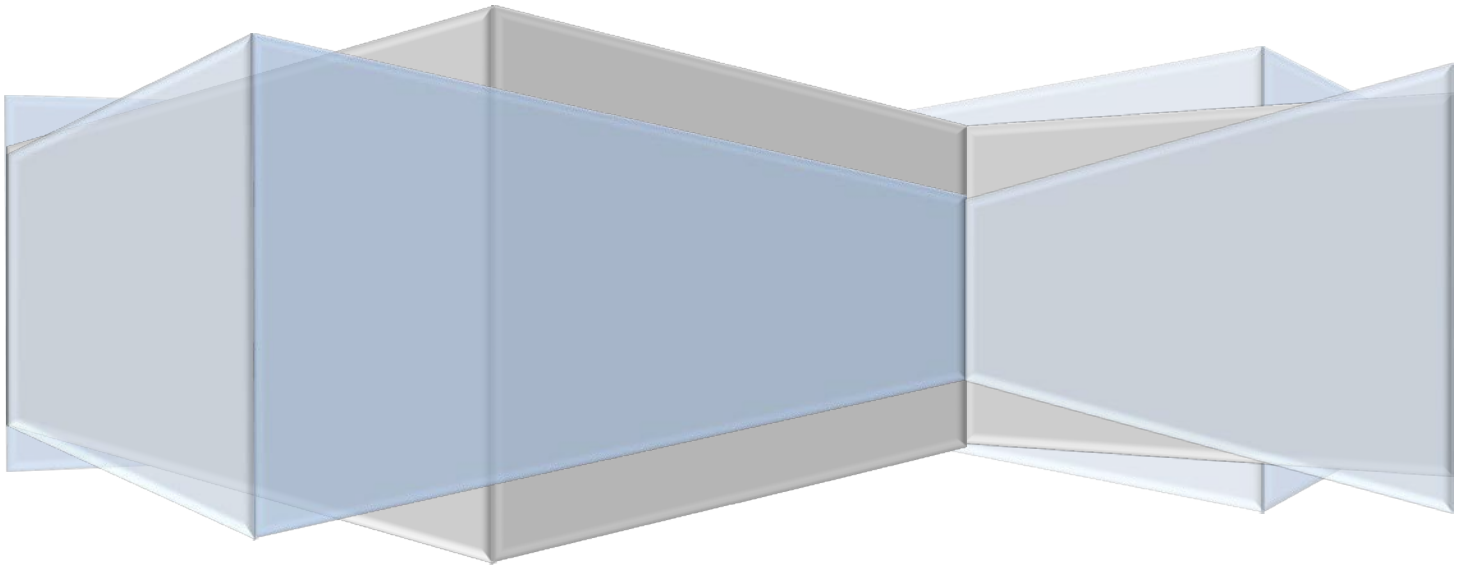
OMB Control Number 0938-1000 (Expires: TBD)

Part D Formulary and Benefit Administration (FA) Program Area

AUDIT PROCESS AND DATA REQUEST



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Audit Purpose and General Guidelines

1. **Purpose:** To evaluate performance in the two areas outlined in this protocol related to Part D Formulary and Benefit Administration (FA). The Centers for Medicare & Medicaid Services (CMS) will perform its audit activities using these instructions (unless otherwise noted).

2. **Review Period:** The review period for the Formulary and Benefit Administration Program Area Audit will be based on your organization's total enrollment. CMS reserves the right to expand the review period to ensure a sufficient universe size.

2.1. Formulary Administration

2.1.1. Rejected Claims

- Sponsors with ≥ 20,000 enrollees: all rejected claims with dates of service for the 1 month period preceding and including, the date of the audit engagement letter (i.e., prior Month, Day, Year through audit engagement Month, Day, Year).
- Sponsors with < 20,000 enrollees: all rejected claims with dates of service for the 2 month period preceding and including, the date of the audit engagement letter (i.e., prior Month, Day, Year through audit engagement letter Month, Day, Year).

2.2. Transition

2.2.1. Rejected Claims - New Contract Year

- Sponsors with ≥ 100,000 enrollees: All rejected claims with dates of service for January of the audit year.
- Sponsors with < 100,000 enrollees: All rejected claims with dates of service for January and February of the audit year.

2.2.2. Rejected Claims - Previous Contract Year

- Beneficiaries with effective enrollment dates of November or December of the contract year immediately prior to the audit year: All rejected claims with dates of service for November and December of the contract year immediately prior to the audit year.

2.2.3. Prescription Drug Event (PDE) Data

- Beneficiaries submitted in either of the Rejected Claims Transition universes (new and previous contract year): All final action PDEs accepted by CMS with dates of service September – December of the contract year immediately prior to the audit year. This will be used with the rejected claims data to test transition.

2.2.4. New Members (including members enrolled in employer plans and Medicare-Medicaid Plans (MMPs)). This will be used with the rejected claims data to test transition for new enrollees.

- Sponsors with ≥ 100,000 enrollees:
  - All beneficiaries with an effective enrollment date of November or December of the contract year immediately prior to the audit year regardless of whether they continued in the same plan during the audit year.
  - All beneficiaries with an effective enrollment date of January of the audit year.
- Sponsors with < 100,000 enrollees:
  - All beneficiaries with an effective enrollment date of November or December of the contract year immediately prior to the audit year regardless of whether they continued in the same plan in the audit year.

- All beneficiaries with an effective enrollment date of January or February of the audit year.

3. **Responding to Documentation Requests:** The sponsor is expected to present its supporting documentation during the audit and take screen shots or otherwise upload the supporting documentation, as requested, to the secure site using the designated naming convention and within the timeframe specified by the CMS Audit Team.

4. **Sponsor Disclosed Issues:** Sponsors will be asked to provide a list of all disclosed issues of non-compliance that are relevant to the program areas being audited and may be detected during the audit. A disclosed issue is one that has been reported to CMS prior to the receipt of the audit start notice (which is also known as the "engagement letter"). Issues identified by CMS through on-going monitoring or other account management/oversight activities during the plan year are not considered disclosed.

   Sponsors must provide a description of each disclosed issue as well as the status of correction and remediation using the Pre-Audit Issue Summary template. This template is due within 5 business days after the receipt of the audit start notice. The sponsor's Account Manager will review the summary to validate that "disclosed" issues were known to CMS prior to receipt of the audit start notice.

   When CMS determines that a disclosed issue was promptly identified, corrected (or is actively undergoing correction), and the risk to beneficiaries has been mitigated, CMS will not apply the ICAR condition classification to that condition.

5. **Impact Analysis (IA):** An impact analysis must be submitted as requested by CMS. The impact analysis must identify all beneficiaries subjected to or impacted by the issue of non-compliance. Sponsors will have up to 10 business days to complete the requested impact analysis templates. CMS may validate the accuracy of the impact analysis submission(s). In the event an impact analysis cannot be produced, CMS will report that the scope of non-compliance could not be fully measured and impacted an unknown number of beneficiaries across all contracts audited.

6. **Calculation of Score:** CMS will determine if each condition cited is an Observation (0 points), Corrective Action Required (CAR) (1 point) or an Immediate Corrective Action Required (ICAR) (2 points). Invalid Data Submission (IDS) conditions will be cited when a sponsor is not able to produce an accurate universe within 3 attempts. IDS conditions will be worth one point.

   CMS will then add the score for that audit element to the scores for the remainder of the audit elements in a given protocol and then divide that number (i.e., total score), by the number of audit elements tested to determine the sponsor's overall FA audit score. Some elements and program areas may not apply to certain sponsors and therefore will not be considered when calculating program area and overall audit scores. Observations will be recorded in the draft and final reports, but will not be scored and therefore will not be included in the program area and audit scores.

7. **Informing Sponsor of Results:** CMS will provide daily updates regarding conditions discovered that day (unless the case has been pended for further review). CMS will provide a preliminary summary of its findings at the exit conference. The CMS Audit team will do its best to be as transparent and timely as possible in its communication of audit findings. Sponsors will also receive a draft audit report which they may formally comment on and then a final report will be issued after consideration of a sponsor's comments on the draft.

Universe Preparation & Submission

1. **Responding to Universe Requests:** The sponsor is expected to provide accurate and timely universe submissions within 15 business days of the engagement letter date. CMS may request a revised universe if data issues are identified. The resubmission request may occur before and/or after the entrance conference depending on when the issue was identified. Sponsors will have a maximum of 3 attempts to provide complete and accurate universes, whether these attempts all occur prior to the entrance conference or they include submissions prior to and after the entrance conference. However, 3 attempts may not always be feasible depending on when the data issues are identified and the potential for impact to the audit schedule. When multiple attempts are made, CMS will only use the last universe submitted.

   If the sponsor fails to provide accurate and timely universe submissions twice, CMS will document this as an observation in the sponsor's program audit report. After the third failed attempt, or when the sponsor determines after fewer attempts that they are unable to provide an accurate universe within the timeframe specified during the audit, the sponsor will be cited an Invalid Data Submission (IDS) condition relative to each element that cannot be tested, grouped by the type of case.

2. **Pull Universes:** The universes collected for this program area test whether the sponsor has deficiencies related to the appropriate point-of-sale claims adjudication. Sponsors will provide universes of all rejected claims and prescription drug event (PDE) data (paid claims) with dates of service that fall within the related review periods. The sponsor needs to ensure that only standing paid claims of members from the rejected claims transition universe are submitted for the PDE universe**.** This may include members that are treated as new by the sponsor, but that were enrolled in a different Plan Benefit Package (PBP) for the same sponsor during the new contract year. The universes should be compiled using the appropriate FA record layout as described in Appendix A. These record layouts include:

   - Rejected Claims Formulary Administration (RCFA)
   - Rejected Claims Transition – New Contract Year (RCT-N)
   - Rejected Claims Transition – Previous Contract Year (RCT-P)
   - Prescription Drug Event (PDE)
   - New Member (NM)

   NOTE: For each respective universe, the sponsor should include all cases that match the description for that universe for all contracts and PBPs in its organization as identified in the audit engagement letter (e.g., all rejected claims for all contracts and PBPs in your organization for dates of service that fall within the applicable review period).

3. **Submit Universes to CMS:** Sponsors should submit each universe in the Microsoft Excel (.xlsx) file format with a header row (or Text (.txt) file format without a header row) following the record layouts shown in Appendix A (Tables 1-5). The sponsor should submit its universes in whole and not separately for each contract and PBP unless otherwise instructed by CMS.

Audit Elements

I. Formulary Administration

1. **Select Sample Cases:** CMS will select a targeted sample of 30 claims from the Formulary Administration Rejected Claims Universe. The sample will consist of protected and non-protected class drug claims rejections relating to formulary administration (e.g., prior authorization, step therapy, non-formulary drugs, and quantity limitations).

2. **Review Sample Case Documentation:** CMS will review all sample case file documentation to determine if the Part D sponsor has deficiencies related to the appropriate point-of-sale claim adjudication. The sponsor will need access to the following documents during the live audit webinar and may be requested to produce screenshots of any of the following:

   2.1. Beneficiary Information
   - Beneficiary Name
   - Cardholder or member ID
   - CMS Contract ID
   - CMS Plan Benefit Package (PBP) number
   - Effective date of enrollment

   2.2. 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, dosage form, route of administration) during the audit year
   - Claim payment information including beneficiary pay amount, LIS amount and sponsor's responsibility

3. **Apply Compliance Standard:** At a minimum, CMS will evaluate cases against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other related FA requirements not being met.

   3.1. Does the claim adjudication process follow the approved CMS formulary?

4. **Sample Case Results:** CMS will test each of the 30 cases. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited.

   NOTE: Cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may have a single condition or multiple conditions of non-compliance.

II. Transition

1. **Select Sample Cases:** CMS will select a targeted sample of 30 claims from the rejected transition claims universes for continuing members as well as for new enrollees. Claims will be selected for both non-protected class drugs and protected class drugs.

   1.1. Continuing members: 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).

   1.2. 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).

2. **Review Sample Case Documentation:** CMS will review all sample case file documentation to determine if the Part D sponsor has deficiencies related to improper claims adjudication logic during the transition period (e.g., logic that prevented beneficiaries who were currently taking a drug from accessing that drug due to a change between contract years). The sponsor will need access to the following documents during the live audit webinar and may be requested to produce screenshots of any of the following:

   2.1. Beneficiary Information
   - Beneficiary Name
   - Cardholder or member ID
   - CMS Contract ID
   - CMS Plan Benefit Package (PBP) number
   - Effective date of enrollment

   2.2. 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 rejected and paid claims for the same drug (brand name, dosage form, route of administration) from the audit year and/or the previous contract year
   - Claim payment information including beneficiary pay amount, LIS amount and sponsor's responsibility

   2.3. Transition Notice
   - Beneficiary transition notice
   - Prescriber transition notice and/or prescriber notification

3. **Apply Compliance Standard:** At a minimum, CMS will evaluate cases against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other related FA requirements not being met.

   3.1. Did the sponsor meet the transition fill requirement?

   3.2. Did the sponsor meet the transition notice requirement?

4. **Sample Case Results:** CMS will test each of the 30 cases. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE:** Cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may have a single condition or multiple conditions of non-compliance.

Appendix

Appendix A—-Part D Formulary and Benefit Administration Record Layouts

The universes for the Formulary and Benefit Administration program area must be submitted as a Microsoft Excel (.xlsx) file with a header row reflecting the field names (or Text (.txt) file without a header row). Do not include the Column ID variable which is shown in the record layout as a reference for a field's column location in an Excel file. Do not include additional information outside of what is dictated in the record layout. Submissions that do not strictly adhere to the record layout will be rejected.

NOTE: There is a maximum of 4000 characters per record row. Therefore, should additional characters be needed for a variable (e.g., for the pharmacy messaging), enter this information on the next record at the appropriate start position.

Table 1: Rejected Claims Formulary Administration (RCFA) Record Layout

- Include all rejected claims with dates of service that fall within the applicable review period timeframe (including members enrolled in employer plans and Medicare-Medicaid Plans (MMPs)).

Column ID	Field Name	Field Type	Field Length	Description
A	Medicare Beneficiary Identifier (MBI)	CHAR Always Required	11	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	Beneficiary First Name	CHAR Always Required	50	First name of the beneficiary.
C	Beneficiary Last Name	CHAR Always Required	50	Last name of the beneficiary.
D	Date of Birth	CHAR Always Required	10	Date of birth of the beneficiary. Submit in CCYY/MM/DD format (e.g., 1940/01/01).
E	Enrollment Effective Date	CHAR Always Required	10	Effective date of enrollment for the beneficiary (PBP level). Submit in CCYY/MM/DD format (e.g., 2020/01/01).
F	Effective Disenrollment Date	CHAR Always Required	10	Effective date of disenrollment for the beneficiary (PBP level). Submit in CCYY/MM/DD format (e.g., 2020/02/01). Answer NA if the beneficiary was not disenrolled.
G	Cardholder ID	CHAR Always Required	20	Cardholder identifier used to identify the beneficiary. This is assigned by the plan.
H	Contract ID	CHAR Always Required	5	The contract number (e.g., H1234) of the organization.
I	Plan ID	CHAR Always Required	3	The plan number (e.g., 001) of the organization.

Column ID	Field Name	Field Type	Field Length	Description
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 of the most expensive drug (or as submitted on the associated PDE). When compound claims do not include any Part D drug products, populate the field with "00000000000" consistent with the NDC 11 format.
K	Date of Service	CHAR Always Required	10	This field contains the date a fill for a rejected claim was attempted. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
L	Date of Rejection	CHAR Always Required	10	Date of rejection for the drug claim. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
M	Claim Quantity	CHAR Always Required	11	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	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	Patient residence code for the beneficiary as submitted by the pharmacy on the claim. Answer "UNK" if this field is left blank by the pharmacy.
P	Pharmacy Service Type	CHAR Always Required	5	Pharmacy service type as submitted by the pharmacy on the claim. Answer "UNK" if this field is left blank by the pharmacy.
Q	Compound Code	CHAR Always Required	1	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	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 should be included. Answer "NA" in the Reject Reason Code field for pharmacy messages included in column S that are not paired with a reject reason code. *If necessary repeat this field as many times as needed to capture each individual reject reason code, followed by the corresponding pharmacy messaging related to the rejected claim.

Column ID	Field Name	Field Type	Field Length	Description
S	Pharmacy Message*	CHAR Always Required	1000	Pharmacy message associated with the rejected claim. All pharmacy messages associated with a claim should be included. *If applicable, this field will be paired with a rejection reason code and should be repeated for each rejection reason code submitted. For example, if there are 3 reject reason codes the record would include 3 pairs of reject codes and pharmacy messages (reject code **1→** pharmacy message **1→** reject code **2→** pharmacy message **2→** reject code **3→** pharmacy message **3→** reject code). Pharmacy messages not paired with a reject code should be preceded with an "NA" in the Reject Reason code field. **If there are multiple messages attached to a single reject code, sponsors should include all applicable messaging in the same message field. ***In the event that specific pharmacy messages are not linked with a corresponding reject code, include all pharmacy messages in this field and repeat for each reject reason code submitted.

Table 2: Rejected Claims Transition – New Contract Year (RCT-N) Record Layout

- Include all rejected claims with dates of service that fall within the applicable review period timeframe (including members enrolled in employer plans and Medicare-Medicaid Plans (MMPs)).

Column ID	Field Name	Field Type	Field Length	Description
A	Medicare Beneficiary Identifier (MBI)	CHAR Always Required	11	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	Beneficiary First Name	CHAR Always Required	50	First name of the beneficiary.
C	Beneficiary Last Name	CHAR Always Required	50	Last name of the beneficiary.
D	Date of Birth	CHAR Always Required	10	Date of birth of the beneficiary. Submit in CCYY/MM/DD format (e.g., 1940/01/01).
E	Enrollment Effective Date	CHAR Always Required	10	Effective date of enrollment for the beneficiary (PBP level). Submit in CCYY/MM/DD format (e.g., 2020/01/01).
F	Effective Disenrollment Date	CHAR Always Required	10	Effective date of disenrollment for the beneficiary (PBP level). Submit in CCYY/MM/DD format (e.g., 2020/02/01). Answer NA if the beneficiary was not disenrolled.
G	Cardholder ID	CHAR Always Required	20	Cardholder identifier used to identify the beneficiary. This is assigned by the plan.
H	Contract ID	CHAR Always Required	5	The contract number (e.g., H1234) of the organization.
I	Plan ID	CHAR Always Required	3	The plan number (e.g., 001) of the organization.
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 of the most expensive drug (or as submitted on the associated PDE). When compound claims do not include any Part D drug products, populate the field with “00000000000” consistent with the NDC 11 format.

Column ID	Field Name	Field Type	Field Length	Description
K	Date of Service	CHAR Always Required	10	This field contains the date a fill for a rejected claim was attempted. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
L	Date of Rejection	CHAR Always Required	10	Date of rejection for the drug claim. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
M	Claim Quantity	CHAR Always Required	11	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	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	Patient residence code for the beneficiary as submitted by the pharmacy on the claim. Answer "UNK" if this field is left blank by the pharmacy.
P	Pharmacy Service Type	CHAR Always Required	5	Pharmacy service type as submitted by the pharmacy on the claim. Answer "UNK" if this field is left blank by the pharmacy.
Q	Compound Code	CHAR Always Required	1	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	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 should be included. Answer "NA" in the Reject Reason Code field for pharmacy messages included in column S not paired with a reject reason code. *If necessary repeat this field as many times as needed to capture each individual reject reason code, followed by the corresponding pharmacy messaging related to the rejected claim.

Column ID	Field Name	Field Type	Field Length	Description
S	Pharmacy Message*	CHAR Always Required	1000	Pharmacy message associated with the rejected claim. All pharmacy messages associated with a claim should be included. *If applicable, this field will be paired with a rejection reason code and should be repeated for each rejection reason code submitted. For example, if there are 3 reject reason codes the record would include 3 pairs of reject codes and pharmacy messages (reject code **1→** pharmacy message **1→** reject code **2→** pharmacy message **2→** reject code **3→** pharmacy message **3→** reject code). Pharmacy messages not paired with a reject code should be preceded with an "NA" in the Reject Reason code field. ** If there are multiple messages attached to a single reject code, sponsors should include all applicable messaging in the same message field. ***In the event that specific pharmacy messaging is not linked with a corresponding reject code, include all pharmacy messages in this field and repeat for each reject reason code submitted.

Table 3: Rejected Claims Transition – Previous Contract Year (RCT-P) Record Layout

- Include all rejected claims with dates of service for November and December of the contract year immediately prior to the audit year, for beneficiaries with effective enrollment dates of November or December of that contract year (including members enrolled in employer plans and Medicare- Medicaid Plans (MMPs)).
- Exclude rejected claims for beneficiaries with effective enrollment dates other than November or December of the contract year immediately prior to the audit year.

Column ID	Field Name	Field Type	Field Length	Description
A	Medicare Beneficiary Identifier (MBI)	CHAR Always Required	11	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	Beneficiary First Name	CHAR Always Required	50	First name of the beneficiary.
C	Beneficiary Last Name	CHAR Always Required	50	Last name of the beneficiary.
D	Date of Birth	CHAR Always Required	10	Date of birth of the beneficiary. Submit in CCYY/MM/DD format (e.g., 1940/01/01).
E	Enrollment Effective Date	CHAR Always Required	10	Effective date of enrollment for the beneficiary (PBP level). Submit in CCYY/MM/DD format (e.g., 2019/11/01).
F	Effective Disenrollment Date	CHAR Always Required	10	Effective date of disenrollment for the beneficiary (PBP level). Submit in CCYY/MM/DD format (e.g., 2019/12/31). Answer NA if the beneficiary was not disenrolled.
G	Cardholder ID	CHAR Always Required	20	Cardholder identifier used to identify the beneficiary. This is assigned by the plan.
H	Contract ID	CHAR Always Required	5	The contract number (e.g., H1234) of the organization.
I	Plan ID	CHAR Always Required	3	The plan number (e.g., 001) of the organization.
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 of the most expensive drug (or as submitted on the associated PDE). When compound claims do not include any Part D drug products, populate the field with “00000000000” consistent with the NDC 11 format.

Column ID	Field Name	Field Type	Field Length	Description
K	Date of Service	CHAR Always Required	10	This field contains the date a fill for a rejected claim was attempted. Submit in CCYY/MM/DD format (e.g., 2019/11/05).
L	Date of Rejection	CHAR Always Required	10	Date of rejection for the drug claim. Submit in CCYY/MM/DD format (e.g., 2019/11/05).
M	Claim Quantity	CHAR Always Required	11	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	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	Patient residence code for the beneficiary as submitted by the pharmacy on the claim. Answer "UNK" if this field is left blank by the pharmacy.
P	Pharmacy Service Type	CHAR Always Required	5	Pharmacy service type as submitted by the pharmacy on the claim. Answer "UNK" if this field is left blank by the pharmacy.
Q	Compound Code	CHAR Always Required	1	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	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 should be included. Answer "NA" in the Reject Reason Code field for pharmacy messages included in column S that are not paired with a reject reason code. *If necessary repeat this field as many times as needed to capture each individual reject reason code, followed by the corresponding pharmacy messaging related to the rejected claim.

Column ID	Field Name	Field Type	Field Length	Description
S	Pharmacy Message*	CHAR Always Required	1000	Pharmacy message associated with the rejected claim. All pharmacy messages associated with a claim should be included. *If applicable, this field will be paired with a rejection reason code and should be repeated for each rejection reason code submitted. For example, if there are 3 reject reason codes the record would include 3 pairs of reject codes and pharmacy messages (reject code **1→** pharmacy message **1→** reject code **2→** pharmacy message **2→** reject code **3→** pharmacy message **3→** reject code). Pharmacy messages not paired with a reject code should be preceded with an "NA" in the Reject Reason code field. ** If there are multiple messages attached to a single reject code, sponsors should include all applicable messaging in the same message field. ***In the event that specific pharmacy messaging is not linked with a corresponding reject code, include all pharmacy messages in this field and repeat for each reject reason code submitted.

Table 4: Prescription Drug Event (PDE) Data Record Layout

- Include all final action PDEs accepted by CMS with dates of service in September – December of the contract year immediately prior to the audit year.
    - Include PDEs only for beneficiaries submitted in either of the Rejected Claims Transition Universes (RCT-N and RCT-P) (including members enrolled in employer plans and Medicare-Medicaid Plans (MMPs)).

Column ID	Field Name	Field Type	Field Length	Description
A	Medicare Beneficiary Identifier (MBI)	CHAR Always Required	11	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	Beneficiary First Name	CHAR Always Required	50	First name of the beneficiary.
C	Beneficiary Last Name	CHAR Always Required	50	Last name of the beneficiary.
D	Date of Birth	CHAR Always Required	10	Date of birth of the beneficiary. Submit in CCYY/MM/DD format (e.g., 1940/01/01).
E	Cardholder ID	CHAR Always Required	20	Cardholder identifier used to identify the beneficiary. This is assigned by the plan.
F	Contract ID	CHAR Always Required	5	The contract number (e.g., H1234) of the organization.
G	Plan ID	CHAR Always Required	3	The plan number (e.g., 001) of the organization.
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 of the most expensive drug (or as submitted on the associated PDE). When compound claims do not include any Part D drug products, populate the field with “00000000000” consistent with the NDC 11 format.
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., 2019/01/01)

Column ID	Field Name	Field Type	Field Length	Description
J	Claim Quantity	CHAR Always Required	11	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	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	0 = Not specified 1 = Not a compound 2 = Compound

Table 5: New Member (NM) Record Layout

- Include eligible members (including members enrolled in employer plans and Medicare-Medicaid Plans (MMPs)) for which the Sponsoring organization does not utilize prior claims history. In some cases, the Sponsoring organization may have the full claims history for the member from the most recent PBP, and thus, the Sponsoring organization may be able to determine new versus ongoing therapy. In this example, the member should not be included in the New Member Universe since they are determined to be a continuing member.
    - For sponsors with ≥ 100,000 enrollees include:
        - All beneficiaries with an effective enrollment date of November or December of the contract year immediately prior to the audit year regardless of whether they continued in the same plan in the audit year.
        - All beneficiaries with an effective enrollment date of January of the audit year.
    - For sponsors with < 100,000 enrollees:
        - All beneficiaries with an effective enrollment date of November or December of the contract year immediately prior to the audit year regardless of whether they continued in the same plan in the audit year.
        - All beneficiaries with an effective enrollment date of January or February of the audit year.

Column ID	Field Name	Field Type	Field Length	Description
A	Medicare Beneficiary Identifier (MBI)	CHAR Always Required	11	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	Beneficiary First Name	CHAR Always Required	50	First name of the beneficiary.
C	Beneficiary Last Name	CHAR Always Required	50	Last name of the beneficiary.
D	Date of Birth	CHAR Always Required	10	Date of birth of the beneficiary. Submit in CCYY/MM/DD format (e.g., 1940/01/01).
E	Enrollment Effective Date	CHAR Always Required	10	Effective date of enrollment for the beneficiary. Submit in CCYY/MM/DD format (e.g., 2020/01/01).
F	Effective Disenrollment Date	CHAR Always Required	10	Effective date of disenrollment for the beneficiary (PBP level). Submit in CCYY/MM/DD format (e.g., 2020/02/01). Answer NA if the beneficiary was not disenrolled.
G	Cardholder ID	CHAR Always Required	20	Cardholder identifier used to identify the beneficiary. This is assigned by the plan.
H	Contract ID	CHAR Always Required	5	The contract number (e.g., H1234, S1234) of the organization.
I	Plan ID	CHAR Always Required	3	The plan number (e.g., 001, 002) of the organization.