MEDICARE PART D
REPORTING REQUIREMENTS

Effective as of January 1, 2012

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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, the individual contract-level, or Sponsor-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 have 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.

*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 the sponsor's 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. Sponsor's 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 (code 61 transactions). Disenrollments must not be included in Section 1 Enrollment.

Section 2 Disenrollment must include all voluntary disenrollment transactions.

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	May 31	August 31	November 30	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 enrollee or his/her authorized representative).
   C. Of the total reported in A, the number of enrollment requests that required requests for additional information.

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 (e.g. individual not having a valid enrollment period).
E. Of the total reported in C, the number of incomplete enrollment requests received that are 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 offered).
I. Of the total reported in A, the number of internet enrollment requests received via plan website (if offered).
J. Of the total reported in A, the number of 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 number reported in A, the number of enrollment transactions submitted using the SEP Election Period code "S" related to creditable coverage.
M. Of the number 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 number 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). 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:

	Period 1
Reporting Period	January 1 - March 31
Data due to CMS/HPMS	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:**
   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.

Reporting timeline for Sections 2 and 3 only:

	YTD
Reporting Period	January 1 – December 31
Data due to CMS/HPMS	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. Access to Extended Day Supplies at Retail Pharmacies

NOTE: This reporting requirement applies only to those Part D Plans that include in their networks mail-order pharmacies offering extended day supplies of covered Part D drugs.

As provided in §423.120 and section 50.10 of Chapter 5 of the Prescription Drug Benefit Manual, Part D Sponsors that include mail-order pharmacies in their networks must permit enrollees to receive benefits, which may include an extended day supply of covered Part D drugs (for example, a 90-day supply), through a network retail pharmacy rather than a network mail-order pharmacy. Part D Sponsors must contract with a sufficient number of retail pharmacies so as to ensure that enrollees have reasonable access to the same extended day supply benefits at retail that are available at mail-order pharmacies. Part D Sponsors must submit data annually that will allow CMS to evaluate access to extended day supplies at retail pharmacies. The number of contracted retail pharmacies reported in subsection A of the Retail, Home Infusion, and Long-term Care Pharmacy Access reporting section will be used to evaluate these data.

Reporting timeline:

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

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

A. The number of contracted retail pharmacies in a Contract's service area (by State for PDPs and regional PPOs, and by service area for local MA-PD plans) that are contracted to dispense an extended day supply of covered Part D drugs.

Section IV. 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. Data will be uploaded to HPMS in a data file.

Reporting timeline:

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

For each beneficiary identified as being eligible for a MTM,program the following information will be collected:

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. LTC Enrollment.
H. Date of MTM program enrollment.
I. Date of MTM program opt-out, if applicable.
J. 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.
K. Offered annual comprehensive medication review.
L. If offered, date of (initial) offer.
M. Received annual comprehensive medication review (CMR).
N. If received, date(s) of annual comprehensive medication review(s). (If more than 1 CMR is received, up to 3 dates will be allowed.)
O. Number of targeted medication reviews.
P. Number of prescriber interventions.
Q. Number of changes to drug therapy made as a result of MTM interventions. Changes include, but are not limited to, dosage changes, therapeutic or generic substitutions, and discontinuation or addition of therapy.

Section V. 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:

	Period 1	**Period 2**
Reporting Period	January 1 - June 30	July 1 - December 31
Data due to CMS/HPMS	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.
F. The interest dollar amount paid on electronic claims that were not paid timely.
G. The interest dollar amount paid on non-electronic claims that were not paid timely.

Section VI. Pharmacy Support of Electronic Prescribing

The success of electronic prescribing under the Medicare Part D program largely depends upon the implementation of electronic prescribing by network pharmacies. The program will be unsuccessful if Part D participating pharmacies are not willing and prepared to implement e-prescribing. Accordingly, CMS expects Part D sponsors to facilitate adoption of electronic prescribing by not only utilizing the Part D e-prescribing standards in transactions that originate with the sponsor and supporting receipt of compliant transactions from dispensers and prescribers, but also by working with their network pharmacies to ensure that such pharmacies have e-prescribing systems that are capable to send and receive transactions that are compliant with the Part D e-prescribing standards. Sponsors should refer to the CMS memorandum issued September 19, 2008 which discussed requirements to support electronic prescribing under Part D.

In order to evaluate the success of their efforts to promote e-prescribing through their network pharmacies, sponsors will report the numbers of pharmacies that are electronic prescribing enabled. Specifically, Part D sponsors must report the numbers of pharmacies that currently have systems that are fully operational and activated to send and receive electronic transactions in compliance with the NCPDP SCRIPT 8.1 standard. Data should be reported by State for PDPs and regional PPOs, and by service area for local MA-PD plans, as of the last day of the reporting period specified. Pharmacy data reported in the Retail, Home Infusion, and Long-Term Care Pharmacy Access reporting section will be utilized to determine the percentage of pharmacies enabled to receive electronic prescriptions.

Reporting timeline:

	Period 1
Reporting Period	January 1 – March 31
Data due to CMS/HPMS	May 31

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

A. The number of retail pharmacies in a Contract's service area (by State for PDPs and regional PPOs, and by service area for local MA-PD plans) enabled to receive electronic prescriptions in compliance with Part D standards as of the last day of the reporting period specified above.
B. The number of long-term care pharmacies in a Contract's service area (by State for PDPs and regional PPOs, and by service area for local MA-PD plans) enabled to receive electronic prescriptions in compliance with Part D standards as of the last day of the reporting period specified above.

C. The number of home infusion pharmacies in a Contract's service area (by State for PDPs and regional PPOs, and by service area for local MA-PD plans) enabled to receive electronic prescriptions in compliance with Part D standards as of the last day of the reporting period specified above.

Section VII. Grievances

According to MMA statute, a grievance is any complaint or dispute, other than one that involves 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 its decisions 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. A 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.

- Sponsors should report data based on the date the grievance decision was made. Multiple grievances by a single complainant should be tracked, followed, and reported as separate grievances.
- Grievances, regardless if they are also reported in the Complaints Tracking Module (CTM), should be reported.
- When categorizing grievances into core categories, Sponsors may report based on their investigations subsequent to the enrollees' filing of the grievances.
- Sponsors should not report requests for coverage determinations, exceptions, or redeterminations as grievances.
- Plans should not report their CTM records to CMS as their grievance logs.
- Sponsors should not report general inquiries or questions as grievances.
- Plans should not dismiss or exclude any grievances filed by beneficiaries or their appointed representatives from this reporting section.

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	May 31	August 31	November 30	February 28

Data to be reported at the Plan (PBP) level:

	Total number of grievances	Number of grievances in which timely notification was given
Enrollment, plan benefits, or pharmacy access		
Customer service		
Coverage determinations and Redeterminations process (e.g. untimely decisions)		
Other		

Section VIII. Pharmacy & Therapeutics (P&T) Committees/ Provision of Part D Functions

In addition to satisfying and maintaining P&T committee requirements described in §423.120, Part D Sponsors will be responsible for providing information to CMS relating to changes made during a contract year to their P&T committees on a periodic basis. CMS recognizes the importance of maintaining confidentiality of these records. Additionally, CMS will provide methods other than HPMS data submission for those Part D Sponsors with contractual limitations in providing these data.

Part D Sponsors are also responsible for providing information to CMS relating to the organizations responsible for providing specific functions. This information must be updated on a timely manner if changes occur. On an annual basis, Part D Sponsors must attest if changes have occurred, and if they have been communicated to CMS.

Reporting timeline for Section 1:

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

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

1. **P&T Committee:**
   A. Indicate if there have been changes in P&T committee membership during the time period specified above.
   B. If changes have occurred, indicate if these changes have been reflected within the Contract Management module. For those Sponsors operating under confidentiality agreements, indicate if these changes have been sent to CMS per those agreements.

Reporting timeline for Section 2:

	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	May 31	August 31	November 30	February 28

2. **Provision of Part D Functions:**
   A. Indicate if there have been changes to the organizations providing Part D functions during the reporting period.
   B. If changes have occurred, indicate if these changes have been reflected within the Contract Management module on the Part D Data page within the Organizations Providing Part D Functions table.

Section IX. Coverage Determinations and Exceptions

Title I, Part 423, Subpart M describes Part D sponsors' requirements for coverage determinations, formulary and tier exceptions, and exceptions to established drug utilization management programs including timeframes for standard and expedited requests. Prior authorization (PA) requests/approvals that relate to Part B versus Part D coverage should be included in this reporting.

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	May 31	August 31	November 30	February 28

Data elements to be entered into the HPMS at the Plan (PBP) 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 formulary restrictions, including non-formulary status, PA requirements, step therapy, and quantity limits (QL). Rejections due to early refills should be excluded.

Prior authorizations:

C. Total number of PAs made in the reporting period	D. Number of timely PA decisions	E. Number of approved PAs (PA requirements satisfied)

Exceptions to utilization management tools (e.g. PA, QL, or step therapy requirements):

F. Total number of UM exceptions made in the reporting period	G. Number of timely UM exception decisions	H. Number of favorable UM exceptions

Tier exceptions:

I. Total number of tier exceptions made in the reporting period	J. Number of timely tier exception decisions	K. Number of favorable tier exceptions

Formulary exceptions:

L. Total number of formulary exceptions made in the reporting period	M. Number of timely formulary exception decisions	N. Number of favorable formulary exceptions

Section X. Redeterminations

Title I, Part 423, Subpart M includes regulations regarding appeals under Part D. As defined in §423.560, an appeal is any of the procedures that deal with the review of adverse coverage determinations made by the Plan on the benefits the enrollee believes he or she is entitled to receive, including a delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage. These procedures include redeterminations by the Plan. Redeterminations may result in reversal or partial reversal of the original decision. Sponsors should report data based on the date the redetermination decision was made.

- Example of an approved redetermination: Non-formulary exception request approved upon redetermination for drug and quantity prescribed.
- Example of a partially approved redetermination: Non-formulary exception request approved upon redetermination for drug, but full quantity prescribed not approved.

CMS will request redeterminations data as part of the monitoring of a Plan's availability, accessibility, and acceptability of its services.

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	May 31	August 31	November 30	February 28

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

A. Total number of redeterminations made in the reporting period	B. Number of redeterminations made within required timeframes	C. Number of partially favorable redeterminations	D. Number of fully favorable redeterminations

Section XI. 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.

The requirements stipulating that the Part D sponsors provided information pertaining to LTC waste are described in 42 CFR § 423.154. Per 42 CFR 423.4, "Brand name drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 USC 355(b)(2))." Per 42 CFR 423.4, "Generic drug means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved."

For monitoring purposes, CMS will collect data for LTC pharmacies' formulary and non-formulary cost and utilization, for comparison to retail pharmacies' cost and utilization patterns, as well as data related to waste. Prescription cost is defined as the sum of ingredient cost, dispensing fee, sales tax and vaccine administration fee. 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.

Under these reporting requirements, Part D sponsors will collect information from the network LTC pharmacies to determine the amount of unused drugs dispensed on behalf of the Part D beneficiaries. We believe that pharmacies have data in their systems pertaining to quantities dispensed and the date a prescription was discontinued or changed. We understand that pharmacies routinely receive a discontinuation date (D/C date) from the LTC facility whenever a medication is discontinued for any reason. The pharmacy will receive a D/C date when a prescription is stopped altogether or if a prescription is changed. For example, when a dose is changed a pharmacy will receive a D/C date for the original prescription and a new prescription with the new dose. (Alternatively, the pharmacy may receive a new prescription for a new dose or substitute drug and would use the start date of the new prescription as the D/C date of the previous prescription.) These D/C orders prevent a patient from receiving the wrong drug or wrong dose or "extra" doses. The pharmacy may also receive census data that informs the pharmacy of when a patient dies or is discharged from the facility. Using this information, the pharmacy can subtract the days supply dispensed prior to the date of discontinuation, discharge, or death from the quantity originally dispensed to determine the quantity of drugs that go unused. While this calculation may not precisely correlate to unused doses, we believe it is close enough to be a very good proxy, and no new data collection would be required on the part of LTC pharmacies. Therefore, we believe pharmacies have the data in their own systems to calculate the difference between the quantity dispensed and the quantity consumed, which can be used to calculate the amount of unused medication. Reporting on the aggregate level on

unused brand and generic drugs must be reported from the pharmacies to the Part D sponsors at least bi-annually. We emphasize that this information does not need to be associated with the original claims transactions and can be provided through summary reporting. Reporting on unused drugs is waived for Part D sponsors for any of their network pharmacies that dispense both brand and generic drugs, as defined in § 423.4, in no greater than 7-day increments.

Reporting timeline:

	Period 1	**Period 2**
Reporting Period	January 1 - June 30	July 1 – December 31
Data due to CMS/HPMS	August 31	February 28

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 (PDPs and regional PPOs will report for each state, MA-PDs will report for the service area).
B. The total number of network retail pharmacies in the service area (PDPs and regional PPOs will report for each state, MA-PDs will report for 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;
    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 XII. 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, "Part D Compliance Plan to Control Fraud, Waste and Abuse", 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 or broker, or beneficiary engaged in the intentional deception or misrepresentation that the individual knows to be false or does not believe to be true, and the individual makes knowing that the deception could result in some unauthorized benefit to himself/herself or some other person.
- An abuse incident/complaint is a statement, oral or written, alleging that a provider, pharmacy, pharmacist, PBM, Plan, Plan Agent or broker or beneficiary engaged in behavior that the individual should have known to be false, and the individual should have known that the deception could result in some unauthorized benefit to himself/herself or some other person.

Reporting timeline:

	YTD
Reporting Period	January 1 - December 31
Data due to CMS/HPMS	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. The number of inquiries initiated by the Sponsor as a result of potential fraud and abuse incidents.
J. The number of corrective actions initiated by the Sponsor as a result of potential fraud and abuse incidents.
K. 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.
L. 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.
M. 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.
N. The number of potential fraud and abuse incidents referred to State Insurance Commissioners (SICs) or state licensing authorities.

Section XIII. 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:

	YTD
Reporting Period	January 1 – December 31
Data due to CMS/HPMS	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. Employer Plan Year Start Date.
I. Current/Anticipated enrollment.

Section XIV. Plan Oversight of Agents

NOTE: This 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. Sponsors should include all disciplinary actions in this reporting.

Reporting timeline:

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

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

A. Total number of agents.
B. Number of agents investigated based on complaints.
C. Number of agents receiving disciplinary actions from the Sponsor based on complaints.
D. Number of complaints reported to State by MAO or Cost contractor.
E. Number of agents whose selling privileges were revoked by the plan based on conduct or discipline.
F. Number of agent-assisted enrollments.