MEDICARE PART D
-REPORTING REQUIREMENTS

Effective as of January 1, 2010

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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 previously been released for 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. ~~Sections that refer to prescriptions should encompass all covered~~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.

For PACE Organizations offering Part D coverage, reporting requirements will be limited to:

- Enrollment;
- Vaccines;
- Prompt Payment by Part D Sponsors;
- Pharmacy Support of Electronic Prescribing;
- Generic Drug Utilization;
- Pharmacy & Therapeutics (P&T) Committees/Provision of Part D Functions (for PACE Organizations utilizing formularies);
- Transition (for PACE Organizations utilizing formularies);
- Coverage Determinations and Exceptions (for PACE Organizations utilizing formularies);
- Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions;
- Long-term Care (LTC) Utilization (for PACE Organizations utilizing formularies); and
- Fraud, Waste and Abuse Compliance Programs.

MA Organizations and Medicare Cost Plans that offer Part D benefits will be required to comply with all reporting requirements contained herein, with the exception of subsections 1, 2 and 3 of the Licensure and Solvency, Business Transactions and Financial Requirements reporting section, ~~and~~ the Employer/Union-Sponsored Group Health Plan Sponsors reporting section, the Agent Training and Testing 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

CMS had provided guidance for Part D sponsors' processing of enrollment requests and transactions (Section 30.2.3 of the PDP Guidance and Section 30.4 of the Medicare Managed Care Manual provide information about appropriate conditions by which an enrollment request may be denied, and Special Enrollment Period (SEP) Election Period code by SEP reason. Section 30.2.2 of the PDP Guidance and Section 40.2.2 of the Managed Care Manual describes allowed timeframes for enrollment requests.) CMS will collect these data, which ~~is~~are otherwise not available to CMS, in order to evaluate the plans' processing of beneficiary applications in accordance with CMS policies and procedures, and to evaluate beneficiaries' understanding of eligibility for participation in Part D. While there are several reasons that plans can offer an SEP, only three SEP codes are reported to CMS on enrollment actions. Plans' reporting of data regarding other SEP reasons will further assist CMS in ensuring plans are providing support to beneficiaries, while complying with CMS policies.

All enrollments should be included for data elements E-J (60, 61, 62 and 71 transactions). Disenrollments should not included in these data elements.

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 15	August 15	November 15	February 15

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

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 denied due to the Plan's determination of the ineligibility of the individual to elect the plan (e.g. individual not having a valid enrollment period to elect a plan).
C. Of the total reported in A, the number of enrollment requests denied due to the individual not providing information to complete the enrollment request within established timeframes.
D. Of the total reported in A, the number of incomplete enrollment requests received~~,~~ that are successfully completed within established timeframes.
E. The number of enrollment transactions submitted using the "Special Enrollment Period" (SEP) Election Period code "S" for Other SEP that are related to contract changes. (This includes Sections 20.3.4, 20.3.8.2, 20.3.8.3 of the PDP Guidance - Eligibility, Enrollment and Disenrollment, and Sections 30.4.3, 30.4.4.2, 30.4.4.3 in Chapter 2: Medicare Advantage Enrollment and Disenrollment of the Medicare Managed Care Manual).
F. The number of enrollment transactions submitted using the "Special Enrollment Period" (SEP) Election Period code "S" for Other SEP that are

related to a change in the beneficiaries' eligibility or status. (This includes Sections 20.3.8.6, 20.3.8.8.A, 20.3.8.8.B, 20.3.8.8.F, 20.3.8.8.G, 20.3.8.13 of the PDP Guidance - Eligibility, Enrollment and Disenrollment, and Sections 30.4.4.6, 30.4.4.7, 30.4.4.8, 30.4.4.13, 30.4.5 in Chapter 2: Medicare Advantage Enrollment and Disenrollment of the Medicare Managed Care Manual).

G. The number of enrollment transactions submitted using the "Special Enrollment Period" (SEP) Election Period code "S" for Other SEP related to credible coverage. (This includes Sections 20.3.5, 20.3.6, 20.3.8.11 of the PDP Guidance - Eligibility, Enrollment and Disenrollment, and Sections 30.4.4.5, 30.4.4.14 in Chapter 2: Medicare Advantage Enrollment and Disenrollment of the Medicare Managed Care Manual).
H. The number of enrollment transactions submitted using the "Special Enrollment Period" (SEP) Election Period code "S" for Other SEP related to Special Plan types and situations such as Special Needs Plans, PACE Plans, Institutions, SPAP. This includes Sections 20.3.8.4, 20.3.8.5, 20.3.8.8.C, 20.3.8.12, 20.3.8.9 of the PDP Guidance - Eligibility, Enrollment and Disenrollment, and Sections 30.4.4.4, 30.4.4.9, 30.4.4.10, 30.4.4.11 in Chapter 2: Medicare Advantage Enrollment and Disenrollment of the Medicare Managed Care Manual).
I. The total number of enrollment transactions submitted using the "Special Enrollment Period" (SEP) Election Period code "S" for Other SEP that coordinate with the Medicare Advantage open enrollment period. (This includes Sections 20.3.8.8.D, 20.3.8.8.E of the PDP Guidance - Eligibility, Enrollment and Disenrollment).
J. The total number of enrollment transactions submitted using the "Special Enrollment Period" (SEP) Election Period code "S" for Other SEP that are not included above.

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 with Part D applications and will be posted on the Prescription Drug Contracting 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).

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 access data elements (e.g., geo-access reports). This may include documentation of the access data elements at the plan (PBP level). 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 Sections A and B only:

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

A. Data elements to be entered into the HPMS at the ~~CMS~~ Contract level:
   1. Percentage of Medicare beneficiaries living within 2 miles of a retail network pharmacy in urban areas of a Contract’s service area (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 above.
   2. Percentage of Medicare beneficiaries living within 5 miles of a retail network pharmacy in suburban areas (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 above.
   3. Percentage of Medicare beneficiaries living within 15 miles of a retail network pharmacy in rural areas (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 above.
   4. 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) as of the last day of the reporting period specified above.

B. Data files to be uploaded through the HPMS at the ~~CMS Part D~~ Contract level, following templates provided in HPMS.
   1. A list of contracted HI network pharmacies into HPMS as of the last day of the reporting period specified above.
   2. A list of contracted LTC network pharmacies into HPMS as of the last day of the reporting period specified above.

Reporting timeline for Sections C and D only:

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

C. Data elements to be entered into the HPMS at the Plan (PBP) level for only those MA-PD and cost plans that own and operate their own pharmacies and have received a waiver of the any willing pharmacy requirement.
   1. Number of prescriptions provided by all pharmacies owned and operated by the plan.
   2. Number of prescriptions provided at all pharmacies contracted by the plan.

D. Data elements to be entered into the HPMS at the Plan (PBP) level for only those 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 data for elements A1-A4.
   1. Number of prescriptions provided by retail pharmacies owned and operated by the plan.
   2. 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.

B. ~~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).~~

Section IV. Vaccines

For monitoring purposes, Part D Sponsors will be responsible for reporting several data elements related to their reimbursement of vaccines, demonstrating their implementation of CMS requirements regarding vaccine access detailed in section 60.2 of Chapter 5 of the Prescription Drug Benefit Manual. For this section, Sponsors are required to report on the vaccine itself, or ingredient cost. Sponsors do not need to report or include vaccine administration claims as part of this reporting requirement.

Data element A should be a sum of data elements B-F; claims should not be reported more than once in data elements B-F. Additionally, elements B through F below intend to capture a number of different methods to provide vaccines to enrollees. This does not imply that each method must be implemented; it is acceptable to submit zero values.

Reporting timeline:

	Period 1	**Period 2 (YTD)**
Reporting Period	January 1 - June 30	~~July~~January 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. The total number of Part D vaccines with dates of dispensing/immunization during the time period specified above, regardless of the method used to process the claim as described in B through F below.
B. Of the total reported in A, the number of Part D vaccines dispensed/immunized in any out-of-network setting where a state recognized immunizer dispenses a Part D vaccine (e.g. physician's office) where the beneficiary retrospectively files paper receipts for reimbursement of the vaccine.
C. Of the total reported in A, the number of vaccines dispensed/immunized at network pharmacies (Including those vaccines dispensed by the pharmacy and submitted electronically but administered by another qualified provider).
D. Of the total reported in A, the number of vaccines processed through a paper enhanced process, where the provider used or navigated a process that facilitated out-of-network access during the time period specified above.
E. Of the total reported in A, the number of vaccines processed through an internet based web tool.
F. Of the total reported in A, the number of vaccines processed through a process not described in data elements B through E.

Section V. Medication Therapy Management Programs

The requirements stipulating that Part D Sponsors provide Medication Therapy Management Programs (MTMP) 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 MTMP. Data will be manually submitted in HPMS, or uploaded in a data file.

I. Data elements to be entered into the HPMS at the Contract level.

Data related to the identification and participation in the MTMP will be submitted according to the following timeline (note: Period 2 encompasses one full year):

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

A. The total number of beneficiaries identified to be eligible for, and were automatically enrolled in, the MTMP during the specified time period above.
B. The total number of beneficiaries who opted-out of enrollment in the MTMP during the time period specified above. This should be a longitudinally cumulative total, and be a subset of the number of beneficiaries identified to be eligible for, and were automatically enrolled in, the MTMP in the specified time period.
C. The number of beneficiaries who opted-out of enrollment in the MTMP due to death at any time during the specified time period above. This should be a subset of the total number of beneficiaries who opted-out of enrollment in the MTMP in the specified time period.
D. The number of beneficiaries who opted-out of enrollment in the MTMP due to disenrollment from the Plan at any time during the specified time period above. This should be a subset of the total number of beneficiaries who opted-out of enrollment in the MTMP in the specified time period.
E. The number of beneficiaries who opted-out of enrollment in the MTMP at their request at any time during the specified time period above. This should be a subset of the total number of beneficiaries who opted-out of enrollment in the MTMP in the specified time period.
F. The number of beneficiaries who opted-out of enrollment in the MTMP for a reason not specified in data elements C-E during the specified time period above. This should be a subset of the total number of beneficiaries who opted-out of enrollment in the MTMP in the specified time period.
G. For beneficiaries enrolled in the MTMP at any time during the specified time period above, provide the prescription cost of all covered* Part D medications on a per MTMP beneficiary per month basis. This should be a currency field,

rounded to the nearest dollar. The numerator represents the total prescription drug costs. The total prescription cost should be limited to covered Part D medications and be calculated using gross drug cost as follows: (Ingredient Cost Paid + Dispensing Fee + Sales Tax). This is based on the sum of all Part D covered prescriptions that were dispensed within the reporting period specified for each beneficiary enrolled in the MTMP. This includes both MTMP beneficiary cost sharing and Part D costs paid. The denominator represents the total number of member months for the MTMP enrolled beneficiaries. These member months should include all months the beneficiary was enrolled in the plan during the reporting period specified, not only the months that the beneficiary enrolled in the MTMP. The following equation also describes this calculation.

Figure 1: Calculating total prescription cost per MTMP beneficiary per month.

$$\begin{bmatrix}\text{Total prescription cost}\\ \text{per MTMP beneficiary}\\ \text{per month}\end{bmatrix} = \frac{\sum_{i}^{n}\left(\sum_{j}^{m}\text{Gross Drug Cost}\right)}{\sum_{i}^{n}(\text{Member Months in Part D Contract during Reporting Period})}$$

{Gross Drug Cost = (Ingredient Cost Paid + Dispensing Fee + Sales Tax).

For beneficiaries i to n, and prescriptions j to m from the i^{th} beneficiary}

$$\begin{bmatrix}\text{Total prescription cost}\\ \text{per MTMP beneficiary}\\ \text{per month}\end{bmatrix} = \frac{\sum_{i}^{n}\left(\sum_{j}^{m}\text{Gross Drug Cost}\right)}{\sum_{i}^{n}(\text{Member Months in Part D Contract during Reporting Period})}$$

{Gross Drug Cost = (Ingredient Cost Paid + Dispensing Fee + Sales Tax).

For beneficiaries i to n, and prescriptions j to m from the i^{th} beneficiary}

H. For beneficiaries enrolled in the MTMP at any time during the specified time period above, provide the number of covered* Part D 30-day equivalent prescriptions on a per MTMP beneficiary per month basis. This should be a numeric field.

This numerator should be calculated by first summing days supply of all covered Part D prescriptions dispensed for beneficiaries enrolled in MTMP as of the last day of the reporting period, and dividing by 30 to determine the number of 30 day equivalent prescriptions dispensed. The denominator represents the total number of member months for the MTMP enrolled beneficiaries. These member months should include all months the beneficiary was enrolled in the plan during the reporting period specified, not only the months that the beneficiary enrolled in the MTMP. The following equation also describes this calculation.

Figure 2: Calculating total number of 30-day prescription equivalents per MTMP beneficiary per month.

$$\left[\text{Total number of 30-day prescription equivalents}\right]$$

$$\left[\begin{array}{c}\text{Total number of 30 - day prescription equivalents} \\ \text{per MTMP beneficiary per month}\end{array}\right] = \frac{\sum_{i}^{n}\left(\sum_{j}^{m}\left(\frac{\text{Days Supply}}{30}\right)\right)}{\sum_{i}^{n}\left(\begin{array}{c}\text{Member Months in Part D Contract} \\ \text{during Reporting Period}\end{array}\right)}$$

{For beneficiaries i to n, and prescriptions j to m from the i^{th} beneficiary}

I. For beneficiaries enrolled in the MTMP at any time during the specified time period above, the number of beneficiaries offered a comprehensive medication review.

J. For beneficiaries enrolled in the MTMP at any time during the specified time period above, the number of beneficiaries who received a comprehensive medication review.

K. ~~The average amount of time spent to complete an annual comprehensive medication review per MTMP enrollee (hh:mm).~~

*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.

II. Data file to be uploaded using Gentran or Connect Direct at the Contract level.

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

For each beneficiary identified as being eligible for MTMP, 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 MTMP enrollment.
I. Date of MTMP opt-out, if applicable.
J. Reason participant opted-out of MTMP (Death; Disenrollment from Plan; Request by beneficiary; or Other). Required if Date of MTMP opt-out is applicable.
K. Received annual comprehensive medication review.
L. Date of annual comprehensive medication review, if applicable.
M. Number of targeted medication reviews.
N. Number of ~~provider~~prescriber interventions.
O. Number of ~~additions~~changes to drug therapy made as a ~~direct~~ result of MTM interventions
P. ~~Number of discontinuations in drug therapy made as a direct result of MTM interventions~~

~~Q. Number of~~. Changes include dosage changes ~~to existing drug therapy made as a direct result of MTM interventions~~

~~R. Number of~~, therapeutic ~~substitutions made as a direct result of MTM interventions~~

~~S. Number of~~or generic substitutions ~~made as a direct result of MTM interventions~~, and discontinuation of therapy.

T. ~~No changes to drug therapy made as a result of MTM interventions~~

Section VI. 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.

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.

	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 VII.~~ 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 ~~retail~~ network pharmacies, sponsors will report the ~~percent of their network retail~~numbers of pharmacies that are electronic prescribing enabled. Specifically, Part D sponsors must report the ~~percent~~numbers of ~~their network~~ 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.

	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 total number of contracted retail network~~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. ~~Of the total, the~~ The number of ~~retail pharmacies enabled to receive electronic prescriptions in compliance with Part D standards.~~

~~D. The total number of all other contracted non-retail types of pharmacies (including~~ home infusion ~~and 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~~).~~

~~E. Of the total, the number of other non-retail types of pharmacies)~~ enabled to receive electronic prescriptions in compliance with Part D standards~~.~~

~~*F.*~~ as of the last day of the reporting period specified above.

Section VIII. Generic Drug Utilization

Cost control requirements for Part D Sponsors are presented in Title I, Part 423, Subpart D. Accordingly, Part D Sponsors will be responsible for reporting data elements needed to monitor utilization of generic drugs ~~(defined by.~~ Title I, Part 423, Sub-Part A, § 423.4~~).~~ provides a definition of generic drugs. Sponsors may elect to utilize drug databases such as First DataBank or Medispan to identify generic drugs.

Claims for non-drug items (e.g. insulin syringes, alcohol pads) should be excluded from 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 15	August 15	November 15	February 15

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

A. The total number of paid claims for Part D generic drugs (regardless of days supply) with dates of service during the specified reporting period identified above.
B. The total number of Part D paid claims (regardless of days supply) with dates of service during the specified reporting period identified above.

Section IX. Grievances

Title I, Part 423, Subpart M of the regulation includes regulations that require Part D Sponsors to maintain grievance information. Part D Sponsors will be responsible for reporting data related to grievances received.

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. Sponsors should not consider requests for coverage determinations, exceptions, or redeterminations as grievances. Sponsors should not report general inquiries or questions as grievances. ~~Complaints captured in the CTM should be excluded from these data.~~Grievances, regardless if they are also reported in the Complaints Tracking Module (CTM), should be reported. Plans should not report their CTM records to CMS as their grievance logs. Plans should not dismiss or exclude any grievances filed by beneficiaries or their appointed representatives from this reporting section.

Grievance data, requested herein by CMS, should be reported based on the date the grievance was received by the Sponsor, and not based on the date the event or incident that precipitated the grievance occurred. Multiple grievances by a single complainant should be tracked, followed, and reported as separate grievances.

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.

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

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 15	August 15	November 15	February 15

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

~~A.~~ Number of LIS beneficiaries who filed grievances.
B. Number of non-LIS* beneficiaries who filed grievances.

C. Grievance data by beneficiary status:

~~Summary grievance data~~			
	Total ~~#~~ number of Grievances	**#Number of grievances which the Sponsor provided timely notification of its decision ~~within the timeframe allowed by statute (include cases where extensions were granted, and then met).~~**	**~~# of grievances which the Sponsor did not provide notification of its decision within the timeframe allowed by statute~~**
# filed by LIS beneficiaries			
# filed by non-LIS* beneficiaries			
~~Subset of grievance data by core grievance categories~~			
~~Fraud, waste or abuse~~			
~~Enrollment, plan benefits, or pharmacy access~~			
~~Customer service~~			
~~Coverage determinations/Exceptions and Appeals process (e.g. untimely decisions)~~			
~~Other~~			
~~# of Distinct Beneficiaries Filing a Grievance~~			
~~# LIS beneficiaries~~			
~~# non-LIS beneficiaries~~			

~~D.~~ Grievance data by core grievance categories

	Total number of Grievances	**Number of grievances which the Sponsor provided timely notification of its decision**
Enrollment, plan benefits, or pharmacy access		
Customer service		
Coverage		

determinations/Exceptions and Appeals process (e.g. untimely decisions)		
Other		

*Beneficiaries that do not receive low-income subsidy (LIS)

Section X. 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 a quarterly basis, Part D Sponsors must attest if changes have occurred, and if they have been communicated to CMS.

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 15	August 15	November 15	February 15

A. Data elements to be entered into the HPMS at the Contract level:
   1. Indicate if there have been changes in P&T committee membership during the time period specified above.
   2. 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.

B. Data elements to be entered into the HPMS at the Contract level:
   1. Indicate if there have been changes to the organizations providing Part D functions during the reporting period.
   2. 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 XI. Transition

As described in §423.120(a)(3) and section 30.4 of Chapter 6 of the Prescription Drug Benefit Manual, Part D Plans must provide for an appropriate transition process for new enrollees who were prescribed non-formulary Part D drugs. For purposes of CMS oversight, Plans (PBPs) will be responsible for reporting various data elements related to minimum plan transition process timeframes on an annual basis.

Reporting timeline:

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

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

A. The minimum number of days supply the Plan's transition policy provides for its one-time, temporary fill for enrollees in the retail setting. (NOTE: This must be at least 30 days, unless the enrollee presents a prescription written for less than 30 days.)
B. The minimum number of days, beginning on the enrollee's effective date of coverage, in a plan's transition process for enrollees in the retail setting. (NOTE: This must be at least 90 days.)
C. The minimum number of days supply the Plan's transition policy provides for its temporary fill (with multiple refills as necessary) for enrollees in the LTC setting. (NOTE: This must be at least 31 days, unless the enrollee presents a prescription written for less than 31 days.)
D. The minimum number of days, beginning on the enrollee's effective date of coverage, in a plan's transition process for enrollees in the LTC setting. (NOTE: This must be at least 90 days.)
E. After the minimum transition period has expired, the minimum number of days supply the Plan provides to LTC enrollees for an emergency supply of non-formulary Part D drugs while an exception is being processed (NOTE: This must be at least 31 days, unless the enrollee presents a prescription written for less than 31 days.)
F. The maximum number of business days after a temporary transition fill within which the Plan will send a written transition notice via U.S. first class mail. (NOTE: This must be 3 business days or less.)

Section XII. Coverage Determinations and Exceptions

Title I, Part 423, Subpart D includes regulations regarding coverage determinations, formulary and tier exceptions, and exceptions to established drug utilization management programs. Plans (PBPs) that implement utilization management tools will be responsible for reporting several data elements related to these activities. Prior authorization 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 15	August 15	November 15	February 15

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 ~~these~~the total reported in A, the number of pharmacy transactions rejected due to formulary restrictions, including non-formulary status, prior authorization requirements, step therapy, and quantity limits (QL). Rejections due to early refills should be excluded.
C. The total number of prior authorizations requested in the time period above.
D. ~~The number of prior authorizations approved, of those requested in~~ Of the ~~time period.~~
~~E. The~~ total ~~number of non-prior authorization coverage determinations requested in~~reported in C, the ~~time period.~~number approved.
F. ~~The number of non-prior authorization coverage determinations approved, of those requested in the time period.~~
~~G.~~ The total number of exceptions requested ~~related~~ to the Plan's utilization management tools, e.g. prior authorization, quantity limits, or step therapy requirements, in the time period above.
H. ~~The~~Of the total reported in E, the number ~~of utilization management exceptions~~ approved~~, of those requested in the time period.~~.
I. The number of tier exceptions requested in the time period above.
J. ~~The~~Of the total reported in G, the number ~~of tier exceptions~~ approved~~, of those requested in the time period.~~ .
K. The number of exceptions requested for non-formulary medications in the time period above.
L. ~~The~~Of the total reported in I, the number ~~of exceptions~~ approved ~~for non-formulary medications, of those requested in the time period.~~ .

Section XIII. Appeals

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.

- Example of a full reversal: Non-formulary exception request approved upon redetermination for drug and quantity prescribed.
- Example of a partial reversal: 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 15	August 15	November 15	February 15

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

A. The total number of ~~requests for~~ redeterminations~~.~~
~~B. The number of requests for redeterminations dismissed by the Plan.~~
~~C.~~ ~~The number of redeterminations~~ made in the time period specified above~~.~~.
D. Of the total reported in A, the number resulting in full reversal of original coverage determination.
E. ~~The number of redeterminations in the time period specified above~~Of the total reported in A, the number resulting in partial reversal of original coverage determination.

Section XIV. Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions

Part D Sponsors will be responsible for reporting multiple data elements related to rebates. These data will be monitored as components of a Part D Sponsor's operational costs. CMS recognizes the importance of maintaining confidentiality of these records.

Rebates, discounts, and other price concessions will be reported at either the CMS Part D Sponsor or Contract level. Reporting will not be combined by the subcontractor PBM to include multiple Part D Sponsors' data. For example: (1) national Part D sponsors with multiple regional plans contracting independently or through a PBM will report rebates from the level of the national Part D sponsor; (2) regional or local Part D sponsor whether utilizing subcontractor PBM or not report at the Part D sponsor specific level; (3) PBM providing Part D coverage outside of a subcontractor role will report rebates at the PBM level. Rebate information should be summarized for each drug, rolled up to include multiple strengths, package sizes, dosage formulations, or combinations. ~~The quarterly reported totals are not cumulative YTD totals.~~

Reporting timeline:

	Period 1
Reporting Period	January 1 – December 31
Data due to CMS/HPMS	June 30

Data files to be uploaded through the HPMS at the CMS Part D Sponsor or Contract level as specified below.

A. Pharmaceutical Manufacturer Rebates: Part D Sponsors/Contracts will report the following data.
   1. Manufacturer Name;
   2. Drug Name;
   3. Rebates Received;
   4. Pending Rebates;
   5. Prior Rebates.

B. Discounts and Other Price Concessions: It is expected that the file specified above will summarize most rebate information. However, for all non-rebate discounts, price concessions, or other value adds such as gift-in-kind or other programs (e.g., coupons or disease management programs specific to a Part D Sponsor), Part D Sponsors will report the following data:
   1. Manufacturer/ Company Name;
   2. Description;
   3. Value;
   4. Justification.

Section XV. 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, ~~in~~for comparison to ~~non-LTC~~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:

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

Data ~~elements~~file to be ~~entered into~~uploaded through the HPMS at the Contract level as specified below:

~~A.~~ The total number of network LTC pharmacies ~~licensed to serve~~ 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 ~~non-LTC~~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 ~~plan~~Contract.

D. For each ~~contracted~~network LTC pharmacy ~~licensed to serve~~ in ~~their~~the service area:
   a. LTC pharmacy name;
   b. LTC pharmacy NPI;
   c. Contract entity name of LTC pharmacy;
   d. Chain code of LTC pharmacy;
   e. Number of 31-day equivalent formulary prescriptions dispensed;
   f. Number of 31-day equivalent non-formulary prescriptions dispensed;

g. Cost of ~~all~~ formulary prescriptions;
h. Cost of ~~all~~ non-formulary prescriptions.

E. In aggregate, for all ~~contracted non-LTC~~ retail pharmacies in ~~their~~the service area:
a. Number of 30-day equivalent formulary prescriptions dispensed;
b. Number of 30-day equivalent non-formulary prescriptions dispensed;
c. Cost of ~~all~~ formulary prescriptions;
d. Cost of ~~all~~ non-formulary prescriptions.

Section XVI. Licensure and Solvency, Business Transactions and Financial Requirements

Title I, Part 423, Subpart I includes regulations regarding Licensure and Solvency. Part D Sponsors ~~and~~ will be responsible for reporting multiple data elements and documentation related to their licensure and solvency and other financial requirements. Employer/Union Direct Contract PDPs (Direct Contract PDP) will be responsible for reporting multiple data elements and documentation related to their solvency and other financial requirements. Direct Contract PDPs are employers or unions that directly contract with CMS to offer a Part D plan exclusively to the employer's/union's retirees. ~~Some data will be entered into the HPMS and other information will be mailed directly to CMS.~~Documentation required in Subsection I & II will be uploaded into the Fiscal Soundness Module in HPMS. Data elements required under Subsection III will be entered into the Fiscal Soundness Module in HPMS. Thus, documentation will no longer be mailed to CMS, nor will data be entered into the Part D Reporting Module in HPMS. Documentation requirements are listed separately for Part D PDPs and Direct Contract PDPs. These data will be used to ensure Part D PDPs and Direct Contract PDPs continue to be fiscally solvent entities.

- Subsection I. Financial and Solvency Requirements Documentation - Part D PDPs
- Subsection II. Financial and Solvency Requirements Documentation – Direct Contract PDPs
- Subsection III. Financial and Solvency Requirements HPMS data– Part D PDPs and Direct Contract PDPs

Reporting timeline:

	Quarter 1 YTD	Quarter 2 YTD	Quarter 3 YTD	Annual
Reporting Period	January 1 - March 31	January 1 - June 30	January 1 - September 30	January 1 - December 31
Data due to CMS/HPMS	May 15	August 15	November 15	120 days after the end of the ~~calendar~~fiscal year or within 10 days of the receipt of the ~~Annual~~Independently Audited F/S, whichever is earlier.

I. ~~I.~~ Financial and Solvency Requirements Documentation for Part D PDP Contracts:

A. According to the quarterly time periods specified above, for quarters 1 – 3 only, Part D PDP Contracts that are licensed will ~~mail~~submit the following completed Health Blank form pages directly to CMS:

- Jurat;
- Assets;
- Liabilities, Capital and Surplus;
- Statement of Revenue and Expenses;
- Capital and Surplus Account; and
- Cash Flow~~.~~;

Note: CMS will accept a copy of the Health Blank form submitted to the state in its entirety.

B. According to the quarterly time periods specified above, non-licensed Part D PDP Contracts will ~~mail~~submit un-audited financial statements, which convey the same information contained in the Health Blank form, directly to CMS. An alternative for non-licensed Part D PDP Contracts would be to complete the Health Blank pages as prescribed in A. above.
C. According to the quarterly time periods specified above, non-licensed Part D PDP Contracts will ~~mail~~submit documentation showing that an insolvency deposit of $100,000 is being held in accordance with CMS requirements by a qualified financial institution.
D. According to the quarterly time periods specified above, Part D PDP Sponsors not licensed in any state must submit documentation that demonstrates they possess the allowable sources of funding to cover projected losses for the greater of 7.5% of the aggregated projected target amount for a given year or resources to cover 100% of any projected losses in a given year. This documentation should include a worksheet indicating how they arrived at the aggregated projected target amount. Pro-forma financial statements including the balance sheet, income statement and statement of cash flows projecting through the next 12 months by quarter. Enrollment projections through the next 12 months by quarter. Guarantees, letters of credit and other documents essential to demonstrating that the funding for projected losses requirement has been met must also be included.
E. All Part D PDP contracts will ~~mail~~submit a copy of their independently audited financial statements (which are statutory based or GAAP based) ~~with a management letter~~ within one hundred twenty days following their fiscal year end or within 10 days of receipt of those statements, whichever is earlier directly to CMS. Licensed entities may not report under GAAP for a period longer than 36 months.
F. All non-licensed Part D PDP Contracts will ~~mail~~submit a copy of an Actuarial Opinion by a qualified actuary within one hundred twenty days following their fiscal year end directly to CMS. The opinion should address the assumptions and methods used in determining loss revenues, actuarial liabilities, and related items.
G. According to the quarterly time periods specified above, Part D PDP sponsors with any state licensure waivers must submit an update on the status of obtaining licensure for each ~~waived~~waivered state.
H. Per § 423.514 each Part D sponsor must report to CMS annually, within 120 days of the end of the fiscal year, significant business transactions, between

the Part D sponsor and a party in interest. Definitions for significant business transactions and a party in interest can be found in § 423.501.
Documentation submitted should include the following:

1. A description of the transaction or transactions taking place with the party in interest.
2. Identification of the party in interest and an explanation of how that party meets the definition of a party in interest.
3. The costs incurred during the fiscal year relating to the transactions between the party in interest and the Part D sponsor and what those costs would have been if incurred at fair market value. If the costs incurred exceed fair market value, provide an explanation justifying that the costs are consistent with prudent management and fiscal soundness requirements.
4. Combined financial statements for the Part D plan sponsor and a party in interest if 35% or more of the costs of operation of the Part D sponsor go to a party in interest, or 35% or more of the revenue of a party in interest is from the Part D sponsor.

~~**Part D PDP Contracts' Documentation should be mailed to the following address:**~~
~~Centers for Medicare & Medicaid Services~~
~~Attn: Part D Licensure & Solvency~~
~~Mail Stop C1-25-04~~
~~7500 Security Boulevard~~
~~Windsor Mill, Maryland 21244~~

~~II.~~ If a Part D PDP sponsor did not have significant business transactions with a party in interest as prescribed in § 423.501 then the Part D PDP sponsor must submit an attestation signed by their President, CEO or CFO indicating that the contracting entity did not have significant business transactions with a party in interest as prescribed in § 423.501.

II. **Financial and Solvency Requirements Documentation for Direct Contract PDPs:**

A. According to the quarterly time periods specified above, Direct Contract PDPs will ~~mail~~submit un-audited financial statements directly to CMS.
B. According to the quarterly time periods specified above, Direct Contract PDPs will ~~mail~~submit documentation showing that an insolvency deposit of $100,000 is being held in accordance with CMS requirements by a qualified financial institution (unless CMS waived this requirement in writing with respect to the sponsor).
C. Direct Contract PDPs will ~~mail~~submit a copy of their independently audited financial statements ~~with a management letter~~ within one hundred twenty days following their fiscal year end or within 10 days of receipt of those statements, whichever is earlier directly to CMS.

D. All Direct Contract PDPs will ~~mail~~submit a copy of their credit rating (or, if they have no credit rating, a Dun & Bradstreet report) on a quarterly basis directly to CMS as follows:

For Quarter 1:	May 15th
For Quarter 2:	Aug. 15th
For Quarter 3:	Nov. 15th
For Quarter 4:	Feb. 15th

E. All Direct Contract PDPs will ~~mail~~submit an ERISA Sec. 411(a) attestation directly to CMS by February 15th.

~~**All Direct Contract PDP Documentation should be mailed to the following address:**~~
~~Centers for Medicare & Medicaid Services~~
~~Attn: Financial Solvency Reporting~~
~~Mail Stop C1-22-06~~
~~7500 Security Boulevard~~
~~Windsor Mill, Maryland 21244~~

~~**III.**~~

III. Financial and Solvency Requirements data elements to be entered into HPMS – For Part D PDP Contracts / Direct Contract PDPs:

The following data is to be entered into HPMS. For Part D PDP Contracts, the following is to be entered at the Part D Contract level per the NAIC #. Each Contract-NAIC# entity will be listed under each contract.

A. Total assets as of the end of the quarterly reporting period identified above. This should be a currency field.
B. Total liabilities as of the end of the quarterly reporting period identified above. This should be a currency field.
C. ~~Total cash~~Cash from operations as of the end of the quarterly reporting period identified above. This should be a currency field.
D. ~~Total cash equivalents~~ Cash and short term investments as of the end of the reporting period identified above. This should be a currency field.
E. ~~Total current~~Current assets as of the end of the quarterly reporting period identified above. This should be a currency field.
F. ~~Total current~~Current liabilities as of the end of the quarterly reporting period identified above. This should be a currency field.
G. Total revenue as of the end of the quarterly reporting period identified above. This should be a currency field.
H. Total expenses as of the end of the quarterly reporting period identified above. This should be a currency field.
I. ~~Total administrative~~Administrative expense as of the end of the quarterly reporting period identified above. This should be a currency field. **NOTE: Direct Contract PDPs are waived from this element**~~.~~

J. ~~Total net~~Net income as of the end of the quarterly reporting period identified above. This should be a currency field.
K. Drug benefit expenses (excluding administrative expenses) as of the end of the quarterly reporting time period. Drug benefit expenses are paid claims costs which would be comprised of negotiated costs and dispensing fees less member share. This should be a currency field.
L. Drug benefit revenues as of the end of the quarterly reporting period. Drug benefit revenues would include premiums, CMS subsidies, rebates and other reinsurance. This should be a currency field.

Section XVII. Drug benefit analyses

Part D Sponsors must provide enrollees with coverage of benefits as described within §423.104. For the purposes of CMS review, Plans (PBPs) will be required to report multiple data elements related to their provision of Part D benefits. HPMS will display each Plan's benefit design for integration with the data reported by Part D Sponsors. If a Plan does not have a coverage gap, the Plan should list the number of people who are pre-catastrophic in the data element D (non-LIS) and E (LIS) fields, and then indicate zero in the data element F (non-LIS) or G (LIS) fields. If a PBP does not have a deductible, HPMS will not display data fields B or C.

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 15	August 15	November 15	February 15

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

A. HPMS will display each Plan's benefit design (e.g. defined standard, enhanced alternative).
B. The total number of non-LIS enrollees in the deductible phase as of the last day of the quarter.
C. The total number of LIS enrollees in the deductible phase as of the last day of the quarter. [List all LIS beneficiaries for all subsidy levels.]
D. The total number of non-LIS enrollees in the pre-initial coverage limit phase as of the last day of the quarter. (If a Plan does not have a coverage gap, the Plan should list the number of people who are pre-catastrophic in this field, and then indicate zero in the data element F.)
E. The total number of LIS enrollees in the pre-initial coverage limit phase as of the last day of the quarter. (If a Plan does not have a coverage gap, the Plan should list the number of people who are pre-catastrophic in this field, and then indicate zero in the data element G.) [List all LIS beneficiaries for all subsidy levels.]
F. The total number of non-LIS enrollees in the coverage gap as of the last day of the quarter. (If a Plan does not have a coverage gap, the Plan should list the number of people who are pre-catastrophic in data element D, and then indicate zero in this field.)
G. The total number of LIS enrollees in the coverage gap as of the last day of the quarter. (If a Plan does not have a coverage gap, the Plan should list the number of people who are pre-catastrophic in data element E, and then indicate zero in this field.) [List all LIS beneficiaries for all subsidy levels.]
H. The total number of non-LIS enrollees in the catastrophic coverage level as of the last day of the quarter.
I. The total number of LIS enrollees in the catastrophic coverage level as of the last day of the quarter. [List all LIS beneficiaries for all subsidy levels.]

Section XVIII. 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 Title 1, Part 423, Subpart K, §423.504~~.~~, including procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to the appropriate government authority. 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 ~~will be responsible for reporting several~~may voluntarily report aggregate data ~~elements~~ related to their anti-fraud, waste and abuse activities ~~that~~. Aggregate reporting will allow CMS to monitor ~~compliance with requirements that Sponsors have a program to control~~Sponsors' fraud, waste and abuse programs. These data will measure the types of incidents, the sources by which incidents are identified to ~~sponsors~~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:

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

Data elements to be entered into the HPMS at the Contract level (note: Period 2 encompasses one full year):

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, broker/agent complaints, and incidents that gave rise to grievances).
F. The total number of potential fraud and abuse incidents identified.
G. Of the total ~~number of potential fraud and abuse incidents~~reported in F, the number identified through internal efforts.
H. Of the total ~~number of potential fraud and abuse incidents~~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 XIX. Employer/Union-Sponsored Group Health Plan Sponsors

NOTE: This reporting requirement applies only to individual PDPs and "800 series" PDPs offered to ~~employer groups are required to report these data.~~ 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:

	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 Plan (PBP) level ~~as specified below.~~:

A. ~~Contract number~~
~~B. Plan ID~~
~~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 XX. Agent Training and Testing

NOTE: This reporting requirement applies only to PDPs. 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.

Per 422.2274 (c) and 423.2274 9 (c), agents selling Medicare products are required to pass written or electronic tests on Medicare rules, regulations, and information on the plan products they intend to sell. Agents must be trained in order to accurately represent plan benefits and the prescription drug benefit programs to prospective enrollees. Testing is an accepted indicator of training success. Reporting should include both salaried and contracted agents, but should exclude sales support staff.

Reporting timeline:

	Period 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:

A. Total number of agents in contract year.
B. Number of agents in contract year that completed training successfully.
C. Number of agents in contract year with a passing score of 85% or above on first testing.
D. Average score of agents in contract year with a passing score of 85% or above on first testing.
E. Number of agents that took a second test.
F. Number of agents in contract year with a passing score of 85% or above on second testing.
G. The average score of agents in contract year with a passing score of 85% or above on second testing.
H. Number of agents in contract year that took the test 3 or more times.

Section XXI. Plan Oversight of Agents

NOTE: This section applies only to Sponsors of stand-alone prescription drug plans, that 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:

	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:

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.