

Scope: Participants enrolled during the audit review period.

Instructions:

- Respond to the relevant questions in the Detailed Sample Information and Root Cause Analysis tabs.
- Detailed Sample Information tab:
 - * Columns A and B - Will be completed by the audit lead.
 - * Column C - The PO will enter details relating to the investigation of each issue identified in Column A.
- Root Cause tab:
 - * Columns A through C - Will be completed by the audit lead.
 - * Columns D and E - The PO must enter the root cause or causes for the issue(s) which is summarized in

Column B

(Details for the individual issues are located in the Detailed Sample Information tab).

* Only complete columns E and if it is easily known (i.e., the root cause is based off of a disclosed issue (full investigation was already done) or the scope is easily determined based on the cause/ type of issue identified). If the scope is not easily known, enter NA in these columns.

* Only complete columns G through L if the condition relates to a disclosed issue for which correction was already initiated/completed. If the condition was first discovered on audit, the organization may enter NA in those columns.

Root Cause 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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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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