

<b>Audit Review Period:</b>		
<b>Issue(s) of non-compliance:</b>	<b>Auditors:</b> Select All that Apply	<b>Issue:</b>
		Written notification prior to implementing palliative care, comfort care, or end-of-life care services
		Explaining palliative care, comfort care, or end-of-life care services
<b>Scope:</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.</li> </ul>	
<b>Instructions:</b>	<p><b>General:</b></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 palliative care, comfort care, or end-of-life care services were implemented during 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 RCA tab.</li> </ul> <p><b>Written notification prior to implementing palliative care, comfort care, or end-of-life care services:</b></p> <ul style="list-style-type: none"> <li>• Review the selected medical records to determine if written notification was provided to the participant before palliative care, comfort care, or end-of-life care services were implemented.</li> <li>• Respond to the questions in the Participant Impact tab.</li> </ul> <p><b>Explaining palliative care, comfort care, or end-of-life care services:</b></p> <ul style="list-style-type: none"> <li>• Review the selected medical records to determine if palliative care, comfort care, or end-of-life care services were explained to the participant before being implemented.</li> <li>• Respond to the questions in the Participant Impact tab.</li> </ul>	
<b>Impact Analysis Due Date:</b>		

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)	Root Cause Analysis for the Issue (Explain why it happened)
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Methodology - Describe the process that was undertaken to determine the # of individuals (e.g. participants) impacted	# of Individuals Impacted	Action Taken to Resolve System/ Operational Issues	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
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**Date Individual Outreach and Remediation  
Initiated  
(MM/DD/YY)**

**Date Individual Outreach and  
Remediation Completed  
(MM/DD/YY)**

Section 1 - General Information: This information is to be completed for all Impact Analyses						To be completed by the PO for each participant
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.	Palliative Care, Comfort Care, or End-of-life Care Services Were palliative care, comfort care, or end-of-life care services initiated during the audit review period? (Yes/No)  If the response to this question is No, enter NA in all remaining columns.

Section 2 - Written notification prior to implementing palliative care, comfort care, or end-of-life care services		
<p>Provision of Written Notification</p> <p>Did the PO inform the participant in writing before implementing palliative care, comfort care, or end-of-life care services?</p> <p>(Yes/No)</p> <p>If the auditor did not select Written notification prior to implementing palliative care, comfort care, or end-of-life care services on the instructions tab enter NA in all columns in Section 2.</p>	<p>Content of Written Notification - Impact to Care</p> <p>Did written notification inform the participant of how the PACE organization's palliative care, comfort care, or end-of-life care services differ from the care the participant was receiving and whether the services would be provided in addition to or in lieu of the care the participant is currently receiving?</p> <p>(Yes/No)</p>	<p>Content of Written Notification - Impact to Services</p> <p>Did written notification inform the participant of all services that would be impacted and provide how the services would be impacted if the participant or designated representative elected to initiate palliative care, comfort care, or end-of-life care?</p> <p>This must include but not limited to, physician services, including specialist services, hospital services, long-term care services, nursing services, social services, dietary services, transportation, home care, therapy, including physical, occupation, and speech therapy, behavioral health, diagnostic testing, including imaging and laboratory services, medications, preventative healthcare services, and PACE center attendance.</p> <p>(Yes/No)</p>

Content of Written Notification - Right to Revoke Consent	If the participant experienced negative outcomes, did they occur, in some part, as a result of a failure to provide written notification prior to initiating Palliative Care, Comfort Care, or End-of-life Care Services?
Did written notification inform the participant of the right to revoke or withdraw their consent to receive palliative, comfort, or end-of-life care at any time and for any reason, either verbally or in writing?	(Yes/No)
(Yes/No)	



Section 3 - Explaining palliative care, comfort care, or end-of-life care services		
<p>Explanation of Palliative Care, Comfort Care, or End-of-life Care Services</p> <p>Did the PO fully explain the palliative care, comfort care, or end-of- life treatment options before initiating palliative care, comfort care, or end-of- life care?</p> <p>(Yes/No)</p> <p>If the auditor did not select Explaining palliative care, comfort care, or end-of-life care services on the instructions tab enter NA in all columns in Section 3.</p>	<p>Written Consent</p> <p>Did the PO obtain written consent before initiating palliative care, comfort care, or end-of-life care?</p> <p>(Yes/No)</p>	<p>If the participant experienced negative outcomes, did they occur, in some part, as a result of a failure to fully explain the PO's Palliative Care, Comfort Care, or End-of-life Care Services?</p> <p>(Yes/No)</p>

Section 4 - General Information: This information is to be completed for all Impact Analyses	
<p>If the participant experienced any negative outcomes, please describe the negative outcomes.</p> <p>Enter NA if there were no negative outcomes.</p>	<p>Optional: Please note, you do not have to complete this column.</p> <p>If there are any mitigating factors that you would like CMS to consider related to a specific appeal, please enter the information in this column.</p>