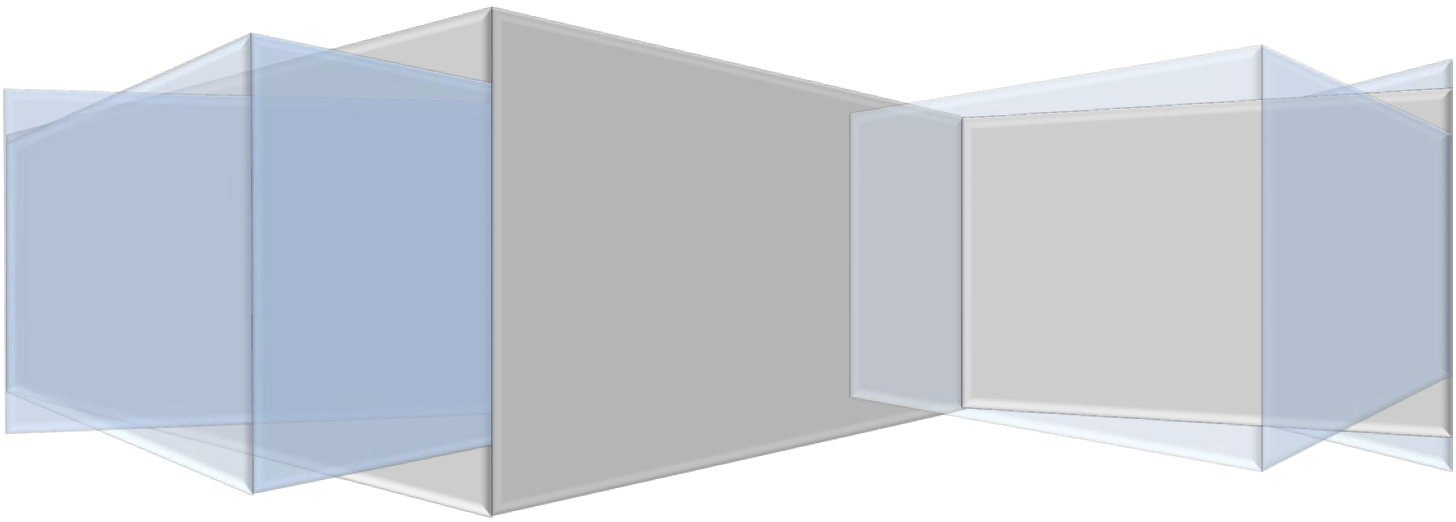
Part D Formulary and Benefit Administration (FA)

PROGRAM AUDIT PROTOCOL AND DATA REQUEST



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Program Audit Protocol

Purpose

To evaluate performance in the areas outlined in this Program Audit Protocol and Data Request related to Part D Formulary and Benefit Administration (FA). The Centers for Medicare and Medicaid Services (CMS) performs its program audit activities in accordance with the FA Program Audit Data Request and applying the compliance standards outlined in this Program Audit Protocol and the Program Audit Process Overview document. At a minimum, CMS will evaluate cases against the criteria listed below. CMS may review factors not specifically addressed below if it is determined that there are other related FA requirements not being met.

Audit Elements Tested

1. Formulary Administration
2. Transition

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Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Not Applicable	Universe Integrity Testing	Universe Table 1: Rejected Claims Formulary Administration (RCFA) Universe Table 2: Rejected Claims Transition (RCT)	Select 5 cases from each universe, Tables 1 and 2, for a total of 10 cases. Prior to field work, CMS will schedule a webinar with the Sponsoring organization to verify accuracy of data within each rejected claims universe submission for each of the sampled cases. Review all cases selected for universe integrity testing. The integrity of the universe will be questioned if data points specific to the sample case(s) are incomplete, do not match, or cannot be verified by viewing the Sponsoring organization's systems and/or other supporting documentation. Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled webinar.	42 CFR § 423.505(e) 42 CFR § 423.505(f)

Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Formulary Administration	1.1	Universe Table 1: Rejected Claims Formulary Administration (RCFA)	Select 30 targeted rejected claims relating to formulary administration (e.g., prior authorization, step therapy, non-formulary drugs, and quantity limitations). Ensure sample set represents a mix of claims for non-protected class drugs and claims for protected class drugs. Sampling criteria could include but is not limited to the following: Rejections for formulary drugs; Prior authorization rejections where the prior authorization edit is not approved; Step therapy rejections where the step therapy edit is not approved; Quantity limit rejections where the quantity limit edit is not approved or the quantity amount and/or day's supply are not within allowed limits; Rejection messaging is inconsistent with a drug's formulary status and the approved benefit. This includes non-formulary drugs; Rejections associated with high cost edits; Rejections for opioid related safety edits; Rejections associated with day supply limitations not consistent with the plan benefit; Rejections for Part B versus Part D medications; Rejections for short cycle fill; and Rejections for prescriber identification. Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled webinar. Review the 30 targeted samples selected above to ensure: The claim adjudication process follows the CMS approved formulary. Unapproved utilization management edits are not applied to restrict formulary and benefit access. Appropriate effectuation of authorization records typically resulting from a coverage determination.	42 CFR § 423.100 42 CFR § 423.104(a) 42 CFR § 423.104(h) 42 CFR § 423.104(c) 42 CFR § 423.154(a) Part D Contract with CMS 42 CFR § 423.120(b) 42 CFR § 423.272(b) CMS Approved Formulary CMS Approved Plan Bid

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Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Formulary Administration	1.2	Universe Table 1: Rejected Claims Formulary Administration (RCFA)	A select number of the 30 samples above will be reviewed to ensure: Appropriate administration of prior authorization or step therapy for enrollees filling protected class medications for the first time or currently taking the drug. Enrollees determined to be currently taking the drug should have access to a day supply consistent with their benefit.	42 CFR § 423.104(a) 42 CFR § 423.104(c) Part D Contract with CMS 42 CFR § 423.120(b)
Formulary Administration	1.3	Universe Table 1: Rejected Claims Formulary Administration (RCFA)	A select number of the 30 samples above will be reviewed to ensure: Appropriate administration of special requirements for long term care dispensing, such as short cycle fill requirements.	42 CFR § 423.154(a)
Formulary Administration	1.4	Universe Table 1: Rejected Claims Formulary Administration (RCFA)	A select number of the 30 samples above will be reviewed to ensure: Appropriate claim rejections based on prescriber identification information.	42 CFR § 423.120(c)
Formulary Administration	1.5	Universe Table 1: Rejected Claims Formulary Administration (RCFA) Universe Table 2: Rejected Claims Transition (RCT) Universe Table 3: Prescription Drug Event (PDE) Data	A select number of the 30 samples above will be reviewed to ensure: Appropriate administration of requirements related to the Part D drug management programs: • Appropriate administration of care coordination opioid safety edits • Pharmacy and prescriber coverage limitations • Appropriate administration of 7 day supply limit for initial opioid fills	42 CFR § 423.153 42 CFR § 423.120(b)

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Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Transition	2.1	Universe Table 1: Rejected Claims Formulary Administration (RCFA) Universe Table 2: Rejected Claims Transition (RCT) Universe Table 3: Prescription Drug Event (PDE) Data Universe Table 4: New Enrollee (NE)	Select a targeted sample of up to 15 claims from Universe Table 2 for continuing enrollees. The sample will consist of rejected claims related to cross-year formulary changes between the audit year and the previous contract year (e.g., formulary deletions). Select a targeted sample of up to 15 claims from Universe Table 2 for new enrollees. The sample will consist of rejected claims related to formulary administration during transition (e.g., prior authorization, step therapy, non-formulary drugs, and quantity limitations). Sample selections will be provided to the Sponsoring organization approximately one hour prior to the scheduled webinar. Review the 30 targeted samples selected above to determine if the rejection is appropriate. Identify and review any protected class rejections to look for broader issues that may affect one or more classes. Specifically review the samples to ensure that: New and continuing enrollees eligible for a transition fill are afforded the full transition benefit consistent with the submitted enrollment and disenrollment date; For continuing enrollees that have prior history of the drug determine the type of change that occurred between contract years for that drug; Enrollees with a November or December effective enrollment date are afforded a full continuing enrollee transition benefit, if applicable; Enrollees in long term care are afforded access to emergency supplies while an exception or prior authorization request is being processed; and Drugs available in their smallest package size are appropriately processed during transition.	42 CFR § 423.120(b)

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Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria Effective 01/01/2021
Transition	2.2	Universe Table 1: Rejected Claims Formulary Administration (RCFA) Universe Table 2: Rejected Claims Transition (RCT) Universe Table 3: Prescription Drug Event (PDE) Data Universe Table 4: New Enrollee (NE)	Review the 30 targeted samples selected above to ensure that: Enrollees and prescribers received appropriate, timely, and accurate transition fill notices.	42 CFR § 423.120(b)

Program Audit Data Request

Audit Engagement and Universe Submission Phase

Universe Submissions

Sponsoring organizations must submit each universe, comprehensive of all contracts and Plan Benefit Packages (PBP) identified in the audit engagement letter, in either Microsoft Excel (.xlsx) file format with a header row or Text (.txt) file format without a header row. Descriptions and clarifications of what must be included in each submission and data field are outlined in the individual universe record layouts below. Characters are required in all requested fields, unless otherwise specified, and data must be limited to the request specified in each record layout. Sponsoring organizations must provide accurate and timely universe submissions within 15 business days of the audit engagement letter date. Submissions that do not strictly adhere to the record layout specifications will be rejected.

Universe Requests

1. Universe Table 1: Rejected Claims Formulary Administration (RCFA) Record Layout
2. Universe Table 2: Rejected Claims Transition (RCT) Record Layout
3. Universe Table 3: Prescription Drug Event (PDE) Data Record Layout
4. Universe Table 4: New Enrollee (NE) Record Layout

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Universe Record Layout	Scope of Universe Request*
Table 1	Sponsoring organizations with – • < 20,000 enrollees: submit all rejected claims with dates of service for the 8-week period preceding and including, the date of the audit engagement letter (i.e., prior Month, Day, Year through audit engagement letter Month, Day, Year). • ≥ 20,000 but < 500,000 enrollees: submit all rejected claims with dates of service for the 4-week period preceding and including, the date of the audit engagement letter (i.e., prior Month, Day, Year through audit engagement Month, Day, Year). • ≥ 500,000 enrollees: submit all rejected claims with dates of service for the 2-week period preceding and including, the date of the audit engagement letter (i.e., prior Month, Day, Year through audit engagement Month, Day, Year).
Table 2	Sponsoring organizations with – • < 100,000 enrollees: submit all rejected claims with dates of service for January and February of the audit year. • ≥ 100,000 enrollees: submit all rejected claims with dates of service for January of the audit year.
Table 3	Submit all final action PDEs accepted by CMS with dates of service September – December of the contract year immediately prior to the audit year for all enrollees in Table 2 and enrollees with effective enrollment dates of November and December of the contract year immediately prior to the audit year.
Table 4	Sponsoring organizations with – • < 100,000 enrollees: submit all enrollees with effective enrollment dates 11/1/previous audit year through 2/1/current audit year. • ≥ 100,000 enrollees: submit all enrollees with effective enrollment dates 11/1/previous audit year through 1/1/current audit year.

***** CMS reserves the right to expand the review period to ensure sufficient universe size.

Please use the guidance below for the following record layouts:

Universe Table 1: Rejected Claims Formulary Administration (RCFA) Record Layout
Universe Table 2: Rejected Claims Transition (RCT) Record Layout

- Include all rejected claims with dates of service that fall within the applicable review period timeframe (including enrollees enrolled in employer plans and Medicare-Medicaid Plans (MMPs)).
- Do not filter data under any circumstances.
- Only fields that are submitted blank by the pharmacy may be submitted blank in the universe submission.

Column ID	Field Name	Field Type	Field Length	Description
A	Enrollee ID	CHAR Always Required	11	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaced the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes.
B	Enrollee First Name	CHAR Always Required	50	Enter the first name of the enrollee.
C	Enrollee Last Name	CHAR Always Required	50	Enter the last name of the enrollee.
D	Date of Birth	CHAR Always Required	10	Enter the date of birth of the enrollee. Submit in CCYY/MM/DD format (e.g., 1940/01/01).
E	Enrollment Effective Date	CHAR Always Required	10	Enter effective date of enrollment for the enrollee (PBP level). Enter the enrollment date relevant to the contract and plan ID of the enrollee at the time of the claim. Submit in CCYY/MM/DD format (e.g., 2020/01/01).

Column ID	Field Name	Field Type	Field Length	Description
F	Effective Disenrollment Date	CHAR Always Required	10	Enter effective date of disenrollment for the enrollee (PBP level). Enter the disenrollment date relevant to the contract and plan ID of the enrollee at the time of the claim. Submit in CCYY/MM/DD format (e.g., 2020/02/01). Enter NA if the enrollee was not disenrolled.
G	Cardholder ID	CHAR Always Required	20	Enter cardholder identifier used to identify the enrollee. This is assigned by the Sponsoring organization.
H	Contract ID	CHAR Always Required	5	Enter the contract number (e.g., H1234) of the Sponsoring organization.
I	Plan Benefit Package (PBP)	CHAR Always Required	3	Enter the PBP (e.g., 001).
J	NDC	CHAR Always Required	11	Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. When less than 11 characters or a blank field is submitted by the pharmacy or delegate, populate the field as submitted. If the pharmacy submits a value greater than 11 characters, enter “valueXeeded” in the field. For multi-ingredient compound claims populate the field with the NDC as would be submitted on a paid claim’s PDE.
K	Date of Service	CHAR Always Required	10	Enter the date of fill for the rejected claim. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
L	Date of Rejection	CHAR Always Required	10	Enter the date of rejection for the drug claim. Submit in CCYY/MM/DD format (e.g., 2020/01/01).

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Column ID	Field Name	Field Type	Field Length	Description
M	Claim Quantity	CHAR Always Required	11	Enter the number of drug dosage units entered in the claim (e.g., 30 [tablets], 0.42 [milliliters of liquid]), including decimal values, when applicable. Units of measurement should not to be reported.
N	Claim Days Supply	NUM Always Required	3	Enter the days' supply of the drug entered on the claim (e.g., 30 [days]). Units of measurement should not to be reported.
O	Patient Residence	CHAR Always Required	5	Enter the patient residence code for the enrollee as submitted by the pharmacy on the claim. While this may typically be an NCPDP value, other values submitted on the claim would be accepted.
P	Pharmacy Service Type	CHAR Always Required	5	Enter the Pharmacy service type as submitted by the pharmacy on the rejected claim. While this may typically be an NCPDP value, other values submitted on the claim would be accepted.
Q	Compound Code	CHAR Always Required	1	Enter code indicating whether or not the drug claim was for a compounded product. Valid values are: 0 = Not specified 1 = Not a Compound 2 = Compound
R	Reject Reason Code	CHAR Always Required	7	Enter the reason code associated with the rejected claim. This field should always be followed by the pharmacy message field. All reject codes associated with a claim must be included. Repeat the Reject Reason Code field as many times as needed to capture each individual reject reason code, followed by the corresponding pharmacy messaging related to the rejected claim. When a pharmacy message is generated without a reject reason code, enter NA in the reject reason code field.

Column ID	Field Name	Field Type	Field Length	Description
S	Pharmacy Message	CHAR Always Required	1,000	All pharmacy messages associated with the rejected claim must be included. If there are multiple messages associated with a single reject code, Sponsoring organizations must include all applicable messaging in the same message field (e.g., reject code 1: list all pharmacy messages, reject code 2: list all pharmacy messages, reject code 3: list all pharmacy messages). Repeat the Pharmacy Message field as needed after each reject reason code submitted. For pharmacy messages generated in the absence of a reject reason code, enter NA in the reject reason code field preceding the pharmacy message field. Likewise, when a reject reason code is generated without a related pharmacy message, enter NA in the pharmacy message field. NOTE: In limited circumstances, when the messaging cannot be separated for purposes of populating the universe, Sponsoring organizations may choose to include all pharmacy messaging in the first pharmacy message field only. For subsequent reject codes, please enter NA in the associated pharmacy message fields.

Please use the guidance below for the following record layout:

Universe Table 3: Prescription Drug Event (PDE) Data Record Layout

- Submit all final action PDEs accepted by CMS with dates of service September – December of the contract year immediately prior to the audit year, for enrollees in Table 2 and enrollees with effective enrollment dates of November and December of the contract year immediately prior to the audit year. Include enrollees in employer plans and Medicare- Medicaid Plans (MMPs).

Column ID	Field Name	Field Type	Field Length	Description
A	Enrollee ID	CHAR Always Required	11	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaces the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes.
B	Enrollee First Name	CHAR Always Required	50	Enter first name of the enrollee.
C	Enrollee Last Name	CHAR Always Required	50	Enter the last name of the enrollee.
D	Date of Birth	CHAR Always Required	10	Enter the date of birth of the enrollee. Submit in CCYY/MM/DD format (e.g., 1940/01/01).
E	Cardholder ID	CHAR Always Required	20	Enter cardholder identifier used to identify the enrollee. This is assigned by the Sponsoring organization.
F	Contract ID	CHAR Always Required	5	Enter the contract number (e.g., H1234) of the Sponsoring organization.
G	Plan Benefit Package (PBP)	CHAR Always Required	3	Enter the PBP (e.g., 001).

Column ID	Field Name	Field Type	Field Length	Description
H	NDC	CHAR Always Required	11	Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. When less than 11 characters or a blank field is submitted by the pharmacy or delegate, populate the field as submitted. If the pharmacy submits a value greater than 11 characters, enter "valueXeeded" in the field. For multi-ingredient compound claims populate the field with the NDC as would be submitted on a paid claim's PDE.
I	Date of Service	CHAR Always Required	10	This field contains the date on which the prescription was filled. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
J	Claim Quantity	CHAR Always Required	11	Enter number of drug dosage units entered in the claim (e.g., 30 [tablets], 0.42 [milliliters of liquid]), including decimal values, when applicable. Units of measurement should not to be reported.
K	Claim Days Supply	NUM Always Required	3	Enter the days' supply of the drug entered in the claim (e.g., 30 [days]). Units of measurement should not to be reported.
L	Compound Code	CHAR Always Required	1	Enter code indicating whether or not the drug claim was for a compounded product. Valid values are: 0 = Not specified 1 = Not a compound 2 = Compound

Please use the guidance below for the following record layout:

Universe Table 4: New Enrollee (NE) Record Layout

- Only include eligible enrollees for which the Sponsoring organization does not **utilize** prior claims history for purposes of providing transition supplies. In some cases, the Sponsoring organization may have the full claims history for the enrollee from the most recent PBP, and thus, the Sponsoring organization may be able to determine new versus ongoing therapy. In this example, the enrollee should not be included in the New Enrollee Universe since they are determined to be a continuing enrollee.

Column ID	Field Name	Field Type	Field Length	Description
A	Enrollee ID	CHAR Always Required	11	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaces the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes.
B	Enrollee First Name	CHAR Always Required	50	Enter the first name of the enrollee.
C	Enrollee Last Name	CHAR Always Required	50	Enter the last name of the enrollee.
D	Date of Birth	CHAR Always Required	10	Enter the date of birth of the enrollee. Submit in CCYY/MM/DD format (e.g., 1940/01/01).
E	Enrollment Effective Date	CHAR Always Required	10	Enter the effective date of enrollment for the enrollee (PBP level). Submit in CCYY/MM/DD format (e.g., 2020/01/01). In this table only, a separate record should be entered each time an enrollee is enrolled and considered a new enrollee.
F	Effective Disenrollment Date	CHAR Always Required	10	Enter the effective date of disenrollment for the enrollee (PBP level). Submit in CCYY/MM/DD format (e.g., 2020/02/01). Enter NA if the enrollee was not disenrolled.

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Column ID	Field Name	Field Type	Field Length	Description
G	Cardholder ID	CHAR Always Required	20	Enter the cardholder identifier used to identify the enrollee. This is assigned by the Sponsoring organization.
H	Contract ID	CHAR Always Required	5	Enter the contract number (e.g., H1234, S1234) of the Sponsoring organization.
I	Plan Benefit Package (PBP)	CHAR Always Required	3	Enter the PBP (e.g., 001).

Supplemental Documentation Submission
Sponsoring organizations must submit the requested documentation identified below in either a Microsoft Word (.docx), Microsoft Excel (.xlsx.), or Adobe Portable Document File (.pdf). Sponsoring organizations must submit this documentation within 5 business days of the audit engagement letter date, unless otherwise specified.

Supplemental Documentation Request

1. FA Supplemental Questionnaire

Audit Field Work Phase

Supporting Documentation Submissions
During audit field work, CMS will review 30 samples selected from Table 1 and up to 30 samples from Table 2 to determine whether the Sponsoring organization is compliant with its Part D contract requirements. To facilitate this review, the Sponsoring organization must have access to, and the ability to save and upload screenshots of, supporting documentation and data relevant to a particular case, including, but not limited to:

- Enrollee Information
  - Enrollee Name
  - Cardholder or enrollee ID
  - CMS Contract ID
  - CMS Plan Benefit Package (PBP) number
  - Effective date of enrollment
- Rejected and/or Paid Claim Information
  - National Drug Code (NDC)
  - Drug name, strength, dosage form, route of administration
  - Quantity
  - Days' supply
  - Date of service
  - Date and time of rejection
  - Rejection code and messaging to pharmacy
  - Dispense As Written (DAW) code
  - Pharmacy National Provider Identifier (NPI)
  - Whether prior authorization was used to process the claim. If an authorization was used, a

screenshot that documents the level (e.g., GPI-6) and duration of the authorization.
  - Comment log associated with the rejected claim that displays the pharmacy messages
  - A history of all rejected and paid claims for the same drug (brand name, dosages form, route of administration) during the audit year
  - Claim payment information including enrollee pay amount, LIS amount, and Sponsoring organization's responsibility
- Transition Notice
  - Enrollee transition notice
  - Prescriber transition notice and/or prescriber notification

Sponsoring organizations must submit supporting documentation within 2 business days of the request.

Root Cause Analysis Submissions
Sponsoring organizations may be required to provide a root cause analysis using the Root Cause Template provided by CMS. Sponsoring organizations have 2 business days from the date of request to respond.

Impact Analysis Submissions
When noncompliance with contract requirements is identified on audit, Sponsoring organizations must submit each requested impact analysis, comprehensive of all contracts and Plan Benefit Packages (PBP) identified in the audit engagement letter, in either Microsoft Excel (.xlsx) file format with a header row or Text (.txt) file format without a header row. Descriptions and clarifications of what must be included in each submission and data field are outlined in the individual tables below. Characters are required in all requested fields, unless otherwise specified, and data must be limited to the request specified in each table. Sponsoring organizations must provide accurate and timely impact analysis submissions within 10 business days of the request. Submissions that do not strictly adhere to the record layout specifications will be rejected.

Impact Analysis Requests
1. Table 1IA: Impact Analysis Summary (IAS) Record Layout
2. Table 2IA: Enrollee Impact Analysis (ENR-IA) Record Layout

Impact Analysis Record Layout	Scope of Impact Analysis Request
Table 1IA Table 2IA	Formulary Administration: Submit a list of all medications and/or enrollees impacted by the noncompliance. The time period must encompass the date the impact analysis is requested through the start date of the universe period.

Table 1IA Table 2IA	Transition: Submit a list of all medications and/or enrollees impacted by the noncompliance. The time period must encompass the date the impact analysis is requested through January 1st of the current year. **Please note:** When testing transition for enrollees with late enrollment in the previous year (November or December), the impact analysis should go back to the date of the enrollee's new enrollee enrollment date in the previous year.

Please use the guidance below for the following record layout:

Table 1IA: Impact Analysis Summary (IAS) Record Layout

- Include all medications impacted by the issue, including those that may not have an associated rejected claim.

Column ID	Field Name	Field Type	Field Length	Description
A	Methodology for Identifying Impact of Noncompliance	CHAR Always Required	4, 000	Describe the process undertaken to determine the medications and enrollees impacted by the issue of noncompliance.
B	List of Medications Affected	CHAR Always Required	4, 000	Provide the list of medications at the RXCUI level (by drug name, strength, and dosage form) affected by the issue in vertical list format.
C	Actions Taken to Resolve System/Operational Issues	CHAR Always Required	4,000	Enter the actions taken to resolve the system/operational issue.
D	Date System/Operational Remediation Initiated	CHAR Always Required	10	Enter the date (CCYY/MM/DD) that the system/operational remediation of the issue was initiated.
E	Date System/Operational Remediation Completed	CHAR Always Required	10	Enter the date (CCYY/MM/DD) that the system/operational remediation of the issued was completed.
F	Actions Taken to Resolve Negatively Impacted Enrollees Including Outreach Description and Status	CHAR Always Required	4,000	Enter the actions taken to resolve negatively impacted enrollees.
G	Date Enrollee Outreach and Remediation Initiated	CHAR Always Required	10	Enter the date (CCYY/MM/DD) that enrollee outreach and remediation was initiated.
H	Date Enrollee Outreach and Remediation Completed	CHAR Always Required	10	Enter the date (CCYY/MM/DD) that enrollee outreach and remediation was completed.

Please use the guidance below for the following record layout:

Table 2IA: Enrollee Impact Analysis (ENR-IA) Record Layout

- Include the following data for impacted enrollees:
  - Rejected claims affected by the issue of noncompliance;
  - Inaccurate records (i.e. authorization, enrollment records) that may not be associated with a rejected claim. In this scenario, Sponsoring organizations should only complete the following fields: Enrollee ID, Contract ID, Plan Benefit Package (PBP), Enrollment Effective Date, and Drug Name and Strength (if applicable).
- Include separate entries for an enrollee each time he/she experienced an inappropriate rejection at the point of sale as a result of the noncompliance.

Column ID	Field Name	Field Type	Field Length	Description
A	Enrollee ID	CHAR Always Required	11	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. An MBI is the non-intelligent unique identifier that replaces the HICN on Medicare cards as a result of The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes.
B	Contract ID	CHAR Always Required	5	Enter the contract number (e.g., H1234) of the Sponsoring organization.
C	Plan Benefit Package (PBP)	CHAR Always Required	3	Enter the PBP (e.g., 001).
D	Enrollment Effective Date	CHAR Always Required	10	Enter the effective date of enrollment for the enrollee (PBP level). Enter the enrollment date relevant to the contract and plan ID of the enrollee at the time of the claim. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
E	Date of Service	CHAR Always Required	10	Enter the date a fill for a rejected claim was attempted. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
F	Date of Rejection	CHAR Always Required	10	Enter date of rejection for the drug claim. Submit in CCYY/MM/DD format (e.g., 2020/01/01).

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Column ID	Field Name	Field Type	Field Length	Description
G	Time of Rejection	CHAR Always Required	8	Enter the time of rejection for the drug claim. Submit in HH:MM:SS military time format (e.g., 23:59:59).
H	NDC	CHAR Always Required	11	Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. When less than 11 characters or a blank field is submitted by the pharmacy or delegate, populate the field as submitted. If the pharmacy submits a value greater than 11 characters, enter "valueXeeded" in the field. For multi-ingredient compound claims populate the field with the NDC as would be submitted on a paid claim's PDE.
I	RxCUI	CHAR Always Required	10	Enter the RxNorm concept unique identifier
J	Drug Name and Strength	CHAR Always Required	150	Enter the drug name and strength.
K	Drug Quantity	CHAR Always Required	11	Enter the number of drug dosage units entered in the claim (e.g., 30 [tablets], 0.42 [milliliters of liquid]), including decimal values, when applicable. Units of measurement should not to be reported.
L	Drug Days Supply	NUM Always Required	3	Enter the days' supply of the drug entered on the claim (e.g., 30 [days]). Units of measurement should not to be reported.

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Column ID	Field Name	Field Type	Field Length	Description
M	Reject Reason Code	CHAR Always Required	7	Enter the reason code associated with the rejected claim. This field should always be followed by the pharmacy message field. All reject codes associated with a claim must be included. Repeat the Reject Reason Code field as many times as needed to capture each individual reject reason code, followed by the corresponding pharmacy messaging related to the rejected claim. When a pharmacy message is generated without a reject reason code, enter NA in the reject reason code field.

Column ID	Field Name	Field Type	Field Length	Description
N	Pharmacy Message	CHAR Always Required	1,000	All pharmacy messages associated with the rejected claim must be included. If there are multiple messages associated with a single reject code, Sponsoring organizations must include all applicable messaging in the same message field (e.g., reject code 1: list all pharmacy messages, reject code 2: list all pharmacy messages, reject code 3: list all pharmacy messages). Repeat the Pharmacy Message field as needed after each reject reason code submitted. For pharmacy messages generated in the absence of a reject reason code, enter NA in the reject reason code field preceding the pharmacy message field. Likewise, when a reject reason code is generated without a related pharmacy message, enter NA in the pharmacy message field. NOTE: In limited circumstances, when the messaging cannot be separated for purposes of populating the universe, Sponsoring organizations may choose to include all pharmacy messaging in the first pharmacy message field only. For subsequent reject codes, please enter NA in the associated pharmacy message fields.
O	Pharmacy Service Type	CHAR Always Required	5	Enter the pharmacy service type as submitted by the pharmacy on the rejected claim. While this may typically be an NCPDP value, other values submitted on the claim would be accepted.

Column ID	Field Name	Field Type	Field Length	Description
P	Patient Residence	CHAR Always Required	5	Enter the patient residence code for the enrollee as submitted by the pharmacy on the rejected claim. While this may typically be an NCPDP value, other values submitted on the claim would be accepted.
Q	Process Date of Subsequent Paid Claim	CHAR Always Required	10	Enter the date of the paid claim subsequent to the rejected claim for the medication utilizing the same RXCUI, GPI, GCN, or HICL. Submit in CCYY/MM/DD format (e.g., 2020/01/01). Enter NA if never received.
R	Process Time of Subsequent Paid Claim	CHAR Always Required	8	Enter the time of the paid claim subsequent to the rejected claim. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter NA if never received.
S	Process Date of Paid Claim for a Related Drug	CHAR Always Required	10	Enter the date of the paid claim for a related drug subsequent to the rejected claim. Submit in CCYY/MM/DD (e.g., 2020/01/01). Enter NA if never received.
T	Process Time of Paid Claim for a Related Drug	CHAR Always Required	8	Enter the time of the paid claim for a related drug subsequent to the rejected claim. Submit in HH:MM:SS military time format (e.g., 23:59:59). Enter NA if never received.

Column ID	Field Name	Field Type	Field Length	Description
U	Related Drug NDC	CHAR Always Required	11	Enter the 11-Digit National Drug Code using the NDC 11 format. Remove special characters separating the labeler, product, and trade package size. When less than 11 characters or a blank field is submitted by the pharmacy or delegate, populate the field as submitted. If the pharmacy submits a value greater than 11 characters, enter "valueXeeded" in the field. For multi-ingredient compound claims populate the field with the NDC as would be submitted on a paid claim's PDE.
V	Related Drug Name and Strength	CHAR Always Required	150	Enter the drug name and strength for the related drug.
W	Related Drug Quantity	CHAR Always Required	11	Enter the number of drug dosage units entered in the claim (e.g., 30 [tablets], 0.42 [milliliters of liquid]), including decimal values, when applicable for related drug. Units of measurement should not to be reported.
X	Related Drug Days Supply	NUM Always Required	3	Enter the days' supply of the drug entered on the claim for related drug (e.g., 30 [days]). Units of measurement should not to be reported.
Y	Number of Days Enrollee Went Without Medication (Target or Related)	CHAR Always Required	5	Enter the number of days the enrollee went without medication (target or related) - Enter NA if never received. A whole number is acceptable in this field. **NOTE**: The Date of Rejection should be used in this calculation (not Date of Service).

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Column ID	Field Name	Field Type	Field Length	Description
Z	Compound Code	CHAR Always Required	1	Enter the code indicating whether or not the drug claim was for a compounded product. Valid values are: 0 = Not specified 1 = Not a Compound 2 = Compound
AA	Patient Paid Amount ($)	CHAR Always Required	10	Enter the amount the enrollee paid for the subsequent paid claim for the target or related drug. Enter NA if the enrollee never received the drug.
AB	Pharmacy Service Type	CHAR Always Required	5	Enter the pharmacy service type as submitted by the pharmacy on the paid claim.
AC	Patient Residence (e.g., LTC)	CHAR Always Required	5	Enter the patient residence code for the enrollee as submitted by the pharmacy on the paid claim.
AD	<Other requested data>	CHAR Always Required	1,000	This field is for any other requested data.
AE	<Other requested data>	CHAR Always Required	1,000	This field is for any other requested data.
AF	<Other requested data>	CHAR Always Required	1,000	This field is for any other requested data.

Verification of Information Collected: CMS may conduct integrity tests to validate the accuracy of all universes, impact analyses, and other related documentation submitted in furtherance of the audit. If data integrity issues are noted, Sponsoring organizations may be required to resubmit their data.