

**Medicare Part D Plan Reporting Requirements:  
Technical Specifications Document  
Contract Year 2010**

**Effective Date: January 1, 2010**

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Last updated: January 2010

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## Introduction

The Part D Plan Reporting Requirements document provides a description of the reporting sections, reporting timeframes and deadlines, and specific data elements for each reporting section. The document has completed OMB review and approval in compliance with the Paper Reduction Act of 1995, and its OMB control number is #0938-0992. The document is located in HPMS under “In the News”, and posted on the CMS website.

For CY2010, there is no Overpayment reporting section. This section was dropped from the CY2009 Part D Reporting Requirements. As of December 2009, the following reporting sections were suspended because these data are being collected elsewhere, mostly through Prescription Drug Event (PDE) data:

- Vaccines,
- Generic Drug Utilization,
- Transition,
- Drug Benefit Analyses, and
- Agent Training and Testing

Additionally, the frequency of reporting was decreased for six reporting sections. The final CY2010 Part D Reporting Requirements incorporates all of these changes.

These technical specifications supplement the Part D Plan Reporting Requirements, and do not change, alter, or add to the data collection described above. They serve to further define data elements and alert Sponsors to how CMS will review and analyze these data.

The purposes of these technical specifications are to help assure a common understanding of the data to be reported by Sponsors, to assist Sponsors in preparing and submitting datasets, to ensure a high level of accuracy in the data reported to CMS, and to reduce the need for Sponsors to correct and resubmit data.

Each Part D reporting section is listed in this document with information regarding the following subjects.

- A. Data element definitions - details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.
- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- E. Notes - additional clarifications to a reporting section. This section incorporates previously answered frequently asked questions.

## General Information

### Level of Data to be Reported

The level of reporting for each section is specified in the reporting requirements document and within each section in HPMS. Sponsor-level reporting indicates data may be submitted from an organization that is associated with more than one CMS-issued Part D contract. Contract-level reporting indicates data should be entered at the H#, S#, R#, or E# level. Plan-level reporting indicates data should be entered at the PBP level, (e.g. Plan 001 for contract H#, R#, S#, or E). Plan-level reporting is necessary to conduct appropriate oversight and monitoring of some areas.

A summary of the reporting level required for each section is below.

REPORTING REQUIREMENT SECTION	LEVEL OF REPORTING
Enrollment	Contract
Retail, Home Infusion, and Long Term Care Pharmacy Access	Contract (elements A&B) Plan (elements C&D)
Access to Extended Day Supplies at Retail Pharmacies	Contract
Medication Therapy Management Programs (MTMP)	Contract
Prompt Payment by Part D Sponsors	Contract
Pharmacy Support by Electronic Prescribing	Contract
Grievances	Plan
Pharmacy & Therapeutics (P&T) Committees and Provision of Part D Functions	Contract
Coverage Determinations and Exceptions	Plan
Appeals	Plan
Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions	Sponsor or Contract
Long-Term Care (LTC) Utilization	Contract
Licensure and Solvency, Business Transactions, and Financial requirements	Contract
Fraud, Waste and Abuse Compliance Programs	Contract
Employer/Union-Sponsored Group Health Plan Sponsors	Plan
Plan Oversight of Agents	Contract

### Timely submission of data

Compliance with these reporting requirements is a contractual obligation of all Part D Sponsors. Compliance requires that the data not only be submitted in a timely manner, but that they also are accurate. Data submissions are due by 11:59 p.m. Pacific time on the date of the reporting deadline.

Only data that reflect a good faith effort by a Sponsor to provide accurate responses to Part D reporting requirements will count as data submitted in a timely manner. Sponsors must not submit “placeholder” data (e.g., submitting the value “0” in reporting fields in HPMS). Sponsors can expect CMS to rely more on compliance notices and enforcement actions in response to reporting requirement failures. Therefore, CMS may issue warning notices or

requests for corrective action plans to non-compliant Sponsors. Should the non-compliance persist, CMS may impose intermediate sanctions (e.g., suspension of marketing and enrollment activities) or civil monetary penalties pursuant to Subpart O of 42 C.F.R. Part 423 or contract termination pursuant to Subpart K of 42 C.F.R. Part 423.

If previously submitted data are incorrect, Part D Sponsors should request the opportunity to correct and resubmit data. Part D Sponsors are not responsible for updating previously submitted sections such as pharmaceutical manufacturer rebates or LTC rebates in which CMS expects Part D Sponsors to receive reconciled data. Part D Sponsors are, however, responsible for correcting previously submitted data if it is determined the data were erroneous. Data corrections may be submitted up to December 31<sup>st</sup> of the year following the last required due date.

Once a reporting deadline has passed, CMS requires the Part D Sponsor to submit a formal request to resubmit any data. HPMS designates this request as a Request Resubmission. Requests for resubmissions will only be approved for 7 days from the date the request is reviewed and approved by CMS. Sponsors should not submit requests to resubmit data until they have data available to submit. Data submitted after the given reporting period deadline shall be considered late, and may not be incorporated within CMS data analyses and reporting. HPMS will not allow the resubmission of data that are identical to the original data submission.

CMS tracks resubmissions, including the number of resubmissions after the deadline. Failure to resubmit after requesting a resubmission is considered as overdue. CMS expects that data are accurate on the date they are submitted. Data resubmissions must be completed by December 31<sup>st</sup> of the year following the last required due date. However, CMS urges Plans to store revised data for CMS auditors.

The following steps must be followed by a Part D Sponsor to request resubmission:

1. On the HPMS Part D Plan Reporting Start Page, click the Resubmission Request link.
2. Select/complete the following:
  - a. Reporting section (e.g. Appeals);
  - b. Time period (e.g., 1<sup>st</sup> quarter 2010);
  - c. Select contracts or plans, depending on reporting level; and
  - d. The reason for the resubmission request.
3. CMS will review the information provided and either accept or reject the request for resubmission.

### **General Data Entry Rules**

HPMS will not allow the entry of greater than sign (>); less than sign (<); or semi-colon (;) in any data entry field or uploaded file.

Unless otherwise noted,

- the entry of a zero is allowed,
- the entry of a negative is not allowed, and
- decimals are not allowed.

## **Exclusions from Reporting**

The Part D reporting requirements apply to Part D Sponsors offering the Part D benefit, including PDPs and MA-PDs. They do not apply to MA only Plans. Data relating to Part B claims should be excluded from these Part D reports, unless otherwise specified. (For example, Coverage Determinations and Exceptions reporting includes Part B related data elements). 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, the Employer/Union-Sponsored Group Health Plan Sponsors reporting section, and the Plan Oversight of Agents reporting section. PACE Organizations are excluded from these Part D reporting requirements.

Based on the information in the Reporting Requirements document and these Technical Specifications, Plans/Sponsors should report data based on interpretation of these documents and be able to support their reporting decisions. Additional formal CMS guidance is not provided outside of these public documents.

General questions about Part D reporting requirements should be sent via email to: [partd-planreporting@cms.hhs.gov](mailto:partd-planreporting@cms.hhs.gov).

## I. Enrollment

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

Element Letter	Element Name	Definition	Allowable Values
A.	Total number of enrollment requests received.	The total number of enrollment requests received in the specified time period.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
B.	Total number of enrollment requests denied due to the Plan's determination of the ineligibility of the individual to elect the plan.	Of the total reported in A, the number of enrollment requests denied due to the Plan's determination of the ineligibility of the individual to elect the plan (e.g. individual not having a valid enrollment period to elect a plan).	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Should be a subset of A.</li> </ul>
C.	Total number of enrollment requests denied due to the individual not providing information to complete the enrollment request within established timeframes.	Of the total reported in A, the number of enrollment requests denied due to the individual not providing information to complete the enrollment request within established timeframes.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Should be a subset of A.</li> </ul>
D.	Total number of incomplete enrollment requests received that are successfully completed within established timeframes.	Of the total reported in A, the number of incomplete enrollment requests received that are successfully completed within established timeframes.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Should be a subset of A.</li> </ul>
E.	Number of enrollment transactions	The number of enrollment transactions submitted using the "Special Enrollment	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
	submitted using the “Special Enrollment Period” (SEP) Election Period code "S" for Other SEP that are related to contract changes.	Period” (SEP) Election Period code "S" for Other SEP that are related to contract changes. This includes Sections 20.3.4, 20.3.8.2, 20.3.8.3 of the PDP Guidance - Eligibility, Enrollment and Disenrollment, and Sections 30.4.3, 30.4.4.2, 30.4.4.3 in Chapter 2: Medicare Advantage Enrollment and Disenrollment of the Medicare Managed Care Manual.	
F.	Number of enrollment transactions submitted using the “Special Enrollment Period” (SEP) Election Period code "S" for Other SEP that are related to a change in the beneficiaries’ eligibility or status.	The number of enrollment transactions submitted using the “Special Enrollment Period” (SEP) Election Period code "S" for Other SEP that are related to a change in the beneficiaries’ eligibility or status. This includes Sections 20.3.8.6, 20.3.8.8.A, 20.3.8.8.B, 20.3.8.8.F, 20.3.8.8.G, 20.3.8.13 of the PDP Guidance - Eligibility, Enrollment and Disenrollment, and Sections 30.4.4.6, 30.4.4.7, 30.4.4.8, 30.4.4.13, 30.4.5 in Chapter 2: Medicare Advantage Enrollment and Disenrollment of the Medicare Managed Care Manual.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
G.	Number of enrollment transactions submitted using the “Special Enrollment Period” (SEP) Election Period code "S" for Other SEP related to credible coverage.	The number of enrollment transactions submitted using the “Special Enrollment Period” (SEP) Election Period code "S" for Other SEP related to credible coverage. This includes Sections 20.3.5, 20.3.6, 20.3.8.11 of the PDP Guidance - Eligibility, Enrollment and Disenrollment, and Sections 30.4.4.5, 30.4.4.14 in Chapter 2: Medicare Advantage	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
		Enrollment and Disenrollment of the Medicare Managed Care Manual.	
H.	Number of enrollment transactions submitted using the "Special Enrollment Period" (SEP) Election Period code "S" for Other SEP related to Special Plan types and situations such as Special Needs Plans, PACE Plans, Institutions, SPAP.	The number of enrollment transactions submitted using the "Special Enrollment Period" (SEP) Election Period code "S" for Other SEP related to Special Plan types and situations such as Special Needs Plans, PACE Plans, Institutions, SPAP. This includes Sections 20.3.8.4, 20.3.8.5, 20.3.8.8.C, 20.3.8.12, 20.3.8.9 of the PDP Guidance - Eligibility, Enrollment and Disenrollment, and Sections 30.4.4.4, 30.4.4.9, 30.4.4.10, 30.4.4.11 in Chapter 2: Medicare Advantage Enrollment and Disenrollment of the Medicare Managed Care Manual.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
I.	Total number of enrollment transactions submitted using the "Special Enrollment Period" (SEP) Election Period code "S" for Other SEP that coordinate with the Medicare Advantage open enrollment period.	The total number of enrollment transactions submitted using the "Special Enrollment Period" (SEP) Election Period code "S" for Other SEP that coordinate with the Medicare Advantage open enrollment period. This includes Sections 20.3.8.8.D, 20.3.8.8.E of the PDP Guidance - Eligibility, Enrollment and Disenrollment.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
J.	Total number of enrollment transactions submitted using the "Special Enrollment	The total number of enrollment transactions submitted using the "Special Enrollment Period" (SEP) Election Period code "S" for Other SEP that are not	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
	Period" (SEP) Election Period code "S" for Other SEP that are not included above.	included above.	

- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
  - N/A.
  
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
  - N/A.
  
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
  - To be determined.
  
- E. Notes – additional clarifications to a reporting section.
  - N/A.

## II. Retail, Home Infusion, and Long Term Care Pharmacy Access

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

I. Retail Pharmacy Access: Data elements to be entered into the HPMS at the CMS Contract level:

Element Letter	Element Name	Definition	Allowable Values
A	Percentage of Beneficiaries Living within 2 Miles of a Network Pharmacy in Urban Areas	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 contracts) as of the last day of the reporting period.	<ul style="list-style-type: none"> <li>Should be reported as a percent less than or equal to 100.</li> <li>Field type: Number.</li> </ul>
B	Percentage of Beneficiaries Living within 5 Miles of a Network Pharmacy in Suburban Areas	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 contracts) as of the last day of the reporting period.	<ul style="list-style-type: none"> <li>Should be reported as a percent less than or equal to 100.</li> <li>Field type: Number.</li> </ul>
C	Percentage of Beneficiaries Living within 15 Miles of a Network Pharmacy in Rural Areas	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 contracts) as of the last day of the reporting period.	<ul style="list-style-type: none"> <li>Should be reported as a percent less than or equal to 100.</li> <li>Field type: Number.</li> </ul>
D	Total Number of Contracted Retail Pharmacies in Plan's Service Area	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 contracts) as of the last day of the reporting period.	<ul style="list-style-type: none"> <li>Should be reported as a percent less than or equal to 100.</li> <li>Field type: Number.</li> </ul>

II. Home Infusion and Long Term Care (LTC) Pharmacy Access: Two Excel data files to be uploaded through the HPMS at the CMS Part D Contract level.

- The file name extension should be ".xls"

- File name=Pharmacies\_(HI or LTC)\_(CONTRACTNAME)\_(CONTRACTYEAR).xls
- Replacing '(HI or LTC)' with the corresponding type of pharmacies
  - Pharmacies\_(HI)\_(CONTRACTNAME)\_(CONTRACTYEAR).xls
  - Pharmacies\_(LTC)\_(CONTRACTNAME)\_(CONTRACTYEAR).xls
- And also replacing '(CONTRACTNAME)' with the Part D Contract's name, and CONTRACTYEAR) with the year.

### Home Infusion Record Layout

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
NCPDP_or_NPI_Number	CHAR Always Required	Exactly 7 or exactly 10	Indicate the contracted Home Infusion pharmacy NCPDP number (exactly 7 digits), or indicate the NPI number (exactly 10 digits) if the NCPDP number is not available.	1024510 or 1234567809
Pharmacy_Name	CHAR Always Required	150	Provide the name of the Home Infusion pharmacy.	CVS Pharmacy
Pharmacy_Street_Address	CHAR Always Required	150	Enter the street address of the pharmacy.	1212 North Luther Street
Pharmacy_City_Address	CHAR Always Required	75	Enter the city in which the pharmacy is located.	Wichita
Pharmacy_State_Address	CHAR Always Required	2	Enter the state abbreviation in which the pharmacy is located.	MO
Pharmacy_Zip_Address	CHAR Always Required	10	Enter the pharmacy's zip code.	22203

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
States_Licensed	CHAR Always Required	No Limit	<p>Enter the states in which the pharmacy is licensed. Use the state abbreviation.</p> <p>This field should be comma-delimited; state abbreviations should be separated with a comma.</p> <p>Please note: the contract must have at least one pharmacy licensed in each state that is covered in the contract's service area.</p>	MA, VA, KS
Pharmacy_Network_Type_PN	CHAR Always Required	1	Is the pharmacy network preferred?	P = Preferred N = Non-Preferred
Chain_YN	CHAR Always Required	1	Is the pharmacy a chain?	N = No Y = Yes
Independent_YN	CHAR Always Required	1	Is the pharmacy independent?	N = No Y = Yes
Group_Purchasing_YN	CHAR Always Required	1	Does the pharmacy allow group purchasing?	N = No Y = Yes

### LTC Pharmacy Record Layout

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
NCPDP_or_NPI_Number	CHAR Always Required	Exactly 7 or Exactly 10	Indicate the contracted LTC pharmacy NCPDP number (exactly 7 digits), or indicate the NPI number (exactly 10 digits) if the NCPDP number is not available.	1024510 or 1234567809
Pharmacy_Name	CHAR Always Required	150	Provide the name of the LTC pharmacy.	CVS Pharmacy
Pharmacy_Street_Address	CHAR Always Required	150	Enter the street address of the pharmacy.	1212 North Luther Street
Pharmacy_City_Address	CHAR Always Required	75	Enter the city in which the pharmacy is located.	Wichita
Pharmacy_State_Address	CHAR Always Required	2	Enter the state abbreviation in which the pharmacy is located.	MO
Pharmacy_Zip_Address	CHAR Always Required	10	Enter the pharmacy's zip code.	22203

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
States_Licensed	CHAR Always Required	No Limit	Enter the states in which the pharmacy is licensed. Use the state abbreviation.  This field should be comma-delimited; state abbreviations should be separated with a comma.  Please note: the contract must have at least one pharmacy in each state that is covered in the contract's service area.	MA, VA, KS
Pharmacy_Network_Type_PN	CHAR Always Required	1	Is the pharmacy network preferred?	P = Preferred N = Non-Preferred
Chain_YN	CHAR Always Required	1	Is the pharmacy a chain?	N = No Y = Yes
Independent_YN	CHAR Always Required	1	Is the pharmacy independent?	N = No Y = Yes
Group_Purchasing_YN	CHAR Always Required	1	Does the pharmacy allow group purchasing?	N = No Y = Yes

III. Sponsors receiving pharmacy access waivers: 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.

Element Letter	Element Name	Definition	Allowable Values
A	Number of prescriptions provided by all pharmacies owned and operated	Number of prescriptions provided in the time period by all pharmacies owned and operated.	<ul style="list-style-type: none"> <li>Should be mutually exclusive.</li> <li>Field type: Number.</li> </ul>
B	Number of prescriptions provided at all pharmacies contracted	Number of prescriptions provided in the time period at all pharmacies contracted.	<ul style="list-style-type: none"> <li>Should be mutually exclusive.</li> <li>Field type: Number.</li> </ul>

IV. Sponsors receiving pharmacy access waivers: Data elements to be entered into the HPMS at the Plan (PBP) level for only those MA-PD and cost plans that own and operate their own retail pharmacies and have received a waiver of the retail pharmacy convenient access standards. These plans are not exempt from reporting Retail Pharmacy Access listed above.

Element Letter	Element Name	Definition	Allowable Values
A	Number of prescriptions provided by retail pharmacies owned and operated	Number of prescriptions provided in the time period by retail pharmacies owned and operated.	<ul style="list-style-type: none"> <li>Should be mutually exclusive.</li> <li>Field type: Number.</li> </ul>
B	Number of prescriptions provided at all retail pharmacies contracted	Number of prescriptions provided in the time period at all retail pharmacies contracted.	<ul style="list-style-type: none"> <li>Should be mutually exclusive.</li> <li>Field type: Number.</li> </ul>

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.

- As stated in the Part D application, Sponsors must establish and maintain retail pharmacy networks as follows.
  - In urban areas, at least 90 percent of Medicare beneficiaries in the Plan's service area, on average, live within 2 miles of a retail pharmacy participating in the Plan's network;
  - In suburban areas, at least 90 percent of Medicare beneficiaries in the Plan's service area, on average, live within 5 miles of a retail pharmacy participating in the Plan's network; and

- In rural areas, at least 70 percent of Medicare beneficiaries in the Plan’s service area, on average, live within 15 miles of a retail pharmacy participating in the Plan’s network.
  - Sponsors may count I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers and Rural Health Centers towards the standards of convenient access to retail pharmacy networks.
  - Sponsors must establish and maintain Home Infusion and Long Term Care Pharmacy Access. CMS will re- evaluate home infusion and long term care pharmacy access by applying the same ratios used for initial Part D applications
  - CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- Percentages should not be greater than 100%.
  - For section I, element A, element B and element C must be less than or equal to 100.
  - For section II, the States Licensed field must include ALL states in the plan's service area. Note, a contract with both individual plans in particular states and 800 series plans with national coverage will be required to report data only for the states in the individual plan’s service area. If a contract only includes 800 series plans, they will be required to report data for all states.
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- CMS will evaluate to ensure access standards are met.
- E. Notes – additional clarifications to a reporting section.
- Employer groups are not exempt from this reporting section.
  - The HI and LTC pharmacy network templates can be found in the HPMS reporting module, under Documentation -> Download File Templates.
  - The download entitled Beneficiary Count Data is a national file used for PDP and MA-PD sponsors, and is updated annually. The file is posted on the Prescription Drug Contracting section of CMS’ website in January. To locate the file on the web, go to <http://www.cms.hhs.gov/PrescriptionDrugCovContra/> , and click on the application guidance link on the left side navigation bar.
  - For subsection II. Home Infusion and Long Term Care (LTC) Pharmacy Access, HPMS will allow the entry of either NCPDP # (7 digits) or NPI # (10 digits) into the “NCPDP\_or\_NPI\_Number field”. Thus, exactly 7 characters or exactly 10 characters must be entered in this field.

### III. Access to Extended Day Supplies at Retail Pharmacies

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

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

Element Letter	Element Name	Definition	Allowable Values
A	Number of contracted retail pharmacies that are contracted to dispense an extended day supply of covered Part D drugs.	The number of contracted retail pharmacies in a Contract's service area that are contracted to dispense an extended day supply of covered Part D drugs as of the last day of the reporting period. PDPs and regional PPOs will report by State for PDPs and regional PPOs, and by service area for local MA-PD plans.	<ul style="list-style-type: none"> <li>Should not be greater than the contract's total number of contracted retail pharmacies.</li> <li>Field type: Number.</li> </ul>

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.

- Data should be a whole number.
- Data should have a value that is less than or equal to data element A. 4 in Section I.
- CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.

C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.

- Should not be greater than the contract's total number of contracted retail pharmacies.

D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.

- CMS will evaluate access to extended day supplies at contracted retail pharmacies by:
  - calculating a ratio of the total number of contracted retail pharmacies that are contracted to dispense an extended day supply of covered Part D drugs to the total number of contracted retail pharmacies in a plan's service area, which is data element A. D in Section I; and
  - conducting an outlier test relative to all other contracts.

E. Notes – additional clarifications to a reporting section.

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

Part D drugs. CMS considers an extended day supply to be any days supply provided that is greater than the number of days identified by a Part D contract as constituting a one-month supply. We note that a one-month supply cannot exceed 34 days.

- If a contract has in its network any mail-order pharmacies that offer extended day supplies, it must offer extended day supplies at some retail pharmacies in its network and must report how many of its network retail pharmacies offer this benefit.
- Contracts that do not have network mail-order pharmacies that offer extended day supplies are exempt from reporting; therefore HPMS will not display this section to exempt contracts.
- This reporting requirement does not apply to 800 series Employer Plans, even when extended day supplies are offered.
- The term “contracted retail pharmacies” means the number of contracted retail pharmacies within a contract’s service area. If the contract has a national service area, the contract would report a total number of pharmacies in their national network. However, if the contract does not have a national service area, the contract should not report a total number of pharmacies in their national network.

#### IV. Medication Therapy Management Programs (MTMP)

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

The following data elements are entered into HPMS at the CMS Contract level.

Element Letter	Element Name	Definition	Allowable Values
A	Total number of beneficiaries identified to be eligible for, and was automatically enrolled in, the MTMP.	The total number of beneficiaries identified to be eligible for, and was automatically enrolled in, the MTMP. This should be a longitudinally cumulative total.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
B	Total number of beneficiaries who opted-out of enrollment in the MTMP.	The total number of beneficiaries who opted-out of enrollment in the MTMP during the time period specified above. This should be a longitudinally cumulative total, and be a subset of the number of beneficiaries identified to be eligible for, and were automatically enrolled in, the MTMP in the specified time period. Ex. Out of 800 beneficiaries eligible for MTMP, 100 beneficiaries opted out.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>This should be a subset of A.</li> <li>This should be the sum of element C through element F.</li> </ul>
C	The number of beneficiaries who opted-out of enrollment in the MTMP due to death.	This should be a subset of the total number of beneficiaries who opted-out of enrollment in the MTMP in the specified time period. Ex. Out of 100 beneficiaries that opted-out of MTMP, 10 opted-out due to death.	<ul style="list-style-type: none"> <li>This should be a subset of B.</li> <li>Field type: Number.</li> </ul>
D	The number of beneficiaries who opted-out of enrollment in the MTMP due to disenrollment from the Plan.	This should be a subset of the total number of beneficiaries who opted-out of enrollment in the MTMP. Ex. Out of 100 beneficiaries that opted-out of MTMP, 70 opted-out due to disenrollment	<ul style="list-style-type: none"> <li>This should be a subset of B.</li> <li>Field type: Number.</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
		from the plan.	
E	The number of beneficiaries who opted-out of enrollment in the MTMP at their request.	This should be a subset of the total number of beneficiaries who opted-out of enrollment in the MTMP. Ex. Out of 100 beneficiaries that opted-out of MTMP, 15 opted-out at their request	<ul style="list-style-type: none"> <li>• This should be a subset of B.</li> <li>• Field type: Number.</li> </ul>
F	The number of beneficiaries who opted-out of enrollment in the MTMP for a reason not specified in data elements C-E during the specified time period above.	This should be a subset of the total number of beneficiaries who opted-out of enrollment in the MTMP in the specified time period. Ex. Out of 100 beneficiaries that opted-out of MTMP, 5 opted-out due to other reasons.	<ul style="list-style-type: none"> <li>• This should be a subset of B.</li> <li>• Field type: Number.</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
G	Total Part D Prescription Cost for MTMP Enrollees (per MTMP enrollee per month)	<p>For beneficiaries enrolled in the MTMP, provide the prescription cost of all covered Part D medications on a per MTMP beneficiary per month basis.</p> <p>Numerator = total prescription drug costs. The total prescription cost should be limited to covered Part D medications and be calculated using gross drug cost as follows: (Ingredient Cost Paid + Dispensing Fee + Sales Tax). This is based on the sum of all Part D covered prescriptions that were dispensed within the reporting period specified for each beneficiary enrolled in the MTMP as of the last day of the reporting period. This includes both MTMP beneficiary cost sharing and Part D costs paid.</p> <p>Denominator = total number of member months for the MTMP enrolled beneficiaries. These member months should include all months the beneficiary was enrolled in the plan during the reporting period specified, not only the months that the beneficiary enrolled in the MTMP.</p> <p>Ex. The total MTMP cost per MTMP beneficiary per month is \$500.</p>	<ul style="list-style-type: none"> <li>• Value is in currency, rounded to the nearest dollar.</li> <li>• Field type: Currency.</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
H	Total Number of 30-day Prescriptions Equivalents (per MTMP enrollee per month)	<p>For beneficiaries enrolled in the MTMP the number of covered Part D 30-day equivalent prescriptions on a per MTMP beneficiary per month basis.</p> <p>Numerator is calculated by first summing days supply of all covered Part D prescriptions dispensed for beneficiaries enrolled in MTMP as of the last day of the reporting period, and dividing by 30 to determine the number of 30 day equivalent prescriptions dispensed.</p> <p>Denominator = total number of member months for the MTMP enrolled 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. Ex. The total 30 day equivalent Prescriptions per MTMP beneficiary per Month is 4.</p>	<ul style="list-style-type: none"> <li>• Up to two decimals may be entered.</li> <li>• Field type: Number.</li> </ul>
I	For beneficiaries enrolled in the MTMP at any time during the specified time period above, the number of beneficiaries offered a comprehensive medication review.	A comprehensive medication review (CMR) must be offered at least annually to all targeted beneficiaries enrolled in the MTM program. Please refer to the 2010 Call Letter for more information about MTMP requirements.	<ul style="list-style-type: none"> <li>• This should be a subset of A.</li> <li>• Field type: Number.</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
J	For beneficiaries enrolled in the MTMP at any time during the specified time period above, the number of beneficiaries who received a comprehensive medication review.	This number may be less than or equal to the number of beneficiaries offered a CMR.	<ul style="list-style-type: none"> <li>This should be a subset of I.</li> <li>Field type: Number.</li> </ul>

A data file containing the following fields for beneficiaries identified as being eligible for the Medication Therapy Management Program will be uploaded using Gentran or Connect Direct: You must not include additional information outside of what is dictated in the record layout. You must not include a header row. Submissions that do not strictly adhere to the record layout will be rejected.

Beneficiaries Eligible for MTM Record Layout					
Field Name	Field Type	Field Length	Start Position	End Position	Field Description
Contract Number	CHAR REQUIRED	5	1	5	The Contract Number (e.g., H1234, S1234) for your organization.
HICN or RRB Number	CHAR REQUIRED	12	6	17	For each beneficiary identified to be eligible for MTM in the reporting period, provide the unique number that the Social Security Administration assigns to each Medicare beneficiary, which is the Health Insurance Claim number (HICN). For Railroad Retirement Board (RRB) beneficiaries, provide the RRB number in this field instead of the HICN.
Beneficiary First Name	CHAR REQUIRED	30	18	47	The first name of each beneficiary identified to be eligible for MTM in the reporting period.

Beneficiaries Eligible for MTM Record Layout					
Field Name	Field Type	Field Length	Start Position	End Position	Field Description
Beneficiary Middle Initial	CHAR OPTIONAL	1	48	48	The middle initial of each beneficiary identified to be eligible for MTM in the reporting period.
Beneficiary Last Name	CHAR REQUIRED	30	49	78	The last name of each beneficiary identified to be eligible for MTM in the reporting period.
Beneficiary Date of Birth	DATE REQUIRED	8	79	86	The date of birth for each beneficiary identified to be eligible for MTM in the reporting period (CCYYMMDD, e.g., 19400101).
LTC Enrollment	CHAR REQUIRED	1	87	87	For each beneficiary eligible for MTM, indicate if the beneficiary was a long-term care (LTC) resident for the entire time they were enrolled in MTM. This should be Y (yes), N (no), or U (unknown). <i>If the beneficiary opted-out of MTM enrollment, indicate whether they were an LTC resident with Y (yes), N (no), or U (unknown).</i>
Date of MTM Enrollment	DATE REQUIRED	8	88	95	For each beneficiary identified to be eligible for the MTM in the reporting period, the date they were automatically enrolled (CCYYMMDD, e.g., 19400101).
Date MTM Opt-out, if applicable	DATE Conditionally REQUIRED	8	96	103	This should be a date field (CCYYMMDD, e.g., 19400101). <i>The date must be provided if the beneficiary opted out of MTM.</i>

Beneficiaries Eligible for MTM Record Layout					
Field Name	Field Type	Field Length	Start Position	End Position	Field Description
Reason Participant Opted-out of MTM, if applicable	CHAR Conditionally REQUIRED	02	104	105	For each beneficiary with a disposition status of opted out of MTM, the reason must be provided. Reasons for opting out must be one of the following: 01 - Death; 02 - Disenrollment from Plan; 03 - Request by beneficiary; or 04 - Other.  Note: If Date MTM Opt-out is provided, then Reason participant Opted-out of MTM is required.
Received annual comprehensive medication review	CHAR REQUIRED	1	106	106	For each beneficiary enrolled in MTM, indicate if the beneficiary received an annual comprehensive medication review. This should be Y (yes), or N (no).
Date of annual comprehensive medication review, if applicable	DATE Conditionally REQUIRED	8	107	114	This should be a date field (CCYYMMDD, e.g., 20100601). <i>The date must be provided if the beneficiary received an annual comprehensive medication review.</i>
Number of targeted medication reviews	CHAR REQUIRED	2	115	116	For each beneficiary enrolled in MTM, indicate the number of targeted medication reviews conducted. This should be a numeric field.
Number of prescriber interventions	CHAR REQUIRED	2	117	118	For each beneficiary enrolled in MTM, indicate the number of prescriber interventions made. This should be a numeric field.
Number of changes to drug therapy made as a result of MTM interventions	CHAR REQUIRED	2	119	120	For each beneficiary enrolled in MTM, indicate the number of changes to drug therapy as a result of MTM interventions. Changes include dosage changes, therapeutic or generic substitutions, and discontinuation of therapy. This should be a numeric field.

- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- Any contract with greater than \$2,000 drug cost per MTMP beneficiary per month will be flagged as an outlier.
  - Any contract with greater than 20 scripts per MTMP beneficiary per month will be flagged as an outlier.
  - The percent of MTM eligibility will be compared to the contracts enrollment as well as the average eligibility for all contracts.
  - CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- The sum of data elements C+D+E+ F should equal data element B.
  - Data Element H may be two decimal points.
  - Data element A should not be greater than the contract's enrollment.
  - If "Date Participant Opted-out of MTM" is provided, then "Reason participant Opted-out of MTM" is required.
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- CMS will evaluate the percentage of beneficiaries enrolling in MTMPs relative to cost and number of prescriptions.
  - CMS will also evaluate the percent of beneficiaries that opt-out of MTM.
  - CMS will evaluate the percent of beneficiaries who are offered and receive a comprehensive medication review.
  - CMS will evaluate initial MTM outcomes, as reported as prescriber interventions and changes to drug therapy.
- E. Notes – additional clarifications to a reporting section.
- The period of MTMP eligibility and enrollment is a contract year, therefore eligibility, enrollment, etc. are counted and reported distinctly for each contract year. A beneficiary may be reported for multiple program years if they remain eligible for MTMP. At the start of each contract year, beneficiaries who continue to meet the eligibility criteria should be automatically enrolled in MTMP. Beneficiaries who no longer meet the eligibility criteria at the start of the new MTM program year would not be automatically enrolled.
  - Members who receive MTMP services outside of the CMS required MTM criteria defined by the plan should be excluded from this reporting.
  - Sponsors have discretion in the designation of a data source in order to complete the "LTC Enrollment" field of the MTMP beneficiary level data file. Sponsors must be able to present rationale for this designation.
  - Sponsors should refer to Chapter 5, Section 10.2 of the Prescription Drug Benefit Manual for a description of the types of facilities which should be considered LTC.

## V. Prompt Payment by Part D Sponsors

- Data element definitions - details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

Element Letter	Element Name	Definition	Allowable Values
A.	Total number of paid claims.	The total number of paid claims.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
B.	Total number of paid electronic claims.	The total number of paid electronic claims.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Should be a subset of A.</li> </ul>
C.	Total number of paid non-electronic claims.	The total number of paid non-electronic (e.g. paper) claims.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Should be a subset of A.</li> </ul>
D.	Total number of paid electronic claims which were not paid timely.	The total number of paid electronic claims which were not paid timely, according to appropriate time-periods.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Should be a subset of B.</li> </ul>
E.	Number of paid non-electronic claims which were not paid timely	The total number of paid non-electronic claims which were not paid timely, according to appropriate time-periods.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Should be a subset of C.</li> </ul>
F.	Interest amount paid on electronic claims that were not paid timely.	The interest dollar amount paid on electronic claims that were not paid timely.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
G.	Interest amount paid on non-electronic claims that were not paid timely.	The interest dollar amount paid on non-electronic claims that were not paid timely.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>

- QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.

- Plans that are in the 95<sup>th</sup> percentile for any element rate will be flagged as an outlier.
- Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
  - The sum of elements B and C should be equal to element A.
- Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
  - To be determined.
- Notes - additional clarifications to a reporting section. This section incorporates previously answered frequently asked questions.
  - N/A.

## VI. Pharmacy Support of Electronic Prescribing

A. Data element definitions - details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

Element Letter	Element Name	Definition	Allowable Values
A.	Number of retail pharmacies in a Contract's service area enabled to receive electronic prescriptions in compliance with Part D standards.	The number of retail pharmacies in a Contract's service area (by State for PDPs and regional PPOs, and by service area for local MA-PD plans) enabled to receive electronic prescriptions in compliance with Part D standards as of the last day of the reporting period specified.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
B.	Number of long-term care pharmacies in a Contract's service area enabled to receive electronic prescriptions in compliance with Part D standards.	The number of long-term care pharmacies in a Contract's service area (by State for PDPs and regional PPOs, and by service area for local MA-PD plans) enabled to receive electronic prescriptions in compliance with Part D standards as of the last day of the reporting period specified.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
C.	Number of home infusion pharmacies in a Contract's service area enabled to receive electronic prescriptions in compliance with Part D standards.	The number of home infusion pharmacies in a Contract's service area (by State for PDPs and regional PPOs, and by service area for local MA-PD plans) enabled to receive electronic prescriptions in compliance with Part D standards as of the last day of the reporting period specified.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.

- N/A.

- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- Ensure data reported for this section are consistent with data reported in the Retail, Home Infusion, and Long-Term Pharmacy Access reporting section.
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- These data will be analyzed with other Sponsor-reported data, including lists of contracted retail, LTC, and HI network pharmacies from the Retail, Home Infusion, and Long-Term Pharmacy Access reporting section, in order to determine the percentage of pharmacies enabled to receive electronic prescriptions.
- E. Notes - additional clarifications to a reporting section. This section incorporates previously answered frequently asked questions.
- N/A.

## VII. Grievances

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

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

Element Letter	Element Name	Definition	Allowable Values
A	Number of LIS beneficiaries who filed grievances.	The number of LIS beneficiaries who filed grievances.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
B	Number of non-LIS beneficiaries who filed grievances.	The number of non-LIS beneficiaries who filed grievances. Non-LIS beneficiaries are beneficiaries that do not receive low-income subsidies (LIS).	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
C	Number of grievances filed by LIS beneficiaries.	The number of grievances filed by LIS beneficiaries. A beneficiary may have filed more than one grievance.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
	Number of grievances filed by LIS beneficiaries which the Sponsor provided timely notification of its decision.	Of the grievances filed by LIS beneficiaries, the number that the Sponsor provided timely notification of its decision.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Should be a subset of the number of grievances filed by LIS beneficiaries.</li> </ul>
	Number of grievances filed by non-LIS beneficiaries.	The number of grievances filed by non-LIS beneficiaries. A beneficiary may have filed more than one grievance.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
	Number of grievances filed by non-LIS beneficiaries which the Sponsor provided timely notification of its decision.	Of the grievances filed by non-LIS beneficiaries, the number that the Sponsor provided timely notification of its decision.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Should be a subset of the number of grievances filed by non-LIS beneficiaries.</li> </ul>
D	Number of Enrollment,	The number of enrollment, plan benefits, or pharmacy	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
	Plan Benefits, or Pharmacy Access Grievances	access grievances received.	
	Number of Enrollment, Plan Benefits, or Pharmacy Access Grievances which the Sponsor provided timely notification of its decision.	Of the enrollment, plan benefits, or pharmacy access grievances received, the number that the Sponsor provided timely notification of its decision.	<ul style="list-style-type: none"> <li>• Field type: Number.</li> <li>• Should be a subset of the enrollment, plan benefits, or pharmacy access grievances received.</li> </ul>
	Number of Customer Service Grievances	The number of customer service grievances received.	<ul style="list-style-type: none"> <li>• Field type: Number.</li> </ul>
	Number of Customer Service Grievances which the Sponsor provided timely notification of its decision.	Of the customer service grievances received, the number that the Sponsor provided timely notification of its decision.	<ul style="list-style-type: none"> <li>• Field type: Number.</li> <li>• Should be a subset of the customer service grievances received.</li> </ul>
	Number of Coverage determinations/ Exceptions and Appeals process (e.g. untimely decisions) Grievances	Number of coverage determinations/exceptions and appeals grievances received.	<ul style="list-style-type: none"> <li>• Field type: Number.</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
	Number of Coverage determinations/ Exceptions and Appeals process (e.g. untimely decisions) Grievances which the Sponsor provided timely notification of its decision.	Of the coverage determinations/exceptions and appeals grievances received, the number that the Sponsor provided timely notification of its decision.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Should be a subset of the coverage determinations/exceptions and appeals grievances received.</li> </ul>
	Number of Other Grievances	Number of other grievances received.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
	Number of Other Grievances which the Sponsor provided timely notification of its decision.	Of the other grievances received, the number that the Sponsor provided timely notification of its decision.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Should be a subset of the other grievances received.</li> </ul>

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.

- Plans that are in the 95th or 5th percentile for any grievance element rate per 1,000 enrollees will be flagged as an outlier.
- A total grievance rate greater than 1,000 grievances per 1,000 enrollees will be considered an outlier.
- CMS will evaluate the total number of grievances for which the plan sponsor provided timely notification of its decision in comparison to the total number of grievances reported.
- CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.

C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.

- Confirm those data elements listed above as subsets of other elements.

D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.

The total grievance rate per 1,000 enrollees is equal to the sum of the total number of grievances divided by average enrollments, multiplied by 1,000.

$$\text{Total Grievance Rate per 1,000 enrollees} = \frac{\text{Total \# Grievances}}{\text{Avg. Enrollment}} \times 1,000$$

The grievance rate by category per 1,000 enrollees is equal to the sum of the grievance element divided by average enrollment, multiplied by 1,000.

$$\text{Grievance Rate by Category per 1,000 enrollees} = \frac{\text{Grievance Element}}{\text{Avg. Enrollment}} \times 1,000$$

- CMS will order plans based on rates of grievances per 1,000 enrollees and determine the percentile ranking.
- CMS will also correlate grievances with complaints in the CMS complaints tracking module (CTM).

E. Notes – additional clarifications to a reporting section.

- Data element A is different than the number of grievances filed by LIS beneficiaries, and data element B is different than the number of grievances filed by non-LIS beneficiaries. Data elements A and B are the numbers of beneficiaries that file grievances, which may not be equivalent to the total number of grievances filed by each beneficiary group.
- All grievances filed with a PBP should be counted in a category. Grievances may be filed by enrollees or appointed representatives.
- Grievances should be categorized by the type of grievance as determined by the PBP, and reported based on the time period they were received by the PBP, or in the first available report to CMS.
- An enrollee's request for a coverage determination or a redetermination for drug coverage is not considered a grievance. Refer to Subpart M section 423.564 of the Voluntary Medicare Prescription Drug Benefit for more information about Part D grievances, including required timeframes for Sponsors to notify enrollees about their decisions.
- Complaints received by 1-800 Medicare or recorded in the CTM should be excluded from these data.

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

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

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

Element Letter	Element Name	Definition	Allowable Values
A	Changes to P & T	Have there been any changes to the P&T Committee membership within the last quarter? If “No” – no more data entry is required.	<ul style="list-style-type: none"> <li>• Yes.</li> <li>• No.</li> </ul>
	Confidentiality agreement	Does this contract operate under a confidentiality agreement? See notes for specific directions regarding how this information should be reported to CMS.	<ul style="list-style-type: none"> <li>• Yes.</li> <li>• No.</li> </ul>
	Changes reported to CMS	If “Yes” to confidentiality agreement question - Have these changes been provided to CMS per those agreements?	<ul style="list-style-type: none"> <li>• Yes.</li> <li>• No.</li> </ul>
		If “No” to confidentiality agreement question - Have these changes been reflected within the Contract Management Module?	<ul style="list-style-type: none"> <li>• Yes.</li> <li>• No.</li> </ul>
B	Changes to the organization	Have changes been made to the Provision of Part D functions?" If “No” – no more data entry is required.	<ul style="list-style-type: none"> <li>• Yes.</li> <li>• No.</li> </ul>
	Changes reported to CMS	If “Yes” to changes to the organization question, - Have these changes been reflected within the Contract Management Module?	<ul style="list-style-type: none"> <li>• Yes.</li> <li>• No.</li> </ul>

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.

- CMS will identify contracts which report no changes occurred in either their P&T Committee membership or the entities that provide Part D functions, yet, changes were reflected in the HPMS Contract management Module.
  - CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- N/A
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- CMS will identify contracts that indicated changes to either P&T Committee membership or the entities providing Part D functions and have not yet been reported to CMS.
- E. Notes – additional clarifications to a reporting section.
- Part D Sponsors operating under a confidentiality agreement with a third party representative with respect to their P&T Committee must follow the following steps to submit P&T Committee membership changes.
    - Complete the “Pharmacy and Therapeutics Committee Disclosure Form” and “Certification for P&T” MS Word documents. When completing the Disclosure form, additional rows may be added to Tables B and C; no other format changes may be made to these documents. Both documents must be submitted to CMS for notification of P&T Committee changes.
    - The completed “Pharmacy and Therapeutics Committee Disclosure Form” should be renamed as, “P&T Committee\_(Contract Number)\_ (Date)”. The date should be in the following format: mo\_day\_year. An example filename is P&T Committee\_H1234\_03112007.doc.
      - A Part D Sponsor, at the contract level, should input all P&T Committee member names in this section. CMS understands that the entire list of names may represent multiple P&T Committees serving different PBPs within one contract.
  - The completed “Certification for P&T” document should be renamed as, “P&T Certification\_(Contract Number)\_(Date)” The date should be in the following format: mo\_day\_year.
    - An example filename is P&T Certification\_H1234\_03\_11\_2007.doc.
    - The Certification document should contain an electronic signature.
  - The naming convention used for P&T Committee Confidentiality documents that apply to more than one contract number should be file name and date. It should be indicated in the email to [partd-planreporting@cms.hhs.gov](mailto:partd-planreporting@cms.hhs.gov) that the submission is for multiple contracts,
  - Submit both documents via email to [partd-planreporting@cms.hhs.gov](mailto:partd-planreporting@cms.hhs.gov). Documents may be sent by either the third party organization or directly from the Part D Sponsor. The subject line must read “P&T Committee Changes – Confidential Submission”. Sponsors may encrypt the email or password protect the documents. If the documents are password protected, Sponsors must provide

the password to CMS in a follow-up email and clearly indicate the files to which the passwords applies.

- Provision of Part D function:
  - Sponsors should refer to the HPMS Contract management module for information regarding Part D Sponsor related functions; this module contains the actual information regarding these entities.

## IX. Coverage Determinations and Exceptions

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

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

Element Letter	Element Name	Definition	Allowable Values
A	Number of Pharmacy Transactions	The total number of pharmacy transactions.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Part D Sponsors should report the total number of pharmacy transactions, including those with final disposition of reversed. CMS understands these numbers may include multiple transactions for the same prescription drug claim.</li> </ul>
B	Number of Pharmacy Transactions Rejected Due to Formulary Restrictions	Of the total number of pharmacy transactions, the number rejected due to formulary restrictions. These include rejections due to non-formulary status, prior authorization requirements, step therapy, and quantity limits (QL).	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Should be a subset of A.</li> <li>Part D Sponsors should report the total number of pharmacy transactions, excluding those rejections due to early refills. CMS understands these numbers may include multiple transactions for the same prescription drug claim.</li> </ul>
C	Number of Prior Authorizations for Requested	The number of prior authorizations (PA) requested	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
D	Number of Prior Authorizations Approved	Of the PA requests, the number approved.	<ul style="list-style-type: none"> <li>Should be a subset of element C.</li> <li>Field type: Number.</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
E	Number of Exceptions to UM Tools Requested	The number of exceptions requested for utilization management (UM) tools, e.g. prior authorization, quantity limits, or step therapy.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
F	Number of Exceptions to UM Tools Approved	Of the UM exception requests, the number approved	<ul style="list-style-type: none"> <li>Should be a subset of element E.</li> <li>Field type: Number.</li> </ul>
G	Number of Tier Exceptions Requested	The number of tier exceptions requested in the time period.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
H	Number of Tier Exceptions Approved	Of the tier exception requests, the number approved.	<ul style="list-style-type: none"> <li>Should be a subset of element G.</li> <li>Field type: Number.</li> </ul>
I	Number of Non-formulary Exceptions Requested	The number of non-formulary exceptions requested.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
J	Number of Non-formulary Exceptions Approved	Of the non-formulary exception requests, the number approved.	<ul style="list-style-type: none"> <li>Should be a subset of element I.</li> <li>Field type: Number.</li> </ul>

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.

- Contracts will be ranked by exception rates.
- Outliers will be identified in the 95<sup>th</sup> percentile.
- CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.

C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.

- Confirm those data elements listed above as subsets of other elements.

D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.

- CMS will evaluate exception rates per 1000 enrollees and will trend rates from quarter to quarter and from previous years.

E. Notes – additional clarifications to a reporting section.

- Prior authorization requests/approvals that relate to Part B versus Part D coverage should be included in this reporting. A drug that is ultimately covered under Part B should be considered for this reporting as a denial for Part D coverage.

- Some exception requests reported in data element E may be included in data element C, for example, if a beneficiary requested and was denied a prior authorization, and then requested an exception to the prior authorization requirement.
- Part D Plans should include all types of quantity limit rejects in these data. (Including but not limited to claim rejections due to quantity limits or time rejections (e.g. a claim is submitted for 20 tablets/10 days, but is only approved for 10 tablets/5 days).

## X. Appeals

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

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

Element Letter	Element Name	Definition	Allowable Values
A	Number of Redeterminations	The total number of redeterminations made.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
B	Number of Redeterminations Resulting in Full Reversal of Original Coverage Determinations	Of the redeterminations reported in A, the number that resulted in full reversal of the original coverage determination.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Should be a subset of A.</li> </ul>
C	Number of Redeterminations Resulting in Partial Reversal of Original Coverage Determinations	Of the redeterminations reported in A, the number that resulted in partial reversal of the original coverage determination.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Should be a subset of A.</li> </ul>

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.

- Rates of appeals per 1000 enrollees will be calculated and outliers will be identified as plans in the 95<sup>th</sup> percentile for any element above.
- CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.

C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.

- Plans should validate that data elements B and C are less than or equal to data element A.
- All data elements should be positive values.

D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.

- Rates of appeals will be calculated per 1,000 enrollees. This means the total appeal rate per 1,000 enrollees is equal to the sum of the total number of appeals divided by average enrollment, times 1,000.

$$\left[ \text{Total Appeal Rate per 1,000 enrollees} \right] = \frac{\text{Total \# Appeals}}{\text{Avg. Enrollment}} \times 1,000$$

E. Notes – additional clarifications to a reporting section.

- N/A

**XI. Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions**

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

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

Element A: Part D Sponsors/Contracts will provide a tab delimited text file 'filename =REBATES\_(SPONSORNAME)\_(CONTRACTYEAR).txt, replacing '(SPONSORNAME)' with the Part D Sponsor's name and '(CONTRACTYEAR)' with the with the year following the below file layout.

**Pharmaceutical Manufacturer Rebate File Record Layout**

Required File Format is ASCII File - Tab Delimited.

Do not include a header record.

Filename extension should be ".TXT".

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
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.	It is acceptable for formulations of the same drug to be rolled up to one record in the rebate file. For example, Zocor is listed with all rebates received for any Zocor formulation.
Rebates Received	NUM REQUIRED	12	For each unique manufacturer/drug name combination, provide the rebate amount received in the reporting period specified.  Limit to 999999999999, can be a negative number.  Zero should be entered in the fields if no data are available.	999999999999

<b>Field Name</b>	<b>Field Type</b>	<b>Field Length</b>	<b>Field Description</b>	<b>Sample Field Value(s)</b>
Pending Rebates	NUM REQUIRED	12	<p>For each unique manufacturer/drug name combination, provide the rebate amount requested for the reporting period specified but not yet received (if applicable.)</p> <p>Limit to 999999999999, can be a negative number</p> <p>Zero should be entered in the fields if no data are available.</p>	999999999999
Prior Rebates	NUM REQUIRED	12	<p>For each unique manufacturer/drug name combination, provide the rebate amount received that is associated with a prior reporting period (if applicable).</p> <p>Limit to 999999999999, can be a negative number.</p> <p>Zero should be entered in the fields if no data are available. If rebates are received after the submission of an annual file, the rebates should be reported in the following year's file as Prior Rebates.</p>	999999999999

Element B: Part D Sponsors will provide an additional tab delimited text file (filename=DISCOUNTS\_ ( SPONSORNAME)\_(CONTRACTYEAR).txt, replacing '(SPONSORNAME)' with the Part D Sponsor's name and '(CONTRACTYEAR)' with the year) following the below file layout.

## Discounts and Other Price Concessions File Record Layout

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
Manufacturer / Company Name	CHAR REQUIRED	100	List the name of each manufacturer or other entity 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 add.	
Value	NUM REQUIRED	12	Provide the value of the discount, price concession, or other value add. Zero is not an allowable value	999999999999
Justification	CHAR OPTIONAL	4000	For each discount, price concession, or value add, provide a justification for receipt.	

- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- Data anomalies and errors will be identified by scatter plots and distribution of rebate information.
  - CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- Sponsors may enter negative numbers in the upload file.
- D. Analysis- steps taken by CMS to evaluate reported data, as well as how other data sources may be monitored along with these data.
- CMS will evaluate rebate data by contract, parent organization and by drug.
- E. Notes – additional clarifications to a reporting section.
- Part D Sponsors should not report estimates until an actual amount can be determined.
  - CMS does not require that a drug manufacturer offer a rebate in order for a Part D Sponsor to cover the manufacturer's drug.
  - A Part D Sponsor's Pharma Rebate Performance Guarantee with a PBM should be reported in element B "Discounts and Other Price Concessions". The PBM's name should be entered in the "Manufacturer/Company Name" field. The Pharma Rebate Performance Guarantee should also be reflected in DIR reporting.

- Part D Sponsors must report 100% of Rebates, and may report 100% of Pharma Admin Fees. The determination of whether to include 100% of Pharma Admin Fees is at the discretion of the Sponsor per the conditions of the contracts between the Sponsor, PBM, and/or manufacturer. If applicable, sponsors should report late payment fees received from pharmaceutical manufacturers who were late paying out their rebates.
- Any grant monies that are related to Part D business should be reported, regardless of the formal recipient in the organization.
- PDEs are data reported after the fact of point-of-sale processing. The rejection of a PDE should not affect the rebates that are being reported for these reporting requirements. Rebates should be based on paid valid claims.
- Rebates are a cumulative total.
- Rebates received that apply to a previous year are to be reported by entering the rebate amount in the following year's rebate report in the Prior Rebates column. Part D Sponsors should not adjust previously submitted files.

## XII. Long-term Care (LTC) Utilization

- A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

Data elements A, B, C and E will be entered into HPMS.

Data listed under data element D will be uploaded into HPMS, per the file layout listed below at the contract level for each state or service area.

Element Letter	Element Name	Definition	Allowable Values
A.	Number of network LTC pharmacies	The total number of network LTC pharmacies in the service area. PDPs and regional PPOs will report for each state, MA-PDs will report for the service area.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Count a pharmacy that is both LTC and retail in both elements A and B, and report corresponding claims/utilization specific to business lines in elements D and E. If claims/utilization cannot be split, report the pharmacy and its claims/utilization as a LTC pharmacy only (data elements A and D).</li> <li>Include LTC pharmacies that do not have utilization; in element D, enter zeroes for number and cost of prescriptions.</li> </ul>
B.	Number of network retail pharmacies	The total number of network retail pharmacies in the service area. PDPs and regional PPOs will report for each state, MA-PDs will report for the service area.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Count a pharmacy that is both LTC and retail in both elements A and B, and report corresponding claims/utilization specific to business lines in elements D and E. If claims/utilization cannot be split, report the pharmacy and its claims/utilization as a LTC pharmacy only (data elements A and D).</li> <li>Include retail pharmacies that do not have utilization.</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
C.	Number of beneficiaries in LTC facilities for whom Part D drugs have been provided	The total number of beneficiaries in LTC facilities for whom Part D drugs have been provided under the Contract.	<ul style="list-style-type: none"> <li>• Field type: Number.</li> <li>• Do not report beneficiaries that received only claims for non-Part D drugs, e.g. excluded or OTC drugs.</li> <li>• Claims with location code 03 may be used to identify enrollees. The LTI report may be another tool for this reporting.</li> <li>• Claims with location code 07 should not be included.</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
D.	<p>For each network LTC pharmacy in the service area:</p> <p>a. LTC pharmacy name</p> <p>b. LTC pharmacy NPI</p> <p>c. Contract entity name of LTC pharmacy</p> <p>d. Chain code of LTC pharmacy</p> <p>e. Number of 31-day equivalent formulary prescriptions dispensed</p> <p>f. Number of 31-day equivalent non-formulary prescriptions dispensed</p> <p>g. Cost of formulary prescriptions</p> <p>h. Cost of non-formulary prescriptions</p>	<p>Non-formulary drugs are drugs that are not on a Plan's Part D formulary but approved for coverage via the exceptions process, or under the transition policy.</p>	<ul style="list-style-type: none"> <li>• These data will be uploaded into HPMS, please refer to file layout below, "Long-term Care (LTC) Pharmacy Data – File Record Layout"</li> <li>• Any pharmacy that is active in the network for 1 or more days in reporting period should be included.</li> <li>• A formulary drug is a drug included on a Part D plan's CMS approved formulary, including drugs with utilization management (UM) restrictions e.g. prior authorization or step therapy.</li> <li>• A non-formulary drug is a drug that is not included on a Part D plan's CMS approved formulary.</li> <li>• The number of 31-day equivalent prescriptions is calculated by summing the days supply of all covered Part D prescriptions dispensed, and dividing by 31.</li> <li>• Cost of prescriptions is defined as the sum of the total ingredient Cost, dispensing fee, and sales tax. The ingredient cost should reflect the Plan's negotiated price.</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
E.	In aggregate, for all retail pharmacies in the service area: a. Number of 30-day equivalent formulary prescriptions dispensed b. Number of 30-day equivalent non-formulary prescriptions dispensed c. Cost of formulary prescriptions d. Cost of non-formulary prescriptions	Non-formulary drugs are drugs that are not on a Plan's Part D formulary but approved for coverage via the exceptions process, or under the transition policy.	<ul style="list-style-type: none"> <li>Number of prescriptions is a numeric field, and cost of prescriptions is a currency field.</li> <li>A formulary drug is a drug included on a Part D plan's CMS approved formulary, including drugs with utilization management (UM) restrictions e.g. prior authorization or step therapy.</li> <li>A non-formulary drug is a drug that is not included on a Part D plan's CMS approved formulary.</li> <li>The number of 30-day equivalent prescriptions is calculated by summing the days supply of all covered Part D prescriptions dispensed, and dividing by 30.</li> <li>Cost of prescriptions is defined as the sum of the total ingredient Cost, dispensing fee, and sales tax. The ingredient cost should reflect the Plan's negotiated price.</li> </ul>

**Long-term Care (LTC) Pharmacy Data – File Record Layout  
(Data listed in data element D above)**

Required File Format = ASCII File - Tab Delimited

Do not include a header record

Filename extension should be ".TXT"

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
NPI_Number	NUM Required	Exactly 10	Indicate the contracted LTC pharmacy NPI number. This should be a numeric field with exactly 10 digits long. Enter 9999999999 if a pharmacy's NPI cannot be identified.	1234567809
Pharmacy_Name	CHAR Required	150	Provide the name of the LTC pharmacy in the service area.	CVS Pharmacy
Contract_Name	CHAR Required	150	Enter the Contract entity name of the LTC pharmacy in the	Aetna

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
			service area.	
Chain_Code	CHAR Required	150	Enter the chain code of the LTC pharmacy in the service area.	ABC
Formulary_Prescriptions_Dispensed	NUM Required	7	Enter the number of 31-day equivalent formulary prescriptions for each network LTC pharmacy in the service area.	9999999
Non_Formulary_Prescriptions_Dispensed	NUM Required	7	Enter the number of 31-day equivalent non-formulary prescriptions for each network LTC pharmacy in the service area.	9999999
Cost_Formulary_Prescriptions	CURRENCY Required	10	Enter the cost of formulary prescriptions for each network LTC pharmacy in the service area.	9999999999
Cost_Non_Formulary_Prescriptions	CURRENCY Required	10	Enter the cost of non-formulary prescriptions for each network LTC pharmacy in the service area.	9999999999

- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- CMS may apply new quality assurance checks and threshold validations based upon data received from Part D Plans.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- N/A
- D. Analysis- steps taken by CMS to evaluate reported data, as well as how other data sources may be monitored along with these data.
- Rates of formulary and non-formulary utilization and costs will be calculated by LTC pharmacy and entity. Retail rates will be used for comparative purposes.
  - The percent of enrollees receiving prescriptions from LTC facilities will be taken into account when identifying LTC utilization outliers.
- E. Notes – additional clarifications to a reporting section.
- Claims from all facilities considered LTC should included, e.g. ICFMR.
  - Claims during a transition period should be included.
  - EGWPs should be excluded from reporting.
  - Medicare Secondary Payer (MSP) claims should be excluded.

### XIII. Licensure and Solvency, Business Transactions and Financial Requirements

NOTE: EFFECTIVE MARCH 2009, THESE DATA ARE SUBMITTED INTO THE HPMS FISCAL SOUNDNESS MODULE; THESE DATA ARE NO LONGER ENTERED INTO THE PART D REPORTING MODULE, OR MAILED TO CMS.

- A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

The following data are to be entered into HPMS at the CMS contract level. For Part D PDP Contracts, the following will be entered at the Part D Contract level per the NAIC #. Contracting entities will be listed under each contract by NAIC#.

Element Letter	Element Name	Definition	Allowable Values
A	Total Assets	Total assets as of the end of the quarterly reporting period.	<ul style="list-style-type: none"> <li>This should be a currency field.</li> </ul>
B	Total Liabilities	Total liabilities as of the end of the quarterly reporting period.	<ul style="list-style-type: none"> <li>This should be a currency field.</li> </ul>
C	Total Cash	Total cash as of the end of the quarterly reporting.	<ul style="list-style-type: none"> <li>This should be a currency field.</li> </ul>
D	Total Cash Equivalents	Total cash equivalents as of the end of the reporting period.	<ul style="list-style-type: none"> <li>This should be a currency field.</li> </ul>
E	Total Current Assets	Total current assets as of the end of the quarterly reporting period.	<ul style="list-style-type: none"> <li>This should be a currency field..</li> </ul>
F	Total Current Liabilities	Total current liabilities as of the end of the quarterly reporting.	<ul style="list-style-type: none"> <li>This should be a currency field.</li> </ul>
G	Total Revenue	Total revenue as of the end of the quarterly reporting period.	<ul style="list-style-type: none"> <li>This should be a currency field.</li> </ul>
H	Total Expenses	Total expenses as of the end of the quarterly reporting period.	<ul style="list-style-type: none"> <li>This should be a currency field.</li> </ul>
I	Total Administrative Expenses	Total administrative expense as of the end of the quarterly reporting period.	<ul style="list-style-type: none"> <li>This should be a currency field.</li> </ul> <p>NOTE: Direct Contract PDPs are waived from this element.</p>
J	Total Net Income	Total net income as of the end of the quarterly reporting period.	<ul style="list-style-type: none"> <li>This should be a currency field.</li> </ul>
K	Drug Benefit Expenses	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	<ul style="list-style-type: none"> <li>This should be a currency field.</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
		and dispensing fees less member share.	
L	Drug Benefit Revenues	Drug benefit revenues as of the end of the quarterly reporting period. Drug benefit revenues would include premiums, CMS subsidies, rebates and other reinsurance.	<ul style="list-style-type: none"> <li>This should be a currency field.</li> </ul>

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.

- CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.

C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.

- Elements G, H, I, K and L should be greater than zero.
- Element A should be greater than element E.
- Element A should be greater than element C.
- Element A should be greater than element D.
- Element B should be greater than element F.
- Element H should be greater than element I.
- Element H should be greater than element K.
- Element G should be greater than element L.
- Element G should be greater than element J.
- Element C should not equal element D.
- Element G1 should be less than element G2; element G2 should be less than element G3; element G3 should be less than element G4.
- Element H1 should be less than element H2; element H2 should be less than element H3; element H3 should be less than element H4.
- Element I1 should be less than element I2; element I2 should be less than element I3; element I3 should be less than element I4.
- Element K1 should be less than element K2; element K2 should be less than element K3; element K3 should be less than element K4.
- Element L1 should be less than element L2; element L2 should be less than element L3; element L3 should be less than element L4.

D. Analysis- steps taken by CMS to evaluate reported data, as well as how other data sources may be monitored along with these data.

- CMS will evaluate Licensure and Solvency data to assess the financial strength of entities.

E. Notes – additional clarifications to a reporting section.

- CMS will accept the corresponding LAH (Life and A&H) Blank pages in lieu of Health Blank pages

- When reporting on claims paid, Part D sponsors should report claims for which they have received Medicare payment, and also include those claims they are working through the reconciliation process.
- A licensed PDP Sponsor refers to one that is licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in at least one state. A non-licensed PDP Sponsor refers to one under which the Sponsor holds no state license (has licensure waivers in all states in the service area).
- Contracting entities licensed in at least one state as a risk-bearing entity would be required to meet Part D reporting requirements for licensed PDP Sponsors.
- Actuarial opinions should address the assumptions and methods used in determining loss reserves, actuarial liabilities and related items.
- A management letter is a statement made by an organization's independent auditor addressing internal controls and other management issues discovered during the audit. It usually covers areas needing improvement and recommendations for addressing those areas.
- A letter of deficiencies from the auditor is not required in all cases.
- Administrative expenses should be shown net of (offset by) Administrative Services Only (ASO) revenue as is statutory procedure.
- Part D Sponsors are required to submit independently audited financial statements which are statutory based or GAAP based. Part D sponsors do not have to submit both but if would like to send both, CMS will accept them.
- Updates on the status of obtaining licensure for each waived state are to be submitted quarterly. All Part D Sponsors shall attest quarterly if changes have been made to the entities which perform Part D activities, and if so, if the Part D Sponsor reported these changes to CMS. The actual information regarding these entities is housed in the HPMS Contract Management module.

#### XIV. Fraud, Waste and Abuse Compliance Programs

A. Data element definitions - details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

Element Letter	Element Name	Definition	Allowable Values
A.	Number of potential fraud and abuse incidents related to inappropriate billing.	The number of potential fraud and abuse incidents related to inappropriate billing. Inappropriate billing by pharmacies should be included.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Subset of F.</li> </ul>
B.	Number of potential fraud and abuse incidents related to providing false information	The number of potential fraud and abuse incidents related to providing false information.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Subset of F.</li> </ul>
C.	Number of potential fraud and abuse incidents related to doctor shopping/drug seeking beneficiary.	The number of potential fraud and abuse incidents related to doctor shopping/drug seeking beneficiary.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Subset of F.</li> </ul>
D.	Number of potential fraud and abuse incidents related to attempting to steal identity/ money.	The number of potential fraud and abuse incidents related to attempting to steal identity/ money.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Subset of F.</li> </ul>
E.	Number of potential fraud and abuse incidents related to other areas not listed above.	The number of potential fraud and abuse incidents related to other areas not listed above (e.g. OIG exclusion list, broker/ agent complaints, and incidents that gave rise to grievances).	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Subset of F.</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
F.	Total number of potential fraud and abuse incidents identified	The total number of potential fraud and abuse incidents identified.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
G.	Number of incidents identified through internal efforts.	Of the total reported in F, the number identified through internal efforts.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>This is a subset of F.</li> </ul>
H.	Number of incidents received from external sources	Of the total reported in F, the number of incidents received from external sources. Incidents reported through the Complaints Tracking Module (CTM) or as grievances should be included.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>This is a subset of F.</li> </ul>
I.	Number of inquiries initiated by the Sponsor	The number of inquiries initiated by the Sponsor as a result of potential fraud and abuse incidents.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
J.	Number of corrective actions initiated by the Sponsor	The number of corrective actions initiated by the Sponsor as a result of potential fraud and abuse incidents.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
K.	Number of potential fraud and abuse incidents referred to CMS for action	The number of potential fraud and abuse incidents referred to CMS for action; includes referrals to CMS staff, MEDICs, or other CMS designated program safeguard contractor.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
L.	Number of potential fraud and abuse incidents referred to federal law enforcement for action.	The number of potential fraud and abuse incidents referred to federal law enforcement for action. This includes referrals to the OIG, FBI, DEA, and FDA.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
M.	Number of potential fraud and abuse incidents referred to local law enforcement for action.	The number of potential fraud and abuse incidents referred to local law enforcement for action; this includes but is not limited to referrals to state, county, township, or province police.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
N.	Number of potential fraud and abuse incidents referred to State Insurance Commissioners (SICs) or state licensing authorities.	The number of potential fraud and abuse incidents referred to State Insurance Commissioners (SICs) or state licensing authorities.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.

- N/A.

C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.

- The sum of elements A, B, C, D, and E should be equal to element F.

D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.

- To be determined.

E. Notes - additional clarifications to a reporting section. This section incorporates previously answered frequently asked questions.

- Employer Direct plan sponsors are exempt from this reporting section.
- Part D Sponsors may voluntarily report aggregate data related to their anti-fraud, waste and abuse activities.

**XV. Employer/Union-Sponsored Group Health Plan Sponsors**

A. Data element definitions - details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

**Employer Group Plan Sponsor Upload File Format**

Required File Format = ASCII File - Tab Delimited

Do not include a header record

Filename extension should be “.TXT”

There can be multiple records per plan.

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
Contract_Number	CHAR Required	5 Exactly	Provide the CMS issued contract number being offered to the Employer Group Plan Sponsor. (Note: The system shall validate the contract number is valid.)	H1234
Plan_ID	NUM Required	3 Exactly	Provide the ID (with leading zeros as appropriate) of the Plan Benefit Package (PBP) being offered to the Employer Group Plan Sponsor. (Note: This is a numeric field only. The system shall validate the plan ID is valid.)	801 or 001
Employer_Legal_Name	CHAR Required	150	Provide the legal name of the Employer Group Plan Sponsor.	United Parcel Service
Employer_DBA_Name	CHAR Optional	150	If applicable provide the doing business as (DBA) name of the Employer Group Plan Sponsor.	United Parcel Service Employees Association
Employer_Federal_Tax_ID	NUM Required	Minimum of 9, Maximum of 20	Provide the federal tax ID of the Employer Group Plan Sponsor. (Note: This is a numeric field only. This must be a minimum of 9 digits and cannot be more than 20 digits.)	223849199
Employer_Street_Address	CHAR Required	150	Provide the street address of the Employer Group Plan Sponsor headquarters.	1212 North Luther Street
Employer_City_Address	CHAR Required	75	Provide the city in which the Employer Group Plan Sponsor headquarters is located.	Wichita

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
Employer_State_Address	CHAR Required	2	Provide the state abbreviation in which the Employer Group Plan Sponsor headquarters is located. (Note: The system shall validate the state abbreviation is appropriate.)	MO
Employer_Zip_Address	NUM Required	10	Provide the Employer Group Plan Sponsor headquarters' zip code. (Note: This is a numeric field only.) This field must be a minimum of 5 digits and leading zeroes are required.)	00123 00123-0123 001230123
Employer_Sponsor_Type	NUM Required	1	Indicate the Employer Group Plan Sponsor Type; acceptable values provided as sample. (Note: This is a numeric field only. The system shall validate the value is 1 through 3.)	1=Employer 2=Union 3=Trustees of a Fund
Employer_Organization_Type	NUM Required	1	Indicate the Employer Group Plan Organization Type; acceptable values provided as sample. (Note: This is a numeric field only. The system shall validate the value is 1 through 7.)	1=State Government 2=Local Government 3=Publicly Traded Corp. 4=Privately Held Corp. 5=Non-Profit 6=Church Group 7=Other
Employer_Contract_Type	NUM Required	1	Indicate the Employer Group Plan Contract Type; acceptable values provided as sample. (Note: This is a numeric field only. The system shall validate the value is 1 through 3.)	1=Insured 2=ASO 3=Other
Employer_Start_Date	NUM Required	6	Provide the month and year when the Employer Group Plan Sponsor started (or will start). The format is MMYYYY, so the sample is intended to depict June 2008 (062008). (Note: This is a numeric field only. The system shall validate that the month is a value of 01 to 12.)	062008
Employer_Enrollment	NUM Required	7	Provide the current enrollment for the Employer Group Plan Sponsor. (Note: This is a	9999999

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
			numeric field only. Do not include commas.)	

- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- N/A.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- N/A.
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- To be determined.
- E. Notes - additional clarifications to a reporting section. This section incorporates previously answered frequently asked questions.
- This reporting requirement applies only to individual PDPs and “800 series” PDPs offered to employers. MA-PD plans already report these data as part of the Part C reporting requirements and are therefore exempt from this Part D reporting section.
  - Each Part D contract will upload a file containing plan level data.

## XVI. Plan Oversight of Agents

A. Data element definitions - details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

Element Letter	Element Name	Definition	Allowable Values
A.	Total number of agents.	Total number of agents. This includes only agents who are licensed to sell on behalf of the sponsor, either by being a direct employee or by contractual arrangement, regardless of whether the agent is actively selling during the reporting period.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
B.	Number of agents investigated based on complaints.	Number of agents investigated based on complaints.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Should be a subset of A.</li> </ul>
C.	Number of agents receiving disciplinary actions from the Sponsor based on complaints.	Number of agents receiving disciplinary actions from the Sponsor based on complaints.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Should be a subset of B.</li> </ul>
D.	Number of complaints reported to State by contract.	Number of complaints reported to State by contract. This includes only those complaints originating with the contract that are then reported to the State.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>
E.	Number of agents whose selling privileges were revoked by the plan based on conduct or discipline.	Number of agents whose selling privileges were revoked by the plan based on conduct or discipline.	<ul style="list-style-type: none"> <li>Field type: Number.</li> <li>Should be a subset of A.</li> </ul>

Element Letter	Element Name	Definition	Allowable Values
F.	Number of agent-assisted enrollments.	Number of agent-assisted enrollments. This is a count of any enrollment effective during the reporting period that a beneficiary used the services of a licensed agent to complete the enrollment process. Examples of this include, but are not limited to: enrollments completed through a call center staffed by licensed agents, in person sales appointments, or public sales meetings where a licensed agent collects the forms. Agent assisted enrollments include both individual and group enrollments in which a licensed agent assisted in completing the enrollment process. The count of agent assisted enrollments should be enrollments that are as a direct result of the participation of the group of agents reported in element A.	<ul style="list-style-type: none"> <li>Field type: Number.</li> </ul>

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.

- N/A.

C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.

- N/A.

D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.

- To be determined.

E. Notes - additional clarifications to a reporting section. This section incorporates previously answered frequently asked questions.

- This section applies only to Sponsors of stand-alone prescription drug plans that do not also have MA-PD plans. Sponsors of MA-PD plans already report these data as part of the Part C reporting requirements and are therefore exempt from this Part D reporting section. Employer/union group plans are exempt from this reporting section.

- If a contract does not have any licensed agents, it is appropriate to report all zeros for each element.
- Complaints refer to both complaints from the HPMS Complaint Tracking Module (CTM) and to other complaints made directly to the MAO or Cost contractor. If a complaint is reported to an organization that cannot be tied to a particular contract, the complaint should be reported under all contracts that the agent is licensed to sell.
- A complaint could result in “disciplinary action” along a broad continuum, from manager-coaching, documented verbal warning, re-training, a documented corrective action plan, suspension, or termination of employment or contract. Any disciplinary action along this continuum would be reportable. A short term revocation (e.g., 1-2 days) is among those which CMS will require reporting. Note that disciplinary action refers to action taken by the Part D sponsor.