

Audit Review Period:	
Issue of non-compliance:	Medication errors
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.
Instructions:	<ul style="list-style-type: none"> • Review only the participant medical records selected by the auditor. The selected participants are identified in the Participant Impact tab. • Review the selected medical records to determine if any medication errors occurred. • 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.
Impact Analysis Due Date:	

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 671 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 <u>1F.02 Only</u> . 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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Root Cause Analysis for the Issue (Explain why it happened)	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
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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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For the purpose of this Impact Analysis, a medication error is defined as: any preventable event that may cause or lead to inappropriate medication use or participant harm while the medication is in the control of the PACE Organization or one of its contracted providers. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

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.	Were all medications provided as ordered or authorized by the IDT during the audit review period? (Yes/No) If Yes, enter NA in all remaining columns.

<p>What type of medication error occurred?</p> <ul style="list-style-type: none"> • Wrong medication • Wrong dose • Wrong route • Not administered as frequently as ordered • Administered more frequently than ordered • Administration began before/after ordered start date (specify before or after) • Administration ended before/after ordered end date (specify before or after) • Dispensing error only (no medication taken/administered in error) • The medication was provided or administered without a PACE PCP order • A necessary medication was not provided or administered because the PACE PCP failed to execute an order for the medication <p>You may enter more than one type of error, if applicable.</p> <p>Enter <u>each</u> type of medication error in a <u>new row</u>. For example, if the participant received an incorrect dosage of Lantus insulin and, on a separate occasion, a dosage of Lantus insulin was omitted, the PO should enter the errors in two separate rows.</p> <p><u>Please note:</u> Impact analyses will be <u>returned</u> for correction if each type of medication error is not listed in a <u>new row</u>.</p>	<p>In what setting was or should the medication have been administered? (PACE Center, SNF, ALF, Home)</p>	<p>Did a medication error occur as a result of a failure to effectively coordinate care with a sub-acute facility such as a skilled nursing facility, nursing facility, assisted living facility, board and care facility, etc.?</p> <p>(Yes/No)</p>
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Medication Name

List each medication that was associated with a medication error in a new row.

Medication Dosage	Medication Route	Medication Frequency	Medication Start Date MM/DD/YYYY	Medication Discontinue Date MM/DD/YYYY Enter NA if the medication has not been discontinued.

Date the Medication Error Began (First occurrence of the medication error) MM/DD/YYYY	Date the Medication Error Ended (Last Occurrence of the medication error) MM/DD/YYYY	How many doses of medication were provided or omitted in error between the first and last date?	If the participant experienced negative outcomes, did they occur, in some part, as a result of a medication error? (Yes/No)

If yes, describe the negative outcomes.

Enter NA if the participant did not experience negative outcomes.

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.