

# MEDICARE PART D REPORTING REQUIREMENTS

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## Introduction

Section 1860D–12(b)(3)(D) of the Act provides broad authority for the Secretary to add terms to the contracts with Part D sponsors, including terms that require the sponsor to provide the Secretary with information as the Secretary may find necessary and appropriate. Pursuant to our statutory authority, we codified these information collection requirements for Part D sponsors in regulation at §423.514.

42 CFR §423.514(a) requires each Part D sponsor to have a procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, statistics indicating the following:

- 1) The cost of its operations.
- 2) The patterns of utilization of its services.
- 3) The availability, accessibility, and acceptability of its services.
- 4) Information demonstrating that the Part D sponsor has a fiscally sound operation.
- 5) Pharmacy performance measures.
- 6) Other matters that CMS may require.

The purpose of this document is to assure a common understanding of the Part D reporting requirements and how these data will be used to monitor the prescription drug benefit provided to Medicare beneficiaries. CMS will use the following terminology to ensure consistency in these reporting requirements:

- Part D sponsor –an organization which has one or more contract(s) with CMS to provide Part D benefits to Medicare beneficiaries. Each contract is assigned a CMS contract number (e.g. H# or S#).
- Plan – a plan benefit package (PBP) offered within a Part D contract (e.g. Plan ID #).

This document lists reporting timeframes, deadlines and required levels of reporting. Reporting deadlines may occur in the subsequent calendar year. Data elements may be reported at the Plan (PBP) level, or the individual Contract level.

The following criteria were used in selecting reporting requirements:

- 1) Minimal administrative burden on Part D sponsors;
- 2) Legislative and regulatory authority;
- 3) Validity, reliability, and utility of data elements requested; and
- 4) Wide acceptance and current utilization within the industry.

Unless otherwise specified, drug utilization data should include all covered\* Part D drugs, including compounded drugs.

PACE Organizations offering Part D coverage are exempt from these Part D reporting requirements.

Medicare/Medicaid Plans (MMPs) should refer to the Medicare-Medicaid Financial Alignment Model Reporting Requirements for additional reporting guidance. Some MMP measures may have specific timelines that may be different.

\*Covered Part D drugs as defined by Section 1860D-2(e)(2) of the Social Security Act (The Act). Drugs offered under enhanced or supplemental drug benefits by sponsors are not covered Part D drugs.

## Section I. Enrollment and Disenrollment

Enrollment and disenrollment periods for Medicare Advantage and Part D plan elections are outlined at 42 CFR 422 Subpart B and 42 CFR 423 Subpart B, respectively.

CMS will collect data on the elements for these requirements, which are otherwise not available to CMS, in order to evaluate sponsors' processing of enrollment, disenrollment, and reinstatement requests in accordance with CMS requirements.

All enrollment and disenrollment activity involving a Part D benefit (e.g. standalone prescription drug plan, MA prescription drug plan, cost plan with Part D optional supplemental benefit) is reported via the Part D requirements. MAOs and 1876 Cost plans report enrollment and disenrollment activity that does not involve a Part D benefit under the Part C reporting requirements.

Section 1 Enrollment, elements 1.A-1.K must include all enrollments. Disenrollments must not be included in Section 1 Enrollment. Section 2 Disenrollment, elements 2.A-2.F, must include all voluntary disenrollment transactions.

Reporting timeline:

	<b>Period 1</b>	<b>Period 2</b>
<b>Reporting Period</b>	January 1 – June 30	July 1 – December 31
<b>Data due to CMS/HPMS</b>	Last Monday of August	Last Monday of February

Data files to be uploaded through the HPMS at the Contract level, following templates provided in HPMS.

### 1. Enrollment:

- A. The total number of enrollment requests (initiated by the beneficiary or his/her authorized legal representative) received in the specified time period. Do not include auto/facilitated or passive enrollments, rollover transactions, or other enrollments effectuated by CMS.
- B. Of the total reported in A, the number of enrollment requests complete at the time of initial receipt.
- C. Of the total reported in A, the 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).
- D. Of the total reported in A, the number of enrollment requests denied due to the sponsor's determination that the applicant was not eligible for an election period.
- E. Of the total reported in C, the number of enrollment requests received that are incomplete upon initial receipt and completed within established timeframes.
- F. Of the total reported in C, the number of enrollment requests denied due to the applicant or his/her authorized legal representative not providing the information required to complete the enrollment request within established timeframes.

- G. Of the total reported in A, the number of paper enrollment requests received.
- H. Of the total reported in A, the number of telephonic enrollment requests received (if sponsor offers this mechanism).
- I. Of the total reported in A, the number of electronic enrollment requests received via an electronic device or secure internet website (if sponsor offers this mechanism).
- J. Of the total reported in A, the number of Medicare Online Enrollment Center (OEC) enrollment requests received.
- K. Of the total reported in A, the number of enrollment requests received from an applicant through an agent or broker.

**2. Disenrollment:**

- A. 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.
- B. Of the total reported in A, the number of disenrollment requests complete at the time of initial receipt.
- C. Of the total reported in A, the number of disenrollment requests that were not complete at the time of initial receipt.
- D. Of the total reported in A, the number of disenrollment requests denied due to the sponsor's determination that the enrollee was not eligible for an election period.
- E. Of the total reported in C, the number of disenrollment requests received that are incomplete upon initial receipt and completed within established timeframes.
- F. Of the total reported in C, the number of disenrollment requests denied due to the enrollee or his/her authorized legal representative not providing information required to complete the disenrollment request within established timeframes.
- G. The total number of involuntary disenrollments for failure to pay plan premium in the specified time period.
- H. Of the total reported in G, the number of disenrolled individuals who submitted a timely request for reinstatement for Good Cause.
- I. Of the total reported in H, the number of favorable Good Cause determinations.
- J. Of the total reported in I, the number of individuals reinstated.

## Section II. Medication Therapy Management Programs

The requirements stipulating that Part D sponsors provide Medication Therapy Management (MTM) programs are described in Title I, Part 423, Subpart D, § 423.153. For monitoring purposes, Part D sponsors will be responsible for reporting several data elements related to their MTM program. Data will be uploaded in a data file.

Reporting timeline:

	YTD
<b>Reporting Period</b>	January 1 - December 31
<b>Data due to CMS/HPMS</b>	Last Monday of February

Sponsors are required to target beneficiaries for the MTM program who meet specific criteria as specified by CMS in § 423.153(d)(2). Some sponsors also offer enrollment in the MTM program to an expanded population of beneficiaries who do not meet the targeting criteria under § 423.153(d)(2).

The following information will be collected for each beneficiary identified as being eligible for the Part D MTM program, whether based on CMS' specifications or other plan-specific expanded targeting criteria within the reporting period. Regardless of this designation, the corresponding MTM services delivered to each beneficiary (such as targeted medication review or comprehensive medication review) must meet CMS definitions. The reported beneficiaries must receive MTM services that meet or exceed CMS' MTM program requirements.

- A. Contract Number.
- B. MBI Number.
- C. Beneficiary first name.
- D. Beneficiary last name.
- E. Beneficiary date of birth.
- F. Beneficiary identified as cognitively impaired at time of comprehensive medication review (CMR) offer or delivery of CMR. (Y (yes), N (no), or U (unknown)).
- G. Beneficiary in a long term care facility at the time of the first CMR offer or delivery of CMR? (Y (yes), N (no), or U (unknown)).
- H. Date of MTM program enrollment.
- I. Targeting criteria met. Required if met the specified targeting criteria per CMS – Part D requirements in § 423.153(d)(2). (Multiple chronic diseases/multiple Part D drugs/cost threshold; Drug management program at-risk beneficiary; Both; None).
- J. Date met the specified targeting criteria per CMS – Part D requirements in § 423.153(d)(2). Required if met the specified targeting criteria per CMS – Part D requirements. (May be same as Date of MTM program enrollment).
- K. Date of MTM program opt-out, if applicable.

- L. Reason participant opted-out of MTM program (Death; Disenrollment from Plan; Request by beneficiary; or Other). Required if Date of MTM program opt-out is applicable.
- M. Offered annual CMR. (Y (yes) or N (no)). Required if met the specified targeting criteria per CMS – Part D requirements.
- N. If offered a CMR, date of (initial) offer.
- O. Received annual CMR with written summary in CMS standardized format. (Y (yes) or N (no)). Required if offered annual CMR.
- P. Date(s) of CMR(s). (If more than 1 CMR is received, report the date of the initial CMR.) Required if received annual CMR.
- Q. Date CMR written summary in CMS standardized format was provided or sent. (If more than 1 CMR was performed, report the date the initial CMR written summary was provided or sent.).
- R. Method of delivery for the annual CMR. (Face-to-face; Telephone; Telehealth consultation; or Other). (If more than 1 CMR is received, report the method of delivery for the initial CMR). Required if received annual CMR.
- S. Qualified Provider who performed the initial CMR. (Physician; Registered Nurse; Licensed Practical Nurse; Nurse Practitioner; Physician's Assistant; Local Pharmacist; LTC Consultant Pharmacist; Plan Sponsor Pharmacist; Plan Benefit Manager (PBM) Pharmacist; MTM Vendor Local Pharmacist; MTM Vendor In-house Pharmacist; Hospital Pharmacist; Pharmacist – Other; Supervised Pharmacy Intern; or Other). Required if received annual CMR.
- T. Recipient of initial CMR. (Beneficiary, Beneficiary's prescriber; Caregiver; or Other authorized individual). Required if received annual CMR.
- U. Number of targeted medication reviews. Required if met the specified targeting criteria per CMS – Part D requirements.
- V. Date the first TMR was performed.
- W. Number of medication therapy problem recommendations made to beneficiary's prescriber(s) as a result of MTM services.
- X. Number of medication therapy problem resolutions resulting from recommendations made to beneficiary's prescriber(s) as a result of MTM recommendations.
- Y. Number of communications sent to beneficiary regarding safe disposal of medications. Required if met the specific targeting criteria per CMS – Part D requirements.
- Z. Method of delivery for information regarding safe disposal of medications (CMR; TMR; Welcome Letter; Other). If more than one communication is sent, report the method of the initial communication.



### Section III. Grievances

Title 42, Part 423, Subpart M describes Part D sponsors requirements for grievances, including timeframes for standard and expedited requests.

Sponsors should:

- Report data based on when the enrollee/enrollee representative is notified (orally or written) of the grievance decision.
- Track multiple grievances by a single complainant and report as separate grievances.

Sponsors should not:

- Include CTM data when reporting grievances.
- Report general inquiries or questions that do not include a complaint as grievances.
- Include grievances filed by prospective enrollees.
- Report withdrawn grievances.

Sponsors will report quarterly data on an annual basis. Data files to be uploaded through the HPMS at the Contract level, following templates provided in HPMS.

Reporting timeline:

	<b>Quarter 1</b>	<b>Quarter 2</b>	<b>Quarter 3</b>	<b>Quarter 4</b>
<b>Reporting Period</b>	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
<b>Data due to CMS/HPMS</b>	First Monday of February (reporting for all quarters due on this date)			

Data to be reported at the Contract level:

	Number of grievances	Number of grievances in which timely notification was given
Total Grievances		
Of the total grievances, the number processed as expedited grievances		
Dismissed Grievances		N/A

## Section IV. Improving Drug Utilization Review Controls

Part D sponsors will report cumulative YTD data by quarter to CMS on the beneficiaries who triggered each of the following opioid safety edits:

- An opioid care coordination safety edit at 90 morphine milligram equivalent dose (MME) per day;
- An optional hard formulary-level cumulative opioid daily MME safety edit at 200 MME or more;
- A hard opioid naïve days supply safety edit for initial opioid prescriptions fills that exceed 7 days for the treatment of acute pain.

All data elements must be uploaded to HPMS at the Contract level. These elements will enable CMS to monitor sponsors' implementation of the opioid point-of-sale (POS) safety edits as well as the impact and outcome of the edits aggregated at both the claim and unique beneficiary levels (i.e. based on count of unique Medicare Beneficiary Identifiers (MBIs)).

Reporting timeline:

	<b>Quarter 1</b>	<b>Quarter 2</b>	<b>Quarter 3</b>	<b>Quarter 4</b>
<b>Reporting Period</b>	January 1 - March 31	January 1 - June 30	January 1 - September 30	January 1 - December 31
<b>Data due to CMS/HPMS</b>	Last Monday of February (reporting for all quarters due on this date)			

### 1. Opioid Care Coordination Safety Edit at 90 MME

- A. The prescriber count criterion used, if applicable.
- B. The pharmacy count criterion used, if applicable.
- C. The number of claims rejected due to the care coordination edit.
- D. Of the total reported in element C, the number of claim rejections overridden by the pharmacy.

Of the total reported in element D:

- E. The number of claim rejections overridden by the pharmacy within 24 hours of the initial claim rejection.
- F. The number of claim rejections overridden by the pharmacy due to an exemption.
- G. Of the total not in element F, the number of claim rejections overridden by the pharmacy as a result of prescriber consultation.
- H. The number of unique beneficiaries with at least one claim rejected due to the care coordination edit.

Of the total reported in element H:

- I. The number of unique beneficiaries with at least one claim rejection overridden by the pharmacy.

- J. The number of unique beneficiaries with at least one claim rejection overridden by the pharmacy within 24 hours of the initial claim rejection.
- K. The number of unique beneficiaries with at least one claim rejection overridden by the pharmacy due to an exemption.
- L. Of the total not in element K, the number of unique beneficiaries with at least one claim rejection overridden by the pharmacy as a result of prescriber consultation.

## **2. Hard MME Safety Edit**

- M. Did the plan have a hard MME edit in place during the time period above? (Y (yes) or N (no)).

If yes to element M:

- N. The cumulative MME threshold used.
- O. The prescriber count criterion used, if applicable.
- P. The pharmacy count criterion used, if applicable.
- Q. The number of claims rejected due to the hard MME edit.
- R. The number of unique beneficiaries with at least one claim rejected due to the hard MME edit.
- S. Of the total reported in element R, the number of unique beneficiaries with at least one claim rejection overridden by the pharmacy due to an exemption.
- T. Of the total reported in element R and not in element S, the number of unique beneficiaries who requested a coverage determination for the prescription(s) subject to the edit.
- U. Of the total reported in element T, the number of unique beneficiaries that had a favorable (either full or partial) coverage determination for the prescription(s) subject to the edit.

## **3. Opioid Naïve Days Supply Safety Edit**

- V. The look-back period used to identify an initial opioid prescription fill for the treatment of acute pain for the opioid naïve days supply edit.
- W. The number of claims rejected due to the opioid naïve days supply edit.

Of the total reported in element W:

- X. The number of rejected claims overridden by the pharmacy due to an exemption.
  - Y. The number of rejected claims overridden by the pharmacy because the beneficiary was not opioid naïve.
  - Z. Of the total not in elements X or Y, the number of rejected claims for which up to a 7 day supply (covered by the plan) was dispensed by the pharmacy.
- AA. The number of unique beneficiaries with at least one claim rejected due to the opioid naïve days supply edit.

Of the total reported in element AA:

BB. The number of unique beneficiaries with at least one rejected claim overridden by the pharmacy due to an exemption.

CC. The number of unique beneficiaries with at least one rejected claim overridden by the pharmacy because the beneficiary was not opioid naïve.

DD. The number of unique beneficiaries for whom up to a 7 day supply (covered by the plan) was dispensed by the pharmacy.

EE. The number of unique beneficiaries with an opioid naïve days supply edit claim rejection who requested a coverage determination for the prescription(s) subject to the edit.

FF. Of the total in element EE, the number of unique beneficiaries with an opioid naïve days supply edit claim rejection who had a favorable (either full or partial) coverage determination for the prescription(s) subject to the edit.

## **Section V. Coverage Determinations, Redeterminations (including At-Risk Redeterminations under a Drug Management Program), and Reopenings**

The requirements relating to coverage determinations (including formulary and tier exceptions, and exceptions to established drug utilization management programs) and redeterminations, including timeframes for standard and expedited requests are described in Title 42, Part 423, Subpart M. Sponsors will be responsible for reporting several data elements related to coverage determinations and redeterminations, including Part B vs. Part D coverage determinations and redeterminations. Sponsors should report data based on the date the enrollee/enrollee's representative is notified in writing of the coverage determination or redetermination decision. A sponsor's complete decision includes making the determination, appropriately notifying the enrollee of the determination, and authorizing coverage or sending payment, where applicable.

Coverage decisions (both coverage determinations and redeterminations) may result in a partially favorable decision.

- Example of a fully favorable decision: Non-formulary exception request approved for drug and quantity prescribed.
- Example of a partially favorable decision: Non-formulary exception request approved for drug, but full quantity prescribed not approved.

Sponsors must also report data relating to redeterminations of at-risk determinations made under a plan sponsor's drug management program pursuant to the rules at 42 CFR §423.153(f), including the number of requests and the disposition. At-risk redeterminations may involve decisions about:

- Being identified as an at-risk beneficiary for prescription drug misuse or abuse;
- Having a limitation, or the continuation of a limitation, on access to coverage for frequently abused drugs (i.e., an enrollee specific point-of-sale (POS) edit or the selection of a prescriber and/or pharmacy for purposes of lock-in);
- Sharing information for subsequent Part D plan enrollments.

Sponsors should report data based on the date the enrollee/enrollee's representative is notified in writing of the at-risk redetermination decision.

Title 42, Part 423, Subpart U describes requirements for reopenings of coverage determinations and redeterminations. Sponsors should also include reopened coverage determination and redetermination data, based on the date the enrollee/enrollee's representative is notified in writing of the revised decision. A reopening may or may not change the disposition of the case.

Sponsors will report quarterly data on an annual basis at the Contract level. Data files to be uploaded through the HPMS at the Contract level, following templates provided in HPMS.

Reporting timeline:

	<b>Quarter 1</b>	<b>Quarter 2</b>	<b>Quarter 3</b>	<b>Quarter 4</b>
<b>Reporting Period</b>	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
<b>Data due to CMS/HPMS</b>	Last Monday of February (reporting for all quarters due on this date)			

**1. Coverage Determinations (including exceptions)**

A. Total Number of Coverage Determinations Processed (including exceptions)	
B. Total Number of Withdrawn Coverage Determinations	
C. Total Number of Dismissed Coverage Determinations	
<b>Disposition – Coverage Determinations (non-exceptions)</b>	
D. The total number of fully favorable decisions.	
E. The total number of partially favorable decisions.	
F. The total number of adverse decisions.	
<b>Disposition – Utilization Management Exceptions</b>	
G. The number of utilization management exceptions.	
H. The number of fully favorable decisions.	
I. The number of partially favorable decisions.	
J. The number of adverse decisions.	
<b>Disposition – Formulary Exceptions</b>	
K. The number of formulary exceptions.	
L. The number of fully favorable decisions.	
M. The number of partially favorable decisions.	
N. The number of adverse decisions.	
<b>Disposition – Tiering Exceptions</b>	
O. The number of tiering exceptions.	
P. The number of fully favorable decisions.	
Q. The number of partially favorable decisions.	
R. The number of adverse decisions.	

**2. Redeterminations (including exceptions and at-risk redeterminations)**

A. Total Number of Redeterminations Processed (including exceptions and at-risk)	
B. Total Number of Withdrawn Redeterminations	
C. Total Number of Dismissed Redeterminations	
<b>Disposition – Redeterminations (non-exceptions)</b>	
D. The number of fully favorable decisions.	
E. The number of partially favorable decisions.	

F. The number of adverse decisions.	
<b>Disposition – Utilization Management Exception Redeterminations</b>	
G. The number of utilization management exceptions.	
H. The number of fully favorable decisions.	
I. The number of partially favorable decisions.	
J. The number of adverse decisions.	
<b>Disposition – Formulary Exception Redeterminations</b>	
K. The number of formulary exceptions.	
L. The number of fully favorable decisions.	
M. The number of partially favorable decisions.	
N. The number of adverse decisions.	
<b>Disposition – Tiering Exception Redeterminations</b>	
O. The number of tiering exceptions.	
P. The number of fully favorable decisions.	
Q. The number of partially favorable decisions.	
R. The number of adverse decisions.	
<b>Disposition – At-Risk Redeterminations</b>	
S. The number of at-risk redeterminations.	
T. The number of fully favorable decisions.	
U. The number of partially favorable decisions.	
V. The number of adverse decisions.	

### 3. Reopenings

- A. The total number of reopened (revised) decisions, for any reason, in the time period above.
- B. For each case that was reopened, the following information will be uploaded in a data file:
  1. Contract Number;
  2. Plan ID;
  3. Case ID;
  4. Case level (Coverage Determination or Redetermination);
  5. Date of original disposition;
  6. Original disposition (Fully Favorable; Partially Favorable or Adverse);
  7. Was case processed under expedited timeframe (Y/N);
  8. Case type (Pre-service; Payment);
  9. Date case was reopened;
  10. Reason(s) for reopening (Clerical Error, Other Error, New and Material Evidence, Fraud or Similar Fault, or Other);
  11. Date of reopening disposition (revised decision);
  12. Reopening disposition (Fully Favorable; Partially Favorable, Adverse, or Pending).

## Section VI. Employer/Union-Sponsored Group Health Plan Sponsors

The information requested is necessary for CMS to fulfill its affirmative oversight obligation to ensure that plans with employer/union group health plan enrollment that provide Part D benefits are properly utilizing these waivers and modifications and that CMS' statutory waiver authority is being implemented in accordance with the requirements of section 1860D-22(b) of the Act.

Reporting timeline:

	<b>YTD</b>
<b>Reporting Period</b>	January 1 – December 31
<b>Data due to CMS/HPMS</b>	First Monday of February

Data file to be uploaded through the HPMS at the Plan (PBP) level:

- A. Employer Legal Name.
- B. Employer DBA Name.
- C. Employer Federal Tax ID.
- D. Employer Address.
- E. Type of Group Sponsor (employer, union, trustees of a fund).
- F. Organization Type (state government, local government, publicly traded organization, privately held corporation, non-profit, church group, other).
- G. Type of Contract (insured, ASO, other).
- H. Is this a calendar year plan? (Y (yes) or N (no)).
- I. If element H is no, provide non-calendar year start date.
- J. Current/Anticipated enrollment.