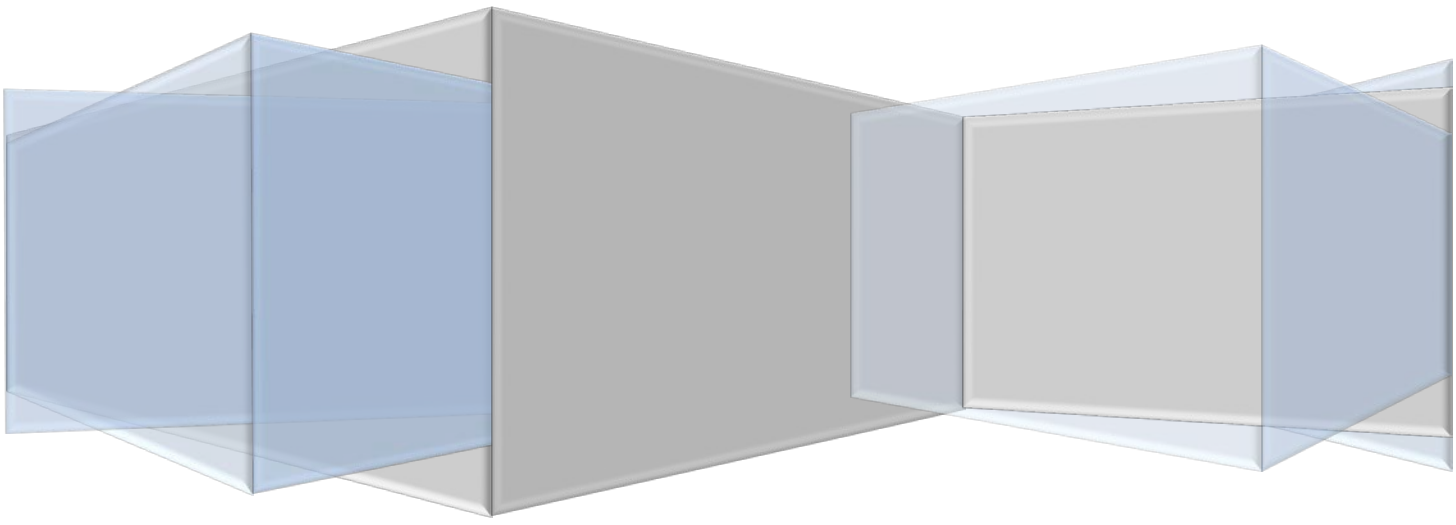
Part D Formulary and Benefit Administration (FA)

PROGRAM AUDIT PROTOCOL AND DATA REQUEST



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Program Audit Protocol and Data Request
Part D Formulary and Benefit Administration (FA)

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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, but reserves the right to modify its scope as requirements are added or revised and reserves the right to select additional samples if further investigation of an issue is required and/or replace samples if the original sample selection is not relevant to the review.

Audit Elements Tested

1. Formulary Administration
2. Transition

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Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
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)

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Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Formulary Administration	1.1	Universe Table 1: Rejected Claims Formulary Administration (RCFA)	Select up to 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 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	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

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			resulting from a coverage determination.	

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Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Formulary Administration	1.2	Universe Table 1: Rejected Claims Formulary Administration (RCFA)	A select number of the 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 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 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)	A select number of the 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
Transition	2.1	Universe Table 1: Rejected Claims Formulary Administration (RCFA) Universe Table 2: Rejected Claims Transition (RCT) Universe Table 3: New Enrollee (NE)	Select up to 15 targeted rejected claims (if available) 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 up to 15 targeted rejected claims (if available) 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 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	42 CFR § 423.120(b)

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			during transition.	

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Audit Element	Compliance Standard	Data Request	Method of Evaluation	Criteria
Transition	2.2	Universe Table 1: Rejected Claims Formulary Administration (RCFA) Universe Table 2: Rejected Claims Transition (RCT) Universe Table 3: New Enrollee (NE)	Review the 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 prepare 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. The Excel or Text file must be converted into Zip file format (.zip) before uploading to the Health Plan Management System (HPMS) audit module. 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: 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	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.

General Record Layout Instructions

- Do not filter or omit data under any circumstances.
- Ensure that all data fields are free of leading and/or trailing spaces.
- Do not skip any rows or columns.
- For all date fields submit in CCYY/MM/DD format (e.g., 2027/01/01).
- Fields populated by the pharmacy should be populated as submitted by the pharmacy. Only fields that are submitted blank by the pharmacy may be submitted blank in the universe submission.
- CMS expects the Sponsoring organization to validate all data submissions & universes before they are provided to CMS, including that the data is readable, complete, and contains the data or documentation specifically responsive to the request. CMS reserves the right to validate any and all data submissions.

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).

- Include claim denials using the BIN, PCN, and Group that can be cross walked to the contract/PBP.

For eligibility rejections:

- When an enrollee cannot be identified in the Sponsoring organization's system based on pharmacy submitted claim information, 'NA' may be entered in the following fields populated by the Sponsoring organization:
  Enrollee ID
  Enrollment Effective Date
  Effective Disenrollment Date
  Plan Benefit Package (PBP)

Column ID	Field Name	Description
A	Enrollee ID	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. This number must be submitted excluding hyphens or dashes.
B	Enrollee First Name	Enter the first name of the enrollee as submitted by the pharmacy.
C	Enrollee Last Name	Enter the last name of the enrollee as submitted by the pharmacy.
D	Date of Birth	Enter the date of birth of the enrollee as submitted by the pharmacy.
E	Enrollment Effective Date	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.
F	Effective Disenrollment Date	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. Enter NA if the enrollee was not disenrolled.

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Column ID	Field Name	Description
G	Cardholder ID	Enter cardholder identifier assigned by the Sponsoring organization and used to identify the enrollee. Field should be populated as submitted by the pharmacy.
H	Contract ID	Enter the contract number (e.g., H1234) of the Sponsoring organization.
I	Plan Benefit Package (PBP)	Enter the PBP (e.g., 001).
J	Drug Name, Strength, and Dosage Form	Enter the full drug name, strength, and dosage form.
K	NDC	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.
L	Date of Service	Enter the date of fill for the rejected claim as submitted by the pharmacy.
M	Date of Rejection	Enter the date of rejection for the drug claim.
N	Claim Quantity	Enter the number of drug dosage units entered in the claim as submitted by the pharmacy (e.g., 30 [tablets], 0.42 [milliliters of liquid]), including decimal values, when applicable. Units of measurement should not be reported.
O	Claim Days Supply	Enter the days’ supply of the drug entered on the claim as submitted by the pharmacy (e.g., 30 [days]). Units of measurement should not be reported.
P	Patient Residence	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.

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Column ID	Field Name	Description
Q	Pharmacy Service Type	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.
R	Compound Code	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
S	Reject Reason Code	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.
T	Pharmacy Message	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: 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 fills. 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	Description
A	Enrollee ID	Enter the Medicare Beneficiary Identifier (MBI) of the enrollee. This number must be submitted excluding hyphens or dashes.
B	Enrollee First Name	Enter the first name of the enrollee.
C	Enrollee Last Name	Enter the last name of the enrollee.
D	Date of Birth	Enter the date of birth of the enrollee.
E	Enrollment Effective Date	Enter the effective date of enrollment for the enrollee (PBP level). 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	Enter the effective date of disenrollment for the enrollee (PBP level). Enter NA if the enrollee was not disenrolled.
G	Cardholder ID	Enter the cardholder identifier used to identify the enrollee. This is assigned by the Sponsoring organization.
H	Contract ID	Enter the contract number (e.g., H1234, S1234) of the Sponsoring organization.
I	Plan Benefit Package (PBP)	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

Sample Selection

During audit field work, CMS will review the selected samples to determine whether the Sponsoring organization is compliant with its Part D regulatory and contract requirements. If the audit fieldwork is done live via webinar, the Sponsoring organization will receive notice of the selected samples 1 hour in advance of the live review. CMS may conduct all or part of the review via desk review. If desk review is conducted, the Sponsoring organization will receive samples five (5) business days in advance in order to prepare and submit full or partial case files.

Supporting Documentation Submissions

During audit field work, CMS will review the samples selected from Table 1 and 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 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 using the requested impact analysis template. The Sponsoring organization must include all requests impacted by the issue of noncompliance during the impact analysis request period. Detailed descriptions along with clarifications of what must be included in each submission and data field are outlined in the corresponding excel document(s). Characters are required in all requested fields, unless otherwise specified, and data must be limited to the request specified in each column. 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 data request specifications will be rejected.

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.

Impact Analysis Requests

Impact Analysis Record Layout	Scope of Impact Analysis Request
Enrollee Impact	Formulary Administration: The time period must encompass the date the impact analysis is requested through January 1st of the current year.
Enrollee Impact	Transition: 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.

CMS will default to the impact analysis scope identified in the table below. However, CMS reserves the right to adjust the periods if necessary.