

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:	

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 <u>1P.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)	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)**

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	Medicare Beneficiary Identifier	Participant ID	Date of Enrollment	Date of Disenrollment
				MM/DD/YYYY	MM/DD/YYYY
					Enter NA if the participant is still enrolled.

<p>Were physical or chemical restraints used at any point during the audit review period?</p> <p>(Yes/No)</p> <p>If the answer to this question is <u>No</u> enter NA in all remaining columns.</p>	<p>Did the PO ensure that <u>all</u> of the following criteria were met:</p> <ul style="list-style-type: none"> • The IDT 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, • The restraints were imposed only when other less restrictive measures have been found to be ineffective 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. <p>(Yes/No)</p> <p>If the answer to this question is <u>Yes</u> enter NA in all remaining columns.</p>	<p>Enter the type of restraint.</p> <p>(Physical/Chemical)</p>
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Did the IDT assess the participant to determine: • If a restraint was needed, • The type of restraint needed, and • How long the restraint was needed? (Yes/No)	Date the IDT determined the restraint was needed. MM/DD/YYYY Enter NA if the IDT did not determine the restraint was needed.	Date the restraint was initiated. MM/DD/YYYY	Date the restraint was discontinued. MM/DD/YYYY

<p>Was the restraint applied for the period of time determined by the IDT and removed or ended at the earliest possible time?</p> <p>(Yes/No)</p> <p>Enter NA if the IDT did not determine how long (the period of time) the restraint was needed</p>	<p>Was a PCP order for the chemical restraint obtained prior to administration of the medication?</p> <p>(Yes/No)</p> <p>Enter NA if chemical restraints were not used.</p>	<p>Were the restraints imposed in accordance with safe and appropriate restraining techniques?</p> <p>(Yes/No)</p>	<p>Were any less restrictive methods utilized prior to the use of physical or chemical restraints?</p> <p>(Yes/No)</p>
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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 continually 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)
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<p>If yes, describe the negative outcomes.</p> <p>Enter NA if the participant did not experience 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 participant, please enter the information in this column.</p>
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