

Audit Review Period:	
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Issue(s) of non-compliance:	Auditors: Select All that Apply	Issue:
		Services provided by caregivers
		Services provided by individuals or entities not employed or contracted by the PACE organization (other than caregivers)

Scope:	<ul style="list-style-type: none"> • The scope of this Impact Analysis is no more than 50% of the participants enrolled during the audit review period who were not included in the provision of services sample selection. • The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.
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Instructions:	<p>General:</p> <ul style="list-style-type: none"> • Review only the participant medical records selected by the auditor. The selected participants are identified in the Participant Impact tab. • Respond to the questions in the participant impact tab. • The review timeframe is the audit review period. Errors noted before or after the audit review period should not be included. • After completing the Impact Analysis, if any changes need to be made to the Root Cause Analysis, please update the RCA tab. <p>Services provided by caregivers:</p> <ul style="list-style-type: none"> • Review the selected medical records to determine if caregivers were utilized by the PACE organization to provide services determined necessary by the IDT. <p>Services provided by individuals or entities not employed or contracted by the PACE organization (other than caregivers):</p> <ul style="list-style-type: none"> • Review the selected medical records to determine if any services determined necessary by the IDT were provided by an individual or entity that was not contracted with the PACE organization (other than caregivers).
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Impact Analysis Due Date:	
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According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1327. This information collection will allow CMS to conduct comprehensive reviews of PACE organizations to ensure compliance with regulatory requirements. The time required to complete this information collection is estimated at 780 per response, including the time to review instructions, search existing data resources, gather the data needed, to review and complete the information collection. This information collection is mandatory per CMS's authority under Section 1894 and 1934 of the Social Security Act and implementing regulations at 42 CFR § 460.190 and 460.194, which state that CMS, in conjunction with the State Administering Agency (SAA), audit PACE organizations (POs) annually for the first 3 contract years (during the trial period), and then on an ongoing basis following the trial period. Additionally, per § 460.200(a) PACE organizations are required to collect data, maintain records, and submit reports as required by CMS and the State administering agency. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

Tracking ID Number	Brief Description Of Issue (Completed By The CMS Audit Lead)	Type of Issue Identified (Completed By The CMS Audit Lead) (Applies to condition 1E.02 Only. For all other conditions enter N/A)	Detailed Description of the Issue (Explain what happened)
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Date Identified (MM/DD/YY) (Completed By The CMS Audit Lead)	Brief Description Of Issue (Completed By The CMS Audit Lead)	Condition Language (Completed By The CMS Audit Lead)
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<p>Root Cause Analysis for the Issue (Explain why it happened)</p>	<p>Methodology - Describe the process that was undertaken to determine the # of individuals (e.g. participants) impacted</p>	<p># of Individuals Impacted</p>	<p>Action Taken to Resolve System/ Operational Issues</p>
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Date System/ Operational Remediation Initiated (MM/DD/YY)	Date System/ Operational Remediation Completed (MM/DD/YY)	Actions Taken to Resolve Negatively Impacted Individuals Including Outreach Description and Status	Date Individual Outreach and Remediation Initiated (MM/DD/YY)	Date Individual Outreach and Remediation Completed (MM/DD/YY)
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Section 1 - General Information: This information is to be completed for all Impact Analyses					
Participant First Name	Participant Last Name	Medicare Beneficiary Identifier	Participant ID	Date of Enrollment MM/DD/YYYY	Date of Disenrollment MM/DD/YYYY Enter NA if the participant is still enrolled.

Section 2 - This information is to be completed if the Impact Analysis is being requested for Services provided by caregivers		
<p>Were any services determined necessary by the IPI provided by a caregiver (family, friends, etc.) who was unwilling, unable, or unsafe to provide the service during the audit review period?</p> <p>Yes/No</p> <p>If No, enter NA in all remaining columns in section 2.</p>	<p>During the audit review period, did the participant's caregiver(s) (family, friends, etc.) report that they were unwilling or unable to provide assistance with ADLs, IADLs, or supervision?</p> <p>Yes/No</p>	<p>If caregivers reported they were unwilling or unable to provide assistance with ADLs, IADLs, or supervision:</p> <ol style="list-style-type: none"> Identify whether the caregiver was unwilling or unable; and briefly describe the type(s) of assistance/supervision the caregivers were unwilling or unable to provide. Only list services that were determined necessary by the IPI and provided by the caregiver. <p>For example:</p> <ul style="list-style-type: none"> Unwilling to provide supervision between 7 PM and 7 AM, 7 days/week. Unable to provide assistance with bathing, 2 days/week. Unwilling to provide assistance with meal preparation, 2x/day, 5 days/week. <p>Enter each service that was in a new row.</p> <p>Please note: Impact analyses will be returned for correction if each service is not listed in a new row.</p> <p>Enter NA if the participant's caregivers were willing and able to provide assistance with ADLs, IADLs, and/or supervision.</p>

<p>Enter the first (earliest) date the participant's caregivers first reported they were unwilling or unable to provide assistance with ADLs, IADLs, or supervision. MM/DD/YYYY</p> <p>Enter NA if the participant's caregivers were willing and able to provide assistance with ADLs, IADLs, and/or supervision.</p>	<p>During the audit review period, did the ET determine that the participant's caregivers (family, friends, etc.) were unsafe to provide assistance with ADLs, IADLs, or supervision? (Yes/No)</p>	<p>If the ET determined the participant's caregivers were unsafe to provide assistance with ADLs, IADLs, or supervision, briefly describe the type(s) of assistance/supervision the caregivers were unsafe to provide. Only list services that were determined necessary by the ITT and provided by the caregiver. For example: <ul style="list-style-type: none"> ■ Unsafe to provide supervision between 7 PM and 7 AM, 7 days/week. ■ Unsafe to provide assistance with bathing, 2 days/week. ■ Unsafe to provide assistance with meal preparation, 2x/day, 5 days/week. Enter each service that was in a new row. Please note: Impact analyses will be returned for correction if each service is not listed in a new row. Enter NA if caregivers were safe to provide assistance with ADLs, IADLs, and/or supervision.</p>	<p>If the ET determined the participant's caregivers (family, friends, etc.) were unsafe to provide assistance with ADLs, IADLs, or supervision, briefly explain why the caregiver was unsafe to provide assistance. Enter NA if caregivers were safe to provide assistance with ADLs, IADLs, and/or supervision.</p>	<p>Enter the first (earliest) date the ET determined the participant's caregivers were unsafe to provide assistance with ADLs, IADLs, or supervision. MM/DD/YYYY</p> <p>Enter NA if caregivers were safe to provide assistance with ADLs, IADLs, and/or supervision.</p>
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If caregivers reported they were unwilling or unable to provide assistance/supervision (noted in columns H and I) or the DT determined caregivers were unsafe to provide assistance/supervision (noted in columns K and L), did the PO provide the services in full? Yes/No	If the PO did not provide the service in full, describe the services that were provided by the PO. Enter NA if the PO provided all services in full.	Enter the date when the PO began providing the services the service that were being provided by the caregiver. MM/DD/YYYY

Section 3 - This information is to be completed if the Impact Analysis is being requested for: Services provided by individuals or entities not employed or contracted by the PACE organization (other than caregivers)					
During the audit review period, did the participant receive any uncontracted, individual or organizational services from an individual or entity that was NOT contracted or employed by the PACE organization (other than a caregiver)?	Identify the services provided by the non-contracted individual or entity. If the service was a specialist visit/consultation, identify the type of specialist.	Enter the ICF determined the service was necessary	Identify the individual or entity that provided the services to the participant.	Date the services were provided to the participant	Why did the participant receive services through individuals or entities not employed or contracted by the PACE organization?
Yes/No If No, answer NA in all remaining columns in section 3.	Enter each service that was provided by a non-contracted individual or entity in a new row. Please note: Impact analyses will be returned for correction if each service is not listed in a grid cell .	MM/DD/YYYY		MM/DD/YYYY	

Section 4 - General Information: This information is to be completed for all Impact Analyses		
<p>Did the participant experience negative outcomes, in some part, as a result of services being provided by individuals or entities other than employees or contractors (including family members or caregivers)?</p> <p>(Yes/No)</p>	<p>If yes, describe the negative outcomes. Enter NA if the participant did not experience negative outcomes.</p>	<p>Optional: Please note, you do not have to complete this column. If there are any mitigating factors that you would like CMS to consider related to a specific participant, please enter the information in this column.</p>