# Instructions

**Part D Formulary and Benefits Administration (FA)**
**Root Cause Analysis and Impact Analysis**

**1. Root Cause Analysis (RCA) - Complete as requested by CMS.**

- 'Description of Issue' tab
  - Complete columns G, H, I & J only. Provide a detailed description of the issue in column G, the root cause of that issue in column H, the methodology used to determine the root cause in column I, and the scope of the noncompliance in column J. The Team Lead will customize Column J for the noncompliance identified, as needed.
- Do not complete the 'Enrollee Impact' tab at this time.
- Remove "TEMPLATE" from the document title and upload the completed file in HPMS as a "Root Cause" File Type.

**2. Impact Analysis (IA)** **IA timeframe:** XX/XX/XXXX - XX/XX/XXXX

- Using the completed RCA document from Step 1, populate the remaining fields and tabs as follows.
- 'Description of Issue' tab:
  - Complete the remaining fields (Columns K through R).
  - After completing the Impact Analysis, review the root cause analysis and update columns G, H, I & J as needed (root cause analysis).
- 'Enrollee Impact' tab:
  - Include separate entries for each instance an enrollee experienced an inappropriate rejection at the point of sale as a result of the noncompliance during the IA timeframe above.
  - Also include enrollees that had the potential to be impacted by the noncompliance during the IA timeframe above, but did not experience rejected claims. For issues involving authorization records, complete columns A-D and J. Complete columns A-D for all other issues.
  - Only include Part D drugs.
  - Use the following calculations for completing column Y - Number of Days Enrollee Went Without Medication (Target or Related)
    *Enrollee received the same drug after the reject:* (Date of Subsequent Paid Claim for the Same Drug) - (Date of Rejected Claim)
    *Enrollee received a related drug after the reject:* (Date of Paid Claim for a Related Drug) - (Date of Rejected Claim)
  - Highlight the sample rows identified during the audit.
- **All fields must be populated.** Revision may be requested if the information provided is incomplete or insufficient.
- Upload the completed file to HPMS as an "Impact Analysis" file type.

| | COMPLETED BY CMS TEAM LEAD | | | | |
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| | **Root Cause Analysis Request** | | | | **Impact Analysis Request** |
| **Date Identified (CCYY/MM/DD)** | **Brief Description Of Issue** | **Condition Language** | **Related to Pre-Audit Issue Summary (PAIS)? (Y/N)** | **PAIS Number (If applicable)** | **Impact Analysis Request (CMS Team Lead to insert requested information here)** |
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| COMPLETED BY SPONSORING ORGANIZATION | | | |
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| **Root Cause Anaylsis Request** | | | |
| **Detailed Description of the Issue (Explain what happened)** | **Root Cause Analysis for the Overall Issue (Explain what happened beyond the case level)** | **Methodology Used to Determine Root Cause (Provide approach used to establish why the issue occurred; explain how the root cause was determined)** | **Scope of Noncompliance (Please describe how this noncompliance impacted your organization including its impact to any entities, systems and/or processes, as well as any potential enrollee impact)** |
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| **Impact Analysis Request** | | | | | | | |
| **# of Enrollees Impacted** | **Methodology Used to Determine the # of Enrollees Impacted** | **Action Taken to Resolve System/ Operational Issues** | **Date System/ Operational Remediation Initiated (CCYY/MM/DD)** | **Date System/ Operational Remediation Completed (CCYY/MM/DD)** | **Actions Taken to Resolve Negatively Impacted Enrollees Including Outreach Description and Status** | **Date Enrollee Outreach and Remediation Initiated (CCYY/MM/DD)** | **Date Enrollee Outreach and Remediation Completed (CCYY/MM/DD)** |
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| Enrollee ID | Contract ID | Plan Benefit Package (PBP) | Enrollment Effective Date | Date of Service | Date of Rejection | Time of Rejection | NDC | RxCUI | Drug Name and Strength |
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| Drug Quantity | Drug Days Supply | Reject Reason Code 1 | Pharmacy Message 1 | Pharmacy Service Type |
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| Patient Residence | Process Date of Subsequent Paid Claim | Process Time of Subsequent Paid Claim | Process Date of Paid Claim for a Related Drug | Process Time of Paid Claim for a Related Drug |
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| Related Drug NDC | Related Drug Name and Strength | Related Drug Quantity | Related Drug Days Supply | Number of Days Enrollee Went Without Medication (Target or Related) |
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| Compound Code | Patient Paid Amount ($) | Pharmacy Service Type | Patient Residence (e.g., LTC) | <Other requested data> | <Other requested data> | <Other requested data> |
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