

**Audit Review Period:**

**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><b>Brief Description Of Issue</b> (Completed By The CMS Audit Lead)</p>	<p><b>Type of Issue Identified</b> (Completed By The CMS Audit Lead) (Applies to condition <u>1P.02</u> Only. For all other conditions enter N/A)</p>	<p><b>Detailed Description of the Issue</b> (Explain what happened)</p>
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<b>Date Identified (MM/DD/YY) (Completed By The CMS Audit Lead)</b>	<b>Brief Description Of Issue (Completed By The CMS Audit Lead)</b>	<b>Condition Language (Completed By The CMS Audit Lead)</b>
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<p><b>Root Cause Analysis for the Issue (Explain why it happened)</b></p>	<p><b>Methodology - Describe the process that was undertaken to determine the # of individuals (e.g. participants) impacted</b></p>	<p><b># of Individuals Impacted</b></p>	<p><b>Action Taken to Resolve System/ Operational Issues</b></p>
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<b>Date System/ Operational Remediation Initiated (MM/DD/YY)</b>	<b>Date System/ Operational Remediation Completed (MM/DD/YY)</b>	<b>Actions Taken to Resolve Negatively Impacted Individuals Including Outreach Description and Status</b>	<b>Date Individual Outreach and Remediation Initiated (MM/DD/YY)</b>	<b>Date Individual Outreach and Remediation Completed (MM/DD/YY)</b>
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