Medicare Part D Plan Reporting Requirements:
Technical Specification Document
Contract Year 2009

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Prepared by:
Centers for Medicare & Medicaid Services
Center for Drug and Health Plan Choice
Medicare Drug Benefit and C&D Data Group

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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. Data collection is cleared under # 0938-0992. The document is located in HPMS under “In the News”, and posted on the CMS website. 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
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
Vaccines	Contract
Medication Therapy Management Programs (MTMP)	Contract
Generic Drug Utilization	Plan
Grievances	Plan
Pharmacy & Therapeutics (P&T) Committees and Provision of Part D Functions	Contract
Transition	Plan
Exceptions	Plan
Appeals	Plan
Overpayment	Contract
Pharmaceutical Manufacturer Rebates, Discounts, and Other price concessions	Sponsor or Contract
Long-term Care (LTC) Rebates	Sponsor or Contract
Licensure and Solvency, Business Transactions, and Financial requirements	Contract
Drug Benefit Analyses	Plan

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 until one year from the required submission 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 due date extension. Due date extension requests will only be approved for 7 days from the date the request is reviewed by CMS. Sponsors should not submit due date extension requests 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. Additionally, any request to submit data after December 31st of the following contract year will be denied by CMS. 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., 1st quarter 2009);
    c. Select contracts or plans, depending on reporting level;
    d. The date the data resubmission will be submitted; and
    e. The reason for the resubmission request.
3. CMS will review the information provided and either accept or reject the request for resubmission.

General Data Restrictions

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

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, Exceptions reporting includes Part B related data elements). All reporting requirements apply to MA-PD organizations with the exception of Licensure and Solvency, Business Transactions and Financial Requirements. For PACE Organizations offering Part D coverage, reporting requirements will be limited to: Vaccines; Generic Drug Utilization; Pharmacy & Therapeutics (P&T) Committees / Provision of Part D Functions (for PACE Organizations utilizing formularies); Transition (for PACE Organizations utilizing formularies); Exceptions (for PACE Organizations utilizing formularies); Overpayment; Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions; and Long-term Care (LTC) Rebates.

Based on the information in the Reporting Requirements document and the 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.

I. 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).	Should be reported as a percent. Field type: Number.
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).	Should be reported as a percent. Field type: Number.
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).	Should be reported as a percent. Field type: Number.
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).	Should not be a negative value. Field type: Number.

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	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 licensed 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

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.	• Should be mutually exclusive. • Field type: Number.
B	Number of prescriptions provided at all pharmacies contracted	Number of prescriptions provided in the time period at all pharmacies contracted.	• Should be mutually exclusive. • Field type: Number.

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.

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.	• Should be mutually exclusive. • Field type: Number.
B	Number of prescriptions provided at all retail pharmacies contracted	Number of prescriptions provided in the time period at all retail pharmacies contracted.	• Should be mutually exclusive. • Field type: Number.

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.

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.

II. 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	The number of contracted retail pharmacies that are contracted to dispense an extended day supply of covered Part D drugs as of the last day of the reporting period	The number of contracted retail pharmacies in the 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 specified.	• Should not be greater than the contract's total number of contracted retail pharmacies. • A value of zero will be accepted. • Field type: Number.

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- Data element A should not be a negative value.
- 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:
  (1) 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
  (2) 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.

III. Vaccines

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	Total Part D Vaccines Processed	The total number of Part D vaccines processed regardless of the method used to process the claim.	• Data element A should be a sum of data elements B-F. • Field type: Number.
B	Number of Part D Vaccines Administered in an Out-of-Network Setting	The number of Part D vaccines provided in any out-of-network setting where a state recognized immunizer dispenses a Part D vaccine (e.g. physician's office) where the beneficiary retrospectively files paper receipts for reimbursement of the vaccine. Vaccines reported in data element B must meet two requirements: (1) the vaccine is provided by out-of-network immunizer; and (2) it is submitted retrospectively submitted to the contract as paper claim. Part D contracts must have a process to receive out-of-network paper claims and should be able to differentiate these types of claims from in-network claims.	• Should be a mutually exclusive number. • Field type: Number.
C	Number of Vaccines Adjudicated through Network Pharmacies	The number of vaccines adjudicated through network pharmacies. (Include those vaccines processed by the pharmacy and submitted electronically, but administered by another qualified provider).	• Should only include adjudicated claims that have been processed. Should be a mutually exclusive number. • Field type: Number.

Element Letter	Element Name	Definition	Allowable Values
D	Number of Vaccines Processed through a Paper Enhanced Process	The number of vaccines processed through a paper enhanced process, where the provider used or navigated a process that facilitated out-of-network access. Vaccines reported in data element D are those administered via any reimbursement process involving a Part D contract providing enrollees with a vaccine-specific notice that the enrollees could bring to their physicians (or other provider recognized by state law to provide immunization). This notice would provide information necessary for a physician to contact the enrollee's Part D contract to receive authorization of coverage for a particular vaccine, reimbursement rates, enrollee cost-sharing to be collected by the physician, and billing instructions. If the Part D contract authorizes payment, the physician would then bill the Part D contract using the physician standard claim form or ASC X 12 electronic format (which Part D contracts must accept).	• Should be a mutually exclusive number. • Field type: Number.
E	Number of Vaccines Processed through an Internet Based Web Tool	The number of vaccines processed through an internet based web tool. Vaccines reported in data element E are those submitted through any internet based process that facilitates physician or other state recognized immunizer billing to the Part D contract without requiring a retrospective paper based claim for reimbursement.	• Should be a mutually exclusive number. • Field type: Number.

Element Letter	Element Name	Definition	Allowable Values
F	Number of Vaccines Processed through Other Process	The number of vaccines through a process not described in data elements B through E.	• Should be a mutually exclusive number. • Field type: Number.

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
   - The total number of vaccines reported will be evaluated in relation to the total number of beneficiaries enrolled.
   - 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.
   - HPMS will allow the entry of zero values.
   - Negative values should not be entered.
   - Element A should be equal to the sum of elements B through F.

D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
   - Total number of vaccines reimbursed for the reportable period across all plans.
   - Total number of vaccines by MA-PD and PDPs.
   - Ranking of all contracts by the number of vaccines reimbursed based upon beneficiary enrollment
   - Ranking of all contracts by each element (elements B-F).

E. Notes – additional clarifications to a reporting section.
   - Refer to section 60.2 of Chapter 5 of the prescription drug benefit manual and the CMS memorandum released in May 2006 on Part D vaccines on the web at (http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/MemoVaccineAccess_05.08.06.pdf) for more information.
   - The Part D contract should report all vaccines that satisfy the definition of a Part D drug outlined in 42 CFR 423.100.

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	Enrollment Method	Method of enrollment may be opt-in, opt-out, a combination of opt-in and opt-out, or other. *Opt-In:* A beneficiary that meets the eligibility criteria must actively choose to participate by mailing acceptance in to the program, calling a number to enroll, etc. *Opt-out:* A beneficiary that meets the eligibility criteria is auto-enrolled and is considered to be participating unless he/she declines to participate. *Combination of opt-in and opt-out:* A hybrid method of enrollment. A Part D contract may vary the method of enrollment by beneficiary setting, intervention, etc.	• This will be selection from a drop-down box. If "other" is selected, a description will be required as a text field. • A value of zero will be accepted. • Field type: Text (Drop-down box selection).
B	Number of Beneficiaries Eligible for MTMP	The number of beneficiaries who met the eligibility criteria for the MTMP. Ex. 1,000 beneficiaries were eligible	• No decimals. • Typically less than 25% of total enrollment for the plan. • A value of zero will be accepted. • Field type: Number.

Element Letter	Element Name	Definition	Allowable Values
C	Total Number of MTMP Participants	The total number of beneficiaries who participated in the MTMP. Ex. Out of 1,000 eligible beneficiaries, 800 beneficiaries actually participated in MTMP.	• No decimals. • This should be less than or equal to B. • This should be a longitudinally cumulative total; a beneficiary who began to participate in a MTMP, discontinued their MTMP participation, and then participated again during a reporting period would be counted only once. • A value of zero will be accepted. • Field type: Number.
D	Number of MTMP Participants who Discontinued MTMP Participation - Total Discontinued	The total number of beneficiaries who discontinued participation from the MTMP. Ex. Out of 800 beneficiaries that participated in MTMP, 100 beneficiaries discontinued.	• No decimals. • This should be a subset of C. • This should be the sum of element E through element H. • A value of zero will be accepted. • Field type: Number.
E	Number of MTMP Participants who Discontinued MTMP Participation - Discontinued due to Death	The number of beneficiaries who discontinued participation from the MTMP due to death. Ex. Out of 100 beneficiaries that discontinued MTMP, 10 discontinued due to death.	• No decimals. • This should be a subset D. • A value of zero will be accepted. • Field type: Number.
F	Number of MTMP Participants who Discontinued MTMP Participation - Discontinued due to	The number of beneficiaries who discontinued participation from the MTMP due to disenrollment from the. Ex. Out of 100 beneficiaries that discontinued MTMP, 70 discontinued due to disenrollment from the plan.	• No decimals. • This should be a subset of D. • A value of zero will be accepted. • Field type: Number.

Element Letter	Element Name	Definition	Allowable Values
	Disenrollment from the Plan		
G	Number of MTMP Participants who Discontinued MTMP Participation - Discontinued at the Participant's Request	The number of beneficiaries who discontinued participation from the MTMP at their request. Ex. Out of 100 beneficiaries that discontinued MTMP, 15 voluntarily discontinued due to their request.	• No decimals. • This should be a subset of D. • A value of zero will be accepted. • Field type: Number.
H	Number of MTMP Participants who Discontinued MTMP Participation - Discontinued due to Other Reason	The number of beneficiaries who discontinued participation from the MTMP for a reason not specified in data elements E-G. Ex. Out of 100 beneficiaries that discontinued MTMP, 5 discontinued due to other reasons.	• No decimals. • This should be a subset of D. • A value of zero will be accepted. • Field type: Number.
I	Number of MTMP Eligible Beneficiaries who Declined MTMP Participation	The number of beneficiaries who declined to participate in the MTMP. Ex. 1,000 beneficiaries were eligible for MTMP, of those eligible, 200 beneficiaries declined to participate.	• No decimals. • This should be a subset B. • A value of zero will be accepted. • Field type: Number.

Element Letter	Element Name	Definition	Allowable Values
J	Number of Beneficiaries with Pending MTMP Participation	The number of beneficiaries whose participation status in the MTMP is pending. Ex. 1,000 beneficiaries were eligible for MTMP, of those eligible there were no beneficiaries whose participation in the MTMP was pending.	• No decimals. • This should be a subset of B. • A value of zero will be accepted. • Reportable only for Period 1. By Period 2, all MTM eligible beneficiaries must be accounted as either participated or declined participation. A beneficiary who did not respond to the Sponsor's invitation to participate in MTM may be reported as pending in Period 1, but would be reported as declined in Period 2 if he/she remains a non-respondent. • Field type: Number.

Element Letter	Element Name	Definition	Allowable Values
K	Total Part D Prescription Cost for MTMP Participants (per MTMP participant per month)	For beneficiaries participating in the MTMP, provide the prescription cost of all covered Part D medications on a per MTMP beneficiary per month basis. 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 participating in the MTMP as of the last day of the reporting period. This includes both MTMP beneficiary cost sharing and Part D costs paid. Denominator = total number of member months for the MTMP participating beneficiaries. These member months should include all months the beneficiary was enrolled in the plan during the reporting period specified, not only the months that the beneficiary enrolled in the MTMP. Ex. The total MTMP cost per MTMP beneficiary per month is $500.	• No decimals. • Value is in currency, rounded to the nearest dollar. • A value of zero will be accepted. • Field type: Currency.

Element Letter	Element Name	Definition	Allowable Values
L	Total Number of 30-day Prescriptions Equivalents (per MTMP participant per month)	For beneficiaries participating in the MTMP the number of covered Part D 30-day equivalent prescriptions on a per MTMP beneficiary per month basis. Numerator is calculated by first summing days supply of all covered Part D prescriptions dispensed for beneficiaries participating in MTMP as of the last day of the reporting period, and dividing by 30 to determine the number of 30 day equivalent prescriptions dispensed. Denominator = total number of member months for the MTMP participating beneficiaries. These member months should include all months enrolled the beneficiary was enrolled in the plan during the reporting period specified, not only the months that the beneficiary enrolled in the MTMP. Ex. The total 30 day equivalent Prescriptions per MTMP beneficiary per Month is 4.	• Up to two decimals may be entered. • A value of zero will be accepted. • Field type: Number.

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.
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).

Beneficiaries Eligible for MTM Record Layout					
Field Name	Field Type	Field Length	Start Position	End Position	Field Description
LTC Enrollment	CHAR REQUIRED	1	87	87	For each beneficiary enrolled in 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). *If the beneficiary declined MTM enrollment, indicate whether they were an LTC resident with Y (yes), N (no), or U (unknown).*
Date of MTM Enrollment	DATE Conditionally REQUIRED	8	88	95	For each beneficiary identified to be eligible for the MTM in the reporting period, who enrolled in MTM, the date MTM enrollment began (CCYYMMDD, e.g., 19400101). *This date must be provided if the beneficiary enrolled in MTM. If no Date of MTM Enrollment is provided, the Date MTM Participation was Declined must be provided.*
Date MTM Participation was Declined	DATE Conditionally REQUIRED	8	96	103	This should be a date field (CCYYMMDD, e.g., 19400101). *The date must be provided if the beneficiary declined participation in MTM. If no Date MTM Participation was Declined is provided, the Date of MTM Enrollment must be provided.*
Date Participant Discontinued MTM	DATE Conditionally REQUIRED	8	104	111	For each beneficiary who enrolled in MTM and then discontinued participation, the date their participation ended. This should be a date field (CCYYMMDD, e.g., 19400101). *If Reason Participant Discontinued is provided, then Date Participant Discontinued MTM is required.*

Beneficiaries Eligible for MTM Record Layout					
Field Name	Field Type	Field Length	Start Position	End Position	Field Description
Reason Participant Discontinued MTM	CHAR Conditionally REQUIRED	02	112	113	For each beneficiary with a MTM disposition status of discontinued participation, the reason for discontinuation must be provided. Reasons for discontinuation must be one of the following: 01 - Death; 02 - Disenrollment from Plan; 03 - Request by beneficiary; or 04 - Other. Note: If Date Participant Discontinued MTM provided, then Reason participant discontinued MTM is required.

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 E+F+G+H should equal data element D.
   - Data Element L must be two decimal points.
   - Data Element C must be less than or equal to Data Element B
   - Data Element I must be less than or equal to Data Element B
   - The sum of C+I must be less than or equal to Data Element B.
   - For Period 1, the sum of C + I + J should equal B.
   - For Period 2, the sum of C + I should equal B.
   - The number of MTM eligible beneficiaries should not be greater than the contract's enrollment.
   - A date should not be entered in both "Date of MTM enrollment" and "Date MTM participation was declined" fields (the file will be rejected by HPMS).
   - If "Date Participant Discontinued MTM" is provided, then "Reason participant discontinued 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 decline participation, and discontinue participation in MTMP.

E. Notes – additional clarifications to a reporting section.
   - The period of MTMP eligibility and enrollment is a contract year, therefore eligibility, participation, 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 invited to participate (per each Part D Sponsor's MTM program's enrollment method) and may re-enroll into the MTMP. In this case, enrollment into the MTMP may begin on the first of the new contract year to avoid gaps in MTMP services. Beneficiaries who no longer meet the eligibility criteria at the start of the new MTM program year would not be asked to participate.
   - A beneficiary who did not respond to the Sponsor's invitation to participate in MTM may be reported as pending in Period 1, but would be reported as declined in Period 2 if he/she remains a non-respondent.' By Period 2, all MTM eligible beneficiaries must be accounted as either participated or declined participation per the appropriate data elements and reported on the MTMP beneficiary-level file with corresponding enrollment or declined dates as determined by the sponsor.
   - 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. Generic Drug 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 to be entered into the HPMS at the CMS Plan (PBP) level:

Element Letter	Element Name	Definition	Allowable Values
A	Number of Paid Claims for Generic Drugs	The total number of paid claims for Part D generic drugs (regardless of days supply).	• No decimals. • Generic drug classifications based on First DataBank or Medispan. • Should be a subset of B. • Field type: Number.
B	Total Number of Paid Claims	The total number of Part D paid claims (regardless of days supply).	• No decimals. • Field type: Number.

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- A generic dispensing rate of greater than 80% or less than 20% will be flagged as a potential outlier.
- A Plan's (PBP's) enrollment size is also considered when identifying potential outliers.
- 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.
- A Plan should validate that data element B is greater than or equal to data element A.
- If there is enrollment in the Plan, B should be greater than 0.

D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- A generic dispensing rate (GDR) will be calculated by dividing element A by B, and multiplying by 100.
- The average GDR across all plans will represent a Part D average GDR.
- The average claims per enrollee will be calculated based on element B divided by the average plan enrollment.
- CMS will identify plans that are less than or equal to the 5^{th} and greater than or equal to the 95^{th} percentile as potential outliers.

E. Notes – additional clarifications to a reporting section.
   - Each prescription fill is reported as one claim, regardless of the quantity dispensed.
   - Prescriptions with a final disposition of reversal should be excluded.
   - Plans are not required to reconcile these data with PDE.

VI. 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	Fraud and Abuse	Number of fraud and abuse grievances received.	• Should be a subset of L. • Each grievance should be mutually exclusive for elements A-K. • Field type: Number.
B	Enrollment / Disenrollment	Number of enrollment/disenrollment grievances received. (If enrollment/ disenrollment grievances cannot be easily distinguished from benefits package grievances, then put in either category, as these will be combined for analysis purposes).	• Should be a subset of L. • Each grievance should be mutually exclusive for elements A-K. • Field type: Number.
C	Benefits Package	Number of benefit package grievances received. (If enrollment/ disenrollment grievances cannot be easily distinguished from benefits package grievances, then put in either category, as these will be combined for analysis purposes).	• Should be a subset of L. • Each grievance should be mutually exclusive for elements A-K. • Field type: Number.
D	Pharmacy Access / Network	Number of pharmacy access/network grievances received.	• Should be a subset of L. • Each grievance should be mutually exclusive for elements A-K. • Field type: Number.

Element Letter	Element Name	Definition	Allowable Values
E	Marketing	Number of marketing grievances received.	• Should be a subset of L. • Each grievance should be mutually exclusive for elements A-K. • Field type: Number.
F	Customer Service	Number of customer service grievances received.	• Should be a subset of L. • Each grievance should be mutually exclusive for elements A-K. • Field type: Number.
G	Confidentiality/ Privacy	Number of confidentiality/privacy grievances received.	• Should be a subset of L. • Each grievance should be mutually exclusive for elements A-K. • Field type: Number.
H	Quality of Care	Number of quality of care grievances received. Quality of care grievances related to Part C should be excluded.	• Should be a subset of L. • Each grievance should be mutually exclusive for elements A-K. • Field type: Number.
I	Exceptions	Number of exception grievances received. (If exception grievances cannot be easily distinguished from appeal grievances, then put in either category, as these will be combined for analysis purposes).	• Should be a subset of L. • Each grievance should be mutually exclusive for elements A-K. • Field type: Number.
J	Appeals	Number of appeal grievances received. (If exception grievances cannot be easily distinguished from appeal grievances, then put in either category, as these will be combined for analysis purposes).	• Should be a subset of L. • Each grievance should be mutually exclusive for elements A-K. • Field type: Number.

Element Letter	Element Name	Definition	Allowable Values
K	Other	Number of other grievances received.	• Should be a subset of L. • Each grievance should be mutually exclusive for elements A-K. • Field type: Number.
L	Total Grievances	Total number of grievances received.	• Should be the total of elements A-K. • Field type: Number.
M	Number of Grievances Filed by LIS Enrollees	Total number of LIS grievances received, specifically the number of grievances which are filed by beneficiaries that receive low-income subsidy. This data should be reported based on a beneficiary's LIS status at the time the grievance was filed.	• Should be a subset of element L. • Field type: Number.

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 percentile for any grievance element rate per 1000 enrollee will be flagged as an outlier.
   - A grievance rate greater than 5,000 per 1,000 enrollees will be considered an outlier.
   - 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 A+B+C+D+E+F+G+H+I+J+K should be equal to data element L.
   - Data element M should be less than or equal to data element L.

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.

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

   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.

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

- 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 M is different from data elements A-K, which are categories of grievances. Data element M reports on a subset of the beneficiary population which has filed grievances.
- 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.
- Complaints received by 1-800 Medicare or recorded in the CTM should be excluded from these data.

VII. 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.	• Yes. • No.
	Confidentiality agreement	Does this contract operate under a confidentiality agreement? See notes for specific directions regarding how this information should be reported to CMS.	• Yes. • No.
	Changes reported to CMS	If "Yes" to confidentiality agreement question - Have these changes been provided to CMS per those agreements?	• Yes. • No.
	Changes reported to CMS	If "No" to confidentiality agreement question - Have these changes been reflected within the Contract Management Module?	• Yes. • No.
B	Changes to the organization	Have changes been made to the Provision of Part D functions?" If "No" – no more data entry is required.	• Yes. • No.
	Changes reported to CMS	If "Yes" to changes to the organization question, - Have these changes been reflected within the Contract Management Module?	• Yes. • No.

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 that the submission is for multiple contracts,
   - Submit both documents via email to 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.

VIII. Transition

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	Retail Setting Minimum days supply for one time, temporary fill	The minimum number of days supply the Plan's transition policy provides for its one-time, temporary fill for enrollees in the retail setting. (Includes all LTC beneficiaries due to the fact that they are eligible for emergency fills)	• Field type: Number.
B	Retail Setting Minimum days in plan's transition process	The minimum number of days, beginning on the enrollee's effective date of coverage, in a plan's transition process for enrollees in the retail setting.	• Field type: Number.
C	LTC Setting Minimum days supply for temporary fill	The minimum number of days supply the Plan's transition policy provides for its temporary fill (with multiple refills as necessary) for enrollees in the LTC setting.	• Field type: Number.
D	LTC Setting Minimum days in plan's transition process	The minimum number of days, beginning on the enrollee's effective date of coverage, in a plan's transition process for enrollees in the LTC setting.	• Field type: Number.
E	Minimum days supply provided to LTC enrollees for emergency	After the minimum transition period has expired, the minimum number of days supply the Plan provides to LTC enrollees for an emergency supply of non-formulary Part D drugs while an exception is being processed.	• Field type: Number.

Element Letter	Element Name	Definition	Allowable Values
F	Maximum days after temporary transition fill for Plan to send written transition notice	The maximum number of business days after a temporary transition fill within which the Plan will send a written transition notice via U.S. first class mail.	• Field type: Number.

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
   - Element A must be at least 30 days, unless the enrollee presents a prescription written for less than 30 days.
   - Elements B and D must be at least 90 days.
   - Elements C and E must be at least 31 days, unless the enrollee presents a prescription written for less than 31 days.
   - Element F must equal 1, 2, or 3 days.
   - See allowable values in table 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.
   - Element A must be greater than or equal to 30 days.
   - Element B must be greater than or equal to 90 days.
   - Element C must be greater than or equal to 31 days.
   - Element D must be greater than or equal to 90 days.
   - Element E must be greater than or equal to 31 days.
   - Element F must equal 1, 2, or 3 days.

D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
   - CMS will analyze transition data to evaluate if plans are appropriately administering transition policies.

E. Notes – additional clarifications to a reporting section.
   - Data included in the Transition Reporting Requirements should be based on the Sponsor's CMS-approved Transition policy.

IX. 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	Transactions Rejected Due to Failure to Complete Step Therapy Edit Requirements	The number of pharmacy transactions rejected due to failure to complete step therapy edit requirements in the time period.	• Part D Sponsors should report the total number of pharmacy transactions. CMS understands these numbers may include multiple transactions for the same prescription drug claim. • Field type: Number.
B	Transactions Rejected Due to Need for Prior Authorization (not including first pass step therapy edits or early refills)	The number of pharmacy transactions rejected due to need for prior authorization (not including first pass step therapy edits or early refills) in the time period.	• Part D Sponsors should report the total number of pharmacy transactions. CMS understands these numbers may include multiple transactions for the same prescription drug claim. • Field type: Number.
C	Transactions Rejected Due to Quantity Limits	The number of pharmacy transactions rejected due to quantity limits in the time period.	• Part D Sponsors should report the total number of pharmacy transactions. CMS understands these numbers may include multiple transactions for the same prescription drug claim. • Field type: Number.

Element Letter	Element Name	Definition	Allowable Values
D	Number of Prior Authorizations for Formulary Drugs Requested	The number of prior authorizations requested for formulary medications in the time period specified (not including first pass step therapy edits, early refills, or quantity limits).	• Should be greater than or equal to element E. • Field type: Number.
E	Number of Prior Authorizations for Formulary Drugs Approved	The number of prior authorizations approved for formulary medications, of those submitted in the time period not including first pass step therapy edits, early refills, or quantity limits).	• Should be a subset of element D. • Field type: Number.
F	Number of Exceptions for Non-Formulary Drugs Requested	The number of exceptions requested for non-formulary medications in the time period (not including early refills).	• Should be greater than or equal to element G. • Field type: Number.
G	Number of Exceptions for Non-Formulary Drugs Approved	The number of exceptions approved for non-formulary medications, of those submitted in the time period (not including early refills).	• Should be a subset of element F • Field type: Number.
H	Number of Tier Exceptions Requested	The number of tier exceptions requested in the time period (not including first pass step therapy edits or early refills).	• Should be greater than or equal to element I. • Field type: Number.
I	Number of Tier Exceptions Approved	The number of tier exceptions approved, of those submitted in the time period (not including first pass step therapy edits or early refills).	• Should be a subset of element H. • Field type: Number.
J	Number of Quantity Limit Exceptions Requested	The number of the quantity limit exceptions requested in the time period (not including early refills).	• Should be greater than or equal to element K. • Field type: Number.
K	Number of Quantity Limit Exceptions Approved	The number of quantity limit exceptions approved, of those submitted in the time period.	• Should be a subset of element J. • Field type: Number.

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 95th 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.
   - Plans should validate that data element E is less than or equal to data element D.
   - Plans should validate that data element G is less than or equal to data element F.
   - Plans should validate that data element I is less than or equal to data element H.
   - Plans should validate that data element K is less than or equal to data element J.

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.
   - 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	Appeals Submitted for Redetermination Standard	The number of appeals submitted for standard redetermination in the time period specified. Do not include those appeals that were submitted as expedited redeterminations and were not granted expedited status.	• Field type: Number.
B	Appeals Submitted for Redetermination Expedited	The number of appeals submitted for expedited redetermination in the time period specified.	• Should be greater than or equal to element C. Should not be included in element A. • Field type: Number.
C	Appeals Submitted for Redetermination Expedited Status Granted	The number of appeals submitted for expedited redetermination that were granted expedited status in the time period specified.	• Should be a subset of element B. • Field type: Number.
D	Appeals Submitted for Redetermination Withdrawn by Enrollee Standard	The number of appeals submitted for standard redetermination withdrawn by the enrollee in the time period specified.	• This should be a subset of element A. • Field type: Number.
E	Appeals Submitted for Redetermination Withdrawn by Enrollee-Expedited	The number of appeals submitted for expedited redetermination withdrawn by the enrollee in the time period specified.	• This should be a subset of element B. • Field type: Number.
F	Appeals Submitted for Redetermination Resulting in Reversal of Original Decision	The number of redeterminations in the time period specified resulting in full reversal of original decision.	• Field type: Number.

Element Letter	Element Name	Definition	Allowable Values
G	Appeals Submitted for Redetermination Resulting in Partial Reversal of Original Decision	The number of redeterminations in the time period specified resulting in partial reversal of original decision.	• Field type: Number.
H	Number of Adverse Redeterminations due to Insufficient Evidence of Medical Necessity	The number of adverse redeterminations in the time period specified due to insufficient evidence of medical necessity from enrollee's prescribing physician. Examples of insufficient evidence of medical necessity may include, but are not limited to, when the plan does not receive the information, or the information received does not support medical necessity.	• Field type: Number.
I	Independent Review Entity (IRE) Reconsiderations Due to Inability to Meet Timeframe for Coverage Determination	The number of appeals submitted for IRE reconsideration in the time period specified due to inability to meet timeframe for coverage determination.	• Field type: Number.
J	Independent Review Entity (IRE) Reconsiderations Due to Inability to Meet Timeframe for Redetermination	The number of appeals submitted for IRE reconsideration in the time period specified due to inability to meet timeframe for redetermination.	• Field type: Number.
K	Independent Review Entity (IRE) Reconsiderations Resulting in Reversal of Original Decision Standard	The number of IRE decisions for standard reconsideration in the time period specified resulting in full reversal of original coverage determination or redetermination.	• Field type: Number.

Element Letter	Element Name	Definition	Allowable Values
L	Independent Review Entity (IRE) Reconsiderations Resulting in Reversal of Original Decision-Expedited	The number of IRE decisions for standard reconsideration in the time period specified resulting in partial reversal of original coverage determination or redetermination.	• Field type: Number.
M	Independent Review Entity (IRE) Reconsiderations Resulting in Partial Reversal of Original Decision Standard	The number of IRE decisions for expedited reconsideration in the time period specified resulting in full reversal of original coverage determination or redetermination.	• Field type: Number.
N	Independent Review Entity (IRE) Reconsiderations Resulting in Partial Reversal of Original Decision Expedited	The number of IRE decisions for expedited reconsideration in the time period specified resulting in partial reversal of original coverage determination or redetermination.	• Field type: Number.
O	Independent Review Entity (IRE) Reconsiderations Resulting in Upholding of Original Decision Standard	The number of IRE decisions for standard reconsideration in the time period specified resulting in upholding of original coverage determination or redetermination.	• Field type: Number.
P	Independent Review Entity (IRE) Reconsiderations Resulting in Upholding of Original Decision Expedited	The number of IRE decisions for expedited reconsideration in the time period specified resulting in upholding of original coverage determination or redetermination.	• Field type: Number.

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 95th 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 element C is less than or equal to data element B.
   - Plans should validate that data element D is less than or equal to data element A.
   - Plans should validate that data element E is less than or equal to data element B.
   - 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. Overpayment

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	Amount to be Recouped	For the time period identified above, the total overpayment dollars identified to be recouped by the Contract (i.e., any funds recovered from any entity it has overpaid, including, pharmacies, providers, Pharmaceutical Benefit Managers, etc.).	• Zero is an allowed value. • Field type: Number.
B	Amount Actually Recouped	For the time period identified above, the total overpayment dollars recouped by the Contract.	• Zero is an allowed value. • Field type: Number.

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.
- See allowable values above.

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 review these data to ensure that overpayments are recovered and that the Medicare Part D Sponsor is developing checks and balances to reduce and eliminate future overpayments.

E. Notes – additional clarifications to a reporting section.
- The definition of an overpayment for purposes of Part D reporting is an overpayment that occurs anytime Medicare directly, or through one of its contractors, erroneously makes a payment. The actual overpayment amount is the amount of money received in excess of the amount due and payable under the Part D drug benefit. Examples may include overpayments made to pharmacies, overpayments a Part D Sponsor makes to a PBM for claims payment, and findings from pharmacy audits. This information is necessary to ensure that overpayments are being identified and recouped appropriately.

- If the Part D Sponsor feels there were payment errors made relating to any type of administrative fees, these amounts should be included in the Part D Sponsor's report. An incorrect administrative fee is considered one example of an overpayment that should be reported to CMS.
- A receivable that was requested in error, deemed uncollectible or considered bad debt should be included in the Collected section of the reporting section. It is very important to keep a detailed record of how the overpayment was collected for CMS auditors

XII. 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)_(CONTRACTYEARQ#).txt, replacing ‘(SPONSORNAME)’ with the Part D Sponsor’s name and ‘(CONTRACTYEAR)’ with the with the year and quarter number 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, no decimals, can be a negative number. Zero should be entered in the fields if no data are available.	999999999999

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
Pending Rebates	NUM REQUIRED	12	For each unique manufacturer/drug name combination, provide the rebate amount requested for the reporting period specified but not yet received (if applicable.) Limit to 999999999999, no decimals, can be a negative number Zero should be entered in the fields if no data are available	999999999999
Prior Rebates	NUM REQUIRED	12	For each unique manufacturer/drug name combination, provide the rebate amount received that is associated with a prior reporting period (if applicable). Limit to 999999999999, no decimals, can be a negative number. Zero should be entered in the fields if no data are available. If the 4th quarter 2007 rebates are received during 1st quarter of the contract year, the rebates would be reported in the 1st quarter contract year file as Prior Rebates.	999999999999

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

Discounts and Other Price Concessions File Record Layout

Field Name	Field Type	Field Length	Field Description	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 to be reported on a quarterly basis, not as a cumulative total. Therefore only those rebates identified to be pending during the specific quarter should be reported for that quarter, and should not be carried forward. For example, in Quarter 1 a Part D Sponsor identifies $100 in pending rebates. The Part D Sponsor reports this value in Q1 report. In Quarter 2, the Part D Sponsor determines that the $100 remains outstanding, but the Part D Sponsor should not carry the pending $100 to Q2's pending rebates report.
- Rebates received that apply to a previous quarter are to be reported by entering the rebate amount in the current quarter's rebate report in both the Pending Rebates and the Prior Rebate column if the rebates were collected after the previous reporting period.
- Rebates received during the current reporting period which apply to a previous quarter but were not identified in the Pending Rebates column previously should be reported by entering the rebate amount in the current quarter's rebate report in both the Pending Rebates and the Prior Rebate column.
- Part D Sponsors should account for short pays, as well as overpays. Below are 2 scenarios that demonstrate how data should be entered:
    - *Short pay*: In this scenario, it is determined in Q2 that a Part D Sponsor has only received $50, and will not receive the remaining $50 as reported in Q1. To account for this, the Part D Sponsor should enter the difference as a negative value in the pending rebate column: (-$50), and the amount received in the prior rebates column.

	Manufacturer Name	**Drug Name**	**Rebates Received**	**Pending Rebates**	**Prior Rebates**
Q1	Manuf A	Drug B	0	100	0
Q2	Manuf A	Drug B	0	-50	50

    - *Overpay*: In this scenario, it is determined in Q2 that a Part D Sponsor received more than the full pending amount reported in Q1, $200. To account for this, the Part D Sponsor should enter the difference as an additional value in the pending rebate column: ($50). The Part D Sponsor will also enter the total rebates received for the prior quarter Q1, $250.

	Manufacturer Name	**Drug Name**	**Rebates Received**	**Pending Rebates**	**Prior Rebates**
Q1	Manuf A	Drug B	0	200	0
Q2	Manuf A	Drug B	0	50	250

XIII. Long-term Care (LTC) Rebates

EFFECTIVE NOVEMBER 2008, THIS REPORTING SECTION IS SUSPENDED

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:

LTC Rebates File Record Layout

Field Name	Field Type	Field Length	Field Description
LTC Pharmacy Name	CHAR REQUIRED	100	For each rebate, provide the name of the LTC pharmacy.
NCPDP #	CHAR REQUIRED	7	Indicate the contracted LTC pharmacy NCPDP number. This field should be a 7 character long string using 0 – 9.
NPI Number	CHAR OPTIONAL	10	Indicate the contracted LTC pharmacy NPI (National Provider Identifier) number.
NDC	CHAR CONDITIONALLY OPTIONAL	11	Provide the 11-digit NDC associated with this rebate. (Only NDCs active or inactive after January 1, 2006 will be accepted.) If one of the 4 fields is blank (NDC, Manufacturer Name, Drug Name, and Rebate $ Unit) all must be blank, and if all 4 fields are blank, the Technical Notes field should be non-missing.
Manufacturer Name	CHAR CONDITIONALLY OPTIONAL	100	For each rebate, provide the contracting manufacturer name. If one of the 4 fields is blank (NDC, Manufacturer Name, Drug Name, and Rebate $ Unit) all must be blank, and if all 4 fields are blank, the Technical Notes field should be non-missing.
Drug Name	CHAR CONDITIONALLY OPTIONAL	100	For each rebate, provide the brand name. If one of the 4 fields is blank (NDC, Manufacturer Name, Drug Name, and Rebate $ Unit) all must be blank, and if all 4 fields are blank, the Technical Notes field should be non-missing.

Field Name	Field Type	Field Length	Field Description
Rebate $ / Unit	NUM CONDITIONALLY OPTIONAL	17	Provide the contractual per unit rebates received during the reporting period (cash basis) associated with the listed drug. Limit to 999999999999.9999, can also be a negative number. If one of the 4 fields is blank (NDC, Manufacturer Name, Drug Name, and Rebate $ Unit) all must be blank, and if all 4 fields are blank, the Technical Notes field should be non-missing.
Technical Notes	CHAR CONDITIONALLY OPTIONAL	4000	Provide any technical notes regarding the LTC pharmacy rebate calculations. If one of the 4 fields is blank (NDC, Manufacturer Name, Drug Name, and Rebate $ Unit) all must be blank, and if all 4 fields are blank, the Technical Notes field should be non-missing.

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 upload negative numbers and zero in the upload file.
   - If one of the following fields is blank, then all of these fields must be blank: Manufacturer Name, Drug Name, Rebate $ per unit received, and NDC.
   - If Manufacturer Name, Drug Name, Rebate $ per unit received, and NDC fields are blank, then Technical Notes is required.
   - HPMS validates NDCs against drug databases such as FDB and Medispan.

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 LTC rebate data to ensure that pharmacies are compliant with reporting rebates to plans.

E. Notes – additional clarifications to a reporting section.
   - To submit these data to HPMS, Part D Sponsors will upload a Text file (filename=REBATES_LTC PHARMACIES_(CONTRACTNAME)_(CONTRACTYEARQ#).TXT, replacing '(CONTRACTNAME)' with the Part D Sponsor's name and

'(CONTRACTYEARQ#)' with the year and quarter number) containing a header record and the fields as described by the table above.

- LTC pharmacies are to report rebates to all contracts with which they are contracted. LTC pharmacies may receive rebates that are not contingent on prescription drug utilization, and therefore must report rebates to Part D Sponsors even if there is no prescription utilization by the plans' enrollees.
- In general, a sponsor is to require reporting for its entire network of LTC pharmacies. However, CMS will permit sponsors to exercise discretion about whether to collect rebate data from their LTC pharmacies that serve less than 5% of LTC beds in an area ("area" is defined as the state in which the LTC pharmacy is licensed). For this reporting exemption, the term pharmacy represents a pharmacy organization at its highest level rather than the discrete NCPDP number or location. A pharmacy organization that includes multiple pharmacy locations should be considered in its entirety by a sponsor to determine if that chain serves less than 5% of the LTC beds in the respective area. For reporting purposes, however, these LTC pharmacies must still be listed in the rebate report to CMS.
    - *For an individual pharmacy, that is not part of a pharmacy chain and serves less than 5% of the LTC beds in the area, the sponsor should list the LTC pharmacy NCPDP # in the report, leave the Manufacturer, Drug name and Rebate unit fields blank, and enter "Not required to report" in the Technical Notes field.*
    - *For a pharmacy chain serving less than 5% of LTC beds of a state in which any of its pharmacies are licensed, the sponsor should list all pharmacies by NCPDP #, leave the Manufacturer, Drug name and Rebate unit fields blank, and enter "Not required to report" in the Technical Notes field.*
    - *For a pharmacy chain with multiple pharmacies serving more than 5% of LTC* beds in a state, a sponsor must list all of the chain's pharmacies licensed in that state and their rebates received. Any pharmacies that did not receive rebates should be reported by listing NCPDP #, leaving the Manufacturer, Drug name and Rebate unit fields blank, and entering "Not required to report" in the Technical Notes field.
        - If a pharmacy is licensed in multiple states and meets the criteria of 5% of the LTC beds served in at least one state, the rebates received by that pharmacy must be reported.
- Sponsors do not need to report zero rebate dollars for a given LTC pharmacy.
- A negative Rebate $/ Unit should be entered by inserting the negative symbol ("-") in front of the value. No parentheses are necessary. (For example, -123,000 is a negative value.)
- Part D Sponsors must adhere to the policies and guidance set forth by CMS, and submit data for Part D Plan Reporting Requirements based on those terms. CMS contracts with each Part D Sponsor, and in turn, a Part D Sponsor typically contracts with other providers. For cases in which a provider, such as a LTC pharmacy, is non-compliant, the Part D sponsor should first consider initiating possible contractual remedies and other legal options to improve compliance. Meanwhile, the sponsor should leave the NPI field blank, leave the Pharmacy Name, Manufacturer, Drug name and Rebate unit fields blank, and in the Technical Notes field enter "Noncompliant."

XIV. 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.	• This should be a currency field.
B	Total Liabilities	Total liabilities as of the end of the quarterly reporting period.	• This should be a currency field.
C	Total Cash	Total cash as of the end of the quarterly reporting.	• This should be a currency field.
D	Total Cash Equivalents	Total cash equivalents as of the end of the reporting period.	• This should be a currency field.
E	Total Current Assets	Total current assets as of the end of the quarterly reporting period.	• This should be a currency field..
F	Total Current Liabilities	Total current liabilities as of the end of the quarterly reporting.	• This should be a currency field.
G	Total Revenue	Total revenue as of the end of the quarterly reporting period.	• This should be a currency field.
H	Total Expenses	Total expenses as of the end of the quarterly reporting period.	• This should be a currency field.
I	Total Administrative Expenses	Total administrative expense as of the end of the quarterly reporting period.	• This should be a currency field. NOTE: Direct Contract PDPs are waived from this element.
J	Total Net Income	Total net income as of the end of the quarterly reporting period.	• This should be a currency field.
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	• This should be a currency field.

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.	• This should be a currency field.

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.
   - Negative numbers and zeros are allowable values for data elements, unless specified below.
   - 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.

XV. Drug Benefit Analyses

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	Benefit Type	Plan's benefit design (e.g. defined standard, enhanced alternative).	• N/A - this information is displayed in HPMS. • Field type: Text (already provided)
B	Deductible Phase Non-LIS Enrollees	The total number of non-LIS enrollees in the deductible phase as of the last day of the month. Report enrollees without claims in this field.	• No Decimals. • For Plans without deductibles, this field will not appear in HPMS. • Field type: Number.
C	Deductible Phase LIS Enrollees	The total number of LIS enrollees in the deductible phase as of the last day of the month. Include all LIS enrollees for all subsidy levels. Report enrollees without claims in this field.	• No Decimals. • For Plans without deductibles, this field will not appear in HPMS. • Field type: Number.
D	Pre-Initial Coverage Limit Phase Non-LIS Enrollees	The total number of non-LIS enrollees in the pre-initial coverage limit (pre-ICL) phase as of the last day of the month. The pre-ICL phase is the period of time in which a beneficiary is beyond the deductible phase, but has not reached the coverage gap. For Plans with no coverage gap, report the number of enrollees who are pre-catastrophic in this field, and report zero in data element F.	• No Decimals. • Field type: Number.
E	Pre-Initial Coverage Limit Phase LIS Enrollees	The total number of LIS enrollees in the pre-initial coverage limit (pre-ICL) phase as of the last day of the month. The pre-ICL phase is the period of time in which a	• No Decimals. • Include all LIS enrollees for all subsidy levels. • Field type: Number.

Element Letter	Element Name	Definition	Allowable Values
		beneficiary is beyond the deductible phase, but has not reached the coverage gap. For Plans with no coverage gap, report the number of enrollees who are pre-catastrophic in this field, and report zero in data element G.	
F	Coverage Gap Non-LIS Enrollees	The total number of non-LIS enrollees in the coverage gap as of the last day of the month. For Plans with no coverage gap, report the number of enrollees who are pre-catastrophic in data element D, and report zero in this field. Plans which offer partial coverage during the coverage gap (e.g. generics only) are still considered to have a coverage gap, and must report data in this field.	• No decimals. • Field type: Number.
G	Coverage Gap LIS Enrollees	The total number of LIS enrollees in the coverage gap as of the last day of the month.	• No decimals. • Include all LIS enrollees for all subsidy levels. • For Plans with no coverage gap, report the number of people who are pre-catastrophic in data element E, and report zero in this field. • Plans which offer partial coverage during the coverage gap (e.g. generics only) are still considered to have a coverage gap, and must report data in this field. • Field type: Number.
H	Catastrophic Coverage Level Non-LIS	The total number of non-LIS enrollees in the catastrophic coverage level as of the last	• No decimals. • Field type: Number.

Element Letter	Element Name	Definition	Allowable Values
	Enrollees	day of the month.	
I	Catastrophic Coverage Level LIS Enrollees	The total number of LIS enrollees in the catastrophic coverage level as of the last day of the month. Include all LIS enrollees for all subsidy levels.	• No decimals. • Field type: Number.

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
   - The sum of elements B through I should be within 10% of CMS' enrollment data records.
   - CMS will identify potential outliers based on the following criteria for the percent of beneficiaries in each phase of the benefit:

Period	Deductible + Pre- ICL	Coverage Gap	Catastrophic Coverage
1st half of the Year	<20%	>50%	>40%
2nd half of the Year	<10%	>60%	>50%

   - As an example, CMS would flag a plan which reports greater than 50 percent of beneficiaries in the coverage gap as a potential outlier.
   - 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 maximum allowable value of elements B through I cannot be greater than 999,999,999,999.

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 sum data elements B+D+F+H to calculate the PBP's total non-LIS enrollment, and the sum of data elements C+E+G+I to calculate the PBP's LIS enrollment.
   - CMS will trend enrollment in each phase of the benefit for each month of the year. This should be consistent with claims and risk scores for the population.

E. Notes – additional clarifications to a reporting section.
   - Each data element is mutually exclusive; an enrollee should be reported only once for each monthly snapshot.
   - Regardless of renewal cycle, these data should be based on the enrollees' status within the given plan's benefit structure for each monthly reporting period.
   - A prescription's fill date should be used to determine where a beneficiary falls in the benefit as of the last day of the month.
   - Data should include adjustments that have been captured during each monthly snapshot. Plans should run reports necessary for this reporting on a monthly

basis, at a point in time that captures as many adjustments as possible. This time period may differ for each Part D Plan (PBP)/PBM, but essentially this should be similar to the process for generation of monthly EOBs.

- Monthly reports should not be resubmitted due to claims retroactivity. CMS' priority is to capture monthly snapshots for trending, with the understanding that many transactions and adjustments may occur after the snapshots are provided. Reports should only be resubmitted if it is determined that errors were made in the original dataset.
- When determining which "deductible" these data elements should apply to for LIS beneficiaries, the LIS member with a total drug spend of $200 in a plan with a defined standard benefit (deductible $275) should be included in Data Element C.
- Plans should report LIS beneficiary counts based on the plan’s main benefit design and not the specific LIS level.
- For plans without deductibles, this field will not appear in HPMS. For example, an 800 series plan does not have a deductible phase, therefore, these columns will not be displayed in the DBA data entry screen.
- For plans with deductibles offered only for some types of drugs, e.g. deductibles for brand name drugs only, no deductible for generic drugs, members should be reported in the furthest phase of the benefit. For example, a member who is in the ICL phase due to generic drug utilization, but in the deductible phase due to brand drug utilization should be reported in the ICL phase.