MEDICARE PART D
REPORTING REQUIREMENTS
Contract Year 2008

Updated: ~~05/22/20~~09/17/07

Table of Contents

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 ~~Contract~~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
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 –~~a parent~~an organization which ~~encompasses a group of Part D Contracts.~~
- ~~Part D Contract – an organization contracted~~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#)
- ~~Part D~~ Plan – a plan benefit package (PBP) offered within a Part D contract (e.g. Plan ID #)

This document ~~represents current expectations of data~~lists reporting timeframes and required levels of reporting. Data elements ~~to~~may be reported ~~by Part D Contracts~~ at the ~~Part D Sponsor (parent organization), Contract, or~~ Plan (PBP) level, ~~reporting timeframes, and monitoring of Part D contracts~~the individual contract-level, or Sponsor-level. These requirements will be in effect for Contract Year 2008 and are subject to change at the discretion of CMS. According to Subpart O, sanctions may be imposed on Part D ~~Contracts~~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 ~~Contracts~~Sponsors
2) Legislative and regulatory authority
3) Validity, reliability, and utility of data elements requested
4) Wide acceptance and current utilization within the Industry

Reporting requirements are described in this document for the following areas: Retail, Home Infusion, and Long-Term Care Pharmacy Access, Access to Extended Day Supplies at Retail Pharmacies, Vaccines, Reversals, Medication Therapy Management Programs, Generic Drug Utilization, Home Infusion Utilization, Grievances, Pharmacy & Therapeutics (P&T) Committees/Part D Activities, Transition, Exceptions, Appeals, Overpayment, Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions, Long-Term Care (LTC) Rebates, Licensure and Solvency, Business Transactions and Financial Requirements, and Drug Benefit Analyses.

Each Part D ~~Contract~~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 ~~Contracts~~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).

Part D ~~Contract~~ Reporting Requirements

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 Part D drugs, including compounded drugs.

For PACE Organizations offering Part D coverage, reporting requirements will be limited to: Vaccines; Generic Drug Utilization; Home Infusion Utilization; Pharmacy & Therapeutics (P&T) Committees (for PACE Organizations utilizing formularies); Transition (for PACE Organizations utilizing formularies); Exceptions (for PACE Organizations utilizing formularies); Overpayment; Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions; and Long-term Care (LTC) Rebates.

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.

Data format

Each reporting section provides details regarding data format and calculations pertaining to specific elements. All data should be reported in whole numbers, rounding to the nearest whole number (ex. 1.78 should be rounded to 2), with the ~~exception of the~~following exceptions:

- MTM section: The number of covered Part D 30-day equivalent prescriptions ~~in the Medication Therapy Management Programs section and the Rebate $ per unit received in the~~ should be entered to two decimal places
- Long-Term Care (LTC) Rebates section~~. For the MTM data element, HPMS will require data to be entered to two decimal places and for the LTC rebate element, HPMS will require data to~~: Rebate $ per unit received should be entered to four decimal places**.**

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

As outlined in §423.120, Part D ~~Contracts~~Sponsors are required to maintain a pharmacy network sufficient for ensuring access to Medicare beneficiaries residing in their service areas. Part D ~~Contracts~~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 ~~Contracts~~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 ~~Contracts~~Sponsors will be required to submit certain data elements on ~~a biannual (twice per year)~~an annual basis that will allow CMS ~~to~~ to evaluate Part D ~~Contracts'~~Sponsors' continued compliance with ~~our~~ pharmacy access requirements. For purposes of evaluating compliance with the retail pharmacy access standards, Part D Sponsors should use the CMS ~~will provide a~~ reference file ~~on a biannual (twice per year) basis~~ that provides counts of Medicare beneficiaries by State, region, and zip code. This reference file is provided by CMS with Part D applications. For purposes of evaluating compliance with the LTC and home infusion pharmacy access standards, CMS will use data elements submitted by Part D ~~contracts~~Sponsors, as well as information from CMS reference files containing counts of nursing home beds and Medicare beneficiaries by State, region, and zip code. Part D Sponsors having received waivers for any willing pharmacy requirement and/or the retail convenient access requirement after the initial pharmacy access submission will submit certain data elements (C and D) on an annual basis for purposes of determining if those plans still meet CMS standards. CMS reserves the right to request appropriate documentation to support a Part D ~~Contract's~~Sponsor's submitted pharmacy access data elements (e.g., geo-access reports). CMS evaluation of compliance with pharmacy access standards will be conducted based on point-in-time information about pharmacy networks submitted by Part D ~~contracts twice~~Sponsors once per year.

Reporting timeline for Sections A and B only:

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

	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 Plan (PBP) level:

1. Percentage of Medicare beneficiaries living within 2 miles of a retail network pharmacy in urban areas of a Plan's service area (State for PDPs and regional PPOs, and service area for local MA-PD plans).
2. Percentage of Medicare beneficiaries living within 5 miles of a retail network pharmacy in suburban areas (State for PDPs and regional PPOs, and service area for local MA-PD plans).
3. Percentage of Medicare beneficiaries living within 15 miles of a retail network pharmacy in rural areas (State for PDPs and regional PPOs, and service area for local MA-PD plans).

4. The number of contracted retail pharmacies in a Plan's service area (State for PDPs and regional PPOs, and service area for local MA-PD plans) as of the last day of the reporting period specified above.

B. Data ~~elements~~files to be uploaded ~~into~~ through the HPMS at the CMS Part D Contract level~~:~~. Part D ~~Contracts~~Sponsors will provide ~~an excel file~~a tab delimited text (filename=Pharmacies_(CONTRACTNAME)_(2008P~~#).xls,~~1).txt replacing '(CONTRACTNAME)' with the Part D Contract's name ~~and '(2008P#)' with the year and period number)~~ containing the following fields~~:~~:

~~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.

~~Part D Contracts will use the templates below for upload of their HI and LTC pharmacy networks.~~

~~NCPDP Number~~	~~Pharmacy Name~~	~~Pharmacy Address~~				-	-	~~Contract Arrangement~~		
		~~Street~~	~~City~~	~~State~~	~~Zip~~	~~States Licensed~~	~~Pharmacy Network Type (P=Preferred; N=Nonpreferred)~~	~~Chain (Y = Yes or N = No)~~	~~Independent (Y = Yes or N=No)~~	~~Group Purchasing (Y = Yes or N= No~~
-	-	-	-	-	-	-	-	-	-	-

Part D Sponsors will use the templates provided in HPMS for upload of their HI and LTC pharmacy networks.

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 Part D Sponsors 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.
2. Number of prescriptions provided at all pharmacies contracted

D. Data elements to be entered into the HPMS at the Plan (PBP) level for only those Part D Sponsors that own and operate their own retail pharmacies and have received a waiver of the retail pharmacy convenient access standards.

1. Number of prescriptions provided by retail pharmacies owned and operated.
2. Number of prescriptions provided at all retail pharmacies contracted.

Section II. 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 Plans 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 Plans 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 Plans must submit data biannually (twice per year) that will allow CMS to evaluate 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.]~~

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 Plan (PBP) level:

A. The number of contracted retail pharmacies that are contracted to dispense an extended day supply of covered Part D drugs.

Section III. Vaccines

For monitoring purposes, Part D ~~Contracts~~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.

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. The total number of Part D vaccines processed during the time period specified above~~.~~, regardless of the method used to process the claim as described in B through F below.
B. The number of Part D vaccines ~~processed through out-of-network access~~ administered in a clinic setting (e.g. physician's office) where the beneficiary retrospectively files paper receipts for reimbursement of the vaccine during the time period specified above.
C. The number of vaccines adjudicated through ~~in~~ network pharmacies during the time specified above. (Including those vaccines processed by the pharmacy and submitted electronically).
D. The number of ~~vaccine~~ 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. The number of vaccines processed through an internet based web tool.
F. The number of vaccines processed during the time period specified above through a process not described in data elements B through ~~F~~E.

Section IV. Reversals

Part D ~~Contracts~~Sponsors will be responsible for reporting data elements related to claim reversals. Information on claim reversals will serve as a component in the monitoring of Part D operational functions

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 either the Contract or Plan (PBP) level:

A. The number of out-of-cycle pharmacy transactions with reversal as the final disposition, which were adjudicated during the time period specified above. [The term "out-of-cycle" refers to the individual billing/processing cycle of each organization. Each organization determines its own payment cycle. An out-of-cycle reversal occurs if a prescription is filled and adjudicated, and then, outside the Part D ~~Contract's~~Sponsor's billing cycle, the pharmacy reverses the claim. Part D ~~Contracts~~Sponsors must report to CMS the total number of (electronic, paper and manual) pharmacy claims ending with a reversed status. Those with a partial reversal as the final disposition should also be included.]

Note: Reversed claim records must be maintained (the number of elements retained per record should at a minimum be equivalent to those of the prescription drug event record), and upon request, submitted to CMS.

Section V. Medication Therapy Management Programs

The requirements stipulating that Part D ~~Contracts~~Sponsors provide Medication Therapy Management Programs (MTMP) are described in Title I, Part 423, Subpart D, § 423.153. For monitoring purposes, Part D ~~Contracts~~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

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

~~A.~~ The method used to enroll beneficiaries into the MTMP. Method of enrollment may be opt-in, opt-out, a combination of opt-in and opt-out, or other. This will be selection from a drop-down box. If "other" is selected, a description will be required as a text field.

B. The number of beneficiaries who met the eligibility criteria for the MTMP in the specified time period above.

C. The total number of beneficiaries who participated in the MTMP at any point during the time period specified above. This should be a longitudinally cumulative total, and be a subset of the number of beneficiaries who met the criteria for the MTMP in the specified time period.

D. The total number of beneficiaries who discontinued participation from the MTMP at any time during the specified time period above. This should be a subset of the total number of beneficiaries who participated in the MTMP in the specified time period.

E. The number of beneficiaries who discontinued participation from 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 discontinued participation from the MTMP in the specified time period.

F. The number of beneficiaries who discontinued participation from 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 discontinued participation from the MTMP in the specified time period.

G. The number of beneficiaries who discontinued participation from 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 discontinued participation from the MTMP in the specified time period.

H. The number of beneficiaries who discontinued participation from the MTMP for a reason not specified in data elements E-G during the specified time period above. This should be a subset of the total number of beneficiaries who discontinued participation from the MTMP in the specified time period.

I. The number of beneficiaries who declined to participate in the MTMP during the specified time period above. This should be a subset of the number of beneficiaries who met the criteria for the MTMP in the specified time period.

J. The number of beneficiaries whose participation status in the MTMP is pending during the specified time period above. This should be a subset of the number of beneficiaries who met the criteria for the MTMP in the specified time period and should only apply to period 1.

K. For beneficiaries participating in the MTMP as of the last day of the reporting period specified, 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 participating in the MTMP as of the last day of the reporting period. This includes both MTMP beneficiary cost sharing and Part D costs paid. The denominator represents the total number of member months for the MTMP participating beneficiaries. These member months should include all months the beneficiary was enrolled in the ~~Part D Contract~~plan during the reporting period specified, not only the months that the beneficiary enrolled in the MTMP.

The following equation also describes this calculation

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

{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}

L. For beneficiaries participating in the MTMP as of the last day of the reporting period specified, 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 participating 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 participating beneficiaries. These member months should include all months enrolled the beneficiary was enrolled in the ~~Part D Contract~~plan during the reporting period specified, not only the months that the beneficiary enrolled in the MTMP.

The following equation also describes this calculation:

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

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

II. Data file to be uploaded ~~through the HPMS~~**using Gentran or Connect Direct at the Contract level** ~~as specified above.~~ **.**

More information regarding the upload process will be forthcoming.

	~~**Period 2**~~**YTD**
Reporting Period	January 1 - December 31
Data due to CMS/HPMS	February 28

A. ~~Part D Contracts will provide a file (filename=MTMP_(CONTRACTNAME)_(2008P#), replacing '(CONTRACTNAME)' with the Part D Contract's name and '(2008P#)' with the year and period number) containing the following fields. These data are for beneficiaries identified as being eligible for the Medication Therapy Management Program~~

1. ~~HICN: The Health Insurance Claim Number (HICN) or unique identifier of each beneficiary identified to be eligible for MTMP in the reporting period. This should be a numeric field.~~
2. ~~Beneficiary first name: The first name of each beneficiary identified to be eligible for MTMP in the reporting period. This should be a text field.~~
3. ~~Beneficiary middle name: The middle name of each beneficiary identified to be eligible for MTMP in the reporting period. This should be a text field.~~
4. ~~Beneficiary last name: The last name of each beneficiary identified to be eligible for MTMP in the reporting period. This should be a text field.~~
5. ~~Beneficiary date of birth: The date of birth of each beneficiary identified to be eligible for MTMP in the reporting period. This should be a date field (mm/dd/yyyy).~~
6. ~~Date of MTMP enrollment: For each beneficiary identified to be eligible for the MTMP in the reporting period, who enrolled in MTMP, the date MTMP enrollment began. This should be a date field (mm/dd/yyyy).~~

~~7. Date MTMP participation was declined: This should be a date field (mm/dd/yyyy).~~
~~8. Date Discontinued participant: For each beneficiary with who enrolled in MTMP and then of discontinued participation, the date their participation ended. This should be a date field (mm/dd/yyyy).~~
~~9. MTMP Discontinued participant: For each beneficiary with a MTMP disposition status of discontinued participation, the reason for discontinuation. Reasons for discontinuation may be one of the following: Death; Disenrollment from Plan; Request by beneficiary; or Other. This should be a text field.~~

The file will contain the following fields for beneficiaries identified as being eligible for the Medication Therapy Management Program:

Beneficiaries Eligible for MTMP Record Layout			
Field Name	**Field Type**	**Field Length**	**Field Description**
HICN	CHAR REQUIRED	10	The Health Insurance Claim Number (HICN) or unique identifier of each beneficiary identified to be eligible for MTMP in the reporting period.
Beneficiary first name	CHAR REQUIRED	30	The first name of each beneficiary identified to be eligible for MTMP in the reporting period.
Beneficiary middle initial	CHAR REQUIRED	1	The middle initial of each beneficiary identified to be eligible for MTMP in the reporting period.
Beneficiary last name	CHAR REQUIRED	30	The last name of each beneficiary identified to be eligible for MTMP in the reporting period.
Beneficiary date of birth	DATE REQUIRED	10	The date of birth of each beneficiary identified to be eligible for MTMP in the reporting period. This should be a date field (mm/dd/yyyy).
LTC Enrollment	CHAR REQUIRED	1	For each beneficiary enrolled in MTMP, indicate if the beneficiary was a long-term care (LTC) resident for the entire time they were enrolled in MTMP. This should be either Y (yes) or N (no).
Date of MTMP enrollment	DATE REQUIRED	10	For each beneficiary identified to be eligible for the MTMP in the reporting period, who enrolled in MTMP, the date MTMP enrollment began. This should be a date field (mm/dd/yyyy).
Date MTMP participation was declined	DATE REQUIRED	10	This should be a date field (mm/dd/yyyy).
Date participant discontinued MTMP	DATE REQUIRED	10	For each beneficiary who enrolled in MTMP and then discontinued participation, the date their participation ended. This should be a date field (mm/dd/yyyy).
Reason participant discontinued MTMP	TEXT REQUIRED	23	For each beneficiary with a MTMP disposition status of discontinued participation, the reason for discontinuation. Reasons for discontinuation may be one of the following: Death; Disenrollment from Plan; Request by beneficiary; or Other. This should be a text field.

Section VI. Generic Drug Utilization

Cost control requirements for Part D ~~Contracts~~Sponsors are presented in Title I, Part 423, Subpart D. Accordingly, Part D ~~Contracts~~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).

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 paid claims for Part D generic drugs (regardless of days supply) with dates of service during the specified reporting period identified above. First DataBank or Medispan generic drug classifications will be used to identify generic drugs.
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 VII. Home Infusion Utilization

On a quarterly basis, Part D ~~Contracts~~Sponsors will be required to report data related to home infusion drug utilization. Home infusion drugs are products administered by IV in settings for which these products are not covered by Part B. These data will be monitored by CMS for purposes of assessing enrollee utilization of and access to home infusion therapy. Appendix A of Chapter 6 of the Prescription Drug Benefit Manual contains a list of common Part D-covered home infusion drugs. However, Appendix A does not represent an exhaustive list of Part D-covered home infusion drugs and should be used simply as a reference for Part D ~~Contracts~~Sponsors to develop their lists of home infusion drugs.

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. ~~The number of beneficiaries receiving Part D-covered home infusion drugs dispensed by any of its network pharmacies in the time period specified above.~~

B. ~~The total number of days supply of Part D-covered home infusion drugs dispensed by any of its network pharmacies in the time period specified above.~~

C. ~~The~~ The number of Part D beneficiaries receiving Part D-covered home infusion drugs dispensed by any of its network providers as part of a bundled service under a Part C supplemental benefit in the time period specified above (if applicable).

D. The total ~~number of days supply of~~claims associated with Part D-covered home infusion drugs dispensed by any of its network providers as part of a bundled service under a Part C supplemental benefit in the time period specified above (if applicable).

Section VIII. Grievances

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

A grievance is defined as 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. Examples of subjects of a grievance provided in the solicitation for applications include, but are not limited to, timeliness, appropriateness, access to, and/or setting of services provided by the PDP, concerns about waiting times, demeanor of pharmacy or customer service staff, a dispute concerning the timeliness of filling a prescription, the accuracy of filling the prescription or enrollment/disenrollment issues or recognition of low income subsidy (LIS) eligibility problems.

Part D ~~Contracts~~Sponsors are required by the regulations to track and maintain records on all grievances received orally and in writing. Grievance data, requested herein by CMS, should be reported based on the date the grievance was received by the Plan (PBP), not the date the event or incident that precipitated the grievance occurred. Multiple grievances by a single complainant should be tracked and followed as separate grievances. Plans may report grievances in the categories as determined by the Plans after initial investigation. 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 elements to be entered into the HPMS at the Plan (PBP) level:

A. For the time period identified above, the number of fraud and abuse grievances received related to Part D. A fraud grievance is 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 grievance 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.
B. For the time period identified above, the number of enrollment/disenrollment grievances received related to Part D. Examples include, but are not limited to, discrimination in the enrollment process, enrollment information and/or identification cards not being received by beneficiaries in a timely manner, and disenrollment requests not being processed in a timely manner.
C. For the time period identified above, the number of benefit package grievances received related to Part D. Examples include, but are not limited to, beneficiary cost sharing, pricing co-insurance issues and issues related to coverage during the coverage gap period.
D. For the time period identified above, the number of pharmacy access/network grievances received related to Part D. Examples include, but are not limited to, network pharmacy refusing to accept a beneficiary's card and network/non-network pharmacy concerns.
E. For the time period identified above, the number of marketing grievances received related to Part D. Examples include, but are not limited to, marketing materials or promotional messages by sales representatives that include misrepresentations or false/misleading information about plans and benefits, overly aggressive marketing practices, and discriminatory practices identified in marketing materials or through oral/written promotional messages.

F. For the time period identified above, the number of customer service grievances received related to Part D. Examples include, but are not limited to, grievances regarding services provided by the pharmacist/pharmacy staff, plan or subcontractor representatives, or customer service representatives.
G. For the time period identified above, the number of confidentiality/privacy grievances received related to Part D. Examples include, but are not limited to, potential violations of medical information privacy standards by the plan or pharmacy.
H. For the time period identified above, the number of quality of care grievances received related to Part D. Examples include, but are not limited to, grievances received from beneficiaries or Quality Improvement Organizations (QIOs) regarding quality of care.
I. For the time period identified above, the number of exception grievances received related to Part D. An example of an exception grievance is one which is filed because an enrollee's request to have their coverage determination expedited was denied.
J. For the time period identified above, the number of appeal grievances received related to Part D. An example of an appeal grievance is one which is filed because an enrollee's request to have a redetermination expedited was denied.
K. For the time period identified above, the number of other grievances received related to Part D not falling into one of the categories described above.
L. For the time period identified above, the total number of grievances received related to Part D.
M. For the time period identified above, the total number of LIS grievances received related to Part D. This number should be based on the beneficiary's LIS status at the time of filing the grievance.

Section IX. 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 ~~Contracts~~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 ~~Contracts~~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 31	August 31	November 30	February 28

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 ~~Contracts~~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 X. 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

*Only one quarter of data will be collected annually

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 XI. Exceptions

Title I, Part 423, Subpart D includes regulations regarding formulary and tier exceptions, and exceptions to established drug utilization management programs. Plans (PBPs) that utilize prior authorization or step therapy edits as utilization management tools (including for non-formulary exceptions) will be responsible for reporting several data elements related to these activities. Prior authorization requests/approvals that relate to Part B vs. 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 number of pharmacy transactions rejected due to failure to complete step therapy edit requirements in the time period specified above.
B. The number of pharmacy transactions rejected due to need for prior authorization (not including first pass step therapy edits or early refills) in the time period specified above.
C. The number of pharmacy transactions rejected due to quantity limits in the time period specified above.
D. The number of prior authorizations requested for formulary medications in the time period specified above (not including first pass step therapy edits, early refills, or quantity limits).
E. The number of prior authorizations approved for formulary medications, of those submitted in the time period specified above (not including first pass step therapy edits, early refills, or quantity limits).
F. The number of exceptions requested for non-formulary medications in the time period specified above (not including early refills).
G. The number of exceptions approved for non-formulary medications, of those submitted in the time period specified above (not including early refills).
H. The number of tier exceptions requested in the time period specified above (not including first pass step therapy edits or early refills).
I. The number of tier exceptions approved, of those submitted in the time period specified above (not including first pass step therapy edits or early refills).
J. The number of quantity limit exceptions requested in the time period specified above (not including early refills).
K. The number of quantity limit exceptions approved, of those submitted in the time period specified above (not including early refills).

Section XII. Appeals

Title I, Part 423, Subpart M includes regulations regarding coverage determinations and 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 and reconsiderations by the independent review entity (IRE). Redeterminations or reconsiderations may result in reversal or partial reversal of the original decision.

- Example of a full reversal of an original decision: Non-formulary exception request approved upon redetermination for drug and quantity prescribed.
- Example of a partial reversal of an original decision: Non-formulary exception request approved upon redetermination for drug, but full quantity prescribed is not approved.

CMS will request appeal 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. The number of appeals submitted for **standard** redetermination in the time period specified above. (Do not include those appeals that were submitted as expedited redeterminations and were not granted expedited status.)
B. The number of appeals submitted for **expedited** redetermination in the time period specified above.
C. The number of appeals submitted for **expedited** redetermination that were granted **expedited** status in the time period specified above.
D. The number of appeals submitted for **standard** redetermination withdrawn by the enrollee in the time period specified above.
E. The number of appeals submitted for **expedited** redetermination withdrawn by the enrollee in the time period specified above.
F. The number of redeterminations in the time period specified above resulting in full reversal of original decision.
G. The number of redeterminations in the time period specified above resulting in partial reversal of original decision.
H. The number of adverse redeterminations in the time period specified above due to insufficient evidence of medical necessity from enrollee's prescribing physician. Examples of insufficient evidence of medical necessity may include, but are not limited to, when the plan does not receive the information, or the information received does not support medical necessity.
I. The number of appeals submitted for IRE reconsideration in the time period specified above due to inability to meet timeframe for **coverage determination**.
J. The number of appeals submitted for IRE reconsideration in the time period specified above due to inability to meet timeframe for **redetermination**.
K. The number of IRE decisions for **standard** reconsideration in the time period specified above resulting in full reversal of original coverage determination or redetermination.
L. The number of IRE decisions for **standard** reconsideration in the time period specified above resulting in partial reversal of original coverage determination or redetermination.
M. The number of IRE decisions for **expedited** reconsideration in the time period specified above resulting in full reversal of original coverage determination or redetermination.
N. The number of IRE decisions for **expedited** reconsideration in the time period specified above resulting in partial reversal of original coverage determination or redetermination.

O. The number of IRE decisions for **standard** reconsideration in the time period specified above resulting in upholding of original coverage determination or redetermination.
P. The number of IRE decisions for **expedited** reconsideration in the time period specified above resulting in upholding of original coverage determination or redetermination.

Section XIII. Overpayment

Part D ~~Contracts~~Sponsors will be responsible for reporting data related to overpayments associated with Part D benefits. An overpayment occurs when a Part D ~~Contract~~Sponsor erroneously makes a payment in excess of the amount due and payable under the Part D drug benefit. Examples would include overpayments a plan makes to pharmacies, sub-contractors, or PBMs for claims payment. This information is necessary to ensure that overpayments are being identified and recouped appropriately.

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. For the time period identified above, the total overpayment dollars identified to be recouped by the Contract (i.e., any funds recovered from any entity it has overpaid, including, pharmacies, providers, Pharmaceutical Benefit Managers, etc.)
B. For the time period identified above, the total overpayment dollars recouped by the Contract.

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

Part D ~~Contracts~~Sponsors will be responsible for reporting multiple data elements related to rebates. These data will be monitored as components of a Part D ~~Contract's~~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:

	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	September 30	December 31	March 31	June 30

Data files to be uploaded through the HPMS at the CMS Part D Sponsor or Contract level as specified ~~above.~~below. HPMS will provide an option to report "No Data to Report" for Part D Sponsors or Contracts that have no rebate or discount/price concessions data; those ~~contracts~~Sponsors will not upload data files.

A. Part D Sponsors/Contracts will provide ~~an Excel~~a tab delimited text file (filename=REBATES_(SPONSORNAME)_(2008Q#).~~XLS~~txt, replacing '(SPONSORNAME)' following the below file layout.

Pharmaceutical Manufacturer Rebate File Record Layout			
Field Name	**Field Type**	**Field Length**	**Field Description**
Manufacturer Name	CHAR REQUIRED	100	For each rebate, provide the contracting manufacturer name. This should be a character field.
Drug Name	CHAR REQUIRED	100	For each rebate, provide the drug name. This should be a character field.
Rebates Received	NUM REQUIRED	12	For each unique manufacturer/drug combination, provide the rebate amount received in the reporting period specified. - Limit to 999999999999, no decimals, can be a negative number. - Zero should be entered in the fields if no rebate was received in the reporting period specified.
Pending Rebates	NUM REQUIRED	12	For each unique manufacturer/brand name combination, provide the rebate amount requested for the reporting period specified but not yet received (if applicable). - Limit to 999999999999, no decimals, can be a negative number - Zero should be entered in the fields if no rebate was requested but not received for the reporting period specified.
Prior Rebates	NUM	12	For each unique manufacturer/brand name

Pharmaceutical Manufacturer Rebate File Record Layout			
Field Name	**Field Type**	**Field Length**	**Field Description**
	REQUIRED		combination, provide the rebate amount received that is associated with a prior reporting period (if applicable). - Limit to 999999999999, no decimals, can be a negative number - Zero should be entered in the fields if no rebate was received that is associated with a prior reporting period.

B. 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 provide an additional ~~Excel~~tab delimited text file (filename=DISCOUNTS_(SPONSORNAME)_(2008Q#).~~XLS~~txt, replacing '(SPONSORNAME)' with the Part D Sponsor's name and '(2008Q#)' with the year and quarter number) following the below file layout.

Discounts and Other Price Concessions File Record Layout			
Field Name	**Field Type**	**Field Length**	**Field Description**
Manufacturer/ Company Name	CHAR REQUIRED	100	List the name of each manufacturer for whom there is an associated discount, price concession, or other value add.
Description	CHAR REQUIRED	250	Describe the discount, price concession, or other value adds.
Value	NUM REQUIRED	12	Provide the value of the discount, price concession, or other value adds. 1•0 is not an allowable value
Justification	CHAR OPTIONAL	4000	For each discount, price concession, or value add, provide a justification for receipt.

Section XV. *Long-Term Care (LTC) Rebates*

As described in the CMS 2008 Call Letters, Part D ~~Contracts~~Sponsors must require disclosure of access/performance rebates or other price concessions received by their long-term care (LTC) network pharmacies designed to or likely to influence or impact utilization of Part D drugs. The term "access/performance rebates" refers to rebates manufacturers provide to pharmacies that are designed to prefer, protect, or maintain that manufacturer's product selection by the pharmacy or to increase the volume of that manufacturer's products that are dispensed by the pharmacy under its formulary (referred to as "moving market share"). As evidence that they are managing and monitoring drug utilization, Part D ~~Contracts~~Sponsors must report these data to CMS for oversight. CMS recognizes the importance of maintaining confidentiality of these records.

Access/performance rebates received and reported by pharmacies will be reported at either the CMS Part D Sponsor or Contract level. Data should include rebates received for all Part D drugs, not limited to formulary/covered drugs. Rebate information should be reported for each applicable NDC. The quarterly reported totals are not cumulative YTD totals.

Special reporting cases:

- LTC pharmacy is not required to report rebates: Sponsors may exercise discretion for requiring rebate reporting from LTC pharmacies that serve less than 5% of LTC beds in an area ("area" is defined as the state in which the LTC pharmacy is licensed.). Sponsors should list the LTC pharmacy NCPDP number in the report, leave the Manufacturer, Drug name and Rebate unit fields blank, and in the Technical Notes field, enter "Not required to report".
- LTC pharmacy is noncompliant in reporting rebates: Sponsor should list that LTC pharmacy NCPDP in the report, leave the Manufacturer, Drug name and Rebate unit fields blank, and in the Technical Notes field, enter "Noncompliant".

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	September 30	December 31	March 31	June 30

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

Part D Sponsors/Contracts will provide ~~an option to select "No Data to Report" for Part D Sponsors or Contracts that have no long-term care rebates; those contracts will not upload data files. Part D Sponsors/Contracts will provide an Excel~~ a tab delimited text file (filename=REBATES_LTC PHARMACIES_(CONTRACTNAME)_(2008Q#).~~XLS~~txt, replacing '(CONTRACTNAME)' with the Part D Sponsor's name and '(2008Q#)' with the year and quarter number) containing the following fields.

1. ~~LTC Pharmacy Name: Provide the name of the LTC pharmacy for which the listed rebates apply. This should be a text field.~~
2. ~~LTC Pharmacy NCPDP Number: Indicate the contracted LTC pharmacy NCPDP number for which the listed rebates apply. This should be a numeric field.~~
3. ~~NPI Number: Indicate the contracted LTC pharmacy NPI (National Provider Identifier) number for which the listed rebates apply. This should be a numeric field.~~
4. ~~NDC: Provide the 11-digit NDC associated with this rebate. This should be a numeric field.~~
5. ~~Manufacturer name: Provide the contracting manufacturer name. This should be a text field.~~
6. ~~Drug name: Provide the brand name. This should be a text field.~~
7. ~~Rebate $ per unit received: Provide the contractual per unit rebates received during the reporting period (cash basis) associated with the listed rebate. This should be a numeric field.~~

8. Technical notes: Provide any technical notes regarding the LTC pharmacy rebate calculations. This should be a text field.

LTC Pharmacy Name	LTC Pharmacy NCPDP Number	NPI Number	NDC	Manufacturer name	Drug name	Rebate $ per unit received	Technical notes
Text	Numeric	Numeric	Numeric	Text	Text	Numeric	Text

LTC Rebates File Record Layout

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
LTC Pharmacy Name	CHAR REQUIRED	100	For each rebate, provide the name of the LTC pharmacy. This should be a character field.	
NCPDP Number	NUM REQUIRED	7	Indicate the contracted LTC pharmacy NCPDP number. This should be a numeric field exactly 7 digits long.	
NPI Number	NUM OPTIONAL	10	Indicate the contracted LTC pharmacy NPI (National Provider Identifier) number. This should be a numeric field.	
NDC	NUM REQUIRED	11	Provide the 11-digit NDC associated with this rebate. This should be a numeric field.	
Manufacturer Name	CHAR REQUIRED	100	For each rebate, provide the contracting manufacturer name. This should be a character field.	
Drug Name	CHAR REQUIRED	100	For each rebate, provide the brand name.	
Rebate $ per unit received	NUM REQUIRED	17	Provide the contractual per unit rebates received during the reporting period (cash basis) associated with the listed drug. • Limit to 999999999999.9999, can also be a negative number	999999999999.9999
Technical Notes	CHAR OPTIONAL	4000	Provide any technical notes regarding the LTC pharmacy rebate calculations.	

Field Name	Field Type	Field Length	Field Description
LTC Pharmacy Name	CHAR REQUIRED	100	For each rebate, provide the name of the LTC pharmacy.

NCPDP Number	CHAR REQUIRED	7	Indicate the contracted LTC pharmacy NCPDP number. This field should be a 7 character long string using 0 – 9.
NPI Number	CHAR OPTIONAL	10	Indicate the contracted LTC pharmacy NPI (National Provider Identifier) number.
NDC	CHAR REQUIRED	11	Provide the 11-digit NDC associated with this rebate.
Manufacturer Name	CHAR REQUIRED	100	For each rebate, provide the contracting manufacturer name.
Drug Name	CHAR REQUIRED	100	For each rebate, provide the brand name.
Rebate $ per unit received	NUM REQUIRED	17	Provide the contractual per unit rebates received during the reporting period (cash basis) associated with the listed drug. • Limit to 999999999999.9999, can also be a negative number
Technical Notes	CHAR OPTIONAL	4000	Provide any technical notes regarding the LTC pharmacy rebate calculations.

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

Title I, Part 423, Subpart I includes regulations regarding Licensure and Solvency. Part D ~~Contracts~~Sponsors and will be responsible for reporting multiple data elements and documentation related to their licensure and solvency and other financial requirements. ~~Part D~~ Employer/Union Direct Contract ~~Employer/Union-Only Group Waiver Plans~~PDPs (Direct ~~EGWPs~~Contract PDP) will be responsible for reporting multiple data elements and documentation related to their solvency and other financial requirements. Direct ~~EGWPs~~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 requirements are listed separately for Part D ~~PDP Contracts~~PDPs and Direct ~~EGWPs.~~Contract PDPs. These data will be used to ensure Part D ~~PDP Contracts~~PDPs and Direct ~~EGWPs~~Contract PDPs continue to be fiscally solvent entities.

~~Additionally, all Part D Contracts will enter PBM information into the HPMS on a quarterly basis.~~

- Subsection 1. Financial and Solvency Requirements Documentation - Part D PDPs
- Subsection 2. Financial and Solvency Requirements Documentation – Direct ~~EGWPs~~Contract PDPs
- Subsection 3. Financial and Solvency Requirements HPMS data– Part D PDPs and Direct ~~EGWPs~~Contract PDPs
- ~~Subsection 4. Performance of Part D Activities HPMS data – MA-PDs, PDPs, and Part D Direct EGWPs~~

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 year or within 10 days of the receipt of the Annual Audited F/S whichever is earlier.

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

A. According to the quarterly time periods specified above, Part D PDP Contracts that are licensed will mail 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
   - 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 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 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 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 Part D PDP Contracts will mail 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 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.

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. Financial and Solvency Requirements Documentation for Direct ~~EGWPs~~Contract PDPs:

A. According to the quarterly time periods specified above, Direct ~~EGWPs~~Contract PDPs will mail un-audited financial statements directly to CMS.
B. According to the quarterly time periods specified above, Direct ~~EGWPs~~Contract PDPs will mail 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 ~~EGWPs~~Contract PDPs will mail 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 ~~EGWPs~~Contract PDPs will mail 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 ~~EGWPs~~Contract PDPs will mail an ERISA Sec. 411(a) attestation directly to CMS by February 15th. See 2008 Solicitation for ~~Application~~Applications for Employer/Union Direct Contract ~~PDPs,~~ Prescription Drug Plan (PDP) Sponsors, Appendix IV, Sec. E.4 for explanation of this attestation.

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

Data to be entered at the Part D Contract level per 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 as of the end of the quarterly reporting period identified above. This should be a currency field.
D. Total cash equivalents as of the end of the reporting period identified above. This should be a currency field.
E. Total current assets as of the end of the quarterly reporting period identified above. This should be a currency field.
F. Total 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 expense as of the end of the quarterly reporting period identified above. This should be a currency field. *NOTE: Direct ~~EGWPs~~Contract PDPs are waived from this element*
J. Total 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.

~~**IV. Performance of Part D Activities data elements to be entered into HPMS – For All Part D Contracts (including MA-PDs, PDPs, and Direct EGWPs)**~~

~~Data to be entered at the Part D Contract level:~~

~~A. Indicate if there have been changes to this information during the quarterly reporting period.~~
~~B. If changes have occurred, indicate if these changes have been reflected within the Contract Management module.~~

~~Section XVII.~~ Drug benefit analyses

Part D ~~Contracts~~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 ~~Contracts.~~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 ~~B field~~D (non-LIS) and E (LIS) fields, and then indicate zero in the data element ~~C field.~~F (non-LIS) or G (LIS) fields. If a PBP does not have a deductible, HPMS will not display data fields ~~A~~B or ~~B~~C.

Reporting timeline: Part D ~~Contracts~~Sponsors will provide data on a monthly basis to CMS.

	Quarter 1			Quarter 2			Quarter 3			Quarter 4		
Reporting Period	1/1 – 1/31	2/1 – 2/28	3/1 – 3/31	4/1 – 4/30	5/1 – 5/31	6/1 – 6/30	7/1 – 7/31	8/1 – 8/31	9/1 – 9/30	10/1 – 10/31	11/1 – 11/30	12/1 – 12/31
Data due to CMS/ HPMS	3/31	4/30	5/31	6/30	7/31	8/31	9/30	10/31	11/30	12/31	1/31	2/28

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 month.
C. The total number of LIS enrollees in the deductible phase as of the last day of the month. [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 month. ~~(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 E.)~~
~~E. The total number of LIS enrollees in the pre-initial coverage limit phase as of the last day of the month.~~ (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.)
F. The total number of LIS enrollees in the pre-initial coverage limit phase as of the last day of the month. (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.]
G. The total number of non-LIS enrollees in the coverage gap as of the last day of the month. ~~(If a Plan does not have a coverage gap, the Plan should list the number of people who are pre-catastrophic in data element C, and then indicate zero in this field.)~~
~~H. The total number of LIS enrollees in the coverage gap as of the last day of the month.~~ (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.)
I. The total number of LIS enrollees in the coverage gap as of the last day of the month. (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.]
J. The total number of non-LIS enrollees in the catastrophic coverage level as of the last day of the month.
K. The total number of LIS enrollees in the catastrophic coverage level as of the last day of the month. [List all LIS beneficiaries for all subsidy levels.]

Table 1. Summary of Reporting Elements

Note: this summary table is for quick reference use only. Please refer to the respective detailed sections for full definitions, timelines, reporting level, and submission procedures.

Section	Element	Format	Frequency	HPMS
Retail, Home Infusion, and Long-Term Care Pharmacy	Percentage of Medicare beneficiaries living within 2 miles of a retail network pharmacy in urban areas of a Plan's service area (State for PDPs and regional PPOs, and service area for local MA-PD plans).	Numeric	Semi-annually	Yes
	Percentage of Medicare beneficiaries living within 5 miles of a retail network pharmacy in suburban areas (State for PDPs and regional PPOs, and service area for local MA-PD plans).	Numeric	Semi-annually	Yes
	Percentage of Medicare beneficiaries living within 15 miles of a retail network pharmacy in rural areas (State for PDPs and regional PPOs, and service area for local MA-PD plans).	Numeric	Semi-annually	Yes
	The number of contracted retail pharmacies in a Plan's service area (State for PDPs and regional PPOs, and service area for local MA-PD plans) as of the last day of the reporting period specified above.	Numeric	Semi-annually	Yes
	Pharmacies_(CONTRACTNAME)_(2008P#)	MS Excel	Semi-annually	Yes
Access to Extended Day Supplies at Retail Pharmacies	The number of contracted retail pharmacies that are contracted to dispense an extended day supply of covered Part D drugs.	Numeric	Semi-annually	Yes
Vaccines	The number of Part D vaccines processed	Numeric	Quarterly	Yes
	The number of Part D vaccines processed through out-of-network access	Numeric	Quarterly	Yes
	The number of vaccines adjudicated through in-network pharmacies.	Numeric	Quarterly	Yes
	The number of vaccine processed through a paper-enhanced process, where the provider used or navigated a process that facilitated out-of-network access	Numeric	Quarterly	Yes
	The number of vaccines processed through an internet based web tool.	Numeric	Quarterly	Yes
	The number of vaccines processed during the time period specified above through a process not described in data elements B through F.	Numeric	Quarterly	Yes
Reversals	Total number of out-of-cycle pharmacy transactions with reversal as the final disposition	Numeric	Quarterly	Yes
Medication Therapy Management Programs (MTMP)	The method used to enroll beneficiaries into the MTMP	Text	Semi-annually	Yes
	Number of beneficiaries who met the eligibility criteria for the MTMP	Numeric	Semi-annually	Yes
	Number of beneficiaries who participated in the MTMP	Numeric	Semi-annually	Yes
	Number of beneficiaries who discontinued participation from the MTMP	Numeric	Semi-annually	Yes
	Number of beneficiaries who discontinued participation from the MTMP due to death	Numeric	Semi-annually	Yes

Section	Element	Format	Frequency	HPMS
	Number of beneficiaries who discontinued participation from the MTMP due to disenrollment from the Plan	Numeric	Semi-annually	Yes
	Number of beneficiaries who discontinued participation from the MTMP at their request	Numeric	Semi-annually	Yes
	Number of beneficiaries who discontinued participation from the MTMP for a reason not specified in data elements E-G	Numeric	Semi-annually	Yes
	Number of beneficiaries who declined to participate in the MTMP	Numeric	Semi-annually	Yes
	Number of beneficiaries whose participation status in the MTMP is pending	Numeric	Semi-annually	Yes
	Prescription cost of all medications for all beneficiaries participating in the MTMP (as of the last day of the reporting period specified) on a per MTMP beneficiary per month basis	Currency	Semi-annually	Yes
	Number of covered Part D 30-day equivalent prescriptions on a per MTMP beneficiary per month basis	Numeric	Semi-annually	Yes
	MTMP_(Contract Name)_(2008P#)	File	Annually	Yes
Generic Drug Utilization	Total number of paid claims for generic drugs	Numeric	Quarterly	Yes
	Total number of paid claims	Numeric	Quarterly	Yes
Home Infusion Utilization	The number of beneficiaries receiving Part D-covered home infusion drugs dispensed by any of its network pharmacies	Numeric	Quarterly	Yes
	The total number of days supplies of Part D-covered home infusion drugs dispensed by any of its network pharmacies	Numeric	Quarterly	Yes
	Number of Part D beneficiaries receiving Part D-covered home infusion drugs dispensed by any of its network providers as part of a bundled service under a Part C supplemental benefit in the time period specified above (if applicable).	Numeric	Quarterly	Yes
	Total number of days supply of Part D-covered home infusion drugs dispensed by any of its network providers as part of a bundled service under a Part C supplemental benefit in the time period specified above (if applicable).	Numeric	Quarterly	Yes
Grievances	Number of fraud and abuse grievances received	Numeric	Quarterly	Yes
	Number of enrollment/disenrollment grievances received	Numeric	Quarterly	Yes
	Number of benefit package grievances received	Numeric	Quarterly	Yes
	Number of pharmacy access/network grievances received	Numeric	Quarterly	Yes
	Number of marketing grievances received	Numeric	Quarterly	Yes
	Number of customer service grievances received	Numeric	Quarterly	Yes
	Number of confidentiality/privacy grievances received	Numeric	Quarterly	Yes
	Number of quality of care grievances received	Numeric	Quarterly	Yes
	Number of exception grievances received	Numeric	Quarterly	Yes
	Number of appeal grievances received	Numeric	Quarterly	Yes
	Number of other grievances received	Numeric	Quarterly	Yes

Section	Element	Format	Frequency	HPMS
	Total number of grievances	Numeric	Quarterly	Yes
	Total number of LIS grievances	Numeric	Quarterly	Yes

~~Pharmacy & Therapeutics Committees~~	~~Indicate if changes in P&T Committee membership.~~	~~Text~~	~~Quarter~~	~~Yes~~
	~~If changes, indicate if these are reflected within Contract Management module.~~	~~Text~~	~~Quarter~~	~~Yes~~
~~Transition~~	~~Minimum number of days supply the Plan's transition policy provides for its one-time, temporary fill for enrollees in the retail setting.~~	~~Numeric~~	~~Quarter~~	~~Yes~~
	~~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~~	~~Numeric~~	~~Quarter~~	~~Yes~~
	~~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.~~	~~Numeric~~	~~Quarter~~	~~Yes~~
	~~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~~	~~Numeric~~	~~Quarter~~	~~Yes~~
	~~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~~	~~Numeric~~	~~Quarter~~	~~Yes~~
	~~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~~	~~Numeric~~	~~Quarter~~	~~Yes~~
~~Exceptions~~	~~Number of pharmacy transactions rejected due to failure to complete step edit requirements~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of pharmacy transactions rejected due to need for prior authorization (not including first pass step therapy edits or early refills)~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of pharmacy transactions rejected due to quantity limits in the time period specified above.~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of prior authorizations requested for formulary medications (not including first pass step therapy edits or early refills)~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of prior authorizations approved for formulary medications (not including first pass step therapy edits or early refills)~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of exceptions requested for non-formulary medications (not including early refills)~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of exceptions approved for non-formulary medications (not including early refills)~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of exceptions requested for tier exceptions (not including first pass step therapy edits or early refills)~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of exceptions approved for tier exceptions (not including first pass step therapy edits or early refills)~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of exceptions requested for quantity limits (not including early refills)~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of exceptions approved for quantity limits (not including early refills)~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
~~Appeals~~	~~Number of appeals submitted for **standard** redetermination~~	~~Numeric~~	~~Quarterly~~	~~Yes~~

	~~Number of appeals submitted for **expedited** redetermination~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of appeals submitted for **expedited** redetermination that were granted **expedited** status~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of appeals submitted for **standard** redetermination withdrawn by the enrollee~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of appeals submitted for **expedited** redetermination withdrawn by the enrollee~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of redeterminations resulting in full reversal of original decision~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of redeterminations resulting in partial reversal of original decision~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of adverse redeterminations due to insufficient evidence of medical necessity from enrollee's prescribing physician~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of appeals submitted for IRE reconsideration due to inability to meet timeframe for **coverage determination**~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of appeals submitted for IRE reconsideration due to inability to meet timeframe for **redetermination**~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of IRE decisions for **standard** reconsideration resulting in full reversal of original coverage determination or redetermination~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of IRE decisions for **standard** reconsideration resulting in partial reversal of original coverage determination or redetermination~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of IRE decisions for **expedited** reconsideration resulting in full reversal of original coverage determination or redetermination~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of IRE decisions for **expedited** reconsideration resulting in partial reversal of original coverage determination or redetermination~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of IRE decisions for **standard** reconsideration resulting in upholding of original coverage determination or redetermination~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Number of IRE decisions for **expedited** reconsideration resulting in upholding of original coverage determination or redetermination~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
~~Overpayment~~	~~Total overpayment dollars identified to be recouped~~	~~Currency~~	~~Semi-Annually~~	~~Yes~~
	~~Total overpayment dollars recouped~~	~~Currency~~	~~Semi-Annually~~	~~Yes~~
~~Pharmaceutical Rebates, Discounts, and Other Price Concessions~~	~~REBATES_(SPONSORNAME)_(2008Q#).XLS~~	~~MS Excel~~	~~Quarterly~~	~~Yes~~
	~~DISCOUNTS_(SPONSORNAME)_(2008Q#).XLS~~	~~MS Excel~~	~~Quarterly~~	~~Yes~~
~~Long-term Care (LTC) Rebates~~	~~REBATES_LTCPHARMACIES_(CONTRACT)_(2008Q#).XLS~~	~~MS Excel~~	~~Quarterly~~	~~Yes~~

Licensure and Solvency, Business Transactions and Financial Requirements	Licensed Part D PDP Contracts will submit Completed Health Blank form pages: Jurat, Assets, Liabilities, Capital and Surplus, Statement of Revenue and Expenses, Capital and Surplus Account, and Cash Flow OR Non-licensed Part D PDP Contracts will submit un-audited financial statements	Mailed to CMS	Quarterly	No
	Documentation showing that an insolvency deposit of $100,000 is being held (for non-licensed Part D PDP Contracts and Direct EGWPs)	Mailed to CMS	Quarterly	No
	Funding for projected losses worksheet (for non-licensed Part D PDP Contracts only)	Mailed to CMS	Quarterly	No
	Independently audited financial statement with a management letter for Part D PDPs and Direct EGWPs	Mailed to CMS	Yearly (fiscal)	No
	Copy of an Actuarial Opinion by a qualified actuary for the Part D PDP	Mailed to CMS	Yearly (fiscal)	No
	Documentation on the status of obtaining licensure for each waived state (for Part D PDP Contracts with any state licensure waivers only)	Mailed to CMS	Quarterly	No
	Documentation of significant business transactions	Mailed to CMS	Yearly (fiscal)	No
	Un-audited financial statements for Direct EGWPs	Mailed to CMS	Quarterly	No
	Copy of credit rating for Direct EGWPs	Mailed to CMS	Quarterly	No
	ERISA Sec. 411(a) attestation for Direct EGWPs	Mailed to CMS	Yearly	No
	Total assets	Currency	Quarterly	Yes
	Total liabilities	Currency	Quarterly	Yes
	Total cash	Currency	Quarterly	Yes
	Total cash equivalents	Currency	Quarterly	Yes
	Total current assets	Currency	Quarterly	Yes
	Total current liabilities	Currency	Quarterly	Yes
	Total revenue	Currency	Quarterly	Yes
	Total expenses	Currency	Quarterly	Yes
	Total administrative expense	Currency	Quarterly	Yes
	Total net income	Currency	Quarterly	Yes
	Drug benefit expenses (excluding administrative expenses)	Currency	Quarterly	Yes
	Drug benefit revenues	Currency	Quarterly	Yes
	Indicate if changes have occurred in entities performing Part D activities.	Text	Quarterly	Yes
	If changes, indicate if these are reflected within Contract Management module.	Text	Quarterly	Yes
Part D Benefit Analyses	Total number of non-LIS enrollees in the deductible phase	Numeric	Quarterly	Yes
	Total number of LIS enrollees in the deductible phase	Numeric	Quarterly	Yes
	Total number of non-LIS enrollees in the pre-initial coverage limit phase	Numeric	Quarterly	Yes
	Total number of LIS enrollees in the pre-initial coverage limit phase	Numeric	Quarterly	Yes

	~~Total number of non-LIS enrollees in the coverage gap~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Total number of LIS enrollees in the coverage gap~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Total number of non-LIS enrollees in the catastrophic coverage level~~	~~Numeric~~	~~Quarterly~~	~~Yes~~
	~~Total number of non-LIS enrollees in the catastrophic coverage level~~	~~Numeric~~	~~Quarterly~~	~~Yes~~

Section	Section	Element	Format
I.	Retail, Home Infusion, and Long-Term Care Pharmacy	Percentage of Medicare beneficiaries living within 2 miles of a retail network pharmacy in urban areas of a Plan's service area (State for PDPs and regional PPOs, and service area for local MA-PD plans).	Numeric
		Percentage of Medicare beneficiaries living within 5 miles of a retail network pharmacy in suburban areas (State for PDPs and regional PPOs, and service area for local MA-PD plans).	Numeric
		Percentage of Medicare beneficiaries living within 15 miles of a retail network pharmacy in rural areas (State for PDPs and regional PPOs, and service area for local MA-PD plans).	Numeric
		The number of contracted retail pharmacies in a Plan's service area (State for PDPs and regional PPOs, and service area for local MA-PD plans) as of the last day of the reporting period specified above.	Numeric
		Pharmacies_(CONTRACTNAME)_(2008P1)	Tab delimited text file
II.	Access to Extended Day Supplies at Retail Pharmacies	The number of contracted retail pharmacies that are contracted to dispense an extended day supply of covered Part D drugs.	Numeric
III.	Vaccines	The total number of Part D vaccines processed regardless of the method used to process the claim.	Numeric
		The number of Part D vaccines administered in a clinic setting (e.g. physician's office) where the beneficiary retrospectively files paper receipts for reimbursement of the vaccine.	Numeric
		The number of vaccines adjudicated through network pharmacies. (Including those vaccines processed by the pharmacy and submitted electronically).	Numeric
		The number of vaccines processed through a paper enhanced process, where the provider used or navigated a process that facilitated out-of-network access.	Numeric
		The number of vaccines processed through an internet based web tool.	Numeric
		The number of vaccines through a process not described in data elements B through E.	Numeric
IV.	Reversals	Total number of out-of-cycle pharmacy transactions with reversal as the final disposition	Numeric
V.	Medication Therapy Management Programs (MTMP)	The method used to enroll beneficiaries into the MTMP	Text
		Number of beneficiaries who met the eligibility criteria for the MTMP	Numeric
		Number of beneficiaries who participated in the MTMP	Numeric
		Number of beneficiaries who discontinued participation from the MTMP	Numeric
		Number of beneficiaries who discontinued participation from the MTMP due to death	Numeric
		Number of beneficiaries who discontinued participation from the MTMP due to disenrollment from the Plan	Numeric
		Number of beneficiaries who discontinued participation from the MTMP at their request	Numeric
		Number of beneficiaries who discontinued participation from the MTMP for a reason not specified in data elements E-G	Numeric

		Number of beneficiaries who declined to participate in the MTMP	Numeric
		Number of beneficiaries whose participation status in the MTMP is pending	Numeric
		Prescription cost of all medications for all beneficiaries participating in the MTMP (as of the last day of the reporting period specified) on a per MTMP beneficiary per month basis	Currency
		Number of covered Part D 30-day equivalent prescriptions on a per MTMP beneficiary per month basis	Numeric
		Data file containing various data fields for beneficiaries identified as being eligible for the Medication Therapy Management Program	Tab delimited text file
VI.	Generic Drug Utilization	Total number of paid claims for generic drugs	Numeric
		Total number of paid claims	Numeric
VII.	Home Infusion Utilization	Number of Part D beneficiaries receiving Part D-covered home infusion drugs dispensed by any of its network providers as part of a bundled service under a Part C supplemental benefit (if applicable).	Numeric
		The total claims associated with Part D-covered home infusion drugs dispensed by any of its network providers as part of a bundled service under a Part C supplemental benefit (if applicable).	Numeric
VIII.	Grievances	Number of fraud and abuse grievances received	Numeric
		Number of enrollment/disenrollment grievances received	Numeric
		Number of benefit package grievances received	Numeric
		Number of pharmacy access/network grievances received	Numeric
		Number of marketing grievances received	Numeric
		Number of customer service grievances received	Numeric
		Number of confidentiality/privacy grievances received	Numeric
		Number of quality of care grievances received	Numeric
		Number of exception grievances received	Numeric
		Number of appeal grievances received	Numeric
		Number of other grievances received	Numeric
		Total number of grievances	Numeric
		Total number of LIS grievances	Numeric
IX.	Pharmacy & Therapeutics Committees/ Provision of Part D Functions	Indicate if changes in P&T Committee membership.	Text
		If changes, indicate if these are reflected within Contract Management module.	Text
		Indicate if changes have occurred in organizations providing Part D functions.	Text
		If changes, indicate if these are reflected within Contract Management module.	Text
X.	Transition	Minimum number of days supply the Plan's transition policy provides for its one-time, temporary fill for enrollees in the retail setting.	Numeric
		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	Numeric
		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.	Numeric
		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	Numeric
		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	Numeric
		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	Numeric

XI.	Exceptions	Number of pharmacy transactions rejected due to failure to complete step edit requirements	Numeric
		Number of pharmacy transactions rejected due to need for prior authorization (not including first pass step therapy edits or early refills)	Numeric
		Number of pharmacy transactions rejected due to quantity limits in the time period specified above.	Numeric
		Number of prior authorizations requested for formulary medications (not including first pass step therapy edits or early refills)	Numeric
		Number of prior authorizations approved for formulary medications (not including first pass step therapy edits or early refills)	Numeric
		Number of exceptions requested for non-formulary medications (not including early refills)	Numeric
		Number of exceptions approved for non-formulary medications (not including early refills)	Numeric
		Number of exceptions requested for tier exceptions (not including first pass step therapy edits or early refills)	Numeric
		Number of exceptions approved for tier exceptions (not including first pass step therapy edits or early refills)	Numeric
		Number of exceptions requested for quantity limits (not including early refills)	Numeric
		Number of exceptions approved for quantity limits (not including early refills)	Numeric
XII.	Appeals	Number of appeals submitted for **standard** redetermination	Numeric
		Number of appeals submitted for **expedited** redetermination	Numeric
		Number of appeals submitted for **expedited** redetermination that were granted **expedited** status	Numeric
		Number of appeals submitted for **standard** redetermination withdrawn by the enrollee	Numeric
		Number of appeals submitted for **expedited** redetermination withdrawn by the enrollee	Numeric
		Number of redeterminations resulting in full reversal of original decision	Numeric
		Number of redeterminations resulting in partial reversal of original decision	Numeric
		Number of adverse redeterminations due to insufficient evidence of medical necessity from enrollee's prescribing physician	Numeric
		Number of appeals submitted for IRE reconsideration due to inability to meet timeframe for **coverage determination**	Numeric
		Number of appeals submitted for IRE reconsideration due to inability to meet timeframe for **redetermination**	Numeric
		Number of IRE decisions for **standard** reconsideration resulting in full reversal of original coverage determination or redetermination	Numeric
		Number of IRE decisions for **standard** reconsideration resulting in partial reversal of original coverage determination or redetermination	Numeric
		Number of IRE decisions for **expedited** reconsideration resulting in full reversal of original coverage determination or redetermination	Numeric
		Number of IRE decisions for **expedited** reconsideration resulting in partial reversal of original coverage determination or redetermination	Numeric
		Number of IRE decisions for **standard** reconsideration resulting in upholding of original coverage determination or redetermination	Numeric
		Number of IRE decisions for **expedited** reconsideration resulting in upholding of original coverage determination or redetermination	Numeric
XIII.	Overpayment	Total overpayment dollars identified to be recouped	Currency
		Total overpayment dollars recouped	Currency
XIV.	Pharmaceutical Rebates,	REBATES_(SPONSORNAME)_(2008Q#).TXT	Tab delimited text file

	Discounts, and Other Price Concessions	DISCOUNTS_(SPONSORNAME)_(2008Q#).TXT	Tab delimited text file
XV.	Long-term Care (LTC) Rebates	REBATES_LTCPHARMACIES_(CONTRACT)_(2008Q#).TXT	Tab delimited text file
XVI.	Licensure and Solvency, Business Transactions and Financial Requirements	Licensed Part D PDP Contracts will submit Completed Health Blank form pages: Jurat, Assets, Liabilities, Capital and Surplus, Statement of Revenue and Expenses, Capital and Surplus Account, and Cash Flow OR Non-licensed Part D PDP Contracts will submit un-audited financial statements	Mailed to CMS
		Documentation showing that an insolvency deposit of $100,000 is being held (for non-licensed Part D PDP Contracts and Direct Contract PDPs)	Mailed to CMS
		Funding for projected losses worksheet (for non-licensed Part D PDP Contracts only)	Mailed to CMS
		Independently audited financial statement with a management letter for Part D PDPs and Direct Contract PDPs	Mailed to CMS
		Copy of an Actuarial Opinion by a qualified actuary for the Part D PDP	Mailed to CMS
		Documentation on the status of obtaining licensure for each waived state (for Part D PDP Contracts with any state licensure waivers only)	Mailed to CMS
		Documentation of significant business transactions	Mailed to CMS
		Un-audited financial statements for Direct Contract PDPs	Mailed to CMS
		Copy of credit rating for Direct Contract PDPs	Mailed to CMS
		ERISA Sec. 411(a) attestation for Direct Contract PDPs s	Mailed to CMS
		Total assets	Currency
		Total liabilities	Currency
		Total cash	Currency
		Total cash equivalents	Currency
		Total current assets	Currency
		Total current liabilities	Currency
		Total revenue	Currency
		Total expenses	Currency
		Total administrative expense	Currency
		Total net income	Currency
		Drug benefit expenses (excluding administrative expenses)	Currency
		Drug benefit revenues	Currency
XVII.	Part D Benefit Analyses	Total number of non-LIS enrollees in the deductible phase	Numeric
		Total number of LIS enrollees in the deductible phase	Numeric
		Total number of non-LIS enrollees in the pre-initial coverage limit phase	Numeric
		Total number of LIS enrollees in the pre-initial coverage limit phase	Numeric
		Total number of non-LIS enrollees in the coverage gap	Numeric
		Total number of LIS enrollees in the coverage gap	Numeric
		Total number of non-LIS enrollees in the catastrophic coverage level	Numeric
		Total number of non-LIS enrollees in the catastrophic coverage level	Numeric

Table 2: Changes made from CY 2007 Reporting Requirements

Reporting Requirements Section	Changes
Retail, Home Infusion, and Long-Term Care Pharmacy Access	This is a new section
Access to Extended Day Supplies at Retail Pharmacies	This is a new section
Vaccines	This is a new section
Reversals	This section can now be reported at the Part D Contract or Plan (PBP) level
Medication Therapy Management Programs	Data element revised: • In Element L revised equation to Days Supply/30 Data elements added: • Number of beneficiaries who discontinued participation from the MTMP for a reason not specified in data elements E-G • Number of beneficiaries whose participation status in the MTMP is pending Data upload for beneficiaries identified as being eligible for the Medication Therapy Management Program
Generic Drug Utilization	The name of the section was changed
Home Infusion	This is a new section
Grievances	Description added: • Added an example of enrollment/disenrollment issues or recognition of LIS eligibility problems. Data element revised: • In element A added Plan Agent or broker in element • In element E added overly aggressive marketing in element Data elements added: • Number of LIS grievances received related to Part D
Pharmacy & Therapeutics (P&T) Committees	• Description added:Element A added during the time period specified above • Elements A& B – deletion of this will be a selection from a drop-down box
Transition	Description revised: New introduction paragraph Data elements deleted: Total number of beneficiaries who are in transition during the reporting time period Number of prescriptions authorized during transition periods within the reporting time period Number of enrollees receiving one or more prescriptions authorized during transition periods within the reporting time period Number of days per transition period field. Data elements added: Minimum number of days supply the Plan's transition policy provides for its one-time, temporary fill for enrollees in the retail setting 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. 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 Minimum number of days, beginning on the enrollee's effective date of

Reporting Requirements Section	Changes
	coverage, in a plan's transition process for enrollees in the LTC setting 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 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
Exceptions	Data elements revised: Elements D and E added quantity limits as an example
Appeals	Data element revised: Element A added description (Do not include those appeals that were submitted as expedited, but were not granted expedited status.)
Call Center Measures: Beneficiary Service line and Pharmacy Support line	This section has been deleted
Overpayment	No changes made to this reporting section
Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions	No changes made to this reporting section
Long-term Care (LTC) Rebates	Data element revised: In Section A, number 5. the description of Drug name has been revised to provide the brand name Data elements added: • Addition of NDC - Provide the 11-digit NDC associated with this rebate
Licensure and Solvency, Business Transactions and Financial Requirements Subsection 1: Financial and Solvency Requirements Documentation for Part D PDP Contracts; Subsection 2: Financial and Solvency Requirements Documentation for Direct EGWPs; Subsection 3: Financial and Solvency Requirements HPMS Data elements for Part D PDPs and Direct EGWPs; Subsection 4: Performance of Part D Activities HPMS Data elements for all Part D Contracts (including MA-PDs, PDPs, and Direct EGWPs)	Description revised: Section description revised to include explanatory language about Direct EGWPsData elements revised: Section I • Element D now reads: 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. • Element E added the sentence: Licensed entities may not report under GAAP for a period longer than 36 months. • Element G now reads: 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 state. • Element H reads: 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. Section II

Reporting Requirements Section	Changes
	Section II also notes that All Direct EGWP Documentation should be mailed to the following found in the document Section III • The Section III header should read Financial and Solvency Requirements data elements to be entered into HPMS – For Part D PDP Contracts / Direct EGWPs: Section IV • Delete from data element A that this selection will be from a drop-down box.
Drug benefit analyses	• Section to be reported monthly Description revised: Section overview now includes an explanatory sentence. If a PBP does not have a deductible, HPMS will not display A or B.Data elements added: • Number of non-LIS enrollees in the deductible phase as of the last day of the month. • Number of LIS enrollees in the deductible phase as of the last day of the month. • Number of LIS enrollees in the pre-initial coverage limit phase as of the last day of the month • Number of LIS enrollees in the coverage gap as of the last day of the month • Number of LIS enrollees in the catastrophic coverage level as of the last day of the month.

	Reporting Requirements Section	Changes
I.	Retail, Home Infusion, and Long-Term Care Pharmacy Access	This is a new section
II.	Access to Extended Day Supplies at Retail Pharmacies	This is a new section
III.	Vaccines	This is a new section
IV.	Reversals	This section can now be reported at the Part D Contract or Plan (PBP) level
V.	Medication Therapy Management Programs	Data element revised: • In Element L revised equation to Days Supply/30 Data elements added: • Number of beneficiaries who discontinued participation from the MTMP for a reason not specified in data elements E-G • Number of beneficiaries whose participation status in the MTMP is pending • Data upload for beneficiaries identified as being eligible for the Medication Therapy Management Program
VI.	Generic Drug Utilization	The name of the section was changed from Generic Drug Rate.
VII.	Home Infusion Utilization	This is a new section
VIII.	Grievances	Description added:

	Reporting Requirements Section	Changes
		• Added an example of enrollment/disenrollment issues or recognition of LIS eligibility problems. Data element revised: • In element A added Plan Agent or broker in element • In element E added overly aggressive marketing in element Data elements added: • Number of LIS grievances received related to Part D
IX.	Pharmacy & Therapeutics (P&T) Committees/Performance of Part D Functions	• The name of this section was renamed to reflect incorporation of Performance of Part D Functions from subsection 4 of the Licensure & Solvency. Description added: Element A1. added during the time period specified above Data elements revised: A1-2, and B1-2 that drop-down box is no longer used.
X.	Transition	Description revised: • New introduction paragraph Data elements deleted: • Total number of beneficiaries who are in transition during the reporting time period • Number of prescriptions authorized during transition periods within the reporting time period • Number of enrollees receiving one or more prescriptions authorized during transition periods within the reporting time period • Number of days per transition period field. Data elements added: • Minimum number of days supply the Plan's transition policy provides for its one-time, temporary fill for enrollees in the retail setting • 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. • 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 • 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 • 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 • 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
XI.	Exceptions	Data elements revised: • Elements D and E added quantity limits as an example
XII.	Appeals	Data element revised: • Element A added description (Do not include those appeals that were submitted as expedited, but were not granted expedited status.)
	Call Center Measures: Beneficiary Service line and Pharmacy Support line	This section has been deleted

	Reporting Requirements Section	Changes
XIII.	Overpayment	No changes made to this reporting section
XIV.	Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions	No changes made to this reporting section
XV.	Long-term Care (LTC) Rebates	Data element revised: • In Section A, number 5. the description of Drug name has been revised to provide the brand name Data elements added: • Addition of NDC - Provide the 11-digit NDC associated with this rebate
XVI.	Licensure and Solvency, Business Transactions and Financial Requirements Subsection 1: Financial and Solvency Requirements Documentation for Part D PDP Contracts; Subsection 2: Financial and Solvency Requirements Documentation for Direct Contract PDPs; Subsection 3: Financial and Solvency Requirements HPMS Data elements for Part D PDPs and Direct Contract PDPs; Subsection 4: Performance of Part D Activities HPMS Data elements for all Part D Contracts (including MA-PDs, PDPs, and Direct Contract PDPs)	Description revised: Section description revised to include explanatory language about Direct Contract PDPs Data elements revised: Section I • Element D now reads: 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. • Element E added the sentence: Licensed entities may not report under GAAP for a period longer than 36 months. • Element G now reads: 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 state. • Element H reads: 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. Section II • Revised to note that All Direct Contract PDP Documentation should be mailed to the following found in the document Section III • Section III header revised to Financial and Solvency Requirements data elements to be entered into HPMS – For Part D PDP Contracts / Direct Contract PDPs: Section IV • This subsection moved to P&T Committee section.
XVII.	Drug benefit analyses	• Section to be reported monthly Description revised: Section overview includes an explanatory sentence, and revised re: how Plans with no coverage gaps or deductibles should report

	Reporting Requirements Section	Changes
		data. Data elements added: • Number of non-LIS enrollees in the deductible phase as of the last day of the month. • Number of LIS enrollees in the deductible phase as of the last day of the month. • Number of LIS enrollees in the pre-initial coverage limit phase as of the last day of the month • Number of LIS enrollees in the coverage gap as of the last day of the month • Number of LIS enrollees in the catastrophic coverage level as of the last day of the month.