MEDICARE PART D
REPORTING REQUIREMENTS
Contract Year 2008

Updated: 12/13/07

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Introduction

In December 2003, Congress passed the Medicare Prescription Drug Benefit, Improvement and Modernization Act (MMA), allowing coverage of outpatient prescription drugs under the Medicare Part D benefit. In accordance with Title I, Part 423, Subpart K (§ 423.514), the Act requires each Part D Sponsor to have an effective procedure to provide statistics indicating:

1) the cost of its operations
2) the patterns of utilization of its services
3) the availability, accessibility, and acceptability of its services
4) information demonstrating it has a fiscally sound operation
5) other matters as required by CMS

The purpose of this document is to assure a common understanding of reporting requirements and how these data will be used to monitor the prescription drug benefit provided to Medicare beneficiaries. CMS will use the following terminology to ensure consistency in these reporting requirements:

- Part D Sponsor –an organization which has one or more contract(s) with CMS to provide Part D benefits to Medicare beneficiaries. Each contract is assigned a CMS contract number (e.g. H# or S#)
- Plan – a plan benefit package (PBP) offered within a Part D contract (e.g. Plan ID #)

This document lists reporting timeframes and required levels of reporting. Data elements may be reported at the Plan (PBP) level, the individual contract-level, or Sponsor-level. These requirements 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 Sponsors who fail to comply with these reporting requirements.

The following criteria were used in selecting reporting requirements:

1) Minimal administrative burden on Part D Sponsors
2) Legislative and regulatory authority
3) Validity, reliability, and utility of data elements requested
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, Medication Therapy Management Programs, Generic Drug 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 Sponsor shall provide necessary data to CMS to support payment, program integrity, program management, and quality improvement activities. Additional reporting requirements are identified in separate guidance documents throughout the year. Guidance has previously been released for formulary, TrOOP, coordination of benefits, payment and 1/3 audit, and low income subsidy.

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

Part D 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 covered Part D drugs, including compounded drugs.

For PACE Organizations offering Part D coverage, reporting requirements will be limited to: Vaccines; Generic Drug 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 following exceptions:

- MTM section: The number of covered Part D 30-day equivalent prescriptions should be entered to two decimal places
- Long-Term Care (LTC) Rebates section: 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 Sponsors are required to maintain a pharmacy network sufficient for ensuring access to Medicare beneficiaries residing in their service areas. Part D Sponsors must ensure that they provide convenient access to retail pharmacies, as provided in §423.120(a)(1); adequate access to home infusion (HI) pharmacies, as provided in §423.120(a)(4); and convenient access to long-term care (LTC) pharmacies, as provided in §423.120(a)(5). After their initial pharmacy access submissions are approved at the time of application, Part D Sponsors are responsible for notifying CMS of any substantive changes in their pharmacy network that may impact their ability to maintain a Part D pharmacy network that meets our requirements, as described in section 50 of Chapter 5 of the Prescription Drug Benefit Manual.

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

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

Supporting documentation is not required to be submitted with the data elements below; however, CMS reserves the right to request appropriate documentation to support a Part D Sponsor's submitted pharmacy access data elements (e.g., geo-access reports). This may include documentation of the access data elements at the plan (PBP level). CMS evaluation of compliance with pharmacy access standards will be conducted based on point-in-time information about pharmacy networks submitted by Part D Sponsors once per year.

Employer/Union Direct contracts and "800 series" plans have the following service area definitions for this section:

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

Reporting timeline for Sections A and B only:

	Period 1
Reporting Period	January 1 - March 31
Data due to	May 31

CMS/HPMS	

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

1. Percentage of Medicare beneficiaries living within 2 miles of a retail network pharmacy in urban areas of a Plan's service area (by State for PDPs and regional PPOs, and by service area for local MA-PD plans) as of the last day of the reporting period specified above.
2. Percentage of Medicare beneficiaries living within 5 miles of a retail network pharmacy in suburban areas (by State for PDPs and regional PPOs, and by service area for local MA-PD plans) as of the last day of the reporting period specified above.
3. Percentage of Medicare beneficiaries living within 15 miles of a retail network pharmacy in rural areas (by State for PDPs and regional PPOs, and by service area for local MA-PD plans) as of the last day of the reporting period specified above.
4. The number of contracted retail pharmacies in a Plan's service area (by State for PDPs and regional PPOs, and by service area for local MA-PD plans) as of the last day of the reporting period specified above.

B. Data files to be uploaded through the HPMS at the CMS Part D Contract level. Part D Sponsors will provide an excel file (filename=Pharmacies_(CONTRACTNAME)_(2008P1).xls replacing '(CONTRACTNAME)' with the Part D Contract's name 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 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 MA-PD and cost plans that own and operate their own pharmacies and have received a waiver of the any willing pharmacy requirement.

1. Number of prescriptions provided by all pharmacies owned and operated.
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 MA-PD and cost plans that own and operate their own retail pharmacies and have received a waiver of the retail pharmacy convenient access standards. MA-PD and cost plans that have received a waiver of the retail pharmacy convenient access standards are not required to submit data elements A1-A4 above.

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 Sponsors that include mail-order pharmacies in their networks must permit enrollees to receive benefits, which may include an extended day supply of covered Part D drugs (for example, a 90-day supply), through a network retail pharmacy rather than a network mail-order pharmacy. Part D Sponsors must contract with a sufficient number of retail pharmacies so as to ensure that enrollees have reasonable access to the same extended day supply benefits at retail that are available at mail-order pharmacies. Part D Sponsors must submit data annually that will allow CMS to evaluate access to extended day supplies at retail pharmacies.

Reporting timeline:

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

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

A. The number of contracted retail pharmacies that are contracted to dispense an extended day supply of covered Part D drugs as of the last day of the reporting period specified above.

Section III. Vaccines

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

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

Reporting timeline:

	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 provided in any out-of-network setting where a state recognized immunizer dispenses a Part D vaccine (e.g. physician's office) where the beneficiary retrospectively files paper receipts for reimbursement of the vaccine during the time period specified above.
C. The number of vaccines adjudicated through network pharmacies during the time specified above. (Including those vaccines processed by the pharmacy and submitted electronically).
D. The number of vaccines processed through a paper enhanced process, where the provider used or navigated a process that facilitated out-of-network access during the time period specified above.
E. 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 E.

Section IV. Medication Therapy Management Programs

The requirements stipulating that Part D Sponsors provide Medication Therapy Management Programs (MTMP) are described in Title I, Part 423, Subpart D, § 423.153. For monitoring purposes, Part D Sponsors will be responsible for reporting several data elements related to their MTMP. Data will be manually submitted in HPMS, or uploaded in a data file.

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

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

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

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. A value of zero will be accepted.
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 plan during the reporting period specified, not only the months that the beneficiary enrolled in the MTMP.

The following equation also describes this calculation

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

$\{\text{Gross Drug Cost} = (\text{Ingredient Cost Paid} + \text{Dispensing Fee} + \text{Sales Tax}).$

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 plan during the reporting period specified, not only the months that the beneficiary enrolled in the MTMP.

The following equation also describes this calculation:

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

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

II. Data file to be uploaded using Gentran or Connect Direct at the Contract level.
More information regarding the upload process will be forthcoming.

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

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. (mm/dd/yyyy, e.g. 01/01/1940).
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 Y (yes), N (no), or U (unknown).
Date of MTMP enrollment	DATE OPTIONAL	10	For each beneficiary identified to be eligible for the MTMP in the reporting period, who enrolled in MTMP, the date MTMP enrollment began. (mm/dd/yyyy, e.g. 01/01/2008).
Date MTMP participation was declined	DATE OPTIONAL	10	This should be a date field (mm/dd/yyyy, e.g. 01/01/2008).
Date participant discontinued MTMP	DATE OPTIONAL	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, e.g. 01/01/2008).
Reason participant discontinued MTMP	TEXT REQUIRED IF 'Date participant discontinued MTMP' SUBMITTED	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 V. Generic Drug Utilization

Cost control requirements for Part D Sponsors are presented in Title I, Part 423, Subpart D. Accordingly, Part D Sponsors will be responsible for reporting data elements needed to monitor utilization of generic drugs (defined by Title I, Part 423, Sub-Part A, § 423.4).

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 VI. Grievances

Title I, Part 423, Subpart M of the regulation includes regulations that require Part D 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 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 VII. Pharmacy & Therapeutics (P&T) Committees/ Provision of Part D Functions

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

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

Reporting timeline:

	Quarter 1	**Quarter 2**	**Quarter 3**	**Quarter 4**
Reporting Period	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
Data due to CMS/HPMS	May 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 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 VIII. 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 IX. 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 versus Part D coverage should be included in this reporting.

Reporting timeline:

	Quarter 1	**Quarter 2**	**Quarter 3**	**Quarter 4**
Reporting Period	January 1 - March 31	April 1 - June 30	July 1 - September 30	October 1 - December 31
Data due to CMS/HPMS	May 31	August 31	November 30	February 28

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

A. The 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 X. 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 XI. Overpayment

Part D Sponsors will be responsible for reporting data related to overpayments associated with Part D benefits. An overpayment occurs when a Part D 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 XII. Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions

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

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

Reporting timeline:

	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 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 Sponsors will not upload data files.

A. Part D Sponsors/Contracts will provide a tab delimited text file (filename=REBATES_(SPONSORNAME)_(2008Q#).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.

Pharmaceutical Manufacturer Rebate File Record Layout			
Field Name	**Field Type**	**Field Length**	**Field Description**
Prior Rebates	NUM REQUIRED	12	For each unique manufacturer/brand name 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 tab delimited text file (filename=DISCOUNTS_(SPONSORNAME)_(2008Q#).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. •0 is not an allowable value
Justification	CHAR OPTIONAL	4000	For each discount, price concession, or value add, provide a justification for receipt.

Section XIII. Long-Term Care (LTC) Rebates

As described in the CMS 2008 Call Letters, Part D 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 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 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.). For this reporting exemption, the term pharmacy represents a pharmacy organization at its highest level rather than the discrete NCPDP number or location. A pharmacy organization that includes multiple pharmacy locations should be considered in its entirety by a Plan to determine if that chain serves less than 5% of the LTC beds in the respective area. For reporting purposes, however, these LTC pharmacies must still be listed in the rebate report to CMS.
    - For an individual pharmacy, that is not part of a pharmacy chain and serves less than 5% of the LTC beds in the area, the sponsor should list the LTC pharmacy NCPDP # in the report, leave the Manufacturer, Drug name and Rebate unit fields blank, and enter "Not required to report" in the Technical Notes field.
    - For a pharmacy chain serving less than 5% of LTC beds of a state in which any of its pharmacies are licensed, the sponsor should list all pharmacies by NCPDP #, leave the Manufacturer, Drug name and Rebate unit fields blank, and enter "Not required to report" in the Technical Notes field.
    - For a pharmacy chain with multiple pharmacies serving more than 5% of LTC beds in a state, a sponsor must list all of the chain’s pharmacies licensed in that state and their rebates received. Any pharmacies that did not receive rebates should be reported by listing NCPDP #, leaving the Manufacturer, Drug name and Rebate unit fields blank, and entering "Not required to report" in the Technical Notes field.
    - If a pharmacy is licensed in multiple states and meets the criteria of 5% of the LTC beds served in at least one state, the rebates received by that pharmacy must be reported.
- 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.

Part D Sponsors/Contracts will provide a tab delimited text file (filename=REBATES_LTC PHARMACIES_(CONTRACTNAME)_(2008Q#).txt, replacing ‘(CONTRACTNAME)’ with the Part D

Sponsor's name and '(2008Q#)' with the year and quarter number) containing the following fields.

LTC Rebates File Record Layout			
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 #	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 $ / Unit	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 XIV. Licensure and Solvency, Business Transactions and Financial Requirements

Title I, Part 423, Subpart I includes regulations regarding Licensure and Solvency. Part D Sponsors and will be responsible for reporting multiple data elements and documentation related to their licensure and solvency and other financial requirements. Employer/Union Direct Contract PDPs (Direct Contract PDP) will be responsible for reporting multiple data elements and documentation related to their solvency and other financial requirements. Direct Contract PDPs are employers or unions that directly contract with CMS to offer a Part D plan exclusively to the employer's/union's retirees. Some data will be entered into the HPMS and other information will be mailed directly to CMS. Documentation requirements are listed separately for Part D PDPs and Direct Contract PDPs. These data will be used to ensure Part D PDPs and Direct Contract PDPs continue to be fiscally solvent entities.

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

Reporting timeline:

	Quarter 1 YTD	Quarter 2 YTD	Quarter 3 YTD	Annual
Reporting Period	January 1 - March 31	January 1 - June 30	January 1 - September 30	January 1 - December 31
Data due to CMS/HPMS	May 15	August 15	November 15	120 days after the end of the calendar 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 Contract PDPs:

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

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

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

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

A. Total assets as of the end of the quarterly reporting period identified above. This should be a currency field.
B. Total liabilities as of the end of the quarterly reporting period identified above. This should be a currency field.
C. Total cash 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 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.

Section XV. Drug benefit analyses

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

Reporting timeline: Part D 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 F.)
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 G.) [List all LIS beneficiaries for all subsidy levels.]
F. The total number of non-LIS enrollees in the coverage gap as of the last day of the 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.)
G. 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.]
H. The total number of non-LIS enrollees in the catastrophic coverage level as of the last day of the month.
I. 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	Section	Element	Format	Frequency	HPMS
I.	Retail, Home Infusion, and Long-Term Care Pharmacy Access	Percentage of Medicare beneficiaries living within 2 miles of a retail network pharmacy in urban areas of a Plan's service area (by State for PDPs and regional PPOs, and by service area for local MA-PD plans)	Numeric	Annually	Yes
		Percentage of Medicare beneficiaries living within 5 miles of a retail network pharmacy in suburban areas (by State for PDPs and regional PPOs, and by service area for local MA-PD plans)	Numeric	Annually	Yes
		Percentage of Medicare beneficiaries living within 15 miles of a retail network pharmacy in rural areas (by State for PDPs and regional PPOs, and by service area for local MA-PD plans)	Numeric	Annually	Yes
		The number of contracted retail pharmacies in a Plan's service area (by State for PDPs and regional PPOs, and by service area for local MA-PD plans)	Numeric	Annually	Yes
		Pharmacies_(CONTRACTNAME)_(2008P1).xls	Excel file	Annually	Yes
		For only those MA-PD and cost plans that own and operate their own retail pharmacies and have received a waiver of the any willing pharmacy requirement - Number of Prescriptions provided by all retail pharmacies owned and operated	Numeric	Annually	Yes
		For only those MA-PD and cost plans that own and operate their own retail pharmacies and have received a waiver of the any willing pharmacy requirement - Number of prescriptions provided at all retail pharmacies contracted	Numeric	Annually	Yes
		For only those MA-PD and cost plans that own and operate their own retail pharmacies and have received a waiver of the retail pharmacy convenient access standards - Number of prescriptions provided by retail pharmacies owned and operated	Numeric	Annually	Yes
		For only those MA-PD and cost plans that own and operate their own retail pharmacies and have received a waiver of the retail pharmacy convenient access standards - Number of prescriptions provided at all retail pharmacies contracted	Numeric	Annually	Yes
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	One Quarter will be collected Annually	Yes
III.	Vaccines	The total number of Part D vaccines processed regardless of the method used to process the claim	Numeric	Quarterly	Yes

Section	Section	Element	Format	Frequency	HPMS
		The number of Part D vaccines provided in any out-of-network setting where a state recognized immunizer dispenses a Part D vaccine (e.g. physician's office) where the beneficiary retrospectively files paper receipts for reimbursement of the vaccine	Numeric	Quarterly	Yes
		The number of vaccines adjudicated through network pharmacies. (Including those vaccines processed by the pharmacy and submitted electronically)	Numeric	Quarterly	Yes
		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	Quarterly	Yes
		The number of vaccines processed through an internet based web tool	Numeric	Quarterly	Yes
		The number of vaccines through a process not described in data elements B through E	Numeric	Quarterly	Yes
IV.	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
		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
		Data file containing various data fields for beneficiaries identified as being eligible for the Medication Therapy Management Program	Tab delimited text file	Annually	No
V.	Generic Drug Utilization	Total number of paid claims for generic drugs	Numeric	Quarterly	Yes
		Total number of paid claims	Numeric	Quarterly	Yes
VI.	Grievances	Number of fraud and abuse grievances received	Numeric	Quarterly	Yes
		Number of enrollment/disenrollment grievances received	Numeric	Quarterly	Yes

Section	Section	Element	Format	Frequency	HPMS
		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
		Total number of grievances	Numeric	Quarterly	Yes
		Total number of LIS grievances	Numeric	Quarterly	Yes
VII.	Pharmacy & Therapeutics Committees/ Provision of Part D Functions	Indicate if changes in P&T Committee membership.	Text	Quarterly	Yes
		If changes, indicate if these are reflected within Contract Management module.	Text	Quarterly	Yes
		Indicate if changes have occurred in organizations providing Part D functions.	Text	Quarterly	Yes
		If changes, indicate if these are reflected within Contract Management module.	Text	Quarterly	Yes
VIII.	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	One Quarter will be collected Annually	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	One Quarter will be collected Annually	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	One Quarter will be collected Annually	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	One Quarter will be collected Annually	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	One Quarter will be collected Annually	Yes

Section	Section	Element	Format	Frequency	HPMS
		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	One Quarter will be collected Annually	Yes
IX.	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
X.	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

Section	Section	Element	Format	Frequency	HPMS
		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
XI.	Overpayment	Total overpayment dollars identified to be recouped	Currency	Semi-Annually	Yes
		Total overpayment dollars recouped	Currency	Semi-Annually	Yes
XII.	Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions	REBATES_(SPONSORNAME)_(2008Q#).txt	Tab delimited text file	Quarterly	Yes
		DISCOUNTS_(SPONSORNAME)_(2008Q#).txt	Tab delimited text file	Quarterly	Yes
XIII.	Long-term Care (LTC) Rebates	REBATES_LTCPHARMACIES_(CONTRACT)_(2008Q#).txt	Tab delimited text file	Quarterly	Yes
XIV.	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 Contract PDPs)	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 Contract PDPs	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

Section	Section	Element	Format	Frequency	HPMS
		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 Contract PDPs	Mailed to CMS	Quarterly	No
		Copy of credit rating for Direct Contract PDPs	Mailed to CMS	Quarterly	No
		ERISA Sec. 411(a) attestation for Direct Contract PDPs s	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
XV.	Part D Benefit Analyses	Total number of non-LIS enrollees in the deductible phase	Numeric	Monthly	Yes
		Total number of LIS enrollees in the deductible phase	Numeric	Monthly	Yes
		Total number of non-LIS enrollees in the pre-initial coverage limit phase	Numeric	Monthly	Yes
		Total number of LIS enrollees in the pre-initial coverage limit phase	Numeric	Monthly	Yes
		Total number of non-LIS enrollees in the coverage gap	Numeric	Monthly	Yes
		Total number of LIS enrollees in the coverage gap	Numeric	Monthly	Yes
		Total number of non-LIS enrollees in the catastrophic coverage level	Numeric	Monthly	Yes
		Total number of non-LIS enrollees in the catastrophic coverage level	Numeric	Monthly	Yes

Table 2: Changes made from CY 2007 Reporting Requirements

	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
	Reversals	This section has been deleted.
IV.	Medication Therapy Management Programs	Data element revised: • Revised equation for Data Element L (in 2008) 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
V.	Generic Drug Utilization	The name of the section was changed from Generic Drug Rate in 2007.
VI.	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: • Total number of LIS grievances received related to Part D
VII.	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. • Additional introduction language. Description added: • Element A1. added during the time period specified above Data elements revised: • A1-2 - drop-down box is no longer used. Data elements added: • Data Element B added o Indicate if there have been changes to the organizations providing Part D functions o If changes have occurred, indicate if these changes

	Reporting Requirements Section	Changes
		have been reflected within the Contract Management module
VIII.	Transition	Reporting Timeline revised: • Changed from quarterly to only one quarter of data will be collected annually 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
IX.	Exceptions	Description revised: • Addition of language: Prior authorization requests/approvals that relate to Part B versus Part D coverage should be included in this report. Data elements revised: • Elements D and E added quantity limits as an example
X.	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
XI.	Overpayment	No changes made to this reporting section
XII.	Pharmaceutical Manufacturer	Upload process change:

	Reporting Requirements Section	Changes
	Rebates, Discounts, and Other Price Concessions	• In Sections A and B - a tab delimited field will now be upload as opposed to an excel file in 2007
XIII.	Long-term Care (LTC) Rebates	Upload process change: • a tab delimited field will now be uploaded as opposed to an Excel file in 2007 Description revised: • Exemption language for LTC Rebate was added for some pharmacies • Language added for non-compliant LTC pharmacies Data element revised in LTC Rebates File Record Layout: • NCPDP # - added language field should be a 7 character long string using 0 – 9. • Drug Name - 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
XIV.	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

	Reporting Requirements Section	Changes
		Part D PDP Contracts / Direct Contract PDPs: Section IV • This subsection moved to P&T Committee/Provision of Part D Functions section.
XV.	Drug benefit analyses	Reporting Timeline revised: • 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 data. Data elements added: • Total number of non-LIS enrollees in the deductible phase as of the last day of the month. • Total number of LIS enrollees in the deductible phase as of the last day of the month. • Total number of LIS enrollees in the pre-initial coverage limit phase as of the last day of the month • Total number of LIS enrollees in the coverage gap as of the last day of the month • Total number of LIS enrollees in the catastrophic coverage level as of the last day of the month.