Audit Review Period:	

Issue of non-compliance:	Restraints

Scope:	• The scope of this Impact Analysis is limited to 50% of the participants enrolled during the audit review period who were not included in the provision of services sample selection. • The auditor will select the participants to be reviewed and enter their identifying information on the Participant Impact tab.

Instructions:	• 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 restraints were utilized for any participants. • Read each question carefully before responding. • Respond to the questions in the participant impact tab. • The review timeframe is the audit review period. Errors noted prior to the audit review period should not be included. • After completing the Impact Analysis, if any changes need to be made to the Root Cause Analysis, please update the changes in the RCA tab.

Impact Analysis Due Date:	

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)

Detailed Description of the Issue (Explain what happened) (Remaining fields to be Completed by PACE Organization)	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

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)

For the purpose of this Impact Analysis, restraints are defined as: (1) A physical restraint is any manual method or physical or mechanical device, materials, or equipment attached or adjacent to the participant's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. (2) A chemical restraint is a medication used to control behavior or to restrict the participant's freedom of movement and is not a standard treatment for the participant's medical or psychiatric condition.

Participant First Name	Participant Last Name	Participant ID	Date of Enrollment MM/DD/YYYY	Date of Disenrollment MM/DD/YYYY	Reason for Disenrollment

Were any physical devices, materials, or equipment used to restrict the participant's movement at any point during the audit review period? (Yes/No) If the answer to this question is no the PO may enter NA in all remaining fields.	Describe the type of physical restraint. Enter NA if no physical restraints were used.	Were any medications used to control behavior or to restrict the participant's freedom of movement that is not a standard treatment for the participant's medical or psychiatric condition? (Yes/No)	Describe the type of chemical restraint. Enter NA if chemical restraints were not used.

Was a physician's order for the chemical restraint obtained prior to administration of the medication? (Yes/No) Enter NA if chemical restraints were not used.	Were any less restrictive methods utilized prior to the use of physical or chemical restraints? (Yes/No) Enter NA if physical and chemical restraints were not used.	Describe the less restrictive methods utilized prior to the use of physical or chemical restraints. Enter NA if physical and chemical restraints were not used.	Describe how it was determined that a physical or chemical restraint was necessary.

Date the restraint was initiated. MM/DD/YYYY Enter NA if no restraints were utilized.	Time the restraint was initiated. Enter NA if no restraints were utilized.	Was an assessment conducted to determine how long the restraint was needed? (Yes/No) Enter NA if no restraints were utilized.	Based on the assessment, how long was the restraint needed? Enter NA if no restraints were utilized or if no assessment was completed.	How frequently was the participant monitored while the restraint was applied? Enter NA if no restraints were utilized.

Date the restraint was discontinued. MM/DD/YYYY Enter NA if no restraints were utilized.	Time the restraint was discontinued. Enter NA if no restraints were utilized.	Were the PO's policies and procedures followed? (Yes/No) Enter NA if no restraints were utilized.	If the participant experienced negative outcomes, did they occur, in some part, as a result of the use of restraints? (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.