

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.

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 0938-1395 (Expires MM/DD/CCYY). This is a mandatory information collection.

The time required to complete this information collection is estimated to average 390 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection.

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.

****CMS Disclosure**** Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office.

Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained.

If you have questions or concerns regarding where to submit your documents, please contact part_c_part_d_audit@cms.hhs.gov.

OMB Approval 0938-1395 (Expires MM/DD/CCYY)

	COMPLETED BY CMS TEAM LEAD				
	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)

COMPLETED BY SPONSORING ORGANIZATION			
Root Cause Analysis 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)

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)

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

Drug Quantity	Drug Days Supply	Reject Reason Code 1	Pharmacy Message 1	Pharmacy Service Type

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

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)

Compound Code	Patient Paid Amount (\$)	Pharmacy Service Type	Patient Residence (e.g., LTC)	<Other requested data>	<Other requested data>	<Other requested data>