

# MEDICARE PART D REPORTING REQUIREMENTS

## PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0992 (expires January 31, 2020). The time required to complete this information collection is estimated to average 15 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

Effective as of January 1, 2021

## **Table of Contents**

Introduction .....	3
Section I. Enrollment and Disenrollment .....	5
Section II. Medication Therapy Management Programs .....	8
Section III. Grievances .....	10
Section IV. Improving Drug Utilization Review Controls .....	11
Section V. Coverage Determinations and Redeterminations.....	14
Section VI. Employer/Union-Sponsored Group Health Plan Sponsors.....	17

## Introduction

In December 2003, Congress passed the Medicare Prescription Drug Benefit, Improvement and Modernization Act (MMA), allowing coverage of outpatient prescription drugs under the Medicare Part D benefit. In accordance with Title I, Part 423, Subpart K (§ 423.514), the Act requires each Part D sponsor to have an effective procedure to provide statistics indicating:

- 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 it has a fiscally sound operation; and
- 5) other matters as required by CMS.

The purpose of this document is to assure a common understanding of 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 and required levels of reporting. Data elements may be reported at the Plan (PBP) level, or the individual Contract level. These requirements are subject to change at the discretion of CMS. According to Subpart O, sanctions may be imposed on Part D sponsors who fail to comply with these reporting requirements.

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.

In each of the sections that follow, the method of submission (e.g. entered into or uploaded via the Health Plan Management System (HPMS)) and the level of reporting are specified following the reporting timeline. Reporting deadlines may occur in the subsequent calendar year. 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 Advantage (MA) Organizations and Medicare Cost Plans (1876 plans only) 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.

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 drug as defined by Section 1860D-2(e)(2) of the MMA. Drugs offered under enhanced or supplemental drug benefits by sponsors are not covered Part D drugs.

## Section I. Enrollment and Disenrollment

CMS provides guidance for Part D Sponsors' processing of enrollment, disenrollment, and reinstatement requests.

Both Chapter 2 of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Manual outline the enrollment and disenrollment periods (Section 30) and enrollment (Section 40), disenrollment (Section 50), and reinstatement (Section 60) procedures for all Medicare health and prescription drug plans.

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. For example, while there are a number of factors that result in an individual's eligibility for a Special Enrollment Period (SEP), sponsors are currently unable to specify each of these factors when submitting enrollment transactions. Sponsors' reporting of data regarding SEP reasons for which a code is not currently available will further assist CMS in ensuring sponsors are providing support to beneficiaries, while complying with CMS policies.

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 requirements.

Section 1 Enrollment, elements 1.A-1.N 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 elements to be entered into the HPMS at the Contract level:

### 1. Enrollment:

- A. The total number of enrollment requests (e.g. requests initiated by the beneficiary or his/her authorized representative/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 of the applicant's ineligibility to elect the plan (i.e. individual 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 representative/legal representative not providing the required information 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 effectuated by sales persons. Medicare Communications and Marketing Guidelines ).
- L. Of the total reported in A, the number of enrollment transactions submitted using the Special Election Period (SEP) Election Period code "S" related to involuntary loss of creditable prescription drug coverage or lack of adequate notification regarding the creditable status of drug coverage provided by an entity required to give such notice.
- M. Of the total reported in A, the number of enrollment transactions submitted using the SEP Election Period code "S" for individuals who belong to a qualified State Pharmaceutical Assistance Program (SPAP) or who lose SPAP eligibility.
- N. For stand-alone prescription drug plans (PDPs) only: Of the number reported in A, the total number of enrollment transactions submitted using the SEP Election Period code "S" that coordinates with the Medicare Advantage Open Enrollment Period (OEP).
- O. 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.

## **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 of the enrollee's ineligibility to elect to disenroll from the plan (i.e. individual 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 representative/legal representative not providing information 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 other members who do not meet the specific CMS targeting criteria.

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 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. HICN (or MBI) or RRB Number.
- C. Beneficiary first name.
- D. Beneficiary last name.
- E. Beneficiary date of birth.
- F. Met the specified targeting criteria per CMS – Part D requirements in § 423.153(d)(2). (Y (yes) or N (no)).
- G. Beneficiary identified as cognitively impaired at time of comprehensive medication review (CMR) offer or delivery of CMR. (Y (yes), N (no), or U (unknown)).
- H. 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))
- I. Date of MTM program enrollment.
- 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. 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)
- L. Date of MTM program opt-out, if applicable.



- M. 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.
- N. Offered annual CMR. (Y (yes) or N (no)). Required if met the specified targeting criteria per CMS – Part D requirements.
- O. If offered a CMR, date of (initial) offer
- P. If offered a CMR, recipient of (initial) offer (Beneficiary, Beneficiary's prescriber; Caregiver; or Other authorized individual).
- Q. Received annual CMR with written summary in CMS standardized format. (Y (yes) or N (no)). Required if offered annual CMR.
- R. Date(s) of CMR(s). (If more than 1 CMR is received, report the date of the initial CMR.) Required if received annual CMR.
- S. 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.)
- T. 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.
- U. 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.
- V. Recipient of initial CMR. (Beneficiary, Beneficiary's prescriber; Caregiver; or Other authorized individual). Required if received annual CMR.
- W. Number of targeted medication reviews. Required if met the specified targeting criteria per CMS – Part D requirements.
- X. Date the first TMR was performed.
- Y. Number of medication therapy problem recommendations made to beneficiary's prescriber(s) as a result of MTM services.
- Z. Number of medication therapy problem resolutions resulting from recommendations made to beneficiary's prescriber(s) as a result of MTM recommendations.
- AA. Number of communications sent to beneficiary regarding safe disposal of medications. Required if met the specific targeting criteria per CMS – Part D requirements.

### 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/appointed representative is notified (orally or written) of the 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 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 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 Plan 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:

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

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

- A. For the care coordination edit, the prescriber count criterion used, if applicable.
- B. For the care coordination edit, 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 care coordination edit claim rejections overridden by the pharmacist at the pharmacy.
- E. Of the total reported in element C, the number of care coordination edit claim rejections overridden by the pharmacist at the pharmacy that also had an opioid claim successfully processed at POS.
- F. The number of unique beneficiaries with at least one claim rejected due to the care coordination edit.
- G. Of the total reported in element F, the number of unique beneficiaries with at least one care coordination edit claim rejection overridden by the pharmacist at the pharmacy.
- H. Of the total reported in element F, 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.

### 2. Hard MME Safety Edit

- I. Did the plan have a hard MME edit in place during the time period above? (Y (yes) or N (no)).
- J. If yes to element I, the cumulative MME threshold used.
- K. If yes to element I, the prescriber count criterion used, if applicable.
- L. If yes to element I, the pharmacy count criterion used, if applicable.
- M. If yes to element I, the number of claims rejected due to the hard MME edit.
- N. Of the total reported in element M, the number of claims successfully processed at POS other than through a favorable coverage determination or appeal, such as pharmacist communication and/or plan override.
- O. Of the total reported in element M, the number of claims successfully processed at POS through a favorable coverage determination or appeal.
- P. If yes to element I, the number of unique beneficiaries with at least one claim rejected due to the hard MME edit.
- Q. Of the total reported in element P, the number of unique beneficiaries with a hard MME edit claim rejection that had an opioid claim successfully processed at POS through any process.
- R. Of the total reported in element P, the number of unique beneficiaries with a hard MME edit claim rejection that 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.
- S. Of the total reported in element P, the number of unique beneficiaries with a hard MME edit claim rejection that had a coverage determination or appeal request for an opioid prescription subject to the edit.
- T. Of the total reported in element P, the number of unique beneficiaries with a hard MME edit claim rejection with a coverage determination or appeal request for an opioid drug subject to the edit that had a favorable (either full or partial) coverage determination or appeal.
- U. Of the total reported in element P, the number of unique beneficiaries with a hard MME edit claim rejection that had an opioid claim successfully processed at POS through a favorable coverage determination or appeal.

### **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.
- X. Of the total reported in element W, the number of claims successfully processed at POS other than through a favorable coverage determination or appeal, such as pharmacist communication and/or plan override.
- Y. Of the total reported in element W, the number of claims successfully processed at POS through a favorable coverage determination or appeal.
- Z. The number of unique beneficiaries with at least one claim rejected due to the opioid naïve days supply edit.

- AA. Of the total reported in element Z, the number of unique beneficiaries with an opioid naïve days supply edit claim rejection that had an opioid claim successfully processed at POS through any process.
- BB. Of the total reported in element Z, the number of unique beneficiaries with an opioid naïve days supply edit claim rejection that 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.
- CC. Of the total reported in element Z, the number of unique beneficiaries with an opioid naïve days supply edit claim rejection that had a coverage determination or appeal request for an opioid prescription subject to the edit.
- DD. Of the total reported in element Z, the number of unique beneficiaries with an opioid naïve days supply edit claim rejection with a coverage determination or appeal request for an opioid prescription subject to the edit that had a favorable (either full or partial) coverage determination or appeal.
- EE. Of the total reported in element Z, the number of unique beneficiaries with an opioid naïve days supply edit claim rejection that had an opioid claim successfully processed at POS through a favorable coverage determination or appeal.

## Section V. Coverage Determinations Redeterminations, and Reopenings

Title 42, Part 423, Subpart M describes Part D sponsors' requirements for coverage determinations (including formulary and tier exceptions, and exceptions to established drug utilization management programs) and redeterminations, including timeframes for standard and expedited requests. Part B vs. Part D coverage determinations and redeterminations should be included in this reporting. 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.

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 i, 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:

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Reporting Period	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
Data due to CMS/HPMS	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

A. Total Number of Redeterminations Processed	
B. Total Number of Withdrawn Redeterminations	
C. Total Number of Dismissed Redeterminations	
<b>Disposition</b>	
D. The number of fully favorable decisions.	
E. The number of partially favorable decisions.	
F. 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

**NOTE:** This reporting requirement applies only to individual PDPs and “800 series” PDPs offered to employers. MA-PD plans already report these data as part of the Part C reporting requirements and are therefore exempt from this Part D reporting section.

The information requested is necessary for CMS to fulfill its affirmative oversight obligation to ensure PDPs and the employer groups that contract with the PDPs 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.