

**Medicare Part D Plan Reporting Requirements:
Technical Specifications Document
Contract Year 2021**

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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 are 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	Plan
Coverage Determinations and Redeterminations	Contract
Employer/Union-Sponsored Group Health Plan Sponsors	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 2021);
 - 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 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). MA Organizations and Medicare Cost Plans that offer Part D benefits will be required to comply with all reporting requirements contained herein, with the exception of the Employer/Union-Sponsored Group Health Plan Sponsors reporting section. PACE Organizations are excluded from these Part D reporting requirements.

- Contracts that terminate prior to July 1st of the following Contract Year are excluded from these reporting requirements.
- Similarly, Plan Benefit Packages (PBPs) that terminate prior to July 1st of the following Contract Year are excluded from reporting data for sections requiring PBP level data.

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

Contracts with no enrollment have the option of reporting that they have no enrollment (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 report all 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 files, contracts with values above the 95th percentile for their contract type will be flagged as outliers.
- 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.

- 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.
- Number of disenrollment requests denied for any reason does not exceed total number of disenrollment requests.

- 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 and 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 TRC, instead of via receipt of a member's disenrollment request, should not be included in this reporting.
6. HPMS displays one module for reporting both Part C and Part D Enrollment/Disenrollment data.
7. 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)): Reporting 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 no longer met the eligibility criteria for the MTM program for the contract year within the reporting period should no longer be enrolled in the MTM program and should not be reported.
 - Beneficiaries who are deceased or were retroactively disenrolled prior to their MTM eligibility date should not be reported.
5. File submissions should exclude Enhanced MTM Model data.
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.
 - The MTM service dates (such as CMR date of (initial) offer (element O), Date(s) of CMR(s) (element R) and Date CMR written summary in CMS standardized format was provided or sent (element S) must be on or after the Date of MTM program enrollment (element I).
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 M, opt-out code "03" 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 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 Q).
13. If a CMR written summary in CMS standardized format is sent and returned, the date that the written summary was sent should still be reported (element S).
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 Q) and Date(s) of CMR(s) with written summary in CMS standardized format (element S) 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 Y) 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. Regarding medication therapy problem resolutions resulting from recommendations made to the beneficiary's prescriber(s) as a result of MTM recommendations (element Z), sponsors should retain documentation supporting the number of medication therapy problem resolutions reported to CMS. 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 January 1 – December 31, 2021, if the beneficiary met the specified targeting criteria per CMS – Part D requirements in § 423.153(d)(2) in Element F, then Element K must be 01 (Multiple chronic diseases/multiple Part D Drugs/cost threshold). [Options 02 (Drug management program at-risk beneficiary) and 03 (Both) are not applicable for the January 1 – December 31, 2021 reporting period.]
21. Element AA is not applicable for the January 1 – December 31, 2021 reporting period. Element AA must be 0 for the January 1 – December 31, 2021 reporting period.

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 percent 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 type will 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 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.

- 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 include 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.

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

- 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.

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

- 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 (orally or written) of the grievance decision.
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 two different issues, report 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 a 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:

1. Complaints received by 1-800 Medicare or recorded only in the CTM.
2. Withdrawn grievances.
3. 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 Plan 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 upon data received from Part D sponsors.
- CMS will evaluate if reported elements related to edit specifications do not match current HPMS opioid safety edit template submissions.
- CMS will evaluate high and low percentages of claim rejections overridden by the pharmacist 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 point-of-sale (POS) safety edit criteria).

- C. Edits and Validation Checks - Part D contracts should validate the following prior to data submission:

Opioid Safety Edit	Element Validations
<i>Care Coordination Edit</i>	The number of claims rejected due to the care coordination edit (Element C) should be greater than or equal to Elements D and E.
<i>Care Coordination Edit</i>	The number of unique beneficiaries with at least one claim rejected due to the care coordination edit (Element F) should be greater than or equal to Elements G and H.
<i>Hard MME Edit</i>	If yes to element I, the number of claims rejected due to the hard MME edit (Element M) should be greater than or equal to Elements N and O.

<i>Hard MME Edit</i>	If yes to element I, the number of unique beneficiaries with at least one claim rejected due to the hard MME edit (Element P) should be greater than or equal to Elements Q, R, S, T, and U.
<i>Opioid Naïve Edit</i>	The number of claims rejected due to the opioid naïve days supply edit (Element W) should be greater than or equal to Elements X and Y.
<i>Opioid Naïve Edit</i>	The number of unique beneficiaries with at least one claim rejected due to the opioid naïve days supply edit (Element Z) should be greater than or equal to Elements, AA, BB, CC, DD and EE.

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

- CMS will monitor data at the contract-level and criteria-level (contracts with the same POS edit criteria).

E. Notes – additional clarifications to a reporting section.

- **General:**

1. MA-only Plans are excluded from reporting.
2. Formulary-level cumulative opioid MME POS edits include the care coordination and the hard MME edit.
3. If a POS edit does not include a prescriber and/or pharmacy count criterion, the plan sponsor should enter “0” in the appropriate elements (elements A, B, K, and L).
4. If a plan sponsor submitted and was approved for multiple cumulative opioid MME or opioid naïve POS edits during the 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, I-L, 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 plan, beneficiary, prescriber, pharmacy, drug (strength and dosage form), quantity, date of service (DOS) and formulary-level cumulative opioid MME POS edit. For example, if multiple transactions are submitted and rejected by the plan for the same formulary-level cumulative opioid MME POS edit from the same pharmacy for the same beneficiary, prescription (drug, quantity and prescriber) and DOS, this would count as one rejected claim. On the other hand, 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 cumulative opioid MME POS edit, this would count as 3 rejected claims.

6. If a claim rejects for both a care coordination or a hard MME edit and an early refill edit, the claim should be excluded from the formulary-level cumulative opioid MME POS 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 safety edits at POS.
 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.
- **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, G, and H.
 - **Cumulative 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 O, T, U, Y, DD, and EE only those coverage determinations or appeals that result in favorable determinations, whether full or partial. The coverage determination or appeal should be associated with a cumulative opioid hard MME edit 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 and Redeterminations

- 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 determinations 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 upon 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 1,000.

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

E. Notes – additional clarifications to a reporting section.

2. 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 only partially favorable to be reported as such. They are not to be reported as favorable decisions.
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 considered for this reporting 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, 2021 - February 29, 2022 the request/decision would only be counted in 2021.
8. Sponsors should include hospice-related coverage determinations in this reporting.
9. Direct Member Reimbursements (DMRs) 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, withdrawn and dismissed coverage determinations has its own total category.

Do not report:

1. 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.
2. IRE decisions
3. Duplicate requests

3. Redeterminations:

12. 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.
13. Redetermination requests are reported based on the date the enrollee/enrollee's representative is notified in writing of the redetermination decision.
14. 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.
15. 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.
16. Beneficiary-specific POS edit, or prescriber or pharmacy coverage limitation appeals (at-risk determination appeals) made under a drug management program should be counted as a redetermination.
17. Withdrawn and dismissed redeterminations are not included in the total number of redeterminations, withdrawn and dismissed redeterminations has its own total category.

Do not report:

1. 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.
2. IRE decisions
3. Duplicate requests

4. Reopenings (Coverage Determinations and Redeterminations):

18. 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.
19. "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.
20. All reopened coverage determinations and redeterminations should be included.
 21. 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.
 22. 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 3/15/2021 and sent the notice of the revised decision on 4/22/2021, 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).
 23. Case ID is the unique internal tracking number the contract assigned to the case that is being reopened.
 24. 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.
 25. Original Disposition Date: This is the date of the original coverage determination decision or the date of the original redetermination decision.
 26. 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.
 27. 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 offered to employers are required to report data for this reporting section. Previously, PDPs with parent organizations that already reported these data for MA-PDs per the Part C reporting requirements were exempt.
 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.
 4. Refer to Part C Technical Specifications for additional guidance.

VII. Summary of CY2021 Part D Reporting Requirements

Section	Report Level	Frequency	Report Period(s)	Data Due date(s)
Enrollment and Disenrollment	Contract	Bi-annually	1/1/2021 - 6/30/2021;	Last Monday of August
			7/1/2021 - 12/31/2021	Last Monday of February
Medication Therapy Management Programs	Contract	Annually	1/1/2021 - 12/31/2021	Last Monday of February
Grievances	Contract	Annually	1/1/2021 - 3/31/2021;	First Monday of February
			4/1/2021 - 6/30/2021;	
			7/1/2021 - 9/30/2021;	
			10/1/2021 - 12/31/2021	
Improving Drug Utilization Review Controls	PBP	Annually	1/1/2021- 3/31/2021;	Last Monday of February
			1/1/2021 - 6/30/2021;	
			1/1/2021 - 9/30/2021;	
			1/1/2021 - 12/31/2021	

Section	Report Level	Frequency	Report Period(s)	Data Due date(s)
Coverage Determinations and Redeterminations	Contract	Annually	1/1/2021 - 3/31/2021; 4/1/2021 - 6/30/2021; 7/1/2021 - 9/30/2021; 10/1/2021 - 12/31/2021	Last Monday of February
Employer/Union-Sponsored Group Health Plan Sponsors	PBP	Annually	1/1/2021 - 12/31/2021	First Monday of February