

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, 2017

Table of Contents

Introduction	3
Section I. Enrollment and Disenrollment	5
Section II. Retail, Home Infusion, and Long-Term Care Pharmacy Access	8
Section III. Medication Therapy Management Programs	10
Section IV. Grievances	12
Section V. Improving Drug Utilization Review Controls	14
Section VI. Coverage Determinations and Redeterminations.....	16
Section VII. Employer/Union-Sponsored Group Health Plan Sponsors.....	19

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.

Sponsors are required to undergo data validation to have some of their Part D data audited. Each Part D sponsor shall provide necessary data to CMS to support payment, program integrity, program management, and quality improvement activities. Additional reporting requirements are identified in separate guidance documents throughout the year. Guidance has been separately released for data validation, formulary, TrOOP, coordination of benefits, payment and 1/3 audit, and low income subsidy.

Part D sponsors may also be required to submit other information as defined by requirements in the application, guidances, or other documents (e.g. pharmacy access and formularies) during the annual contract bidding, application, or renewal process. Information is also required to be submitted throughout the contract year as allowable changes are made (e.g. formulary changes).

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.

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

Reporting timeline:

	Period 1	Period 2
Reporting Period	January 1 - June 30	July 1 – December 31
Data due to CMS/HPMS	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 (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.
- B. Of the total reported in A, the number of enrollment requests complete at the time of initial receipt (i.e. required no additional information from applicant or his/her authorized representative).
- C. Of the total reported in A, the number of enrollment requests 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 incomplete 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 not providing 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 internet enrollment requests received via plan or affiliated third-party 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. For stand-alone prescription drug plans (PDPs) only: 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).
- L. Of the total reported in A, the number of enrollment transactions submitted using the SEP Election Period code "S" related to creditable coverage.
- M. Of the total reported in A, the number of enrollment transactions submitted using the SEP Election Period code "S" related to SPAP.
- 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 Disenrollment Period.
- 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.

Elements 1.P. through 1.S. apply only to MA organizations approved by CMS to offer seamless conversion enrollment:

- P. The total number of individuals included in the advance notification for seamless conversion enrollment for effective dates occurring within the reporting period.
- Q. Of the total reported in 1P, the number of individuals whose Medicare eligibility is based on age.
- R. Of the total reported in 1P, the number of individuals whose Medicare eligibility is based on disability.
- S. Of the total reported in 1P, the number of enrollments submitted to CMS.

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 (i.e. required no additional information from enrollee or his/her authorized representative).
- C. Of the total reported in A, the number of disenrollment requests denied by the sponsor for any reason.
- D. The total number of involuntary disenrollments for failure to pay plan premium in the specified time period.
- E. Of the total reported in 2D, the number of disenrolled individuals who submitted a timely request for reinstatement for Good Cause.
- F. Of the total reported in 2E, the number of favorable Good Cause determinations.
- G. Of the total reported in 2F, the number of individuals reinstated.

Section II. Retail, Home Infusion, and Long-Term Care Pharmacy Access

As outlined in §423.120, Part D sponsors are required to maintain a pharmacy network sufficient for ensuring access to Medicare beneficiaries residing in their service areas. Part D sponsors must ensure that they provide convenient access to retail pharmacies, as provided in §423.120(a)(1); adequate access to home infusion (HI) pharmacies, as provided in §423.120(a)(4); and convenient access to long-term care (LTC) pharmacies, as provided in §423.120(a)(5). After their initial pharmacy access submissions are approved at the time of application, Part D sponsors are responsible for notifying CMS of any substantive changes in their pharmacy network that may impact their ability to maintain a Part D pharmacy network that meets our requirements, as described in section 50 of Chapter 5 of the Prescription Drug Benefit Manual.

Part D sponsors will be required to submit certain data elements on an annual basis that will allow CMS to evaluate Part D sponsors' continued compliance with pharmacy access requirements. For purposes of evaluating compliance with the retail pharmacy access standards, Part D sponsors should use the CMS reference file that provides counts of Medicare beneficiaries by State, region, and ZIP code. This reference file is provided by CMS for the Part D applications and will be posted on the Prescription Drug Contracting, Application Guidance section of CMS' website in January (http://www.cms.hhs.gov/PrescriptionDrugCovContra/04_RxContracting_ApplicationGuidance.asp#TopOfPage). Note that this file contains total Medicare beneficiary counts, not plan enrollee counts, and that the total Medicare beneficiary count is the appropriate number to use for purposes of ensuring compliance with the standards for convenient access to retail pharmacies as provided in §423.120(a)(1), and adequate access to home infusion pharmacies as provided in §423.120(a)(4).

For purposes of evaluating compliance with the LTC and home infusion pharmacy access standards, CMS will use data elements submitted by Part D sponsors, as well as information from CMS reference files containing counts of nursing home beds and Medicare beneficiaries by State, region, and ZIP code, as detailed in sections 50.4 and 50.5.1 of Chapter 5 of the Prescription Drug Benefit Manual. MA-PD plans or cost plan sponsors having received waivers of the any willing pharmacy requirement and/or the retail convenient access requirement after the initial pharmacy access submission will submit certain data elements (subsections 2 and/or 3) on an annual basis for purposes of determining if those plans still meet CMS standards for a waiver.

Submission of supporting documentation with the data elements below is not required; however, CMS reserves the right to request appropriate documentation to support a Part D sponsor's submitted pharmacy networks. CMS evaluation of compliance with pharmacy access standards will be conducted based on point-in-time information about pharmacy networks submitted by Part D sponsors once per year.

Employer/Union Direct contracts and "800 series" plans must submit the list of network retail, home infusion, and long term care pharmacies for their entire individual and employer service area. For Part D sponsors that offer both individual and "800 series"

plans, compliance with pharmacy access standards will only be assessed for the individual service area. For Part D Sponsors that offer only employer group plans, including Employer/Union Direct contracts, compliance will be assessed for the entire service area.

Reporting timeline for Section 1 only:

	Period 1
Reporting Period	January 1 - March 31
Data due to CMS/HPMS	First Monday of May

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

1. Network Pharmacy data files, as of the last day of the reporting period specified above:

- A. A list of contracted network retail pharmacies, including preferred/non-preferred status as applicable to network design;
- B. A list of contracted Home Infusion pharmacies, and
- C. A list of contracted Long-term Care pharmacies.

Please note that contracts will be required to submit pharmacy data using only the NPI number.

Reporting timeline for Sections 2 and 3 only:

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

Data elements to be entered into the HPMS at the Plan (PBP) level:

2. For MA-PD and cost plans that own and operate their own pharmacies and have received a waiver of the any willing pharmacy requirement:

- A. Number of prescriptions provided by all pharmacies owned and operated by the plan.
- B. Number of prescriptions provided at all pharmacies contracted by the plan.

3. For MA-PD and cost plans that own and operate their own retail pharmacies and have received a waiver of the retail pharmacy convenient access standards: (These plans are not exempt from reporting retail pharmacy data).

- A. Number of prescriptions provided by retail pharmacies owned and operated by the plan.
- B. Number of prescriptions provided at all retail pharmacies contracted by the plan.

Section III. 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
Reporting Period	January 1 - December 31
Data due to CMS/HPMS	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). 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 RRB Number.
- C. Beneficiary first name.
- D. Beneficiary middle initial.
- E. Beneficiary last name.
- F. Beneficiary date of birth.
- G. Met the specified targeting criteria per CMS – Part D requirements. (Y (yes) or N (no)).
- H. Beneficiary identified as cognitively impaired at time of comprehensive medication review (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. 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.
- 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, 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. Number of CMRs received with written summary in CMS standardized format. Required if received annual CMR.
- Q. Date(s) of CMR(s) with written summary in CMS standardized format. (If more than 1 CMR is received, up to 2 dates will be allowed.) Required if received annual CMR.
- 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 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. Number of drug therapy problem recommendations made to beneficiary's prescriber(s) as a result of MTM services. (For reporting purposes, a recommendation is defined as a suggestion to take a specific course of action related to the beneficiary's drug therapy. If the same recommendation is made to multiple prescribers or repeated on multiple dates, then that recommendation should only be counted and reported once. Examples include, **but are not limited to**: Needs additional therapy; Unnecessary drug therapy; Dosage too high; Dosage too low; More effective drug available; Adverse drug reaction; or Medication Non-compliance/Non-adherence).
- W. Number of drug therapy problem resolutions resulting from recommendations made to beneficiary's prescriber(s) as a result of MTM recommendations. (For reporting purposes, a resolution is defined as a change or variation from the beneficiary's previous drug therapy. Examples include, **but are not limited to**: Initiate drug; Change drug (such as product in different therapeutic class, dose, dosage form, quantity, or interval); Discontinue or substitute drug (such as discontinue drug, generic substitution, therapeutic substitution, or formulary substitution); Medication compliance/adherence).

Section IV. Grievances

According to MMA statute, all Part D sponsors must provide meaningful procedures for hearing and resolving grievances between an enrollee and the sponsor, including an entity or individual through which the sponsor provides benefits. A grievance is any complaint or dispute, other than a coverage determination, or appeal about any aspect of the operations, activities, or behavior of a Part D organization, regardless of whether remedial action is requested. Part D sponsors are required to notify enrollees of their decision no later than 30 days after receiving their grievance based on the enrollee's health condition. An extension up to 14 days is allowed if it is requested by the enrollee, or if the Part D sponsor needs additional information and documents that this extension is in the interest of the enrollee. An expedited grievance that involves refusal by a Part D sponsor to process an enrollee's request for an expedited coverage determination or redetermination requires a response from the Part D sponsor within 24 hours.

When categorizing grievances into core categories, Sponsors may report based on their investigations subsequent to the enrollees' filing of the grievances.

Sponsors should:

- Report data based on the date the grievance decision was made.
- Track multiple grievances by a single complainant and report as separate grievances.

Sponsors should not:

- Report requests for coverage determinations, including exceptions, or redeterminations inappropriately as grievances.
- Limit grievance reporting to include only CTM data.
- Report general inquiries or questions that do not include a complaint as grievances.
- Exclude any grievances filed by beneficiaries or their appointed representatives from this reporting section.

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:

	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	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		
Expedited Grievances		
Dismissed Grievances		N/A
Grievance Category		
Enrollment/Disenrollment Grievances		
Plan Benefit Grievances		
Pharmacy Access Grievances		
Marketing Grievances		
Customer Service Grievances		
Coverage Determination and Redetermination Process Grievances		
Quality of Care Grievances		
Grievances related to "CMS Issues"		
Other		

Section V. Improving Drug Utilization Review Controls

In the section entitled, “Improving Drug Utilization Review Controls in Part D” of the Final 2013 Call Letter issued on April 2, 2012 and in supplemental guidance, September 6, 2012, CMS described how Medicare Part D sponsors can comply with drug utilization management (DUM) requirements of 42 C.F.R §423.153 et seq. to prevent overutilization of opioids. As described in the 2017 Call Letter issued on April 4, 2016, we expect sponsors to implement either a soft and/or hard formulary-level cumulative opioid morphine equivalent dose (MED) edit at point of sale (POS), while excluding beneficiaries with known exceptions from the edit.

We expect sponsors’ Pharmacy and Therapeutics (P&T) committees to develop the specifications for their formulary-level cumulative MED POS edit(s) based on the observed opioid overutilization in their Part D plans, and the reasonableness of the numbers of targeted beneficiaries for plan oversight. We recommend that a soft opioid edit threshold be set at levels no lower than 90 mg MED, and a hard opioid edit threshold be set no lower than 200 mg MED. We also expect sponsors to apply specifications to minimize false positives by accounting for known exceptions, such as hospice care, certain cancer diagnoses, reasonable overlapping dispensing dates for prescription refills or new prescription orders for continuing fills, and high-dose opioid usage previously determined to be medically necessary such as through case management or the coverage determination and appeals process. If sponsors decide to include a provider count criterion in the soft or hard edit specifications, we recommend a prescriber threshold set no lower than two prescribers. Sponsors may also include a pharmacy count criterion. We do not recommend a consecutive high-MED days criterion because it would not prevent beneficiaries from reaching high opioid doses (meaning averaging the MED may be preferred).

Part D sponsors will report cumulative YTD data each quarter to CMS on the beneficiaries who triggered either a soft and/or hard formulary-level cumulative opioid MED POS edits(s) as implemented by the sponsor. All data elements must be uploaded to HPMS at the Plan level. These elements will enable CMS to monitor sponsors’ implementation of the cumulative opioid MED POS 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 health insurance claim numbers, or HICNs).

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)			

A. Did the plan have a soft formulary-level cumulative opioid MED edit at POS in place during the time period above? (Y (yes) or N (no)).

- B. If yes to element A, the cumulative MED threshold used.
- C. If yes to element A, the provider count criterion used, if applicable.
- D. If yes to element A, the pharmacy count criterion used, if applicable.
- E. If yes to element A, the number of claims rejected due to the soft formulary-level cumulative opioid MED edit at POS.
- F. If yes to element A, the number of unique beneficiaries with at least one claim rejected due to the soft formulary-level cumulative opioid MED edit at POS.
- G. Of the total reported in element E, the number of soft edit claim rejections overridden by the pharmacist at the pharmacy.
- H. Of the total reported in element F, the number of beneficiaries with at least one soft edit claim rejection overridden by the pharmacist at the pharmacy.
- I. Did the plan have a hard formulary-level cumulative opioid MED edit at POS in place during the time period above? (Y (yes) or N (no)).
- J. If yes to element I, the cumulative MED threshold used.
- K. If yes to element I, the provider 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 formulary-level cumulative opioid MED edit at POS.
- N. If yes to element I, the number of unique beneficiaries with at least one claim rejected due to the hard formulary-level cumulative opioid MED edit at POS.
- O. Of the total reported in element N, the number of unique beneficiaries with at least one hard edit claim rejection that also had a coverage determination request for an opioid drug subject to the hard opioid MED edit.
- P. Of the total reported in element N, the number of unique beneficiaries with at least one rejected claim that also had a claim successfully processed (paid) for an opioid drug subject to the hard opioid MED edit such as, but not limited to, through a favorable coverage determination or process.

Section VI. Coverage Determinations and Redeterminations

Title I, 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 coverage determination or redetermination decision is made. 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 should also include reopened coverage determination and redetermination data in this reporting, based on the date the revised decision is made. A reopening is any revision to a binding determination for any reason that is not processed as an appeal, including but not limited to clerical errors and new and material evidence not available or known at the time of the determination. 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. Rejected Pharmacy Transactions

- A. The total number pharmacy transactions.
- B. The number of pharmacy transactions rejected due to non-formulary status.
- C. The number of pharmacy transactions rejected due to prior authorization (PA) requirements.
- D. The number of pharmacy transactions rejected due step therapy requirements.

- E. The number of pharmacy transactions rejected due to quantity limits based on CMS approved formulary. Safety edits and rejections due to early refills should be excluded.
- F. Did the plan have high cost edits for non-compounds? If yes, what is the cost threshold used? N/A, if no.
- G. The number of pharmacy transaction claims rejected due to high cost edits for non-compounds.

2. Coverage Determinations (including exceptions)

A. Total Number of Coverage Determinations	
Timeliness - All Coverage Determinations	
B. The number processed timely.	
C. The number not processed timely and auto-forwarded to the IRE.	
D. The number not processed timely but not auto-forwarded to the IRE.	
Disposition – All Coverage Determinations	
E. The total number of fully favorable decisions.	
F. The total number of partially favorable decisions.	
G. The total number of adverse decisions.	
H. The total number withdrawn.	
I. The total number dismissed.	
Disposition – Utilization Management Exceptions	
J. The number of utilization management exceptions.	
K. The number of fully favorable decisions.	
L. The number of partially favorable decisions.	
M. The number of adverse decisions.	
N. The number withdrawn.	
O. The number dismissed.	
Disposition – Formulary Exceptions	
P. The number of formulary exceptions.	
Q. The number of fully favorable decisions.	
R. The number of partially favorable decisions.	
S. The number of adverse decisions.	
T. The number withdrawn.	
U. The number dismissed.	
Disposition – Tiering Exceptions	
V. The number of tiering exceptions.	
W. The number of fully favorable decisions.	
X. The number of partially favorable decisions.	

Y. The number of adverse decisions.	
Z. The number withdrawn.	
AA. The number dismissed.	

3. Redeterminations

A. Total Number of Redeterminations	
Timeliness	
B. The number processed timely.	
C. The number not processed timely and auto-forwarded to the IRE.	
D. The number not processed timely but not auto-forwarded to the IRE.	
Disposition	
E. The number of fully favorable decisions.	
F. The number of partially favorable decisions.	
G. The number of adverse decisions.	
H. The number withdrawn.	
I. The number dismissed.	

4. 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 VII. 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.

CMS has statutory authority to waive or modify requirements that hinder the design of, the offering of, or the enrollment in, employer/union sponsored PDPs, as set forth in section 1860D-22(b) of the Social Security Act. Under the above-referenced statutory authority, PDPs are permitted to utilize these waivers to contract with employer and union group sponsors to facilitate the enrollment of their Medicare-eligible retirees into PDPs. (Please note that in addition to these “indirect contract” arrangements, CMS also has separate statutory authority to directly contract with employers and union group plan sponsors to offer prescription drug benefits to their retirees). When exercising our discretion to grant these statutory waivers or modifications to PDPs offering these plans, these waivers and/or modifications are conditioned upon the PDP meeting a set of conditions and complying with certain requirements, which may include these kinds of reporting requirements.

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.

The Tax Identification Number (TIN) is the standard unique employer identifier. The Medicare program uses the TIN to identify employers and businesses in other areas of the program. For example, insurers are required to report TIN information in order to comply with the mandatory Medicare Secondary Payer insurer reporting requirements of Section 111 of the Medicare, Medicaid, and SCHIP Extensions Act of 2007 (Public Law 110-173). Thus, some of these same entities (such as employer/union sponsors) affected by our reporting requirements will similarly be required by law to collect and report TIN information to CMS for Medicare secondary payment purposes.

Collection of TINs from the employer/union sponsors as outlined above may be a challenge for PDP sponsors. Employer/union sponsors unable or unwilling to provide TINs or other required information should be notified by PDP sponsors that they will be unable to utilize the waivers available to employer/union group health plans and should work with them to explore other Medicare options for their retirees.

Reporting timeline:

	YTD
Reporting Period	January 1 – December 31
Data due to CMS/HPMS	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.