# Medicare Part D Plan Reporting Requirements: Technical Specifications Document Contract Year 2020

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# **Table of Contents**

Introduction	3
I. Enrollment and Disenrollment	
II. Medication Therapy Management (MTM) Programs	
III. Grievances	19
IV. Improving Drug Utilization Review Controls	22
V. Coverage Determinations and Redeterminations	26
VI. Employer/Union-Sponsored Group Health Plan Sponsors	30
VII.Summary of CY2020 Part D Reporting Requirements	

#### Introduction

The Part D Plan Reporting Requirements document provides a description of the reporting sections, reporting timeframes and deadlines, and specific data elements for each reporting section. The document has completed the Office of Management and Budget (OMB) review and approval process in compliance with the Paper Reduction Act of 1995, and its OMB control number is #0938-0992. The document is located on the CMS website <a href="https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting">https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting</a> ReportingOversight.html.

These technical specifications supplement the Part D Plan Reporting Requirements, and do not change, alter, or add to the data collection described above. 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

Compliance with these reporting requirements is a contractual obligation of all Part D sponsors. Compliance requires that the data not only be submitted in a timely manner, but that they also are accurate. 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.

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

In order to accommodate data validation activities, data corrections must be submitted prior to March 31<sup>st</sup> following the end of year reporting deadline. If data are determined to be incorrect after March 31<sup>st</sup>, CMS requires the Part D sponsor to submit a formal request to resubmit those data. HPMS designates this request as a Request Resubmission. Requests for resubmissions will be evaluated on a case by case basis.

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 2020);
  - c. Select contracts or plans, depending on reporting level; and
  - d. The reason for the resubmission request.

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 (<);</li>
- 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 and/or Plan Benefit Packages (PBPs) that terminate prior to July 1st of the following Contract Year are excluded from these reporting requirements.

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: <a href="mailto:partd-planreporting@cms.hhs.gov">partd-planreporting@cms.hhs.gov</a>.

## 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.

# **Enrollment**

Data elements to be entered into the HPMS at the Contract level:

Element Letter	Element Name	Definition	Allowable Values
A.	Total number of enrollment requests (i.e., requests initiated by the beneficiary or his/her authorized representative) received in the specified time period. Do not include auto/facilitated or passive enrollments, rollover transactions or other enrollments effectuated by CMS.	The total number of enrollment requests received in the specified time period.	<ul> <li>Field type: Number</li> <li>Note – this element is based on initial receipt date, not effective date.</li> </ul>
B.	Total number of enrollment requests complete at the time of initial receipt (i.e., required no additional information from applicant or his/her authorized representative).	Of the total reported in A, the number of enrollment requests complete, as defined in guidance, at the time of initial receipt. (i.e., required no additional information from applicant or his/her representative).	<ul> <li>Field type: Number</li> <li>Is a subset of A</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
C.	Total number of enrollment requests for which the sponsor was required to request additional information from the applicant (or his/her representative).	Of the total reported in A, the number of enrollment requests that were not complete at the time of initial receipt as defined in guidance, and for which the sponsor was required to request additional information from the applicant (or his/her representative). Do not report as a distinct enrollment request information received from an applicant in response to a request for information necessary to complete an enrollment request.	<ul> <li>Field type: Number</li> <li>Is a subset of A</li> </ul>
D.	Total number of enrollment requests denied due to the sponsor's determination of the applicant's ineligibility to elect the plan (i.e., individual not eligible for an election period).	Of the total reported in A, the number of enrollment requests denied due to the sponsor's determination of the applicant's ineligibility to elect the plan (i.e., individual not eligible for an election period.)	<ul> <li>Field type: Number</li> <li>Is a subset of A</li> </ul>
E.	Number of incomplete enrollment requests received that are completed within established timeframes.	Of the total reported in C, the number of enrollment requests received that are incomplete upon initial receipt and completed within established timeframes.	<ul><li>Field type: Number</li><li>Is a subset of C</li></ul>

Element Letter	Element Name	Definition	Allowable Values
F.	Number of enrollment requests denied due to the applicant or his/her authorized representative not providing information to complete the enrollment request within established timeframes.	Of the total reported in C, the number of enrollment requests denied due to the applicant or his/her authorized representative not providing information to complete the enrollment request within established timeframes.	<ul> <li>Field type: Number</li> <li>Is a subset of C</li> </ul>
G.	Number of paper enrollment requests received.	Of the total reported in A, the number of paper enrollment requests received.	<ul><li>Field type: Number</li><li>Is a subset of A</li></ul>
H.	Number of telephonic enrollment requests received (if offered).	Of the total reported in A, the number of telephonic enrollment requests received (if sponsor offers this mechanism).	<ul><li>Field type: Number</li><li>Is a subset of A</li></ul>
I.	Number of internet enrollment requests received via plan or affiliated third-party website (if sponsor offers this mechanism).	Of the total reported in A, the number of internet enrollment requests received via plan or affiliated third-party website (if sponsor offers this mechanism). Include electronic enrollment requests received via an electronic device.	<ul> <li>Field type: Number</li> <li>Is a subset of A</li> </ul>
J.	Number of Online Enrollment Center (OEC) enrollment requests received.	Of the total reported in A, the number of Medicare Online Enrollment Center (OEC) enrollment requests received.	<ul><li>Field type: Number</li><li>Is a subset of A</li></ul>

Element Letter	Element Name	Definition	Allowable Values
K.	Number of enrollment requests effectuated by sales persons (as defined in Chapter 3 of the Medicare Managed Care Manual).	Of the total reported in A, the number of enrollment requests effectuated by sales persons (as defined in Chapter 3 of the Medicare Managed Care Manual).	<ul> <li>Field type: Number</li> <li>Is a subset of A</li> </ul>
L.	Number of enrollment transactions submitted using the SEP Election Period code "S" related to creditable coverage.	Of the total reported in A, the number of enrollment transactions submitted using the SEP Election Period code "S" related to creditable coverage. For individuals who involuntarily lose creditable coverage or who were not adequately informed of a loss of creditable coverage or that they never had creditable coverage.	<ul> <li>Field type: Number</li> <li>Is a subset of A</li> </ul>
M.	Number of enrollment transactions submitted using the SEP Election Period code "S" related to SPAP.	Of the total reported in A, the number of enrollment transactions submitted using the SEP Election Period code "S" related to SPAP. For individuals who belong to a Qualified SPAP or who lose SPAP eligibility.	<ul><li>Field type: Number</li><li>Is a subset of A</li></ul>
N.	Number of enrollment transactions submitted using the SEP Election Period code "S" that coordinates with the Medicare Advantage Disenrollment Period.	Of the total reported in A, the number of enrollment transactions submitted using the SEP Election Period code "S" that coordinates with the Medicare Advantage Disenrollment Period (MADP).  Please note that the MADP is not available after 2018.	<ul> <li>Field type: Number</li> <li>Is a subset of A</li> <li>For stand-alone PDPs only.</li> </ul>

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Element	Element Name	Definition	Allowable Values
O.	Number of enrollment transactions submitted using the SEP Election Period code "S" for individuals affected by a contract nonrenewal, plan termination or service area reduction.	Of the total reported in A, the number of enrollment transactions submitted using the SEP Election Period code "S" for individuals affected by a contract nonrenewal, plan termination or service area reduction.	<ul> <li>Field type: Number</li> <li>Is a subset of A</li> </ul>
P.	The total number of individuals included in the advance notification for seamless conversion enrollment <sup>1</sup>	The total number of individuals included in the advance notification for seamless conversion enrollment for effective dates occurring within the reporting period.	<ul> <li>Field type: Number</li> <li>Applicable only to MA organizations approved by CMS to offer seamless conversion enrollment.</li> </ul>
Q.	Number of individuals whose Medicare eligibility is based on age.	Of the total reported in 1P, the number of individuals whose Medicare eligibility is based on age.	<ul> <li>Field type: Number</li> <li>Is a subset of 1P</li> <li>Applicable only to MA organizations approved by CMS to offer seamless conversion enrollment.</li> </ul>

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<sup>&</sup>lt;sup>1 1</sup> In CMS 4182-F (83 FR 16440, April 16, 2018), CMS codified the current seamless conversion enrollment process and for contract year 2020 and beyond will refer to this activity as the "default enrollment" process starting with enrollments effective 1/1/19 and later. As such, the reporting requirements for the seamless conversion enrollment process outlined in this document and in the 2020 Medicare Part D Reporting Requirements (Elements 1.P. through 1.S.) apply to 2020 default enrollment activity.

Element Letter	Element Name	Definition	Allowable Values
R.	Number of individuals whose Medicare eligibility is based on disability.	Of the total reported in 1P, the number of individuals whose Medicare eligibility is based on disability.	<ul> <li>Field type: Number</li> <li>Is a subset of 1P</li> <li>Applicable only to MA organizations approved by CMS to offer seamless conversion enrollment.</li> </ul>
S.	Number of enrollments submitted to CMS.	Of the total reported in 1P, the number of enrollments submitted to CMS.	<ul> <li>Field type: Number</li> <li>Is a subset of 1P</li> <li>Applicable only to MA organizations approved by CMS to offer seamless conversion enrollment.</li> </ul>

# Disenrollment

Data elements to be entered into the HPMS at the Contract level:

Element Letter	Element Name	Definition	Allowable Values
A.	Total number of voluntary disenrollment requests received in the specified time period. Do not include disenrollments resulting from an individual's enrollment in another plan.	The total number of voluntary disenrollment requests received in the specified time period. Do not include disenrollments resulting from an individual's enrollment in another plan.	<ul> <li>Field type: Number</li> <li>Note – this element is based on initial receipt date, not effective date.</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
B.	Total number of disenrollment requests complete at the time of initial receipt (i.e., required no additional information from enrollee or his/her authorized representative).	Of the total reported in A, the number of disenrollment requests complete at the time of initial receipt (i.e., required no additional information from enrollee or his/her representative).	<ul> <li>Field type: Number</li> <li>Is a subset of A</li> </ul>
C.	Total number of disenrollment requests for which the sponsor was required to request additional information from the enrollee (or his/her representative).	Of the total reported in A, the number of disenrollment requests that were not complete at the time of initial receipt, as defined in guidance, and for which the sponsor was required to request additional information from the enrollee (or his/her representative).	<ul> <li>Field type: Number</li> <li>Is a subset of A</li> </ul>
D.	Total number of disenrollment requests denied due to the sponsor's determination of the enrollee's ineligibility to elect to disenroll from the plan (i.e., individual not eligible for an election period).	Of the total reported in A, the number of disenrollment requests denied due to the sponsor's determination of the enrollee's ineligibility to elect to disenroll from the plan (i.e., individual not eligible for an election period).	<ul> <li>Field type: Number</li> <li>Is a subset of A</li> </ul>

Element	Element Name	Definition	Allowable Values
Letter E.	Number of	Of the total reported in C, the	- Field type: Number
Е.	incomplete disenrollment requests received that are completed within established timeframes.	number of disenrollment requests received that are incomplete upon initial receipt and completed within established timeframes.	<ul><li>Field type: Number</li><li>Is a subset of C</li></ul>
F.	Number of disenrollment requests denied due to the enrollee or his/her authorized representative not providing information to complete the disenrollment request within established timeframes.	Of the total reported in C, the number of disenrollment requests denied due to the enrollee or his/her authorized representative not providing information to complete the disenrollment request within established timeframes.	<ul> <li>Field type: Number</li> <li>Is a subset of C</li> </ul>
G.	The total number of involuntary disenrollments for failure to pay plan premium in the specified time period.	The total number of involuntary disenrollments for failure to pay plan premium in the specified time period.	<ul> <li>Field type: Number</li> <li>Note – this element is based on disenrollment effective date.</li> </ul>
H.	Number of disenrolled individuals who submitted a timely request for reinstatement for Good Cause.	Of the total reported in G, the number of disenrolled individuals who submitted a timely request for reinstatement for Good Cause.	<ul><li>Field type: Number</li><li>Is a subset of G</li></ul>
I.	Number of favorable Good Cause determinations.	Of the total reported in H, the number of favorable Good Cause determinations.	<ul><li>Field type: Number</li><li>Is a subset of H</li></ul>

Element	Element Name	Definition	Allowable Values
Letter			
J.	Number of	Of the total reported in I, the	<ul> <li>Field type: Number</li> </ul>
	individuals	number of individuals	Is a subset of I
	reinstated.	reinstated.	

- 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 does 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 95<sup>th</sup> 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 95<sup>th</sup> 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 Plans.
- 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 determine the number of MA or standalone enrollments coming in through an agent broker.
- 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.

- 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.
- 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 as defined in guidance, 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.
- 8. Enrollment Element N- Number of enrollment transactions submitted using SEP Election Period code "S" that coordinates with the Medicare Advantage Disenrollment Period:
  - Plans should report "0" for this data element.

# 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 does 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 Plans.
- 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 the percent of beneficiaries who are offered and receive a CMR with written summary in CMS' standardized format.
  - CMS will evaluate initial MTM outcomes, as reported as drug therapy problem recommendations and drug therapy problem resolutions.
- E. Notes additional clarifications to a reporting section.
  - 1. CMS will accept either HICN or 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.
  - 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 N) and Date(s) of CMR(s) with written summary in CMS' standardized format (element Q)) must be on or after the Date of MTM program enrollment (element I).
- Only CMRs that met CMS Part D requirements should be reported for any beneficiary enrolled in the contract's MTM program. Refer to the 2020 MTM Program Guidance and Submission memo for CMR requirements and definitions.
- 10. When reporting the MTM program opting-out reason in element L, 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 P).
- 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 R).
- 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, the CMR (element P) and summary (element

- R) 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 drug therapy problem recommendations made to prescriber(s) as a result of MTM services (element X) 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 drug therapy problem recommendations.
  - For example, if 3 drug 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 drug therapy recommendations were sent to a second prescriber, this should still be reported as 3 recommendations (not 6).
- 16. Regarding drug therapy problem resolutions resulting from recommendations made to the beneficiary's prescriber(s) as a result of MTM recommendations (element Y), sponsors should retain documentation supporting the number of drug 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 drug therapy problem recommendation made within the current reporting period, the change may be reported for the current reporting period. However, this change to drug 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 optout, 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.

## 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 does 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 Plans.
- 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.

[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.

- 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.
  - 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 the grievance decision date.
  - 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 disensols 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 does 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 Plans.
  - 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 POS edit criteria).
- C. Edits and Validation Checks Part D contracts should validate the following prior to data submission:
  - The number of claims with at least one care coordination edit claim rejection overridden by the pharmacist at the pharmacy (data element D) is a value less than or equal to the minimum number of claims rejected due to the care coordination edit (data element C).
  - The number of unique beneficiaries with at least one care coordination edit claim rejection overridden by the pharmacist at the pharmacy (data element F) is a value less than or equal to the unique beneficiaries with at least one claim rejected due to the care coordination edit (data element E).
  - The number of unique beneficiaries with at least one care coordination edit claim rejection overridden by the pharmacist at the pharmacy that also had an opioid claim successfully processed at POS (data element G) is a value less than or equal to the unique beneficiaries with at least one claim rejected due to the care coordination edit (data element E).
  - The number of unique beneficiaries with at least one hard MME edit claim rejection that also had an opioid claim successfully processed at POS other than through a favorable coverage determination or appeal, such as

- a pharmacist communication and/or plan override (data element N) is a value less than or equal to the number of unique beneficiaries with at least one claim rejected due to the hard MME edit (data element M).
- The number of unique beneficiaries with at least one hard MME edit claim rejection that also had a coverage determination or appeal request for an opioid drug subject to the hard MME edit (data element O) is a value less than or equal to the number of unique beneficiaries with at least one claim rejected due to the hard MME edit (data element M).
- The number of unique beneficiaries with at least one hard MME edit claim rejection with a coverage determination or appeal request for an opioid drug subject to the hard MME edit that had a favorable (either full or partial) coverage determination or appeal (data element P) is a value less than or equal to the number of unique beneficiaries with at least one claim rejected due to the hard MME edit (data element M).
- The number of unique beneficiaries with at least one hard MME claim rejection that also had an opioid claim successfully processed for an opioid drug subject to the hard MME edit through a favorable (either full or partial) coverage determination or appeal (data element Q) is a value less than or equal to the number of unique beneficiaries with at least one claim rejected due to the hard MME edit (data element M).
- The number of unique beneficiaries with at least one opioid naïve days supply claim rejection that also had an opioid claim successfully processed at POS other than through a favorable coverage determination or appeal, such as pharmacist communication and/or plan override (data element U) is a value less than or equal to the number of unique beneficiaries with at least one claim rejected due to the opioid naïve days supply edit (data element T).
- The number of unique beneficiaries with at least one opioid naïve days supply edit claim rejection that also had a coverage determination or appeal request for an opioid drug subject to the opioid naïve days supply edit (data element V) is a value less than or equal to the number of unique beneficiaries with at least one claim rejected due to the opioid naïve days supply edit (data element T).
- The number of unique beneficiaries with at least one opioid naïve days supply edit claim rejection that also had a coverage determination or appeal request for an opioid drug subject to the opioid naïve days supply edit that had a favorable (either full or partial) coverage determination or appeal (data element W) is a value less than or equal to the number of unique beneficiaries with at least one claim rejected due to the opioid naïve days supply edit (data element T).
- The number of unique beneficiaries with at least one opioid naïve days supply edit claim rejection that also had a claim successfully processed for an opioid drug subject to the opioid naïve days supply edit through a favorable (either full or partial) coverage determination or appeal (data element X) is a value less than or equal to the number of unique beneficiaries with at least one claim rejected due to the opioid naïve days supply edit (data element T).

- 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, J, and K).
- 4. If a plan sponsor submitted and was approved for multiple cumulative opioid MME or opioid naive 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 and H-K). 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 an opioid 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. Claims submitted and/or reversed as a result of a data entry error are not counted (e.g., wrong quantity or day supply entered).

## Care coordination edit:

 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 F and G.

## • 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. If the coverage determination or appeal was initiated in the calendar year after the current reporting period and before the reporting deadline, but was the result of a claim rejection within the current reporting period, the coverage determination or appeal request and/or approval may be reported for the current reporting period. However, this coverage determination or appeal should not be reported again in the following reporting period.
- 3. Count in elements P, Q, W, and X 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 does 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 Plans.
  - 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.

[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:

- Plan sponsors should refer to 42 CFR §423.566, §423.568, §423.570, §423.572, §423.576, and the Part C & D 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 decision date.
- 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, 2020 February 29, 2021 the request/decision would only be counted in 2020.
- 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 Grievances, Organization/Coverage Determinations, and Appeals Guidance for additional information regarding Part D redeterminations.
- 13. Redetermination requests are reported based on the decision date.
- 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 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. 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 3/15/2020 and sent the notice of the revised decision on 4/22/2020, 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).
- 22. Case ID is the unique internal tracking number the contract assigned to the case that is being reopened.
- 23. 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.
- 24. Original Disposition Date: This is the date of the original coverage determination decision or the date of the original redetermination decision.
- 25. 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.
- 26. 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 does 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 Plans.
  - 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 2019.
- 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. Effective for 2020 reporting, 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 CY2020 Part D Reporting Requirements

Section	Report Level	Frequency	Report Period(s)	Data Due date(s)
Enrollment and Disenrollment	Contract	Bi-annually	1/1/2020 - 6/30/2020;	Last Monday of August
			7/1/2020 - 12/31/2020	Last Monday of February
Medication Therapy Management Programs	Contract	Annually	1/1/2020 - 12/31/2020	Last Monday of February
Grievances	Contract	Annually	1/1/2020 - 3/31/2020; 4/1/2020 - 6/30/2020; 7/1/2020 - 9/30/2020; 10/1/2020 - 12/31/2020	First Monday of February
Improving Drug Utilization Review Controls	PBP	Annually	1/1/2020- 3/31/2020; 1/1/2020 - 6/30/2020; 1/1/2020 - 9/30/2020; 1/1/2020 - 12/31/2020	Last Monday of February

Section	Report Level	Frequency	Report Period(s)	Data Due date(s)
Coverage Determinations and Redeterminations	Contract	Annually	1/1/2020 - 3/31/2020; 4/1/2020 - 6/30/2020; 7/1/2020 - 9/30/2020; 10/1/2020 - 12/31/2020	Last Monday of February
Employer/Union- Sponsored Group Health Plan Sponsors	PBP	Annually	1/1/2020 - 12/31/2020	First Monday of February