

Audit Review Period:	
Issue of non-compliance:	Restraints
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 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 RCA tab.
Impact Analysis Due Date:	

<p>Brief Description Of Issue (Completed By The CMS Audit Lead)</p>	<p>Type of Issue Identified (Completed By The CMS Audit Lead)</p> <p>(Applies to condition <u>1P.02 Only</u>. For all other conditions enter N/A)</p>	<p>Detailed Description of the Issue (Explain what happened)</p>
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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 purposes of this report, devices, restraints are defined as: 1) A physical restraint; 2. any mechanical or electronic mechanical device, appliance, or equipment attached or adjacent to the participant's body that he or she cannot easily remove that restricts freedom of movement or access to one's body; 3) 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	Research Branch/Study Identifier	Participant ID	Date of Enrollment	Date of Disenrollment	Were physical or chemical restraints used at any point during the study/review period?	Did the IRT ensure that all of the following criteria were met:	Enter the type of restraint	Did the IRT ensure the participant is dissatisfied?	Enter the IRT determined the restraint was needed.	Enter the restraint was released.	Enter the restraint was discontinued.	Was the restraint applied for the period of time determined by the IRT and removed or ended at the earliest possible time?	Was a PCT order for the chemical restraint obtained prior to administration of the medication?
				MM/DD/YYYY	MM/DD/YYYY [Enter NA if the participant is still enrolled.]	(Yes/No) If the answer to this question is No , enter NA in all remaining columns. + The IRT determined that a restraint was needed to ensure the participant's physical safety or the safety of others. + The restraints were imposed for a defined, limited period of time, based upon the assessed needs of the participant. + The restraints were imposed in accordance with safe and appropriate restraining techniques, sufficient to protect the participant or others from harm. + The restraints were removed or ended at the earliest possible time, and + The condition of the restrained participant was continually assessed, monitored, and reevaluated. If the answer to this question is Yes , enter NA in all remaining columns.	(Physical/Chemical) + A restraint was needed, + The type of restraint needed, and + How long the restraint was needed? (Yes/No)		MM/DD/YYYY [Enter NA if the IRT did not determine the restraint was needed.]	MM/DD/YYYY	MM/DD/YYYY	MM/DD/YYYY	(Yes/No) [Enter NA if the IRT did not determine how long the period of time the restraint was needed]	(Yes/No) [Enter NA if chemical restraints were not used.]

Pending OMB Approval (0938-New)

Were the restraints imposed in accordance with safe and appropriate restraining techniques? (Yes/No)	Were any less restrictive methods utilized prior to the use of physical or chemical restraints? (Yes/No)	Describe the less restrictive methods utilized prior to the use of physical or chemical restraints.	Did staff document that less restrictive methods were ineffective in protecting the participant and/or others from harm before the use of the restraint was initiated? (Yes/No)	Was the condition of the restrained participant continuously assessed, monitored, and reevaluated? (Yes/No)	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 OMB to consider related to a specific participant, please enter the information in this column.