Medicare Part D Plan Reporting Requirements:
Technical Specifications Document
Contract Year 2023

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Introduction

These technical specifications supplement the Part D Plan Reporting Requirements (OMB 0938-0992), and do not change, alter, or add to the data collection. They serve to further define data elements and alert sponsors to how CMS will review and analyze these data.

The purpose of these technical specifications is to help ensure a common understanding of the data to be reported by sponsors, to assist sponsors in preparing and submitting datasets, to ensure a high level of accuracy in the data reported to CMS, and to reduce the need for sponsors to correct and resubmit data.

Each Part D reporting section is listed in this document with information regarding the following subjects.

A. Data element definitions: details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.
B. QA checks/Thresholds: procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
C. Edits and Validation Checks: validation checks that should be performed by each Part D sponsor prior to data submission.
D. Analysis: how CMS will evaluate reported data, as well as how other data sources may be monitored.
E. Notes: additional clarifications to a reporting section. This section incorporates previously answered frequently asked questions.

General Information

Level of Data to be Reported

The level of reporting for each reporting section is specified in the Reporting Requirements document and within each reporting section in HPMS. Sponsor-level reporting indicates data may be submitted from an organization that is associated with more than one CMS-issued Part D contract. Contract-level reporting indicates data should be entered at the H#, S#, R#, or E# level. Plan-level reporting indicates data should be entered at the plan benefit package (PBP) level, (e.g., Plan 001 for contract H#, R#, S#, or E). Plan-level reporting is necessary to conduct appropriate oversight and monitoring of some areas.

A summary of the reporting level required for each reporting section is below.

REPORTING REQUIREMENT SECTION	LEVEL OF REPORTING
Enrollment and Disenrollment	Contract
Medication Therapy Management (MTM) Programs	Contract
Grievances	Contract
Improving Drug Utilization Review Controls	Contract
Coverage Determinations and Redeterminations	Contract & Plan
Employer/Union-Sponsored Group Health Plan Sponsors	Contract & Plan

Timely submission of data

Data submissions are due by 11:59 p.m. Pacific time on the date of the reporting deadline.

Only data that reflect a good faith effort by a sponsor to provide accurate responses to Part D Reporting Requirements will count as data submitted in a timely manner. Sponsors must report all data based on the most current Technical Specifications as of the reporting deadline.

- Sponsors should not submit “placeholder” data.
- HPMS will not allow the resubmission of data that are identical to the original data submission.

In order to accommodate data validation activities, data corrections must be submitted prior to 11:59 p.m. Pacific time on March 31st.

The following steps must be followed by a Part D sponsor to request resubmission:

1. On the HPMS Part D Plan Reporting Start Page, click the Resubmission Request link.
2. Select/complete the following:
    a. Reporting section (e.g., Redeterminations);
    b. Time period (e.g., 1st quarter 2023);
    c. Contracts or plans, depending on reporting level; and
    d. The reason for the resubmission request.

Please note, data submitted after the resubmission deadline shall be considered late, and will not be incorporated within CMS data analyses and reporting.

CMS urges sponsors to store final data entered in HPMS for CMS auditors and data validation reviewers. Sponsors should report data based on the interpretation of these documents and retain documentation supporting their reported data. Per Section 6.1 of the Data Validation manual, the Sponsoring Organization (SO) must retain this complete archive for the 10-year retention period required per federal regulations and be prepared to provide the archive to CMS upon request.

General Data Entry Rules

HPMS will allow the entry of a zero.

HPMS will not allow the entry of the following:

- a negative;
- a greater than sign (>);
- a less than sign (<);
- a semi-colon (;) or
- decimals.

Exclusions from Reporting

The Part D Reporting Requirements apply to Part D sponsors offering the Part D benefit, including stand-alone Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs). They do not apply to MA-only Plans. Data relating to Part B claims are excluded from these Part D reports unless otherwise specified (e.g., Coverage Determinations and Redeterminations reporting). PACE Organizations are excluded from these Part D Reporting Requirements.

- If a contract terminates before July 1 in the following year after the contract year (CY) reporting period, the contract is not required to report any data for the respective two years – the CY reporting period, and the following year.
    - Example: Contract terminates June 2023. The contract will not report CY 2022 (“contract year reporting period”) or CY 2023 data (“following year”).
- If a PBP (Plan) under a contract terminates at any time in the CY reporting period and the contract remains active through July 1 of the following year, the contact must still report data for all PBPs, including the terminated PBP.

Medicare/Medicaid Plans (MMPs) should refer to the Medicare-Medicaid Financial Alignment Model Reporting Requirements for additional reporting guidance.

Contracts with no enrollment should select the “no data to report” button (no enrollment signifies that the contract has no enrollees for all months within the reporting period). If a contract has any enrollment during the reporting period, it is required to reportall sections. General questions about Part D reporting requirements should be sent via email to: partd-planreporting@cms.hhs.gov.

I. Enrollment and Disenrollment

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

Data elements to be uploaded into HPMS at the Contract level. Please refer to HPMS layouts and templates for more information.

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.

- CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed and do not indicate that submitted data are incorrect, or that resubmissions are required.
- The percent of enrollment requests denied by the contract will be examined for outlier data. After accounting for the number of enrollment requests filed, contracts with values above the 95th percentile for their contract type will be flagged as outliers.
- The percent of disenrollment requests denied by the contract will be examined for outlier data. After accounting for the number of disenrollment requests filed, contracts with values above the 95th percentile for their contract type will be flagged as outliers.
- CMS may apply new or may adjust existing quality assurance checks and threshold validations based upon data received from Part D sponsors.

C. Edits and Validation Checks - validation checks that should be performed by each Part D sponsor prior to data submission.

- Number of enrollment requests complete at the time of initial receipt does not exceed total number of enrollment requests received.
- Number of enrollment requests for which the sponsor was required to request additional information does not exceed total number of enrollment requests received.
- Number of disenrollment requests complete at time of initial receipt does not exceed total number of disenrollment requests received.
- Number of disenrollment requests denied for any reason does not exceed total number of disenrollment requests received.

D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.

- CMS will evaluate sponsors' processing of enrollment requests, enrollment transactions and involuntary disenrollments.
- CMS will monitor trends in enrollments requests submitted to sponsors.

E. Notes – additional clarifications to a reporting section.

1. EGWPs and all-800 series plans are waived from this reporting section. For contracts with both non-800-series and 800-series plans, data for the 800-series plan(s) may be excluded.

2. Data are based on beneficiary-initiated enrollment and disenrollment requests or submitted transactions. Auto-assignments and other CMS-initiated actions should not be included in these data.
3. Reporting should include all enrollment and disenrollment requests received during the period, including those which may subsequently “fail” after the period, and/or reporting deadline.
4. Enrollment/disenrollment requests for which a timely cancellation request is received should not be included in this reporting.
5. Voluntary disenrollments for which the plan sponsor is notified solely via Daily Transaction Reply Report (DTRR), instead of via receipt of a member's disenrollment request, should not be included in this reporting.
6. HPMS displays separate modules for reporting Part C and Part D Enrollment/Disenrollment data.
7. Reporting for Enrollment Element C (Total number of enrollment requests that were not complete at the time of initial receipt and for which the sponsor was required to request additional information from the applicant (or his/her representative)) should include all forms of potential contact.

II. Medication Therapy Management (MTM) Programs

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

   Data elements to be uploaded into HPMS at the Contract level. Please refer to HPMS layouts and templates for more information.

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.

   - CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and do not indicate that submitted data are incorrect, or that resubmissions are required.
   - The percent of eligible MTM program enrollees who opted out of an MTM program will be examined for outlier data.
   - The percent of MTM program enrollees who received a CMR with written summary in CMS' standardized format will be examined for outlier data. Dates of enrollment and opt-out will be considered.
   - CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D sponsors.

C. Edits and Validation Checks - validation checks that should be performed by each Part D sponsor prior to data submission.
   - See column "Field Type" for data fields that are conditionally required.

D. Analysis - how CMS will evaluate reported data, as well as how other data sources may be monitored.
   - CMS will evaluate the percent of beneficiaries that opt out of MTM.
   - CMS will evaluate CMR recipients.
   - CMS will evaluate the percent of beneficiaries who are offered and receive a CMR with written summary in CMS' standardized format.
   - CMS will evaluate initial MTM outcomes, reported as medication therapy problem recommendations and medication therapy problem resolutions.

E. Notes - additional clarifications to a reporting section.
   1. CMS will only accept MBI.
   2. Sponsors should refer to the annual MTM Program Guidance and Submission memo for information about the Part D MTM program requirements and definitions. It is posted on the CMS MTM web page at www.cms.gov > Medicare > Prescription Drug Coverage Contracting > Medication Therapy Management. All distinct beneficiaries enrolled in the contract's MTM program (either met the specified targeting criteria per CMS – Part D requirements or other expanded plan-specific targeting criteria) at any time in the reporting period should be reported.
   3. Sponsors should refer to the annual MTM Program Data Submission Instructions memo for information regarding MTM data file submission. It is

posted on the CMS Part D Reporting Requirements web page at www.cms.gov>Medicare>Prescription Drug Coverage Contracting>Part D Reporting Requirements.

4. The period of MTM eligibility and enrollment is a contract year (which aligns with the reporting period); therefore, eligibility, enrollment, etc. are captured and reported distinctly for each contract year.
    - Beneficiaries should be reported for each contract year in which they were eligible and enrolled in the contract's MTM program. A distinct MTM program enrollment date should be generated and reported for each year of enrollment.
    - Beneficiaries who were enrolled in the MTM program in the previous contract year and who met the eligibility criteria and were enrolled in the MTM program in the current reporting period should be reported.
    - Beneficiaries who were newly targeted for eligibility (i.e., beneficiaries not enrolled in the contract's MTM program during the previous contract year) and enrolled in the MTM program for the current contract year within the reporting period should be reported.
    - Beneficiaries who are deceased or were retroactively disenrolled prior to their MTM eligibility date should not be reported.
5. If a beneficiary meets both sets of targeting criteria (multiple chronic diseases/multiple Part D drugs/cost threshold AND drug management program at-risk beneficiary) as specified in § 423.153(d)(2), sponsors should report the date the beneficiary first met either set of the targeting criteria.
6. For beneficiaries who opted out of the MTM program due to disenrollment from the plan, only mid-year disenrollments from the plan should be reported. Do not report end of year disenrollments (such as 12/31).
7. Sponsors should refer to Chapter 5, Section 10.2 of the Prescription Drug Benefit Manual for a description of the types of facilities, which are considered LTC.
8. The reported beneficiaries must have received MTM services within the reporting period that met or exceeded CMS' MTM program requirements.
    - Only activities that were completed within the reporting period should be reported (see #14 and #16 for exceptions).
    - The MTM service dates (such as CMR date of (initial)) offer (element N), Date(s) of CMR(s) (element P) and Date CMR written summary in CMS standardized format was provided or sent (element Q) must be on or after the Date of MTM program enrollment (element H).
9. Only CMRs that met CMS – Part D requirements should be reported for any beneficiary enrolled in the contract's MTM program.
10. When reporting the MTM program opt-out reason in element L, opt-out code "03" - Request by beneficiary includes request by beneficiary or beneficiary's authorized representative.

11. The enrolled beneficiaries may refuse or decline individual MTM services or the CMR without having to opt out (disenroll) from the MTM program. These beneficiaries should not be reported as opted-out from the MTM program.
12. For reporting received annual CMR with written summary in CMS standardized format, the beneficiary must receive the CMR written summary. Therefore, returned mail does not count as a received CMR (element O).
13. If a CMR written summary in CMS standardized format is sent and returned, element O should be reported as "N" and elements P, Q, R, S, and T should still be reported based on when the CMR summary was provided/sent (even if returned) and based on when and how the interactive CMR consultation was provided.
14. If the CMR summary was sent in the calendar year after the current reporting period and before the reporting deadline, but was the result of a CMR completed within the current reporting period, received annual CMR with written summary in CMS standardized format (element O) and Date(s) of CMR(s) (element P) may be reported for the current reporting period. However, this CMR and summary should not be reported again in the following reporting period.
15. The number of medication therapy problem recommendations made to prescriber(s) as a result of MTM services (element W) should be reported based on the count of unique recommendations made to prescribers within the reporting period regardless of the success or result of the recommendations; it is not equal to the total number of prescribers that received medication therapy problem recommendations.
    - For example, if 3 medication therapy problem recommendations were identified for a member and were sent to the prescriber in a fax, this should be reported as 3 recommendations. If these 3 medication therapy recommendations were sent to a second prescriber, this should still be reported as 3 recommendations (not 6).
16. Sponsors should retain documentation supporting the number of medication therapy problem resolutions reported toCMS (element X). If the resolution was observed in the calendar year after the current reporting period and before the reporting deadline, but was the result of a MTM intervention and medication therapy problem recommendation made within the current reporting period, the change may be reported for the current reporting period. However, this change to medication therapy should not be reported again in the following reporting period.
17. When a beneficiary moves between contracts:
    - The beneficiary should be reported in the beneficiary-level files for each contract in which they were enrolled in the contract's MTM program at any time in the reporting period. Each contract must qualify and enroll the beneficiary based on the contract's own MTM program criteria.
    - The dates of enrollment, disenrollment elements, and other elements (such as CMRs and TMRs) should be reported distinctly per the specific activities that occurred for the beneficiary when enrolled in the MTM program for the specific contract ID within the reporting period

(contract year). For example, if the beneficiary received a CMR while enrolled in contract 1's MTM program but did not receive a CMR while enrolled in contract 2's MTM program, the CMR should be reported for contract 1 only.

18. When a beneficiary enrolls in a Part D contract and is enrolled in their MTM program, disenrolls from the contract, and re-enrolls in the same Part D contract during the reporting period:
    - The Part D contract may re-enroll the beneficiary into the MTM program. The beneficiary does not need to be re-qualified for the MTM program again within the reporting period (contract year).
    - Report the beneficiary only once per contract file per contract year.
    - Regardless of the duration of the gap in MTM program enrollment, report the initial date of MTM program enrollment, no date of MTM program opt-out, and all other applicable elements for activity across all MTM program enrollment periods within the reporting period.
19. Sponsors should not upload the MTM beneficiary-level data file if they have no MTM enrollees to report. Instead, sponsors should report that they have no MTM data to report via HPMS.
20. For reporting number of communications (element Y) and method of delivery for information (element Z) regarding safe disposal of medications, the beneficiary must receive the information. Therefore, returned mail does not count as received.

III. Grievances

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

Data elements to be uploaded into HPMS at the Contract level. Please refer to HPMS layouts and templates for more information.

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.

- CMS' outlier notifications serve only to give Part D plan sponsors the opportunity to correct submitted data if needed, and do not indicate that submitted data are incorrect, or that resubmissions are required.
- The percentage of beneficiaries filing grievances will be examined for outlier data. After accounting for enrollment, plans with values above the 95th percentile for their plan type or below the 5th percentile for their plan typewill be flagged as outliers.
- The percent of grievances for which the plan sponsor provided timely notification of its decision will be examined for outlier data. All plan sponsors with values below the 5th percentile for their plan type will be flagged as outliers.
- CMS may apply new or adjust existing quality assurance checks and threshold validations based on data received from Part D sponsors.

C. Edits and Validation Checks - validation checks that should be performed by each Part D sponsor prior to data submission.

- Contracts should validate that the total number of grievances includes expedited grievances.
- Contracts should validate that the total number of grievances excludes withdrawn grievances.
- Contracts should validate that the total number of timely notifications includes expedited grievances.

D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.

- The total grievance rate per 1,000 enrollees is equal to the sum of the total number of grievances divided by average enrollments, multiplied by 1,000.

$$[\text{ Total Grievance Rate per 1,000 enrollees }] = \frac{\text{Total \# Grievances}}{\text{Avg. Enrollment}} \text{ x } 1{,}000$$

- The grievance rate by category per 1,000 enrollees is equal to the sum of the grievance element divided by average enrollment, multiplied by 1,000.

$$[\text{ Grievance Rate by Category per 1,000 enrollees }] = \frac{\text{Grievance Element}}{\text{Avg. Enrollment}} \text{ x } 1{,}000$$

- CMS will order contracts based on rates of grievances per 1,000 enrollees and determine the percentile ranking.
- CMS will also correlate grievances with complaints in the CMS complaints tracking module (CTM).

E. Notes – additional clarifications to a reporting section.

1. Grievances can be filed either orally or in writing. Plan sponsors should refer to 42 CFR §423.564 and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for definitions, and procedures for handling Part D grievances.
2. Plan sponsors should conduct the appropriate outreach/investigation to determine which plan a grievance should be reported under. In rare instances where a plan sponsor is unclear as to which plan the grievance pertains to, the plan sponsor should assign the grievance to the plan with the highest enrollment.
3. Grievances are reported based on when the enrollee/enrollee representative is notified of the grievance decision. The plan should refer to 42 CFR §423.564 to determine when the decision may be provided orally and when it must be provided in writing.
4. A grievance decision (disposition) is timely when the plan sponsor appropriately notifies the enrollee of the decision no later than 30 calendar days from receipt of the grievance (24 hours for expedited grievances), or as expeditiously as the enrollee's health condition requires.
5. In the event that an enrollee files multiple grievances during a reporting period, plans should follow the guideline below:
    - If an enrollee files a grievance and then files a grievance again on the same issue, prior to the plan sponsor's decision or the deadline for decision notification (whichever is earlier), report as one grievance.
    - If an enrollee files a grievance and then files a subsequent grievance on the same issue after the plan sponsor's decision or deadline for decision notification (whichever is earlier), report as a separate grievance.
    - If an enrollee files a grievance about multiple issues during a call or in writing, report them as separate grievances.
6. MA-PDs should report a grievance as either a Part C or Part D grievance, depending on the process the plan used to investigate/resolve the grievance. Where a clear distinction is not available for an MA-PD, cases should be reported as Part C grievances.
7. Grievances should be reported even if the member filing the grievance disenrolls from the contract.
8. Dismissed grievances are not included in the total number of grievances.
9. Expedited grievances are included in the total number of grievances.

Do not report:

- Complaints received by 1-800 Medicare or recorded only in the CTM.
- General inquiries or questions that do not include a complaint.
- Withdrawn grievances.
- Grievances filed by prospective enrollees.

IV. Improving Drug Utilization Review Controls

A. Data element definitions are details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

Data elements are to be uploaded into HPMS at the Contract level. Please refer to HPMS layouts and templates for more information.

B. QA checks/Thresholds are procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.

- CMS' outlier notifications serve only to give Part D sponsors the opportunity to review submitted data if needed and do not indicate that submitted data are incorrect, or that resubmissions are required.
- CMS may apply new or adjust existing quality assurance checks and threshold validations based on data received from Part D sponsors.
- CMS will evaluate if reported elements related to editing specifications do not match current HPMS opioid safety edit submissions.
- CMS will evaluate high and low numbers of claim rejections.
- CMS will evaluate high and low percentages of claim rejections overridden at the pharmacy.
- CMS will evaluate high and low percentages of coverage determination requests and approvals.
- CMS will evaluate other high and low outliers at the contract level and criteria level (contracts with the same opioid safety edit criteria).

C. Edits and Validation Checks - Part D contracts should validate the following prior to data submission. For a complete list of edit checks, refer to the Data Entry Edit Rules in HPMS.

Opioid Safety Edit	**Element Validations**
Care Coordination Edit	The number of claims rejected due to the care coordination edit (element C) should be greater than or equal to elements D, E, F, and G.
Care Coordination Edit	The number of unique beneficiaries with at least one claim rejected due to the carecoordination edit (element H) should be greater than or equal to elements I, J, Kand L.
Hard MME Edit	If yes to element M, the number of uniquebeneficiaries with at least one claim rejected due to the hard MME edit (element R) should be greater than or equal to elements, S, T, and U.

Opioid Naïve Edit	The number of claims rejected due to the opioid naïve days supply edit (element W) should be greater than or equal toelements X, Y and Z.
Opioid Naïve Edit	The number of unique beneficiaries withat least one claim rejected due to the opioid naïve days supply edit (element AA) should be greater than or equal toelements BB, CC, DD, EE and FF.

D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
   - CMS will monitor and evaluate data at the contract level and criteria-level (contracts with the same opioid safety edit criteria).

E. Notes – additional clarifications to a reporting section.

General:

1. MA-only Contracts are excluded from reporting.
2. Formulary-level opioid safety edits include the care coordination edit, the hard MME edit, and the opioid naïve hard edit.
3. If an opioid safety edit does not include a prescriber and/or pharmacy count, the plan sponsor should enter “0” in the appropriate elements (elements A, B, O, and P).
4. If a plan sponsor submitted and was approved for multiple opioid safety edits during the plan year, meaning the edit criteria changed during the reporting period, report the edit specifications in place during the majority of a reporting period (elements A-B, N-P, and V). The other reported data (totals) should account for activity for the entire reporting period across all edit criteria in place.
5. Rejected claims are counted at the unique contract, beneficiary, prescriber, pharmacy, drug (strength and dosage form), quantity, date of service (DOS) and formulary-level opioid safety edit. For example, if multiple transactions are submitted and rejected by the sponsor for the same formulary-level opioid safety edit from the same pharmacy for the same beneficiary, prescription (drug, quantity and prescriber) and DOS, this would count as one rejected claim. However, if a beneficiary attempted to fill the same prescription at 3 different pharmacies, either on the same day or on different days, and the prescription was rejected each time for the same formulary-level opioid safety edit, this would count as 3 rejected claims.
6. If a claim rejects for both a care coordination, hard MME edit, and/or an opioid naïve hard edit and an early refill edit, the claim should be excluded from the formulary- level opioid safety edit rejection counts.

7. The same claim and beneficiary should be reported in multiple reporting sections of the opioid safety edits if a claim triggers multiple opioid safety edits.
8. If a claim override, paid claim, coverage determination or appeal request, or favorable coverage determination or appeal was initiated after the current reporting period but was the result of a claim rejection during the calendar year and within the current reporting period, it may be reported for the current reporting period. It should not be reported again in the following reporting period.
9. Claims submitted and/or reversed as a result of a data entry error are not counted (e.g., wrong quantity or day supply entered). CMS does not expect plan sponsors to search for reversed claims due to reporting errors, but only to exclude them if they are found. The examples given are not an exhaustive list of potential data entry errors.
10. For elements F, S, X and BB, a beneficiary who is a resident of a long-term care facility, is receiving hospice, palliative or end-of-life care, has sickle cell disease, or is being treated for active cancer related pain is exempt from these safety edits. This does not include beneficiaries who are not opioid naïve; they are reported in elements Y and CC.
11. Sponsors should refer to National Council of Prescription Drug Programs (NCPDP) telecommunication standards guidance for information about response codes related to opioid safety edits: https://www.ncpdp.org/NCPDP/media/pdf/VersionD-Questions.pdf.

Care coordination edit:

1. Care coordination edit claim rejections that resulted in requests for coverage determinations or appeals are currently not collected. Care coordination edit claims overridden by the pharmacist at the pharmacy with assistance from the plan (for example, the plan provides an override code) should be included in elements D, E, F, and G.
2. For elements E and J, report the first time the beneficiary meets the condition or the first time the claim is rejected.

Hard MME edit/opioid naïve days supply safety edit:

1. The rejected claim is generally not a coverage determination and should NOT be reported as a coverage determination. However, if the enrollee, the enrollee's representative, or the enrollee's prescriber then contacts the plan to request coverage, that request must be processed and reported as a coverage determination.
2. Count in elements U and FF only those coverage determinations that result in favorable determinations, whether full or partial.The coverage determination should be associated with a hard MME or opioid naïve safety edit claim rejection. A favorable determination may result in the original or a modified (e.g., different daily dose, quantity, etc.) opioid prescription or a different opioid being covered.

V. Coverage Determinations, Redeterminations (including At–Risk Redeterminations under a Drug Management Program), and Reopenings

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated

Data elements to be uploaded into HPMS at the Contract level. Please refer to HPMS layouts and templates for more information.

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.

- CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed and do not indicate that submitted data are incorrect, or that resubmissions are required.
- The rate of exception requests per 1,000 enrollees will be examined for outlier data. After accounting for enrollment, plans with values above the 95th percentile for their plan type or below the 5th percentile for their plan type will be flagged as outliers.
- The percent of coverage determination requests approved by the contract will be examined for outlier data. Contracts with values above the 95th percentile or below the 5th percentile will be flagged as outliers.
- CMS may apply new or adjust existing quality assurance checks and threshold validations based on data received from Part D sponsors.
- The rate of redeterminations per 1,000 enrollees will be examined for outlier data. After accounting for enrollment, contracts with values above the 95th percentile or below the 5th percentile will be flagged as outliers.
- The percent of redeterminations resulting in a full or partial reversal of the original decision will be examined for outlier data. After accounting for the number of redeterminations filed, contracts with values above the 95th percentile or below the 5th percentile will be flagged as outliers.
- The percent of redeterminations resulting in upholding the original decision will be examined for analysis purposes.
- The rate of reopenings per 1,000 enrollees will be examined for outlier data. After accounting for enrollment, contracts with values above the 95th percentile or below the 5th percentile will be flagged as outliers. CMS will also identify outliers in the percent of coverage determinations and redeterminations that are reopened.

C. Edits and Validation Checks - validation checks that should be performed by each Part D sponsor prior to data submission.

- Contracts should validate that the Case_Reopened_Date field is later than or equal to the Original_Disposition_Date field and that Reopening_Disposition_Date field is later than or equal to Case_Reopened_Date field.
- All data elements should be positive values.

D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
    - CMS will evaluate exception rates per 1,000 enrollees and will trend rates from quarter to quarter and from previous years.
    - Rates of appeals will be calculated per 1,000 enrollees. This means the total appeal rate per 1,000 enrollees is equal to the sum of the total number of appeals divided by average enrollment, times

$$[\text{ Total Appeal Rate per 1,0000 enrollees }] = \frac{\text{Total \# Appeals}}{\text{Avg. Enrollment}} \text{ x } 1{,}000$$

E. Notes – additional clarifications to a reporting section.

Coverage Determinations and Exceptions:

1. Plan sponsors should refer to 42 CFR §423.566, §423.568, §423.570, §423.572, §423.576, and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for additional information regarding Part D coverage determinations, including exceptions.
2. To ensure consistent reporting by all plan sponsors, CMS has included data fields to report partially favorable decisions and expects decisions that are partially favorable to be reported as such.
3. Requests for coverage determinations, including exceptions, are reported based on the date the enrollee/enrollee's representative is notified in writing of the coverage determination decision.
4. Report requests that relate to Part B versus Part D coverage. Point of Sale (POS) claims adjudications (e.g., a rejected claim for a drug indicating a B vs. D PA is required) are NOT included unless the plan subsequently processed a coverage determination. A drug that is ultimately covered under Part B should be reported as an adverse decision under Part D.
5. In the event that a beneficiary files one coverage determination request containing multiple distinct disputes (i.e., multiple drugs), each dispute should be counted as a separate request.
6. Report a request for an exception to a plan sponsor's PA criteria as a coverage determination. Reporting should be based on the manner in which each request for exception to a sponsor's PA criteria is processed.
7. Beneficiaries who have Utilization Management (UM) requirements waived based on an exception decision that cross-plan years are only reported in the initial year. For example, if an approval is effective from March 1, 2023 - February 29, 2024 the request/decision would only be counted in 2023.
8. Sponsors should include hospice-related coverage determinations in this reporting.
9. Direct Member Reimbursements (DMRs) are considered a coverage determination request; therefore, the plan disposition of the DMR should be reported under the appropriate coverage determination type.

10. Cumulative opioid MED POS edit coverage determination exceptions should be categorized as Utilization Management (elements G-J)
11. Withdrawn and dismissed coverage determinations are not included in the total number of coverage determinations. Instead, withdrawn coverage determinations (which are dismissed as a result of a withdrawal request) and dismissed coverage determinations are distinct categories.
12. If the plan processes a timely withdrawal request, the plan must report the withdrawn coverage determination request and the plan's dismissal of that coverage determination request.

Do not report:

- Drug or classes of drugs which are statutorily excluded from coverage under Part D. This exclusion is in place for the context of reporting only.
- IRE decisions.
- Duplicate requests.

Redeterminations:

13. Refer to 42 CFR §423.580, §423.582, §423.584, and §423.590 and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for additional information regarding Part D redeterminations.
14. Requests for redeterminations, including exceptions, are reported based onthe date the enrollee/enrollee's representative is notified in writing of the redetermination decision.
15. Redetermination requests that relate to Part B versus Part D coverage are included in this reporting if they are processed under the plan's Part D redetermination process.
16. In the event that a beneficiary files one redetermination request containing multiple distinct disputes (i.e., multiple drugs), plans should count each dispute as a separate request.
17. At-risk determination appeals (beneficiary-specific POS edit, or prescriber or pharmacy coverage limitation appeals, sharing information for subsequent Part D enrollments) made under a drug management program should be counted as a redetermination.
18. Redetermination requests relating to at-risk determinations made under a plan sponsor's drug management program should be reported based on the date the enrollee/enrollee's representative is notified in writing of the at-risk redetermination decision.
19. The denial of a Direct Member Reimbursement (DMR) request in whole or in part may be appealed. The disposition of that DMR redetermination request should be reported under the appropriate redetermination type.
20. Withdrawn and dismissed redeterminations are not included in the total number of redeterminations. Instead, withdrawn redeterminations (which are dismissed as a result of a withdrawal request) and dismissed redeterminations are distinct categories.
21. If the plan processes a timely withdrawal request, the plan must report the withdrawn redetermination request and the plan's dismissal of that redetermination request.

Do not report:

- Drug or classes of drugs that are statutorily excluded from coverage under Part D. This exclusion is in place for the context of reporting only.
- IRE decisions.
- Duplicate requests.
- An appeal by an enrollee (or another party) of the plan's dismissal of a coverage determination.
- A decision by the plan to uphold or reverse its dismissal of a coverage determination as a result of an enrollee (or another party) appealing a dismissal.
- Plan decisions regarding a request to vacate a dismissal.

Reopenings (Coverage Determinations and Redeterminations):

21. Refer to 42 CFR §423.1978-1986 and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for additional information related to reopenings.
22. "Other" refers to cases that would not be considered a "clerical error", "other error", "new and material evidence", "fraud or similar fault". Examples of "other" may include policy/procedure change, business configuration change, provider update, other adjustments etc.
23. All reopened coverage determinations and redeterminations should be included.
24. Sponsors should include reopened coverage determination and redetermination data, based on the date the enrollee/enrollee's representative is notified in writing of the revised decision.
25. For cases that are in a reopening status across multiple reporting periods, contracts should report those cases in each applicable reporting period. For example, if a plan reopened a coverage determination on 3/15/2023 and sent the notice of the revised decision on 4/22/2023, that case should be reported as "pending" in the Q1 data file and then as resolved in Q2 (either fully favorable, partially favorable or adverse).
26. Case ID is the unique internal tracking number the contract assigned to the case that is being reopened.
27. If the plan sponsor assigns a new case ID when it reopens a case, the plan should populate the case ID for the original coverage determination or redetermination in this field.
28. Original Disposition Date: This is the date of the original coverage determination decision or the date of the original redetermination decision.
29. Case Reopened Date: This may be the same as the date of the reopening disposition, and should fall in the quarter for which the data are being reported. If the Reopening Disposition is resolved (fully favorable, partially favorable, or adverse), the date of reopening disposition is expected to fall in the quarter for which the data is being reported.
30. Reopening Disposition Date is the date the plan revised the original disposition in its system and sent written notification to the enrollee. See 42 CFR §423.1982.

VI. Employer/Union-Sponsored Group Health Plan Sponsors

A. Data element definitions - details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

   Data elements to be uploaded into HPMS at the Plan (PBP) and contract level. Please refer to HPMS layouts and templates for more information.

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
   - CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and do not indicate that submitted data are incorrect, or that resubmissions are required.
   - CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D sponsors.
   - CMS will evaluate large differences between plan reported total employer enrollment and December HPMS enrollment [where (HPMS enrollment for plan / Total employer enrollment) >1.2 or <0.8 and |(HPMS enrollment for plan - Total employer enrollment)| >100]

C. Edits and Validation Checks - validation checks that should be performed by each Part D sponsor prior to data submission.
   - Total employer enrollment for plan equals zero, but December HPMS enrollment for plan is not equal to zero.
   - Contract did not submit data for all expected PBPs with enrollment in the prior year.

D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
   - CMS will evaluate for formulary oversight.

E. Notes - additional clarifications to a reporting section. This section incorporates previously answered frequently asked questions.
   1. All 800 series PDPs are required to report data for this reporting section. This includes direct contract PDPs.
   2. HPMS displays one module for reporting both Part C and Part D Employer/Union-Sponsored Group Health Plan Sponsors data.
   3. Each Part D contract will upload a file containing plan level data. An MA-PD may submit Part C and Part D data in one upload, the upload file should include all applicable plan IDs for a contract.
   4. Refer to Part C Technical Specifications for additional guidance.

VII. Summary of CY 2023 Part D Reporting Requirements

Section	Report Level	Frequency	Report Period(s)	Data Due date(s)
Enrollment and Disenrollment	Contract	Bi-annually	1/1/2023 - 6/30/2023; 7/1/2023 - 12/31/2023	Last Monday ofAugust Last Monday of February
Medication Therapy Managemen tPrograms	Contract	Annually	1/1/2023 - 12/31/2023	Last Monday of February
Grievances	Contract	Annually	1/1/2023 - 3/31/2023; 4/1/2023 - 6/30/2023; 7/1/2023 - 9/30/2023; 10/1/2023 - 12/31/2023	First Monday of February
Improving Drug Utilization ReviewControls	Contract	Annually	1/1/2023- 3/31/2023; 1/1/2023 - 6/30/2023; 1/1/2023 - 9/30/2023; 1/1/2023 - 12/31/2023	Last Monday of February

Section	Report Level	Frequency	Report Period(s)	Data Due date(s)
Coverage Determinations, Redeterminations and Reopenings	Contract and PBP	Annually	1/1/2023 - 3/31/2023; 4/1/2023 - 6/30/2023; 7/1/2023 - 9/30/2023; 10/1/2023 - 12/31/2023	Last Monday of February
Employer/Union-Sponsored Group Health Plan Sponsors	Contract and PBP	Annually	1/1/2023 - 12/31/2023	First Monday of February