

## **MEDICARE PART D REPORTING REQUIREMENTS**

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Effective as of January 1, 2014

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## 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.

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, and the Plan Oversight of Agents reporting section.

Medicare/Medicaid Plans (MMP) that offer Part D benefits will be required to comply with all reporting requirements contained herein, with the exception of the Retail, Home Infusion and Long-Term Care Pharmacy Access, and Employer/Union-Sponsored Group Health Plan Sponsors reporting sections.

\*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 and disenrollment 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) enrollment (Section 40) and disenrollment procedures (Section 50) 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 and disenrollment 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.

Data 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:

	<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>	August 31	February 28

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

### 1. Enrollment:

- A. The total number of enrollment requests received in the specified time period.
- 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 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.

**2. Disenrollment:**

- A. The total number of voluntary disenrollment requests received in the specified time period.
- 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.

## **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](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 (C and/or D) 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 have the following service area definitions for this section:

- Part D Sponsors that offer both individual plans and "800 series" plans need only to demonstrate pharmacy access (retail, home infusion, long term care) for their individual service area. There are no separate requirements for their EGWP-Only service area.
- Part D Sponsors that offer plans to employer groups only (i.e., "800 Series Only" contracts) need to demonstrate pharmacy access (retail, home infusion, long term care) for their entire service area.
- Employer/Union Direct contracts need to demonstrate pharmacy access (retail, home infusion, long term care) for their entire service area.

Reporting timeline for Section 1 only:

	<b>Period 1</b>
<b>Reporting Period</b>	January 1 - March 31
<b>Data due to CMS/HPMS</b>	May 31

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:**

1. A list of contracted network retail pharmacies, including preferred/non-preferred status as applicable to network design;
2. A list of contracted Home Infusion pharmacies, and
3. 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:

	<b>YTD</b>
<b>Reporting Period</b>	January 1 – December 31
<b>Data due to CMS/HPMS</b>	February 28

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
<b>Reporting Period</b>	January 1 - December 31
<b>Data due to CMS/HPMS</b>	February 28

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 5 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; 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).

- X. Topics discussed with the beneficiary during the CMR, including the medication or care issue to be resolved or behavior to be encouraged. (If more than 1 topic discussed, up to 5 topics will be allowed to be reported.) These are the descriptions of the topics listed on the beneficiary's written summary in CMS standardized format in the Medication Action Plan under '*What we talked about*'. Required if received annual CMR.

## Section IV. Prompt Payment by Part D Sponsors

The Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 added requirements with regard to prompt payment by Part D Sponsors for all clean claims submitted by network pharmacies within specified timeframes for electronic and all other (non-electronically submitted) claims. Mail-order and long-term care (LTC) pharmacies are excluded from these provisions.

Consistent with section 1860D-12(b)(4)(A)(ii) of the Act, a clean claim is defined as a claim that has no defect or impropriety – including any lack of any required substantiating documentation – or particular circumstance requiring special treatment that prevents timely payment of the claim from being made. Part D Sponsors must make payment for clean claims within 14 calendar days of the date on which an electronic claim is received and within 30 calendar days of the date on which non-electronically submitted claims are received. Claims submitted with 100% beneficiary responsibility, i.e., zero plan payment amount, are excluded from this requirement (it is not possible for a Sponsor to pay a pharmacy late for a \$0.00 dollar due claim).

Receipt of an electronic claim is defined as the date on which the claim is transferred, and receipt of a non-electronically submitted claim as the 5th calendar day after the postmark day of the claim or the date specified in the time stamp of the transmission, whichever is sooner.

A claim will be deemed to be a clean claim to the extent that the Part D Sponsor that receives the claim does not issue notice to the submitting network pharmacy of any deficiency in the claim within 10 calendar days after an electronic claim is received and within 15 calendar days after a non-electronically submitted claim is received. A claim deemed to be a clean claim must be paid by the Sponsor within 14 calendar days (for an electronic claim) or 30 calendar days (for a non-electronic claim) of the date on which the claim is received.

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>	August 31	February 28

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

- A. Total number of paid claims.
- B. Total number of paid electronic claims.
- C. Total number of paid non-electronic (e.g. paper) claims.
- D. Total number of paid electronic claims which were not paid timely, according to appropriate time-periods.

E. Total number of paid non-electronic claims which were not paid timely, according to appropriate time-periods.

## Section V. Grievances

According to MMA statute, a grievance is any complaint or dispute, other than a coverage determination, expressing dissatisfaction with 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. 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 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.

For reporting, 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.

For reporting, Sponsors should not:

- Report requests for coverage determinations, exceptions, or redeterminations inappropriately as grievances.
- Only base grievances reporting on CTM data.
- Report general inquiries or questions as grievances.
- Dismiss or exclude any grievances filed by beneficiaries or their appointed representatives from this reporting section.

Sponsors will report quarterly data on an annual basis.

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>	February 28 (reporting for all quarters due on this date)			

Data to be reported at the Contract level:

	Total number of grievances	Number of grievances in which timely notification was given
Total Grievances		
Number of Expedited Grievances		
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 Grievances		



## 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. Reopening includes any revision to a binding determination for any reason, including but not limited to clerical errors and new and material evidence not available or known at the time of the determination.

Sponsors will report quarterly data on an annual basis. All data elements to be entered into the HPMS at the Contract level, except reopenings data in element B to be uploaded in a data file.

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>	February 28 (reporting for all quarters due on this date)			

### 1. Coverage Determinations and Exceptions

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

- A. The total number of pharmacy transactions in the time period above.
- B. Of the total reported in A, the number of pharmacy transactions rejected due to non-formulary status.
- C. Of the total reported in A, the number of pharmacy transactions rejected due to prior authorization (PA) requirements.
- D. Of the total reported in A, the number of pharmacy transactions rejected due to step therapy requirements.

- E. Of the total reported in A, the number of pharmacy transactions rejected due to quantity limits (QL) requirements 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 compounds in place during the time period above? ((Y (yes) or N (no)).
- G. If yes to element F, the cost threshold used.
- H. Did the plan have high cost edits for non-compounds in place during the time period above? ((Y (yes) or N (no)).
- I. If yes to element H, the cost threshold used.
- J. Of the total reported in A, the total number of claims rejected due to high cost edits for compounds.
- K. Of the total reported in A, the total number of claims rejected due to high cost edits for non-compounds.
- L. The total number of coverage determinations decisions made in the reporting time period above.
- M. Of the number reported in element L, the total number of exception decisions made in the reporting time period above.
- N. Of the number reported in element L, the number processed timely.
- O. Of the number reported in element L, the number that were fully favorable.
- P. Of the number reported in element L, the number that were partially favorable.
- Q. Of the number reported in element L, the number that were adverse.
- R. The total number of requests for coverage determinations that were withdrawn in the reporting time period above.
- S. The total number of requests for coverage determinations that were dismissed in the reporting time period above.

## **2. Redeterminations**

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

- A. The total number of redeterminations made in the reporting time period above.
- B. Of the number reported in element A, the total number of exception decisions made in the reporting time period above.
- C. Of the number reported in element A, the number processed timely.
- D. Of the number reported in element A, the number that were fully favorable.
- E. Of the number reported in element A, the number that were partially favorable.
- F. Of the number reported in element A, the number that were adverse.
- G. The total number of requests for redeterminations that were withdrawn in the reporting time period above.
- H. The total number of requests for redeterminations that were dismissed in the reporting time period above.

## **3. Reopenings**

Data elements to be uploaded in a data file at the Contract level:

- 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. Date of original disposition;
  - 5. Original disposition (Fully Favorable; Partially Favorable or Adverse);
  - 6. Case level (Coverage Determination or Redetermination);
  - 7. Date case was reopened;
  - 8. Reason(s) for reopening (Clerical Error, New and Material Evidence, Fraud or Similar Fault, or Other)
  - 9. Date of reopening disposition (revised decision);
  - 10. Reopening disposition (Fully Favorable; Partially Favorable or Adverse).

## Section VII. Long-Term Care (LTC) Utilization

LTC network pharmacies receive access/performance rebates that may create financial incentives that conflict with Part D Sponsors' formularies or drug utilization management (DUM) programs. These incentives can negatively impact formulary adherence as well as overall drug costs associated with beneficiaries served by LTC pharmacies. CMS will collect data for LTC pharmacies' formulary and non-formulary cost and utilization, for comparison to retail pharmacies' cost and utilization patterns.

Sponsors will report the number of 31-day equivalent prescriptions dispensed by each LTC pharmacy, and the aggregate number of 30-day equivalent prescriptions dispensed by network retail pharmacies. These are calculated by summing days supply of all covered Part D prescriptions dispensed by the respective pharmacy or group of pharmacies, and then dividing by either 31 or 30 days. Prescription cost is defined as the sum of ingredient cost, dispensing fee, and sales tax; the ingredient cost should reflect the Sponsor's negotiated price. A network LTC pharmacy is a network pharmacy owned by or under contract with a LTC facility to provide prescription drugs to the facility's residents.

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>	August 31	February 28

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

Data file to be uploaded through the HPMS at the Contract level as specified below:

- A. The total number of network LTC pharmacies in the service area.
- B. The total number of network retail pharmacies in the service area.
- C. The total number of beneficiaries in LTC facilities for whom Part D drugs have been provided under the Contract.
- D. For each network LTC pharmacy in the service area:
  1. LTC pharmacy name;
  2. LTC pharmacy NPI number;
  3. Contract entity name of LTC pharmacy;
  4. Chain code of LTC pharmacy;
  5. Number of 31-day equivalent formulary prescriptions dispensed;
  6. Number of 31-day equivalent non-formulary prescriptions dispensed;
  7. Cost of formulary prescriptions;
  8. Cost of non-formulary prescriptions.
- E. In aggregate, for all retail pharmacies in the service area:
  1. Number of 30-day equivalent formulary prescriptions dispensed;
  2. Number of 30-day equivalent non-formulary prescriptions dispensed;

3. Cost of formulary prescriptions;
4. Cost of non-formulary prescriptions.

## **Section VIII. Fraud, Waste and Abuse Compliance Programs**

Note: Employer Direct plan Sponsors are exempt from this reporting section.

Compliance plan requirements for Part D Sponsors are described in 42 C.F.R. §423.504 (b)(4)(vi)(G), including procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to CMS or its designees. Chapter 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual, Compliance Program Guidelines”, provides interpretive rules and guidelines to Part D Sponsors for implementing the regulatory requirements to have a compliance plan under 42 C.F.R. §423.504(b)(4)(vi)(A-G), and the requirement mandated by Congress in section 1860D-4(c)(1)(D) of the Act that Part D Sponsors have a “program to control fraud, waste and abuse”.

Part D Sponsors may voluntarily report aggregate data related to their anti-fraud, waste and abuse activities. Aggregate reporting will allow CMS to monitor Sponsors’ fraud, waste and abuse programs. These data will measure the types of incidents, the sources by which incidents are identified to Sponsors, as well as the activities taken by Sponsors to respond to the incidents. Sponsors should refer to §423.504(b)(4)(vi)(G)(1) and § 423.504(b)(4)(vi)(G)(2) for sponsors’ requirements to conduct inquiries and to design corrective actions to prevent future misconduct as well as address underlying problems.

For this data collection, the following definitions will apply:

- A fraud incident/complaint is defined as a statement, oral or written, alleging that a provider, pharmacy, pharmacist, PBM, Plan, Plan Agent, broker, or beneficiary knowingly and willfully executed, or attempted to execute, a scheme or artifice to defraud any health care benefit program or to obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the custody or control of any health care benefit program.
- Abuse includes actions that may, directly or indirectly, result in: unnecessary costs to the Medicare Program, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are medically unnecessary. Abuse involves payment for items or services when there is no legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment. This applies to a provider, pharmacy, pharmacist, PBM, Plan, Plan Agent, broker or beneficiary.
- Closed incidents include, but are not limited to, incidents with corrective action(s) initiated and completed, and incidents referred to appropriate authorities and accepted.

Reporting timeline:

	YTD
<b>Reporting Period</b>	January 1 - December 31
<b>Data due to CMS/HPMS</b>	February 28

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

- A. The number of potential fraud and abuse incidents related to inappropriate billing. Inappropriate billing by pharmacies should be included.
- B. The number of potential fraud and abuse incidents related to providing false information.
- C. The number of potential fraud and abuse incidents related to doctor shopping/drug seeking beneficiary.
- D. The number of potential fraud and abuse incidents related to attempting to steal identity/money.
- E. The number of potential fraud and abuse incidents related to other areas not listed above (e.g. OIG exclusion list, and broker/agent complaints).
- F. The total number of potential fraud and abuse incidents identified.
- G. Of the total reported in F, the number identified through internal efforts.
- H. Of the total reported in F, the number of incidents received from external sources. Incidents reported through the Complaints Tracking Module (CTM) or as grievances should be included.
- I. Of the total reported in F, the number of potential fraud and abuse incidents that were closed.
- J. The number of inquiries initiated by the Sponsor as a result of potential fraud and abuse incidents.
- K. The number of corrective actions initiated by the Sponsor as a result of potential fraud and abuse incidents.
- L. The number of potential fraud and abuse incidents referred to CMS for action; includes referrals to CMS staff, MEDICs, or other CMS designated program safeguard contractor.
- M. The number of potential fraud and abuse incidents referred to federal law enforcement for action. This includes referrals to the OIG, FBI, DEA, and FDA.
- N. The number of potential fraud and abuse incidents referred to local law enforcement for action; this includes but is not limited to referrals to state, county, township, or province police.
- O. The number of potential fraud and abuse incidents referred to State Insurance Commissioners (SICs) or state licensing authorities.

## **Section IX. 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 a 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:

	<b>YTD</b>
<b>Reporting Period</b>	January 1 – December 31
<b>Data due to CMS/HPMS</b>	February 28

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.

## Section X. Plan Oversight of Agents

NOTE: This reporting section applies only to Sponsors of stand-alone prescription drug plans, which do not also have MA-PD plans. Sponsors of 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. Employer/union group plans are exempt from this reporting section.

Sponsors are required to comply with State requests for information about the performance of licensed agents or brokers as part of a state investigation into the individual's conduct. Plans are responsible for monitoring the conduct of their agents. While the states oversee agent licensing, CMS will monitor agent complaints to determine if Sponsors are investigating identified complaints and imposing disciplinary actions as well as reporting poor conduct to the state.

Complaints include both complaints from the Complaint Tracking Module (CTM) and other complaints or grievances made directly to the Sponsor. Complaints may result in various disciplinary actions, ranging from verbal warning to termination of employment or contract.

Reporting timeline:

	YTD
<b>Reporting Period</b>	January 1 - December 31
<b>Data due to CMS/HPMS</b>	February 28

Data elements to be uploaded in two data files at the Contract level:

### 1. Agent/Broker:

For each agent that received compensation (including commission and salary) in the reporting period (initial enrollments and renewal payments received), indicate:

- A. Contract Number.
- B. Agent/Broker Type (Captive, Employed, Independent, None).
- C. Agent/Broker Last Name.
- D. Agent/Broker First Name.
- E. Agent/Broker Middle Initial.
- F. Agent/Broker State Licensed. For agents licensed in multiple states, complete a row for each state in which the agent is licensed.
- G. Agent/Broker National Producer Number (NPN).
- H. Plan Assigned Agent/Broker Identification Number.
- I. Agent/Broker Current License Effective Date.
- J. Agent/Broker Appointment Date.

- K. Agent/Broker Training Completion Date.
- L. Agent/Broker Testing Completion Date.
- M. In aggregate, the number of Agent/Broker complaints for the reporting period. If multiple lines are needed for an agent (licensed in more than one state) only fill out this data element for the first line. For example, if an agent has four complaints and is licensed in Florida and Georgia, all four complaints should be listed under the Florida line.
- N. In aggregate, the number of Agent/Broker disciplinary actions taken in the reporting period (related to Marketing). Examples of disciplinary actions include: retraining, verbal or written warnings, suspension, termination, etc. If multiple lines are needed for an agent (licensed in more than one state) only fill out this data element for the first line. For example, if an agent has received two disciplinary actions and is licensed in Florida and Georgia, both actions should be listed under the Florida line.
- O. Agent/Broker Termination Date (if applicable).
- P. Termination for Cause? (Y(yes) or N (no)).
- Q. Third-party Marketing Organization (TMO)/Field Marketing Organization Name(FMO), if applicable.
- R. The number of new enrollments in the reporting period. If more than one line is filled out because of agent being licensed in multiple states, please put enrollments in by state.

## **2. New Enrollments:**

For all new enrollments (initial or renewal) during the reporting period for which an Agent/Broker is associated (includes instances where the agent/broker was assigned after the enrollment was initiated), indicate:

- A. Contract Number.
- B. Plan Beneficiary Package (PBP) Number.
- C. Beneficiary Last Name.
- D. Beneficiary First Name.
- E. Beneficiary Middle Initial.
- F. Beneficiary HICN or RRB Number.
- G. Agent/Broker Last Name.
- H. Agent/Broker First Name.
- I. Agent/Broker Middle Initial.
- J. Agent/Broker National Producer Number (NPN).
- K. Plan Assigned Agent/Broker Identification Number.
- L. Enrollment Mechanism. (Plan/Plan Representative Online; CMS Online Enrollment Center; Plan Call Center; 1-800-MEDICARE; Paper Application; Auto-Assigned/Facilitated; Other).
- M. Enrollment Application Date.
- N. Enrollment Effective Date.
- O. The number of Agent/Broker complaints filed by the beneficiary in the reporting period.
- P. Of the number reported in O, the number of Marketing related complaints.