the participant was evaluated/treated in an ER, what was the final ER diagnosis?  This question applies to all ER visits regardless of whether the participant/caregiver contacted the PO	Increase - low
EmergencyCare1P07 Participant Impact Tab	Question added	Added to simplify the Impact Analysis based on comments.	Was the participant admitted to the hospital or held for observation?  Yes/No  Enter NA if the participant did not utilize emergency services.  This question applies to all ER visits regardless of whether the participant/caregiver contacted the PO.	Increase - low
EmergencyCare1P07 Participant Impact Tab  Original Column AC	Following an emergency room/department visit did the IDT review the ER/ED records to either approve or deny the visit?  (Yes/No)  Enter NA if the participant did not utilize emergency services.	Removed based on comments.	Removed	Decrease - low

Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
EmergencyCare1P07 Participant Impact Tab  Original Column AD	Was the visit approved or denied?  (approved/denied)  Enter NA if the participant did not utilize emergency services.	Removed based on comments.	Removed	Decrease - low
EmergencyCare1P07 Participant Impact Tab  Original Column AE	At any point, did the participant receive a bill for the emergency services?  (Yes/No)  Enter NA if the participant did not utilize emergency services.	Revised for clarity based on comments.	Was the participant held responsible for <u>any</u> of the cost of the ER visit?  Yes/No  This question applies to all ER visits regardless of whether the participant/caregiver contacted the PO.	No change
EmergencyCare1P07	Did the PO pay, in full, for this emergency service?	Revised for clarity based on	If yes, how much?	No change

Participant Impact Tab  Original Column AF	(Yes/No)  Enter NA if the participant did not utilize emergency services.	comments.	This question applies to all ER visits regardless of whether the participant/caregiver contacted the PO.  Enter NA if the PO covered 100% of the cost of the ER visit.	
EmergencyEquipment1P79	Removed	Removed based on comments.	Removed	Decrease - high
Grievances1P311P751P77  Instructions Tab  Scope	Resolution of participant grievances: <ul style="list-style-type: none"> <li>All grievances during the audit review period.</li> </ul> Recognizing complaints as grievances: <ul style="list-style-type: none"> <li>All participants enrolled in the PO during the audit review period.</li> <li>Review all participant medical records, on-call records, PAC minutes, etc. during the audit review period to determine if complaints were processed.</li> </ul> Discussing grievances with participants: <ul style="list-style-type: none"> <li>Review all documentation that pertains to the review of the PO's grievance process.</li> </ul>	Modified the scope of the review based on comments.	Resolution of participant grievances: <ul style="list-style-type: none"> <li>All grievances during the audit review period.</li> </ul> Recognizing complaints as grievances: <ul style="list-style-type: none"> <li>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 grievance sample selection. • The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.</li> </ul> Discussing grievances with participants: <ul style="list-style-type: none"> <li>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 grievance sample selection. • The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.</li> </ul>	Decrease - high

Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
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<p>Grievances1P311P751P77</p> <p>Instructions Tab</p> <p>Instructions</p>	<p>General:</p> <ul style="list-style-type: none"> <li>The review timeframe is the audit review period. Errors noted prior to the audit review period should not be included.</li> <li>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.</li> </ul> <p>Resolution of participant grievances:</p> <ul style="list-style-type: none"> <li>Review each grievance and respond to the questions in the Participant Impact tab.</li> </ul> <p>Recognizing complaints as grievances:</p> <ul style="list-style-type: none"> <li>Review all medical records, on-call records, PAC minutes, etc. during the audit review period to determine if the participant, participant's family members, or participant representative submitted a compliant verbally or in writing.</li> <li>Answer the questions in the Participant Impact tab.</li> </ul> <p>Discussing grievances with participants:</p> <ul style="list-style-type: none"> <li>Answer the questions in the Participant Impact tab.</li> </ul>	<p>Modified the instructions to reflect the change in the scope of the review based on comments.</p>	<p>General:</p> <ul style="list-style-type: none"> <li>The review timeframe is the audit review period. Errors noted prior to the audit review period should not be included.</li> <li>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.</li> </ul> <p>Resolution of participant grievances:</p> <ul style="list-style-type: none"> <li>Review each grievance and respond to the questions in the Participant Impact tab.</li> </ul> <p>Recognizing complaints as grievances:</p> <ul style="list-style-type: none"> <li>Review only the participant medical records selected by the auditor. The selected participants are identified in the Participant Impact tab.</li> <li>Review the selected medical records to determine if the participant, participant's family members, or participant representative submitted a compliant verbally or in writing.</li> <li>Respond to the questions in the Participant Impact tab.</li> </ul> <p>Discussing grievances with participants:</p> <ul style="list-style-type: none"> <li>Review only the participant medical records selected by the auditor. The selected participants are identified in the Participant Impact tab.</li> <li>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. • Respond to the questions in the Participant Impact tab.</li> </ul>	<p>No change</p>
<p>Grievances1P311P751P77</p> <p>Participant Impact Tab</p> <p>Original Column G</p>	<p>Enter the number of unique issues contained within the grievance.</p>	<p>Added language to clarify how to respond when the questions is not applicable based on comments.</p>	<p>Enter the number of unique issues contained within the grievance.</p> <p>If the auditor did not select Resolution of participant grievances on the instructions tab the PO may enter NA in fields G-L.</p>	<p>No change</p>
<p>Grievances1P311P751P77</p> <p>Participant Impact Tab</p> <p>Original Column J</p>	<p>Which issues were unresolved? Enter a brief description.</p>	<p>Added language to clarify how to respond when the questions is not applicable based on comments.</p>	<p>Which issues were unresolved? Enter a brief description.</p> <p>Enter NA if all issues within the grievance were resolved.</p>	<p>No change</p>

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Grievances1P311P751P77 Participant Impact Tab Original Column K	Why were the issues not resolved?	Added language to clarify how to respond when the questions is not applicable based on comments.	Why were the issues not resolved?  Enter NA if all issues within the grievance were resolved.	No change
Grievances1P311P751P77 Participant Impact Tab Original Column L	Did the participant experience any negative outcomes as a result of the failure to resolve all issues within a grievance?  (Yes/No)	Added language to clarify how to respond when the questions is not applicable based on comments.	Did the participant experience any negative outcomes as a result of the failure to resolve all issues within a grievance?  (Yes/No)  Enter NA if all issues within the grievance were resolved.	No change
Grievances1P311P751P77 Participant Impact Tab Original Column M	Did the participant, their family members, or representative express a complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished during the audit review period?  (Yes/No)	Added language to clarify how to respond when the questions is not applicable based on comments.	Did the participant, their family members, or representative express a complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished during the audit review period?  (Yes/No)  If the auditor did not select Recognizing complaints as grievances on the instructions tab the PO may enter NA in fields M-V.  If the answer to this question is No enter NA in columns N-V	No change
Grievances1P311P751P77 Participant Impact Tab Original Column T	If yes, what was the resolution?	Added language to clarify how to respond when the questions is not applicable based on comments.	If yes, what was the resolution?  Enter NA if the complaint was not resolved outside of the grievance process.	No change
Grievances1P311P751P77 Participant Impact Tab Original Column U	If yes, when was it resolved?	Added language to clarify how to respond when the questions is not applicable based on comments.	If yes, when was it resolved?  Enter NA if the complaint was not resolved outside of the grievance process.	No change

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<p>Grievances1P311P751P77</p> <p>Participant Impact Tab</p> <p>Original Column W</p>	<p>Is their documentation that the participant was informed of the grievance process, in writing, upon enrollment?</p> <p>(Yes/No)</p> <p>Enter NA if the participant was not newly enrolled during the audit review period.</p>	<p>Added language to clarify how to respond when the questions is not applicable based on comments.</p>	<p>Is their documentation that the participant was informed of the grievance process, in writing, upon enrollment?</p> <p>(Yes/No)</p> <p>If the auditor did not select Discussing grievances with participants on the instructions tab the PO may enter NA in fields W-Z.</p> <p>Enter NA if the participant was not newly enrolled during the audit review period.</p>	<p>No change</p>
<p>HomeCare1P02</p> <p>Instructions Tab</p> <p>Scope</p>	<p>All participants enrolled at any point during the audit review period.</p>	<p>Modified the scope of the review based on comments.</p>	<ul style="list-style-type: none"> <li>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.</li> <li>The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.</li> </ul>	<p>Decrease - high</p>
<p>HomeCare1P02</p> <p>Instructions Tab</p> <p>Instructions</p>	<ul style="list-style-type: none"> <li>Review all relevant participant information/documentation to determine if home care services were not provided, delayed, or reduced at any point during the audit review period.</li> <li>The review timeframe is the audit review period. Issues noted before or after the audit review period should not be included.</li> <li>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.</li> <li>Respond to the questions in the participant impact tab for all participants. If a participant was not impacted by the condition (i.e., they received all home care services in a timely manner), the PO should enter No in Column F and NA in all additional blue fields. Please do not leave any blank spaces.</li> <li>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.</li> </ul>	<p>Modified the instructions to reflect the change in the scope of the review based on comments.</p>	<ul style="list-style-type: none"> <li>Review only the participant medical records selected by the auditor. The selected participants are identified in the Participant Impact tab.</li> <li>Review the selected medical records to determine if home care services were not provided, delayed, or reduced at any point during the audit review period.</li> <li>The review timeframe is the audit review period. Issues noted before or after the audit review period should not be included.</li> <li>Respond to the questions in the participant impact tab for all participants. If a participant was not impacted by the condition (i.e., they received all home care services in a timely manner), the PO should enter No in Column F and NA in all additional blue fields. Please do not leave any blank spaces.</li> <li>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.</li> </ul>	<p>No change</p>

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HomeCare1P02 Participant Impact Tab Original Column F	During the Audit Review Period  a. Did the IDT recommend or approve home care; b. Did a physician or NP 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 recommended, approved or ordered. (Yes/No)	Revised for clarity based on comments.	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.	No change
HomeCare1P02 Participant Impact Tab Original Column G	If the answer to column F is Yes, please indicate whether the home care was:  a. IDT recommended; b. Approved as part of a service delivery request; b. Approved a part of an appeal; c. Ordered by a physician or NP?  If the answer to column F is No, enter NA	Revised for clarity based on comments.	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?	No change
HomeCare1P02 Participant Impact Tab Original Column I	Enter the type of home care that was approved or recommended (e.g., chore services, medication administration, etc)  If the participant was approved for multiple types of home care services, please identify each on a separate line in the IA.	Revised for clarity based on comments.	Enter the type of home care that was determined necessary, approved or ordered (e.g., chore services, medication administration, etc.).  If the participant was approved for multiple types of home care services, please identify each on a separate line in the IA.	No change
HomeCare1P02 Participant Impact Tab Original Column J	Enter the date when home care was first recommended, approved, ordered, or care planned (start date).	Revised for clarity based on comments.	Enter the date when home care was first determined necessary, approved, ordered, or care planned (start date).	No change
HomeCare1P02 Participant Impact Tab Original Column L	Enter the total number of hours per week home care services were recommended, approved, ordered, or care planned.	Revised for clarity based on comments.	Enter the total number of hours per week home care services were determined necessary, approved, ordered, or care planned.	No change

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HomeCare1P02 Participant Impact Tab Original Column M	If there was a delay in providing home care, enter Delayed.  If home care services were never provided enter Not Provided.  If home care services were reduced, enter Reduced.	Revised for clarity based on comments.	If there was a delay in providing home care, enter Delayed.  If home care services were never provided enter Not Provided.  If home care services were reduced, enter Reduced.  Enter NA if home care services were promptly provided as approved/ordered.	No change
HomeCare1P02 Participant Impact Tab Original Column N	If there was a delay, when did the participant begin receiving the number of home care hours/schedule recommended, approved, ordered, or care planned?  If home care services were never provided enter Not Provided.	Revised for clarity based on comments.	If there was a delay, when did the participant begin receiving the number of home care hours/schedule determined necessary, approved, ordered, or care planned?  If home care services were never provided enter Not Provided.  Enter NA if home care services were promptly provided as approved/ordered.	No change
HomeCare1P02 Participant Impact Tab Original Column R	If the participant's recommended, approved, ordered, or care planned home care services were delayed or reduced or not provided, please explain the cause.	Revised for clarity based on comments.	If the participant's necessary, approved, ordered, or care planned home care services were delayed or reduced or not provided, please explain the cause.	No change
HomeCare1P02 Participant Impact Tab Original Column T	If Yes, please describe the Negative Outcomes?	Added language to clarify how to respond when the questions is not applicable based on comments.	If Yes, please describe the Negative Outcomes?  Enter NA if there were no negative outcomes.	No Change
MedErrors1P02 Instructions Tab Scope	All participants enrolled at any point during the audit review period.	Modified the scope of the review based on comments.	<ul style="list-style-type: none"> <li>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.</li> <li>The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.</li> </ul>	Decrease - high

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MedErrors1P02 Instructions Tab Instructions	<ul style="list-style-type: none"> <li>Review all participant documentation during the audit review period to determine if there were any medication errors.</li> <li>Respond to the questions in the participant impact tab.</li> <li>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.</li> <li>The review timeframe is the audit review period. Errors noted before or after the audit review period should not be included.</li> <li>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.</li> </ul>	Modified the instructions to reflect the change in the scope of the review based on comments.	<ul style="list-style-type: none"> <li>Review only the participant medical records selected by the auditor. The selected participants are identified in the Participant Impact tab.</li> <li>Review the selected medical records to determine if any medication errors occurred.</li> <li>Respond to the questions in the participant impact tab.</li> <li>The review timeframe is the audit review period. Errors noted before or after the audit review period should not be included.</li> <li>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.</li> </ul>	No change
MedErrors1P02 Participant Impact Tab Original Column S	If yes, describe the negative outcomes.	Added language to clarify how to respond when the questions is not applicable based on comments.	If yes, describe the negative outcomes.  Enter NA if the participant did not experience negative outcomes.	No change
MedRecs1P22	Removed	Removed based on comments.	Removed	Decrease - high
PACEIDT1P101P131P15	Removed	Removed based on comments.	Removed	Decrease - high
Personnel Instructions Tab Scope	<p>Initial personnel competencies:</p> <ul style="list-style-type: none"> <li>All staff, employed and contracted, who had direct participant contact in the PACE center or participant home AND were newly hired during the audit review period. Do not include any staff hired before the start of the audit review period.</li> </ul> <p>Personnel licensure:</p> <ul style="list-style-type: none"> <li>All staff, employed and contracted, who had direct participant contact in the PACE center or participant home during the audit review period.</li> </ul> <p>Background checks:</p> <ul style="list-style-type: none"> <li>All staff, employed and contracted, who had direct participant contact in the PACE center or participant home AND were newly hired during the audit review period. Do not include any staff hired before the start of the audit review period.</li> </ul>	Modified the scope of the review based on comments.	<p>Initial personnel competencies:</p> <ul style="list-style-type: none"> <li>The scope of the Impact Analysis is limited to 50% of staff (including employees and contractors) during the audit review period who were not included in the personnel sample selection and meet the following criteria: <ol style="list-style-type: none"> <li>Were newly hired during the audit review period; and</li> <li>Had direct participant contact in the PACE centers or participant homes.</li> </ol> </li> </ul> <p>Personnel licensure:</p> <ul style="list-style-type: none"> <li>The scope of the Impact Analysis is limited to 50% of staff (including employees and contractors) during the audit review period who were not included in the personnel sample selection and had direct participant contact in the PACE centers or participant homes.</li> </ul>	Decrease - high

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Personnel  Instructions Tab <i>(continued)</i>  Scope	<p>OIG exclusion checks:</p> <ul style="list-style-type: none"> <li>All staff, employed and contracted, who had direct participant contact in the PACE center or participant home AND were newly hired during the audit review period. Do not include any staff hired before the start of the audit review period.</li> </ul> <p>Background checks:</p> <ul style="list-style-type: none"> <li>All staff, employed and contracted, who had direct participant contact in the PACE center or participant home AND were newly hired during the audit review period. Do not include any staff hired before the start of the audit review period.</li> </ul> <p>Communicable disease clearance:</p> <ul style="list-style-type: none"> <li>All staff, employed and contracted, who had direct participant contact in the PACE center or participant home AND were newly hired during the audit review period. Do not include any staff hired before the start of the audit review period.</li> </ul> <p>Driver specific training:</p> <ul style="list-style-type: none"> <li>All staff, employed and contracted, who transported (drove) participants on behalf of the PACE organization.</li> </ul>	Modified the scope of the review based on comments.	<p>OIG exclusion checks:</p> <ul style="list-style-type: none"> <li>The scope of the Impact Analysis is limited to 50% of staff (including employees and contractors) during the audit review period who were not included in the personnel sample selection and meet the following criteria:               <ol style="list-style-type: none"> <li>Were newly hired during the audit review period; and</li> <li>Had direct participant contact in the PACE centers or participant homes.</li> </ol> </li> </ul> <p>Background checks:</p> <ul style="list-style-type: none"> <li>The scope of the Impact Analysis is limited to 50% of staff (including employees and contractors) during the audit review period who were not included in the personnel sample selection and meet the following criteria:               <ol style="list-style-type: none"> <li>Were newly hired during the audit review period; and</li> <li>Had direct participant contact in the PACE centers or participant homes.</li> </ol> </li> </ul> <p>Communicable disease clearance:</p> <ul style="list-style-type: none"> <li>The scope of the Impact Analysis is limited to 50% of staff (including employees and contractors) during the audit review period who were not included in the personnel sample selection and meet the following criteria:               <ol style="list-style-type: none"> <li>Were newly hired during the audit review period; and</li> <li>Had direct participant contact in the PACE centers or participant homes.</li> </ol> </li> </ul> <p>Driver specific training:</p> <ul style="list-style-type: none"> <li>The scope of the Impact Analysis is limited to 50% of staff (including employees and contractors) during the audit review period who were not included in the personnel sample selection and transported participants.</li> </ul>	Decrease - high

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Personnel Participant Impact Tab Original Column J	Is there documentation that the staff member's competency was evaluated prior to them working independently?  (Yes/No)  *This requirement only applies to personnel newly hired during the audit review period.  Enter NA if the employee did not have direct participant contact during the audit review period.	Added language to clarify how to respond when the questions is not applicable based on comments.	Is there documentation that the staff member's competency was evaluated prior to them working independently?  (Yes/No)  *This requirement only applies to personnel newly hired during the audit review period.  If the auditor did not select Initial personnel competencies on the instructions tab the PO may enter NA in fields J-L.  Enter NA if the employee did not have direct participant contact during the audit review period.	No change
Personnel Participant Impact Tab Original Column M	Is the staff member required to have a license in order to perform care in the PO's state?  (Yes/No)  *This requirement applies to all personnel.	Added language to clarify how to respond when the questions is not applicable based on comments.	Is the staff member required to have a license in order to perform care in the PO's state?  (Yes/No)  *This requirement applies to all personnel.  If the auditor did not select Personnel licensure on the instructions tab the PO may enter NA in fields M-O.	No change
Personnel Participant Impact Tab Original Column N	Type of license(s) required?  *This requirement applies to all personnel.	Added language to clarify how to respond when the questions is not applicable based on comments.	Type of license(s) required?  *This requirement applies to all personnel.  Enter NA if the staff member is not required to have a license.	No change
Personnel Participant Impact Tab Original Column O	Is there documentation that the staff member had a valid license during the audit review period?  (Yes/No)  *This requirement applies to all personnel.  Enter NA if the employee did not have direct participant contact during the audit review period.	Added language to clarify how to respond when the questions is not applicable based on comments.	Is there documentation that the staff member had a valid license during the audit review period?  (Yes/No)  *This requirement applies to all personnel.  Enter NA if the staff member is not required to have a license or did not have direct participant contact during the audit review period.	No change

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<p>Personnel</p> <p>Participant Impact Tab</p> <p>Original Column P</p>	<p>Is there documentation that an OIG exclusion check was completed before the date of hire?</p> <p>(Yes/No)</p> <p>*This requirement only applies to personnel newly hired during the audit review period.</p>	<p>Added language to clarify how to respond when the questions is not applicable based on comments.</p>	<p>Is there documentation that an OIG exclusion check was completed before the date of hire?</p> <p>(Yes/No)</p> <p>*This requirement only applies to personnel newly hired during the audit review period.</p> <p>If the auditor did not select OIG exclusion checks on the instructions tab the PO may enter NA in fields P-Q.</p>	<p>No change</p>
<p>Personnel</p> <p>Participant Impact Tab</p> <p>Original Column R</p>	<p>Is there documentation that a background check was completed before the date of hire?</p> <p>(Yes/No)</p> <p>*This requirement only applies to personnel newly hired during the audit review period.</p>	<p>Added language to clarify how to respond when the questions is not applicable based on comments.</p>	<p>Is there documentation that a background check was completed before the date of hire?</p> <p>(Yes/No)</p> <p>*This requirement only applies to personnel newly hired during the audit review period.</p> <p>If the auditor did not select Background checks on the instructions tab the PO may enter NA in fields R-S.</p>	<p>No change</p>
<p>Personnel</p> <p>Participant Impact Tab</p> <p>Original Column T</p>	<p>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?</p> <p>(Yes/No)</p> <p>*This requirement only applies to personnel newly hired during the audit review period.</p> <p>Enter NA if the staff member did not have direct participant contact during the audit review period.</p>	<p>Added language to clarify how to respond when the questions is not applicable based on comments.</p>	<p>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?</p> <p>(Yes/No)</p> <p>*This requirement only applies to personnel newly hired during the audit review period.</p> <p>If the auditor did not select Communicable disease clearance on the instructions tab the PO may enter NA in fields T-U.</p> <p>Enter NA if the staff member did not have direct participant contact during the audit review period.</p>	<p>No change</p>
<p>Personnel</p> <p>Participant Impact Tab</p> <p>Original Column U</p>	<p>Date the individual was screened/medically cleared of communicable diseases.</p> <p>MM/DD/YYYY</p> <p>Enter Not Completed if the individual was never medically cleared.</p>	<p>Added language to clarify how to respond when the questions is not applicable based on comments.</p>	<p>Date the individual was screened/medically cleared of communicable diseases.</p> <p>MM/DD/YYYY</p> <p>Enter Not Completed if the individual was never medically cleared.</p> <p>Enter NA if the staff member did not have direct participant contact during the audit review period.</p>	<p>No change</p>

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Personnel Participant Impact Tab Original 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.	Added language to clarify how to respond when the questions is not applicable based on comments.	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.	No change
Personnel Participant Impact Tab Original Column Y	Removed	Removed based on comments.	Removed	Decrease - high
Personnel Participant Impact Tab Original Column Z	Removed	Removed based on comments.	Removed	Decrease - moderate
PracticeScope1P33	Removed	Removed based on comments.	Removed	Decrease - high
ProvisionofServices1P021P81 Instructions Tab Scope	<ul style="list-style-type: none"> <li>All participants enrolled at any point during the audit review period.</li> </ul>	Modified the scope of the review based on comments.	<ul style="list-style-type: none"> <li>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.</li> <li>The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.</li> </ul>	Decrease - high

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ProvisionofServices1P021P81  Instructions Tab  Instructions	<ul style="list-style-type: none"> <li>Review all relevant participant documentation (e.g., medical record documentation) during the audit review period to determine if any necessary services or items were not provided. POs should consider any documentation and/or evidence that shows provision of services including the medical record, invoices, outside specialist notes, etc.</li> <li>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.</li> <li>Respond to the questions in the participant impact tab for all participants. If a participant was not impacted by the condition (i.e., they received all services in a timely manner), the PO should enter No in column F and then NA in all additional blue fields.</li> <li>Following the completion of the Participant Impact tab, POs should review and revised the Root Cause Analysis tab to reflect the final impact and make any additional changes necessary.</li> </ul>	Modified the instructions to reflect the change in the scope of the review based on comments.	<ul style="list-style-type: none"> <li>Review only the participant medical records selected by the auditor. The selected participants are identified in the Participant Impact tab.</li> <li>Review the selected medical records (e.g., medical record documentation) to determine if any necessary services or items were not provided. POs should consider any documentation and/or evidence that shows provision of services including the medical record, invoices, outside specialist notes, etc.</li> <li>Respond to the questions in the participant impact tab. If a participant was not impacted by the condition (i.e., they received all services in a timely manner), the PO should enter No in column F and then NA in all additional blue fields.</li> <li>Following the completion of the Participant Impact tab, POs should review and revised the Root Cause Analysis tab to reflect the final impact and make any additional changes necessary.</li> </ul>	No change
ProvisionofServices1P021P81  Participant Impact Tab  Original Column F	During the audit review period, were any services or items: <ul style="list-style-type: none"> <li>recommended by the IDT or an IDT member;</li> <li>Approved by IDT; or</li> <li>ordered by a PCP or physician extender;</li> </ul> <u>NOT</u> provided or delayed?  Enter <u>Yes</u> if the participant did <u>not</u> receive services, or if services were delayed.  Enter <u>No</u> if the participant received all services (in a timely manner).	Revised for clarity based on comments.	During the audit review period, were any services or items: <ul style="list-style-type: none"> <li>determined necessary by the IDT or an IDT member;</li> <li>Approved by IDT; or</li> <li>ordered by a PCP or physician extender;</li> </ul> <u>NOT</u> provided or delayed?  Enter <u>Yes</u> if the participant did <u>not</u> receive services, or if services were delayed.  Enter <u>No</u> if the participant received all services (in a timely manner).  If No, the organization may enter NA in all remaining fields.	No change

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ProvisionofServices1P021P81 Participant Impact Tab Original Column G	Was the delayed service/item:  <ul style="list-style-type: none"> <li>recommended by the IDT or an IDT member;</li> <li>Approved by IDT; or</li> <li>ordered by a PCP or physician extender?</li> </ul> If another scenario applies, please enter a brief description.  Enter NA if all services/items were provided to the participant.	Revised for clarity based on comments.	Was the delayed service/item:  <ul style="list-style-type: none"> <li>determined necessary by the IDT or an IDT member;</li> <li>Approved by IDT; or</li> <li>ordered by a PCP or physician extender?</li> </ul> If another scenario applies, please enter a brief description.	No change
ProvisionofServices1P021P81 Participant Impact Tab Original Column L	If the service/item was delayed, when was it provided to the participant?  MM/DD/YYYY  Enter Not Provided if the service/item was never provided.	Added language to clarify how to respond when the questions is not applicable based on comments.	If the service/item was delayed, when was it provided to the participant?  MM/DD/YYYY  Enter Not Provided if the service/item was never provided.  Enter NA if the service/item was not delayed.	No change
ProvisionofServices1P021P81 Participant Impact Tab Original Column P	If yes, describe the negative outcomes.	Added language to clarify how to respond when the questions is not applicable based on comments.	If yes, describe the negative outcomes.  Enter NA if the participant did not experience negative outcomes.	No change
Restraints1P09 Instructions Tab Scope	All participants enrolled during the audit review period.	Modified the scope of the review based on comments.	<ul style="list-style-type: none"> <li>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.</li> <li>The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.</li> </ul>	Decrease - high

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<p>Restraints1P09</p> <p>Instructions Tab</p> <p>Instructions</p>	<ul style="list-style-type: none"> <li>Review all participant medical record documentation during the audit review period to determine if restraints were utilized for any participants.</li> <li>Read each question carefully before responding.</li> <li>Respond to the questions in the participant impact tab.</li> <li>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.</li> <li>The review timeframe is the audit review period. Errors noted prior to the audit review period should not be included.</li> <li>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.</li> </ul>	<p>Modified the instructions to reflect the change in the scope of the review based on comments.</p>	<ul style="list-style-type: none"> <li>Review only the participant medical records selected by the auditor. The selected participants are identified in the Participant Impact tab.</li> <li>Review the selected medical records to determine if restraints were utilized for any participants.</li> <li>Read each question carefully before responding.</li> <li>Respond to the questions in the participant impact tab.</li> <li>The review timeframe is the audit review period. Errors noted prior to the audit review period should not be included.</li> <li>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.</li> </ul>	<p>No change</p>
<p>Restraints1P09</p> <p>Participant Impact Tab</p> <p>Original Column G</p>	<p>Were any physical devices, materials, or equipment used to restrict the participant's movement at any point during the audit review period?</p> <p>(Yes/No)</p>	<p>Added language to clarify how to respond when the questions is not applicable based on comments.</p>	<p>Were any physical devices, materials, or equipment used to restrict the participant's movement at any point during the audit review period?</p> <p>(Yes/No)</p> <p>If the answer to this question is no the PO may enter NA in all remaining fields.</p>	<p>No change</p>
<p>Restraints1P09</p> <p>Participant Impact Tab</p> <p>Original Column X</p>	<p>If yes, describe the negative outcomes.</p>	<p>Added language to clarify how to respond when the questions is not applicable based on comments.</p>	<p>If yes, describe the negative outcomes.</p> <p>Enter NA if the participant did not experience negative outcomes.</p>	<p>No change</p>
<p>SDRExtensions1P58</p>	<p>Removed</p>	<p>Removed based on PO comments to reduce burden.</p>	<p>Removed</p>	<p>Decrease - high</p>

SDRIdentification1P76  Instructions Tab  Scope	Review all participant medical records, on-call records, PAC minutes, etc. during the audit review period.	Modified the scope of the review based on comments.	<ul style="list-style-type: none"> <li>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.</li> <li>The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.</li> </ul>	Decrease - high
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Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
SDRIdentification1P76  Instructions Tab  Instructions	<ul style="list-style-type: none"> <li>Review all medical records, on-call records, PAC minutes, etc. during the audit review period to determine if the participant or participant's representative requested to initiate, eliminate, or continue a particular service.</li> <li>Answer the questions in the participant impact tab.</li> <li>The review timeframe is the audit review period. Errors noted before or after the audit review period should not be included.</li> <li>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.</li> </ul>	Modified the instructions to reflect the change in the scope of the review based on comments.	<ul style="list-style-type: none"> <li>Review only the participant medical records selected by the auditor. The selected participants are identified in the Participant Impact tab.</li> <li>Review the selected medical records to determine if the participant or participant's representative requested to initiate, eliminate, or continue a particular service.</li> <li>Respond to the questions in the participant impact tab.</li> <li>The review timeframe is the audit review period. Errors noted before or after the audit review period should not be included.</li> <li>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.</li> </ul>	No change
SDRIdentification1P76  Participant Impact Tab  Column N	Did the participant ever receive the requested item or service?  (Yes/No)	Modified and added language to clarify how to respond when the questions is not applicable based on comments.	<p>If the request was approved but the service was not provided, explain why.</p> <p>Enter NA if the request was never processed or the request was denied.</p>	No change
SDRIdentification1P76  Participant Impact Tab  Column P	What documentation/evidence is available to show that the participant received the service?  Enter Not Received if the participant never received the service.	Moved column and added language to clarify how to respond when the questions is not applicable based on comments.	<p>What documentation/evidence is available to show that the participant received the service?</p> <p>Enter Not Received if the participant never received the service.</p> <p>If the participant received the requested service, in full (i.e., as initially requested) the organization may enter</p>	Decrease - moderate

			NA in all remaining columns.	
SDRIdentification1P76  Participant Impact Tab  Column R	If yes, describe the negative outcomes.	Added language to clarify how to respond when the questions is not applicable based on comments.	If yes, describe the negative outcomes.  Enter NA if the participant did not experience negative outcomes.	No change

<b>Section in Current CMS-10630 (04/16/2019)</b>	<b>Original Language</b>	<b>Clarification or Change</b>	<b>Revised Language</b>	<b>Burden</b>
SDRs1P601P611P85  Participant Impact Tab  Original Column H	Is there documentation or evidence that the participant received oral notification of the denial?  (Yes/No)	Added language to clarify how to respond when the questions is not applicable based on comments.	Is there documentation or evidence that the participant received oral notification of the denial?  (Yes/No)  If the auditor did not select Oral and/or written service delivery request denial rationale on the instructions tab the PO may enter NA in fields H-K.	No change
SDRs1P601P611P85  Participant Impact Tab  Original Column L	Were there any negative participant outcomes as a result of the failure to provide oral and/or written notification including the specific reason for the denial in understandable language?  (Yes/No)	Removed based on comments.	Removed	Decrease - high
SDRs1P601P611P85  Participant Impact Tab  Original Column M	Is there documentation or evidence that the participant received oral notification of the denial?  (Yes/No)	Added language to clarify how to respond when the questions is not applicable based on comments.	Is there documentation or evidence that the participant received oral notification of the denial?  (Yes/No)  If the auditor did not select Oral and/or written service delivery request denial appeal notification on the instructions tab the PO may enter NA in fields L-O.	No change
SDRs1P601P611P85  Participant Impact Tab  Original Column Q	Were there any negative participant outcomes as a result of the failure to provide oral and/or written notification including appeal rights?  (Yes/No)	Removed based on comments.	Removed	Decrease - high

SDRs1P601P611P85 Participant Impact Tab Original Column R	Is there documentation that, at some point during the processing of the service delivery request, the request was reviewed by all 11 disciplines of the IDT?  (Yes/No)  In order to answer Yes, the organization must have documentation or evidence that all 11 disciplines reviewed the request between the request being made (participant indicating a need) and the decision being rendered (approving or denying the request).	Added language to clarify how to respond when the questions is not applicable based on comments.	Is there documentation that, at some point during the processing of the service delivery request, the request was reviewed by all 11 disciplines of the IDT?  (Yes/No)  In order to answer Yes, the organization must have documentation or evidence that all 11 disciplines reviewed the request between the request being made (participant indicating a need) and the decision being rendered (approving or denying the request).  If the auditor did not select Service delivery request review by IDT members on the instructions tab the PO may enter NA in fields P-U.	No change
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Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
SDRs1P601P611P85 Participant Impact Tab Original Column S	Which IDT members were involved in the review of the service delivery request?	Removed based on comments.	Removed	Decrease - low
SDRs1P601P611P85 Participant Impact Tab Original Column T	Which IDT members were NOT involved in the review of the service delivery request?	Added language to clarify how to respond when the questions is not applicable based on comments.	Which IDT members were NOT involved in the review of the service delivery request?  Enter NA if the service delivery request was reviewed by all 11 IDT disciplines.	No change
SDRs1P601P611P85 Participant Impact Tab Original Column V	For approvals, did the participant receive the service/item?  (Yes/No)	Added language to clarify how to respond when the questions is not applicable based on comments.	For approvals, did the participant receive the service/item?  (Yes/No)  Enter NA is the service delivery request was denied.	No change
SDRs1P601P611P85 Participant Impact Tab Original Column X	If the participant received the item/service, what was the date received?  MM/DD/YYYY	Added language to clarify how to respond when the questions is not applicable based on comments.	If the participant received the item/service, what was the date received?  MM/DD/YYYY  Enter NA is the service delivery request was denied.	No change

SDRs1P601P611P85 Participant Impact Tab Original Column X	What documentation or evidence is there to show the participant received the item or service?	Added language to clarify how to respond when the questions is not applicable based on comments.	What documentation or evidence is there to show the participant received the item or service?  Enter NA is the service delivery request was denied.	No change
SDRs1P601P611P85 Participant Impact Tab Original Column Y	Were there any negative participant outcomes as the result of a failure to ensure that the service delivery request was reviewed by the complete IDT?  (Yes/No)	Removed to reduce burden based on comments.	Removed	Decrease - high
SDRs1P601P611P85 Participant Impact Tab Original Column Z	If yes, describe the negative outcomes.	Removed based on comments.	Removed	Decrease - moderate

Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
SDR Identification1P76 Participant Impact Tab Original Column J	Is their documentation that the request was processed as a service delivery request?  (Yes/No)	Revised and relocated to column H for clarity based on comments.	Is their documentation that the request was processed as a service delivery request?  (Yes/No)  If there is documentation that the request was processed as a service delivery request, and included in the SDR universe submitted to CMS, you may enter NA in all remaining fields.	No change
SDR Identification1P76 Participant Impact Tab Original Column J	Did the participant ever receive the requested item or service?  (Yes/No)  Enter Not Received if the participant never received the service.	Revised for clarity based on comments.	Did the participant ever receive the requested item or service?  (Yes/No)  Enter Not Received if the participant never received the service.	No change
SrvcRestrict_1P.90 Instructions Tab Scope	All participants enrolled during the audit review period.	Modified the scope of the review based on comments.	<ul style="list-style-type: none"> <li>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.</li> <li>The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.</li> </ul>	Decrease - high

<p>SrvcRestrict_1P.90</p> <p>Instructions Tab</p> <p>Instructions</p>	<ul style="list-style-type: none"> <li>Review all participant medical records, service delivery requests, appeals, grievances and any other relevant documentation during the audit review period to determine if any limitations were applied to Medicare, Medicaid, or PACE benefits.</li> <li>Respond to the questions in the participant impact tab.</li> <li>The review timeframe is the audit review period. Errors noted before or after the audit review period should not be included.</li> <li>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.</li> </ul>	<p>Modified the instructions to reflect the change in the scope of the review based on comments.</p>	<ul style="list-style-type: none"> <li>Review only the participant medical records selected by the auditor. The selected participants are identified in the Participant Impact tab.</li> <li>Review the selected medical records to determine if any limitations were applied to Medicare, Medicaid, or PACE benefits.</li> <li>Respond to the questions in the participant impact tab.</li> <li>The review timeframe is the audit review period. Errors noted before or after the audit review period should not be included.</li> <li>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.</li> </ul>	<p>No change</p>
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Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
<p>SrvcRestrict_1P.90</p> <p>Participant Impact Tab</p> <p>Original Column F</p>	<p>During the audit review period, were any limitations applied to the amount, duration, or scope of Medicare or Medicaid benefits that were:</p> <ul style="list-style-type: none"> <li>requested by the participant/participant representative ;</li> <li>recommended by the IDT or an IDT member;</li> <li>Approved by IDT;</li> <li>Included in the participant's care plan; or</li> <li>ordered by a PCP or physician extender?</li> </ul> <p>(Yes/No)</p> <p>These limitation may include but are not limited to, Home Care, DME, Medications, Dental Services, Hearing Services, Nursing Facility stays/placement, ER use, etc.</p> <p>If no, the PO may enter NA in all remaining fields.</p>	<p>Revised for clarity based on comments.</p>	<p>During the audit review period, were any limitations applied to the amount, duration, or scope of Medicare or Medicaid benefits that were:</p> <ul style="list-style-type: none"> <li>requested by the participant/participant representative ;</li> <li>determined necessary by the IDT or an IDT member;</li> <li>Approved by IDT;</li> <li>Included in the participant's care plan; or</li> <li>ordered by a PCP or physician extender?</li> </ul> <p>(Yes/No)</p> <p>These limitation may include but are not limited to, Home Care, DME, Medications, Dental Services, Hearing Services, Nursing Facility stays/placement, ER use, etc.</p> <p>If no, the PO may enter NA in all remaining fields.</p>	<p>No change</p>
<p>SrvcRestrict_1P.90</p> <p>Participant Impact Tab</p> <p>Original Column G</p>	<p>Date of initial request/recommendation/approval.</p> <p>MM/DD/YYYY</p> <p>Each limitation must be described on a new line.</p>	<p>Revised for clarity based on comments.</p>	<p>Date of initial request/determination/approval.</p> <p>MM/DD/YYYY</p> <p>Each limitation must be described on a new line.</p>	<p>No change</p>



SrvcRestrict_1P.90 Participant Impact Tab Original Column H	Was the service:  <ul style="list-style-type: none"> <li>requested by the participant/participant representative</li> <li>;</li> <li>recommended by the IDT or an IDT member;</li> <li>Approved by IDT;</li> <li>Included in the participant's care plan;</li> <li>ordered by a PCP or physician extender; or</li> <li>ordered or recommended by a contracted or non-contracted provider?</li> </ul> If another scenario applies, please enter a brief description.	Revised for clarity based on comments.	Was the service:  <ul style="list-style-type: none"> <li>requested by the participant/participant representative;</li> <li>determined necessary by the IDT or an IDT member;</li> <li>Approved by IDT;</li> <li>Included in the participant's care plan;</li> <li>ordered by a PCP or physician extender; or</li> <li>ordered or recommended by a contracted or non-contracted provider?</li> </ul> If another scenario applies, please enter a brief description.	No change
SrvcRestrict_1P.90 Participant Impact Tab Original Column J	If the service was <u>requested</u> or <u>recommended</u> , what was the request or recommendation?  (Example: participant requested overnight home care)	Revised for clarity based on comments.	If the service was <u>requested</u> or <u>determined necessary by the IDT</u> , what was the request or recommendation?  (Example: participant requested overnight home care)	No change

Section in Current CMS-10630 (04/16/2019)	Original Language	Clarification or Change	Revised Language	Burden
SrvcRestrict_1P.90 Participant Impact Tab Original Column O	Did the participant ever receive the service without limitation (or as requested or recommended)?  (Y/N)	Revised for clarity based on comments.	Did the participant ever receive the service without limitation (per the original request or determination)?  (Y/N)	No change
SrvcRestrict_1P.90 Participant Impact Tab Original Column P	If yes, date the participant received the unlimited service (as requested or recommended).  MM/DD/YYYY	Revised for clarity and added language to clarify how to respond when the questions is not applicable based on comments.	If yes, date the participant received the unlimited service (per the original request or determination).  MM/DD/YYYY  Enter NA if there was a limitation applied.	No change
SrvcRestrict_1P.90 Participant Impact Tab Original Column P	If yes, describe the negative outcomes.	Added language to clarify how to respond when the questions is not applicable based on comments.	If yes, describe the negative outcomes.  Enter NA if the participant did not experience negative outcomes.	No change

WoundCare1P02 Instructions Tab Scope	All participants enrolled during the audit review period.	Modified the scope of the review based on comments.	<ul style="list-style-type: none"> <li>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.</li> <li>The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.</li> </ul>	Decrease - high
WoundCare1P02 Instructions Tab Instructions	<ul style="list-style-type: none"> <li>Review all relevant participant documentation during the audit review period to determine if each participant had one or more wounds.</li> <li>Respond to the questions in the participant impact tab.</li> <li>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.</li> <li>The review timeframe is the audit review period. Errors noted before or after the audit review period should not be included.</li> <li>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.</li> </ul>	Modified the instructions to reflect the change in the scope of the review based on comments.	<ul style="list-style-type: none"> <li>Review only the participant medical records selected by the auditor. The selected participants are identified in the Participant Impact tab.</li> <li>Review the selected medical records to determine if each participant had one or more wounds.</li> <li>Respond to the questions in the participant impact tab.</li> <li>The review timeframe is the audit review period. Errors noted before or after the audit review period should not be included.</li> <li>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.</li> </ul>	No change
<b>Section in Current CMS-10630 (04/16/2019)</b>	<b>Original Language</b>	<b>Clarification or Change</b>	<b>Revised Language</b>	<b>Burden</b>
WoundCare1P02 Participant Impact Tab Original Column I	If the wound was a pressure ulcer, enter the initial stage.	Added language to clarify how to respond when the questions is not applicable based on comments.	If the wound was a pressure ulcer, enter the initial stage.  Enter NA if the wound was not a pressure ulcer.	No change
WoundCare1P02 Participant Impact Tab Original Column K	Was wound care ordered by a physician, nurse practitioner, or physician assistant?  (Yes/No)	Updated requirement to reflect PACE regulatory changes effective 08/02/2019.	Was wound care ordered by a PCP?  (Yes/No)	No change
WoundCare1P02 Participant Impact Tab Original Column L	When was wound care ordered?  MM/DD/YYYY	Added language to clarify when questions are not applicable	When was wound care ordered?  MM/DD/YYYY  Enter NA if wound care was not ordered.	No change

WoundCare1P02 Participant Impact Tab Original Column M	Enter the wound care order, if applicable.	Added language to clarify when questions are not applicable	Enter the wound care order, if applicable. Enter NA if wound care was not ordered.	No change
WoundCare1P02 Participant Impact Tab Original Column O	How frequently was wound care to be completed?	Added language to clarify when questions are not applicable	How frequently was wound care to be completed? Enter NA if wound care was not completed.	No change
WoundCare1P02 Participant Impact Tab Original Column T	If wound care was not provided as ordered, please describe how the wound care provided differed from the wound care ordered.	Added language to clarify how to respond when the questions is not applicable based on comments.	If wound care was not provided as ordered, please describe how the wound care provided differed from the wound care ordered. Enter NA if wound care was provided as ordered.	No change
WoundCare1P02 Participant Impact Tab Original Column V	If yes, describe the negative outcomes.	Added language to clarify how to respond when the questions is not applicable based on comments.	If yes, describe the negative outcomes. Enter NA if participant did not experience negative outcomes.	No change
RootCauseTemplate	No change	No change	No change	No change