Medicare Part D Plan Reporting Requirements:
Technical Specifications Document
Contract Year 2018

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Introduction

The Part D Plan Reporting Requirements document provides a description of the reporting sections, reporting timeframes and deadlines, and specific data elements for each reporting section. The document has completed OMB review and approval in compliance with the Paper Reduction Act of 1995, and its OMB control number is #0938-0992. The document is located on the CMS website https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.html.

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 reporting section is specified in the reporting requirements document and within each reporting 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 reporting section is below.

REPORTING REQUIREMENT SECTION	LEVEL OF REPORTING
Enrollment and Disenrollment	Contract
Retail, Home Infusion, and Long Term Care Pharmacy Access	Contract (Section I) Plan (Sections II and III)
Medication Therapy Management (MTM) Programs	Contract
Grievances	Contract
Improving Drug Utilization Review Controls	Plan
Coverage Determinations and Redeterminations	Contract
Employer/Union-Sponsored Group Health Plan Sponsors	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.

Please note the quarterly reports are due annually and will be available in HPMS on or after 12/28/2018. Sponsors should generate these reports at the end of each quarter of the contract year and hold them for the annual submission.

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, responsible for correcting previously submitted data if it is determined the data were erroneous. If CMS changes the technical

specifications during the contract year, which requires a change in reporting methodology, CMS is requiring that reports be regenerated for the prior reporting periods for Part D reporting. In order to accommodate data validation activities, data corrections may only be submitted until March 31st following the last quarter or end of year reporting deadline.

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

CMS tracks resubmissions, including the number of resubmissions after the deadline. Failure to resubmit after requesting a resubmission is considered as overdue. CMS expects that data are accurate on the date they are submitted. Data resubmissions may only be submitted until March 31st following the last quarter or end of year reporting deadline. CMS urges Plans to store revised data for CMS auditors and data validation reviewers. Plans should retain documentation supporting their reported data.

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. Redeterminations);
    b. Time period (e.g., 1st quarter 2018);
    c. Select contracts or plans, depending on reporting level; and
    d. The reason for the resubmission request.

General Data Entry Rules

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

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

General Data File Upload Rules

Please note that each time a data file submission is made, the previously submitted file will be ignored, regardless if the second file submission successfully passes validation. This also applies to MTM submissions via Gentran. Sponsors may face compliance actions for failing to meet Reporting Requirements and Data Validation requirements. Additionally, CMS will not be able to include such contracts in any associated performance measures, or the Reporting Requirements Public Use File (PUF).

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 are excluded from these Part D reports, unless otherwise specified (e.g., Coverage Determinations and Redeterminations reporting). MA Organizations and Medicare Cost Plans that offer Part D benefits will be required to comply with all reporting requirements contained herein, with the exception of the Employer/Union-Sponsored Group Health Plan Sponsors reporting section. PACE Organizations are excluded from these Part D reporting requirements. Contracts that terminate during the reporting period are also excluded from these reporting requirements.

Medicare/Medicaid Plans (MMPs) should refer to the Medicare-Medicaid Financial Alignment Model Reporting Requirements for additional reporting guidance.

Based on the information in the Reporting Requirements document and these Technical Specifications, Plans/Sponsors should report data based on interpretation of these documents and be able to support their reporting decisions.

Contracts with no enrollment have the option of reporting for the following sections: Enrollment/Disenrollment; Grievances; Coverage Determinations and Redeterminations; Employer/union-Sponsored Group Health Plan Sponsors (No enrollment signifies that the contract has no enrollees for all months within the reporting period). If a contract has any enrollment during the reporting period, it is required to report all sections.

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

I. Enrollment and Disenrollment

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

Enrollment

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

Element Letter	Element Name	Definition	Allowable Values
A.	Total number of enrollment requests (i.e., requests initiated by the beneficiary or his/her authorized representative) received in the specified time period. Do not include auto/facilitated or passive enrollments, rollover transactions or other enrollments effectuated by CMS.	The total number of enrollment requests received in the specified time period.	• Field type: Number • Note – this element is based on initial receipt date, not effective date.
B.	Total number of enrollment requests complete at the time of initial receipt (i.e. required no additional information from applicant or his/her authorized representative).	Of the total reported in A, the number of enrollment requests complete at the time of initial receipt (i.e. required no additional information from applicant or his/her representative).	• Field type: Number • Is a subset of A

Element Letter	Element Name	Definition	Allowable Values
C.	Total number of enrollment requests for which the Sponsor was required to request additional information from the applicant (or his/her representative).	Of the total reported in A, the number of enrollment requests for which the Sponsor was required to request additional information from the applicant (or his/her representative). Do not report as a distinct enrollment request information received from an applicant in response to a request for information necessary to complete an enrollment request.	• Field type: Number • Is a subset of A
D.	Total number of enrollment requests denied due to the Sponsor's determination of the applicant's ineligibility to elect the plan (i.e. individual not eligible for an election period).	Of the total reported in A, the number of enrollment requests denied due to the Sponsor's determination of the applicant's ineligibility to elect the plan (i.e. individual not eligible for an election period.)	• Field type: Number • Is a subset of A
E.	Number of incomplete enrollment requests received that are completed within established timeframes.	Of the total reported in C, the number of incomplete enrollment requests received that are incomplete upon initial receipt and completed within established timeframes.	• Field type: Number • Is a subset of C

Element Letter	Element Name	Definition	Allowable Values
F.	Number of enrollment requests denied due to the applicant or his/her authorized representative not providing information to complete the enrollment request within established timeframes.	Of the total reported in C, the number of enrollment requests denied due to the applicant or his/her authorized representative not providing information to complete the enrollment request within established timeframes.	• Field type: Number • Is a subset of C
G.	Number of paper enrollment requests received.	Of the total reported in A, the number of paper enrollment requests received.	• Field type: Number • Is a subset of A
H.	Number of telephonic enrollment requests received (if offered).	Of the total reported in A, the number of telephonic enrollment requests received (if sponsor offers this mechanism).	• Field type: Number • Is a subset of A
I.	Number of internet enrollment requests received via plan or affiliated third-party website (if Sponsor offers this mechanism).	Of the total reported in A, the number of internet enrollment requests received via plan website (if Sponsor offers this mechanism).	• Field type: Number • Is a subset of A
J.	Number of Online Enrollment Center (OEC) enrollment requests received.	Of the total reported in A, the number of Medicare Online Enrollment Center (OEC) enrollment requests received.	• Field type: Number • Is a subset of A

Element Letter	Element Name	Definition	Allowable Values
K.	Number of enrollment requests effectuated by sales persons (as defined in Chapter 3 of the Medicare Managed Care Manual).	Of the total reported in A, the number of enrollment requests effectuated by sales persons (as defined in Chapter 3 of the Medicare Managed Care Manual).	• Field type: Number • Is a subset of A • For stand-alone PDPs only.
L.	Number of enrollment transactions submitted using the SEP Election Period code “S” related to creditable coverage.	Of the total reported in A, the number of enrollment transactions submitted using the SEP Election Period code “S” for individuals who involuntarily lose creditable coverage or who were not adequately informed of a loss of creditable coverage or that they never had creditable coverage.	• Field type: Number • Is a subset of A
M.	Number of enrollment transactions submitted using the SEP Election Period code “S” related to SPAP.	Of the total reported in A, the number of enrollment transactions submitted using the SEP Election Period code “S” for individuals who belong to a Qualified SPAP or who lose SPAP eligibility.	• Field type: Number • Is a subset of A
N.	Number of enrollment transactions submitted using the SEP Election Period code “S” that coordinates with the Medicare Advantage Disenrollment Period.	Of the total reported in A, the number of enrollment transactions submitted using the SEP Election Period code “S” that coordinates with the Medicare Advantage Disenrollment Period.	• Field type: Number • Is a subset of A • For stand-alone PDPs only.

Element Letter	Element Name	Definition	Allowable Values
O.	Number of enrollment transactions submitted using the SEP Election Period code “S” for individuals affected by a contract nonrenewal, plan termination or service area reduction.	Of the total reported in A, the number of enrollment transactions submitted using the SEP Election Period code “S” for individuals affected by a contract nonrenewal, plan termination or service area reduction.	• Field type: Number • Is a subset of A
P.	The total number of individuals included in the advance notification for seamless conversion enrollment	The total number of individuals included in the advance notification for seamless conversion enrollment for effective dates occurring within the reporting period.	• Field type: Number • Applicable to only MA organizations approved by CMS to offer seamless conversion enrollment.
Q.	Number of individuals whose Medicare eligibility is based on age.	Of the total reported in 1P, the number of individuals whose Medicare eligibility is based on age.	• Field type: Number • Is a subset of P • Applicable to only MA organizations approved by CMS to offer seamless conversion enrollment.
R.	Number of individuals whose Medicare eligibility is based on disability.	Of the total reported in 1P, the number of individuals whose Medicare eligibility is based on disability.	• Field type: Number • Is a subset of P • Applicable to only MA organizations approved by CMS to offer seamless conversion enrollment.

Element Letter	Element Name	Definition	Allowable Values
S.	Number of enrollments submitted to CMS.	Of the total reported in 1P, the number of enrollments submitted to CMS.	• Field type: Number • Is a subset of P • Applicable to only MA organizations approved by CMS to offer seamless conversion enrollment.

Disenrollment

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

Element Letter	Element Name	Definition	Allowable Values
A.	Total number of voluntary disenrollment requests received in the specified time period. Do not include disenrollments resulting from an individual's enrollment in another plan.	The total number of voluntary disenrollment requests received in the specified time period.	• Field type: Number • Note – this element is based on initial receipt date, not effective date.
B.	Total number of disenrollment requests complete at the time of initial receipt (i.e. required no additional information from enrollee or his/her authorized representative).	Of the total reported in A, the number of disenrollment requests complete at the time of initial receipt (i.e. required no additional information from enrollee or his/her representative).	• Field type: Number • Is a subset of A

Element Letter	Element Name	Definition	Allowable Values
C.	Total number of disenrollment requests denied by the Sponsor for any reason.	Of the total reported in A, the number of disenrollment requests denied by the Sponsor for any reason.	• Field type: Number • Is a subset of A
D.	Total number of involuntary disenrollments for failure to pay plan premium in the specified time period.	The total number of involuntary disenrollments effectuated in the specified time period.	• Field type: Number • Note – this element is based on disenrollment effective date.
E.	Total number of disenrolled individuals who submitted a timely request for reinstatement for Good Cause.	Of the total reported in D, the number of disenrolled individuals who submitted a timely request for reinstatement for Good cause.	• Field type: Number • Is a subset of D
F.	Total number of favorable Good Cause determinations	Of the total reported in E, the number of favorable Good Cause determinations.	• Field type: Number • Is a subset of E
G.	Total number of individuals reinstated.	Of the total reported in F, the number of individuals reinstated.	• Field type: Number • Is a subset of F

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
   - CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.
   - The percent of enrollment requests denied by the contract will be examined for outlier data. After accounting for the number of enrollment requests filed, contracts with values above the 95th percentile for their contract type will be flagged as outliers.
   - The percent of disenrollment requests denied by the contract will be examined for outlier data. After accounting for the number of disenrollment requests files, contracts with values above the 95th percentile for their contract type will be flagged as 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.
   - N/A.

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

E. Notes – additional clarifications to a reporting section.
1. EGWPs and all-800 series plans are waived from this reporting section. For contracts with both non 800-series and 800-series plans, data for the 800-series plan(s) may be excluded.
2. Data are based on beneficiary initiated enrollment and disenrollment requests or submitted transactions. Auto-assignments and other CMS initiated actions should not be included in these data.
3. Reporting should include all enrollment and disenrollment requests received during the period, including those which may subsequently "fail" after the period, and/or reporting deadline.
4. Enrollment/disenrollment requests for which a timely cancellation request is received should not be included in this reporting.
5. Voluntary disenrollments for which the plan sponsor is notified solely via TRC, instead of via receipt of a member's disenrollment request, should not be included in this reporting.
6. HPMS displays one module for reporting both Part C and Part D Enrollment/Disenrollment data.
7. Element B- *Total number of enrollment requests complete at the time of initial receipt (i.e. required no additional information from applicant or representative):*
   - Reporting should include all enrollment requests received during the reporting period that at the time of initial receipt included a response for each of the required data elements (see Appendix 2 in both the MMCM and MPDBM for a list of required elements). Alternatively, if one or more of these required elements is missing at the time of initial receipt but is available to the plan sponsor via CMS systems, the enrollment request is considered "complete at the time of initial receipt" for reporting purposes.
   - An enrollment request is considered incomplete at the time of initial receipt if at the time of initial receipt it does not include a response for all of the required data elements and the missing but required data is not available via CMS systems. The method by which the plan sponsor requests the missing information of the applicant is irrelevant for reporting purposes.
8. Element C- *Total number of enrollment requests for which the sponsor was required to request additional information from the applicant or representative:*
   - Reporting should include all forms of potential contact.
9. Element D- *Total number of enrollment requests denied due to the Sponsor's determination of the applicant's ineligibility to elect the plan (i.e. individual not eligible for an election period):*

- An enrollment request is considered complete even if the only information missing is that which is necessary for the plan sponsor to determine the applicant's eligibility for an election period. For this element, reporting should include those instances in which the plan sponsor denied the enrollment request based on its determination that the applicant was not eligible for an election period.

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

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

I. Retail Pharmacy Access, Home Infusion (HI), and Long Term Care (LTC) Pharmacy Access: Three data files to be uploaded through HPMS at the CMS Part D Contract level; please refer to HPMS layouts and templates for more information. Plans should submit their entire contracted pharmacy network (including pharmacies that may be physically located outside of their service area).

II. 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	The number of prescriptions provided in the time period by all pharmacies owned and operated.	• Is mutually exclusive. • Field type: Number
B.	Number of prescriptions provided at all pharmacies contracted	The number of prescriptions provided in the time period at all pharmacies contracted.	• Is mutually exclusive. • Field type: Number

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 retail pharmacies and have received a waiver of the retail pharmacy convenient access standards. These plans are not exempt from reporting Retail Pharmacy Access listed above.

Element Letter	Element Name	Definition	Allowable Values
A.	Number of prescriptions provided by retail pharmacies owned and operated by the plan.	The number of prescriptions provided in the time period by retail pharmacies owned and operated.	• Is mutually exclusive. • Field type: Number
B.	Number of prescriptions provided at all retail pharmacies contracted by the plan.	The number of prescriptions provided in the time period at all retail pharmacies contracted.	• Is 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.
   - CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.
   - The number of contracted retail pharmacies reported for this reporting section will be combined with data from the Pharmacy Support of Electronic Prescribing reporting section to determine outliers for the percent of retail pharmacies enabled to receive electronic prescribing.
   - 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.
   - For section I (HI and LTC pharmacy reporting), the States Licensed field must include ALL states in the plan's service area for the HI and LTC data file uploads.

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.
   - For contracts with both employer-only (800 series) and individual market plans, access standards will only be evaluated for the individual portion of their service area.
   - For contracts that only offer employer plans (including Employer/Union Direct Contracts), access standards will be evaluated for their entire service area.

E. Notes – additional clarifications to a reporting section.

1. Employer/union group plans and 800 series plans are exempt from this reporting section. For contracts with both non-800 series and 800-series plans, data for the 800-series plan(s) may be excluded.
2. The Retail, HI and LTC pharmacy network templates can be found in HPMS Plan Reporting module, select Contract Year, under Documentation -> Download File Templates.
3. 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.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance.html and click on the Beneficiary Count 2017 zip file.

III. Medication Therapy Management (MTM) Programs

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

- A data file containing the following fields for all beneficiaries enrolled in the contract's Medication Therapy Management (MTM) program (either met the specified targeting criteria per CMS – Part D requirements or other expanded plan-specific targeting criteria) at any time in the reporting period will be uploaded using Gentran or Connect Direct. A detailed HPMS memo will be released by CMS around January 2019.
- 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.

Important notes and clarifications are provided below in E. Notes.

MTM Record Layout

Element Letter	Field Name	Field Type	Field Length	Start Position	End Position	Field Description
A.	Contract Number	CHAR REQUIRED	5	1	5	The Contract Number (e.g., H1234, S1234) for your organization.
B.	HICN or RRB Number	CHAR REQUIRED	12	6	17	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. Distinct beneficiaries should only be reported once per contract year per contract file. If the beneficiary's HICN changed during the reporting period, only report the most current HICN. Do not report beneficiary if deceased or retroactively disenrolled prior to their MTM eligibility date.
C.	Beneficiary first name	CHAR REQUIRED	30	18	47	Provide the first name of the beneficiary.
D.	Beneficiary middle initial	CHAR OPTIONAL	1	48	48	Provide the middle initial of the beneficiary.

Element Letter	Field Name	Field Type	Field Length	Start Position	End Position	Field Description
E.	Beneficiary last name	CHAR REQUIRED	30	49	78	Provide the last name of the beneficiary.
F.	Beneficiary date of birth	DATE REQUIRED	8	79	86	Provide the date of birth for the beneficiary (CCYYMMDD, e.g., 19400130).
G.	Met the specified targeting criteria per CMS – Part D requirements	CHAR REQUIRED	1	87	87	Indicate if the beneficiary met the specified targeting criteria per CMS – Part D requirements. This should be Y (yes) or N (no).
H.	Beneficiary identified as cognitively impaired at time of Comprehensive Medication Review (CMR) offer or delivery of CMR	CHAR REQUIRED	1	88	88	Indicate if the beneficiary was identified as being cognitively impaired at time of the CMR offer or delivery of the CMR. This should be Y (yes), N (no), or U (unknown).
I.	Date of MTM program enrollment	DATE REQUIRED	8	89	96	Provide the date the beneficiary was enrolled in the MTM program within the reporting period (CCYYMMDD, e.g., 20180102).

J.	Date met the specified targeting criteria per CMS – Part D requirements	DATE Conditionally REQUIRED (if element G is 'Yes')	8	97	104	Provide the date the beneficiary met the specified targeting criteria per CMS – Part D requirements within the reporting period (CCYYMMDD, e.g. 20180102). *This date must be provided if the beneficiary met the specified targeting criteria per CMS – Part D requirements. Leave blank if beneficiary was enrolled based upon other expanded, plan-specific targeting criteria and never met the specified targeting criteria per CMS – Part D requirements within the reporting period.* This date should be the same as Date of MTM program enrollment if the beneficiary was first enrolled based on meeting the targeting criteria per CMS – Part D requirements. This date should be different from the MTM enrollment date if the beneficiary was first enrolled based on other expanded plan-specific targeting criteria and then met the targeting criteria per CMS – Part D requirements later in the reporting period. In this scenario, this date would be after the Date

Element Letter	Field Name	Field Type	Field Length	Start Position	End Position	Field Description
						of MTM program enrollment. The date should be blank if the beneficiary was only enrolled in the MTM program based on other expanded, plan-specific targeting criteria.
K.	Date MTM program opt-out, if applicable	DATE Conditionally REQUIRED	8	105	112	Provide the date the beneficiary opted-out within the reporting period (CCYYMMDD, e.g., 20180130). *The date must be provided if the beneficiary opted-out of the MTM program.*
L.	Reason participant opted-out of MTM program (Death; Disenrollment from Plan; Request by beneficiary; or Other). Required if Date of MTM Opt-out is applicable.	CHAR Conditionally REQUIRED (If element K is provided)	2	113	114	For each beneficiary who opted-out of the MTM program, provide the reason. Reasons for opting out must be one of the following: 01 - Death; 02 - Disenrollment from Plan; 03 - Request by beneficiary; or 04 - Other. *If Date MTM program opt-out is provided, then Reason participant opted-out of MTM program is required.*

Element Letter	Field Name	Field Type	Field Length	Start Position	End Position	Field Description
M.	Offered annual Comprehensive Medication Review (CMR)	CHAR REQUIRED	1	115	115	Indicate if the beneficiary was offered a CMR per CMS – Part D requirements within the reporting period. This should be Y (yes) or N (no).
N.	If offered a CMR, date of (initial) offer	DATE Conditionally REQUIRED (If element M is provided)	8	116	123	Provide the date the CMR was offered within the reporting period (CCYYMMDD, e.g. 20180601). *The date must be provided if the beneficiary was offered a CMR.*
O.	Received annual CMR with written summary in CMS standardized format	CHAR REQUIRED	1	124	124	Indicate if the beneficiary received an annual CMR per CMS – Part D requirements with written summary in CMS' standardized format within the reporting period. This should be Y (yes) or N (no).
P.	Number of CMRs received with written summary in CMS standardized format	NUMERIC REQUIRED	2	125	126	Indicate the number of CMRs received per CMS – Part D requirements with written summary in CMS' standardized format within the reporting period. This is a numeric field. If the beneficiary received no CMRs per CMS – Part D requirements with written summary in CMS' standardized format, report 0.

Element Letter	Field Name	Field Type	Field Length	Start Position	End Position	Field Description
Q.	Date(s) of CMR(s) with written summary in CMS standardized format	DATE Conditionally REQUIRED (If element O is 'Yes')	8	127	134	For each beneficiary enrolled who received at least one annual CMR per CMS – Part D requirements with written summary in CMS' standardized format, provide the date of the first CMR within the reporting period. This is a date field (CCYYMMDD, e.g. 20180615). *The date must be provided if the beneficiary received a CMR per CMS – Part D requirements with written summary in CMS' standardized format.*
	Date(s) of CMR(s) with written summary in CMS' standardized format, second date of CMR.	DATE Conditionally REQUIRED (If element O is 'Yes' and element P is greater than 1)	8	135	142	For each beneficiary who received more than 1 CMR per CMS – Part D requirements with written summary in CMS' standardized format, provide the date of the last CMR. This is a date field (CCYYMMDD, e.g. 20180615). *The date must be provided if the beneficiary received more than 1 CMR per CMS – Part D requirements with written summary in CMS' standardized format.*

Element Letter	Field Name	Field Type	Field Length	Start Position	End Position	Field Description
R.	Method of delivery for the annual CMR	CHAR Conditionally REQUIRED (If element O is 'Yes')	2	143	144	For each beneficiary who received a CMR per CMS – Part D requirements with written summary in CMS' standardized format within the reporting period, indicate the method of delivery for the CMR. The method of delivery must be one of the following: 01 – Face-to-face; 02 – Telephone; 03 – Telehealth consultation (e.g. video-conference); or 04 – Other *If the beneficiary received a CMR per CMS – Part D requirements with written summary in CMS' standardized format, then method of delivery of the annual CMR is required.* If the beneficiary received more than 1 CMR, report the method of delivery for the initial CMR.

S.	Qualified Provider who performed the initial CMR	CHAR Conditionally REQUIRED (If element O is 'Yes')	2	145	146	For each beneficiary who received a CMR per CMS – Part D requirements with written summary in CMS' standardized format, indicate the Qualified Provider who performed the CMR. Qualified Provider must be one of the following: 01 – Physician; 02 – Registered Nurse; 03 – Licensed Practical Nurse; 04 – Nurse Practitioner; 05 – Physician's Assistant; 06 – Local Pharmacist; 07 – LTC Consultant Pharmacist; 08 – Plan Sponsor Pharmacist; 09 – Plan Benefit Manager (PBM) Pharmacist; 10 – MTM Vendor Local Pharmacist; 11 – MTM Vendor In-house Pharmacist; 12 – Hospital Pharmacist; 13 – Pharmacist – Other; 14 - Supervised Pharmacy Intern 15 – Other *If beneficiary received a CMR, then the Qualified Provider who performed the CMR is required.* If the beneficiary received more than 1

Element Letter	Field Name	Field Type	Field Length	Start Position	End Position	Field Description
						CMR, report the Qualified Provider who performed the initial CMR.
T.	Recipient of CMR	CHAR Conditionally REQUIRED (If element O is 'Yes')	2	147	148	For each beneficiary who received a CMR per CMS – Part D requirements with written summary in CMS' standardized format, indicate the recipient of the CMR. Report the recipient of the CMR interaction and not the recipient of the CMR documentation. The recipient of the CMR must be one of the following: 01 – Beneficiary 02 – Beneficiary's prescriber 03 – Caregiver 04 – Other authorized individual *If the beneficiary received a CMR, then the recipient of the CMR is required.* If the beneficiary received more than 1 CMR, report the recipient of the initial CMR.

Element Letter	Field Name	Field Type	Field Length	Start Position	End Position	Field Description
U.	Number of targeted medication reviews	NUMERIC REQUIRED	3	149	151	Indicate the number of targeted medication reviews conducted per CMS – Part D requirements within the reporting period. This is a numeric field. If no targeted medication reviews were performed for the beneficiary, report 0.

Element Letter	Field Name	Field Type	Field Length	Start Position	End Position	Field Description
V.	Number of drug therapy problem recommendations made to beneficiary's prescriber(s) as a result of MTM services	NUMERIC REQUIRED	2	152	153	Indicate the number of drug therapy problem recommendations made to beneficiary's prescriber(s) as a result of MTM services. For reporting purposes, a recommendation is defined as a suggestion to take a specific course of action related to the beneficiary's drug therapy. If the same recommendation is made to multiple prescribers or repeated on multiple dates, then that recommendation should only be counted and reported once. Examples include, <u>but are not limited to</u>, Needs additional therapy; Unnecessary drug therapy; Dosage too high; Dosage too low; More effective drug available; Adverse drug reaction; or Medication Non-compliance/Non-adherence. This is a numeric field. If there were no drug therapy problem recommendations made to the beneficiary's prescriber(s) as a result of MTM services, report 0.

Element Letter	Field Name	Field Type	Field Length	Start Position	End Position	Field Description
W.	Number of drug therapy problem resolutions resulting from recommendations made to beneficiary's prescriber(s) as a result of MTM recommendations	NUMERIC REQUIRED	2	154	155	Indicate the number of drug therapy problem resolutions resulting from recommendations made to beneficiary's prescriber(s) as a result of MTM services. For reporting purposes, a resolution is defined as a change or variation from the beneficiary's previous drug therapy. Examples include, but are not limited to, Initiate drug; Change drug (such as product in different therapeutic class, dose, dosage form, quantity, or interval); Discontinue or substitute drug (such as discontinue drug, generic substitution, or formulary substitution); Medication compliance/ Adherence. This is a numeric field. If there were no drug therapy problem resolutions resulting from recommendations made to beneficiary's prescriber(s) as a result of MTM services, report 0.

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
    - CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.

- The percent of eligible MTM program enrollees who opted out of an MTM program will be examined for outlier data.
- The percent of MTM program enrollees who received a CMR with written summary in CMS' standardized format will be examined for outlier data. Dates of enrollment and opt-out will be considered.
- 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 column "Field Type" for data fields that are conditionally required.

D. Analysis - how CMS will evaluate reported data, as well as how other data sources may be monitored.
    - CMS will evaluate the percent of beneficiaries that opt-out of MTM.
    - CMS will evaluate the percent of beneficiaries who are offered and receive a CMR with written summary in CMS' standardized format.
    - CMS will evaluate initial MTM outcomes, as reported as drug therapy problem recommendations and drug therapy problem resolutions.

E. Notes - additional clarifications to a reporting section.
    1. For 2018, CMS will accept either HICN or Medicare Beneficiary Identifier (MBI).
    2. Sponsors should refer to the annual Guidance and Submission memo for information about the Part D MTM program requirements and definitions. It is posted on the CMS MTM web page at www.cms.gov > Medicare > Prescription Drug Coverage Contracting > Medication Therapy Management. All distinct beneficiaries enrolled in the contract's MTM program (either met the specified targeting criteria per CMS – Part D requirements or other expanded plan-specific targeting criteria) at any time in the reporting period should be reported. Per guidance, sponsors must auto-enroll the targeted beneficiaries when they meet the eligibility criteria.
    3. Sponsors should refer to the annual MTM Submission Instructions memo for information regarding MTM file submission. It is posted on the CMS Part D Reporting Requirements web page at www.cms.gov>Medicare>Prescription Drug Coverage Contracting>Part D Reporting Requirements.
    4. The period of MTM eligibility and enrollment is a contract year (which aligns with the reporting period); therefore eligibility, enrollment, etc. are captured and reported distinctly for each contract year.
        - Beneficiaries should be reported for each contract year in which they were eligible and enrolled in the contract's MTM program. A distinct MTM program enrollment date should be generated and reported for each year of enrollment.
        - Beneficiaries who were enrolled in the MTM program in the previous contract year and who met the eligibility criteria and were enrolled in the MTM program in the current reporting period should be reported.
        - Beneficiaries who were newly targeted for eligibility (i.e., beneficiaries not enrolled in the contract's MTM program during the previous contract year)

and enrolled in the MTM program for the current contract year within the reporting period should be reported.
    - Beneficiaries who no longer met the eligibility criteria for the MTM program for the contract year within the reporting period should no longer be enrolled in the MTM program and should not be reported.
    - Beneficiaries who are deceased or were retroactively disenrolled prior to their MTM eligibility date should not be reported.
5. The drug costs used to determine if a beneficiary's total annual cost of covered Part D drugs is likely to equal or exceed the specified annual cost threshold for MTM program eligibility includes the ingredient cost, dispensing fee, sales tax, and vaccine administration fee, if applicable. This projection may be based on claims within the reporting period or based on historical claims from the previous contract year.
6. For beneficiaries who opted-out of the MTM program due to disenrollment from the plan, only mid-year disenrollments from the plan should be reported. Do not report end of year disenrollments (such as 12/31).
7. Sponsors should refer to Chapter 5, Section 10.2 of the Prescription Drug Benefit Manual for a description of the types of facilities which are considered. LTC.
8. The CMR may be performed with the beneficiary's prescriber, caregiver, or other authorized individual if a beneficiary is offered the annual CMR and is unable to accept the offer to participate (cognitively impaired). This does not apply to situations where the sponsor is simply unable to reach the beneficiary or there is no evidence of cognitive impairment. Sponsors should be able to present documentation or rationale for these determinations. Sponsors should refer to the 2018 MTM Program Guidance and Submission memo for more requirements and guidance about MTM services.
9. The reported beneficiaries must have received MTM services within the reporting period that met or exceeded CMS' MTM program requirements.
    - Only activities that were completed within the reporting period should be reported.
    - The MTM service dates (such as CMR date of (initial) offer (element N) and Date(s) of CMR(s) with written summary in CMS' standardized format (element Q)) must be on or after the Date of MTM program enrollment (element I).
10. Only CMRs that met CMS – Part D requirements should be reported for any beneficiary enrolled in the contract's MTM program. Refer to the 2018 MTM Program Guidance and Submission memo for CMR requirements and definitions, which includes:
    - an interactive, person-to-person, or telehealth medication review and consultation of the beneficiary's medications (including prescriptions, over-the-counter (OTC) medications, herbal therapies, and dietary supplements), and
    - performed in real-time by a pharmacist or qualified provider with the beneficiary (or their authorized representative), and
    - with a written summary of the results of the review provided to the targeted individual in CMS' standardized format.
11. Offers for a CMR may be delivered via many methods such as spoken conversations, voicemail messages, or mailed letters. For reporting CMR offers, the beneficiary must receive the offer. Therefore, returned mail or incorrect

phone numbers do not count as an offer. Sponsors should maintain documentation of all offers.

12. When reporting the MTM program opting-out reason in element L, opt-out code "03" includes request by beneficiary or beneficiary's authorized representative.
13. The enrolled beneficiaries may refuse or decline individual MTM services or the CMR without having to opt-out (disenroll) from the MTM program. These beneficiaries should not be reported as opted-out from the MTM program.
14. The number of drug therapy problem recommendations made to prescriber(s) as a result of MTM services (element V) should be reported based on the count of unique recommendations made to prescribers within the reporting period regardless of the success or result of the recommendations; it is not equal to the total number of prescribers that received drug therapy problem recommendations.
    - For example, if 3 drug therapy problem recommendations were identified for a member and were sent to the prescriber in a fax, this should be reported as 3 recommendations. If these 3 drug therapy recommendations were sent to a second prescriber, this should still be reported as 3 recommendations (not 6).
15. Regarding drug therapy problem resolutions resulting from recommendations made to the beneficiary's prescriber(s) as a result of MTM recommendations (element W), sponsors should retain documentation supporting the number of drug therapy problem resolutions reported to CMS. If the resolution was observed in the calendar year after the current reporting period and before the reporting deadline, but was the result of a MTM intervention and drug therapy problem recommendation made within the current reporting period, the change may be reported for the current reporting period. However, this change to drug therapy should not be reported again in the following reporting period.
16. When a beneficiary moves between contracts:
    - The beneficiary should be reported in the beneficiary level files for each contract in which they were enrolled in the contract's MTM program at any time in the reporting period. Each contract must qualify and enroll the beneficiary based on the contract's own MTM program criteria.
    - The dates of enrollment, disenrollment elements, and other elements (such as CMRs and TMRs) should be reported distinctly per the specific activities that occurred for the beneficiary when enrolled in the MTM program for the specific contract ID within the reporting period (contract year). For example, if the beneficiary received a CMR while enrolled in contract 1's MTM program but did not receive a CMR while enrolled in contract 2's MTM program, the CMR should be reported for contract 1 only.
17. When a beneficiary enrolls in a Part D contract and is enrolled in their MTM program, disenrolls from the contract, and re-enrolls in the same Part D contract during the reporting period:
    - The Part D contract may re-enroll the beneficiary into the MTM program. The beneficiary does not need to be re-qualified for the MTM program again within the reporting period (contract year).
    - Report the beneficiary only once per contract file per contract year.
    - Regardless of the duration of the gap in MTM program enrollment, report the initial date of MTM program enrollment, no date of MTM program opt-

out, and all other applicable elements for activity across all MTM program enrollment periods within the reporting period.

18. Sponsors should not upload the MTM beneficiary-level data file if they have no MTM enrollees to report. Instead Sponsors should report that they have no MTM enrollees via e-mail to: partd-planreporting@cms.hhs.gov.

IV. 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 uploaded into HPMS at the Contract level. Please refer to HPMS layouts and templates for more information.

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

- CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.
- The percent of beneficiaries filing grievances will be examined for outlier data. After accounting for enrollment, plans with values above the 95th percentile for their plan type or below the 5th percentile for their plan type will be flagged as outliers.
- The percent of grievances for which the plan provided timely notification of its decision will be examined for outlier data. All plans with values below the 5th percentile for their plan type will be flagged as 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.

- Contracts should validate that the total number of grievances should be the sum of the grievances by category Grievances processed in an expedited manner would also be reported in a grievance category; sponsors should not double-count expedited grievances when verifying the number of total grievances has been reported correctly. See note 4 below for additional clarification.
- Contracts should validate that the total number of timely notifications is equal to the sum of the total number of timely notifications for each category excluding expedited grievances.

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 contracts 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.

1. Grievances can be filed either orally or in writing. Sponsors should refer to 42 CFR §423.564 and Chapter 18, of the Prescription Drug Benefit Manual for additional information regarding procedures for handling Part D grievances. Sponsors can also refer to 20.2.4.2 for examples of grievances, and definitions.
2. An enrollee's request for a coverage determination or a redetermination for drug coverage is not considered a grievance.
3. Complaints received by 1-800 Medicare or recorded only in the CTM are excluded from these data; however, complaints filed separately as grievances with the plan are included in this reporting.
4. Sponsors should report expedited grievances in 2 elements: First, in the total number of expedited grievances. Second, in the appropriate grievance category. For example, if an enrollee files an expedited grievance because the plan denied their request for an expedited coverage determination, that grievance should be reported both as an "Expedited Grievance" and also as a "Coverage Determination and Redetermination Process" grievance.
5. Sponsors should conduct the appropriate outreach/investigation to determine which plan a grievance should be reported under. In rare instances where a Sponsor is unclear which plan the grievance pertains to, the sponsor should assign the grievance to its plan with the highest enrollment.
6. Grievances are categorized by the type of grievance as determined by the plan, and reported based on the grievance decision date.
7. A grievance decision (disposition) is timely when the sponsor appropriately notifies the enrollee of the decision no later than 30 calendar days from receipt of the grievance (24 hours for expedited

grievances), or as expeditiously as the enrollee's health condition requires.

8. In the event that an enrollee files multiple grievances during a reporting period, plans should consider the following:
    - If an enrollee files a grievance and then files a grievance again on the same issue, prior to the Plan's decision or the deadline for decision notification (whichever is earlier), then that should only be counted as one grievance.
    - If an enrollee files a grievance and then files a subsequent grievance on the same issue after the Plan's decision or deadline for decision notification (whichever is earlier), then that counts as a separate grievance.
    - If an enrollee files a grievance about two different issues, then they are counted as separate grievances.
9. MA-PDs should report a grievance as either a Part C or Part D grievance, depending on the process the plan used to investigate/resolve the grievance. For most complaints or grievances, a plan will be able to determine which is more applicable. For the minority of cases where a clear distinction is not available for a MA-PD, cases should be reported as Part C grievances and therefore should be excluded from Part D reporting.
10. If the enrollee files a grievance with a previous contract, but enrolls in a new contract before the grievance is resolved, the previous contract is still responsible for investigating, resolving and reporting the grievance.
11. The "CMS Issues" grievance category is meant to identify those grievances that are related to issues outside of the Plan's direct control and where the plan cannot take further action without assistance from CMS. This same type of categorization is used in the Complaint Tracking Module (CTM) and allows CMS to exclude complaints when calculating a contract's complaint rate by enrollment. Examples include instances where a beneficiary seeks a Special Enrollment Period that is not explicitly outlined in CMS enrollment guidance, or a beneficiary who has lost coverage due to an erroneous loss of Part A/B entitlement. Refer to CTM Exclusion List in the Star Ratings Technical Notes for more information.
12. Withdrawn grievances should be excluded from this reporting.
13. Grievances should be reported even if the member filing the grievance disenrolls from the contract.
14. Dismissals: CMS expects that dismissed grievances represent a very small percentage of total Part D grievances a plan receives. However, this element has been added to provide plans with a means to report grievances that are received but not processed by the plan because they do not meet the requirements for a valid grievance. Generally, a dismissal would occur when the procedure requirements for a valid grievance are not met and the plan is unable to cure the defect. For example, a grievance is received from a purported representative of the enrollee, but a properly executed appointment of representative form has not been

filed and there is no other documentation to show that the individual is legally authorized to act on the enrollee's behalf and the plan is unable to obtain the required documentation in a reasonable amount of time and therefore, dismisses the grievance. See guidance set forth in section 10.4.1 of Chapter 13.

V. Improving Drug Utilization Review Controls

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 uploaded into HPMS at the Plan level. Please refer to HPMS layouts and templates for more information.

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

- CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.
- 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.

- Contracts should validate that the number of unique beneficiaries with at least one claim rejected due to the soft formulary-level cumulative opioid morphine equivalent dose (MED) edit at point of sale (POS) (data element F) is a value less than or equal to the minimum number of claims rejected (data element E).
- Contracts should validate that the number of soft edit claim rejections overridden at the pharmacy level by the pharmacist (data element G) is a value less than or equal to the number of claims rejected (data element E).
- Contracts should validate that the number of beneficiaries with at least one soft edit claim rejection overridden by the pharmacist at the pharmacy (data element H) is a value less than or equal to the unique beneficiaries with at least one claim rejected due to the soft formulary-level cumulative opioid MED edit at POS (data element F).
- Contracts should validate that the number of unique beneficiaries with at least one claim rejected due to the hard formulary-level cumulative opioid MED edit at POS (data element N) is a value less than or equal to the minimum number of claims rejected due to the hard formulary-level cumulative opioid MED edit at POS(data element M).
- Contracts should validate that the number of unique beneficiaries with at least one hard edit claim rejection that also had a coverage determination request for an opioid drug subject to the hard opioid MED edit (data element O) is a value less than or equal to the number of unique beneficiaries with at least one claim rejected due to the hard formulary-level cumulative opioid MED edit at POS (data element N).
- Contracts should validate that the number of unique beneficiaries with at least one claim rejected that also had a claim successfully processed

(paid) for an opioid drug subject to the hard opioid MED edit such as, but not limited to, through favorable coverage determination (data element P) is a value less than or equal to the number of unique beneficiaries with at least one hard edit claim rejection that also had a coverage determination request (data element O).

D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
CMS will calculate at the plan-level and aggregate across contracts with the same POS edit criteria:

- The claim and beneficiary rejection rates for soft and hard opioid MED POS edits per 1,000 opioid claims and opioid users.
- The percentage of soft-edit claim rejections that are overridden [(G/E)*100].
- The average number of soft-edit rejected claims per beneficiary with at least one claim rejected (E/F).
- The percentage of beneficiaries with at least one soft-edit rejected claim whose edit was overridden [(H/F)*100].
- The average number of hard-edit rejected claims per beneficiary with at least one claim rejected (M/N).
- The percent of beneficiaries with at least one hard-edit rejected claim that requested a coverage determination [(O/N)*100].
- The percent of coverage determination requested with a favorable review resulting in the coverage of an opioid drug [(P/O)*100].

We will trend rates from quarter to quarter and from previous years.

E. Notes – additional clarifications to a reporting section.

1. If a plan sponsor submitted and was approved for multiple opioid MED POS edits during the year, meaning the edit criteria changed during the reporting period, report the edit specifications in place during the majority of a reporting period (elements A-D and I-L). The other reported data (totals) should account for activity for the entire reporting period across all edit criteria in place.
2. Soft opioid MED edit claims overridden by the pharmacist at the pharmacy with assistance from the plan for technical reasons should also be included in element G and H. The claim (and unique beneficiaries with at least one claim) rejected due to the soft edit would be reported in elements E and F.
3. The rejected claim is generally not a coverage determination, and should NOT be reported as a coverage determination. However, if the enrollee, the enrollee's representative, or the enrollee's prescriber then contacts the plan to request coverage, that request must be processed as a coverage determination. The coverage determination should be reported, as appropriate, in elements O and P of this section, as well as in section VI - Coverage Determinations and Redeterminations.
    - A coverage determination request for an opioid MED edit should be reported as a utilization management exception (i.e., a request for UM requirement to be waived for that enrollee).

4. If the coverage determination was observed in the calendar year after the current reporting period and before the reporting deadline, but was the result of a claim rejection within the current reporting period, the coverage determination may be reported for the current reporting period. However, this coverage determination should not be reported again in the following reporting period.
5. Soft opioid MED edit claim rejections that resulted in requests for coverage determinations are currently not collected.
6. If a plan sponsor does not have a soft or hard formulary-level cumulative opioid MED POS edit in place during the time period, enter “0” in the appropriate elements.
7. If a POS edit does not include a prescriber and/or pharmacy count criterion, the plan sponsor should enter “0” in the appropriate elements (elements C, D, K, and L).
8. Count in element P only those coverage determinations that result in a favorable determination that requires the plan to cover an opioid(s). The coverage determination should be associated with a cumulative opioid POS hard-edit claim rejection. A favorable determination may result in the original or a modification (i.e., different daily dose, quantity, etc.) of the rejected opioid prescription or a different opioid being covered. If a claim rejects for both a formulary-level cumulative opioid MED POS edit and an early refill edit, the claim should be excluded from the formulary-level cumulative opioid MED POS edit rejection counts. The assumption is that the high dose is the result of the claim being filled too early and not the prescriber’s intentional dosing.
    i. Rejected claims are counted at the unique contract, beneficiary, prescriber, pharmacy, drug (strength and dosage form), quantity, date of service (DOS) and formulary-level cumulative opioid MED POS edit. For example, if multiple transactions are submitted and rejected by the plan for the same formulary-level cumulative opioid MED POS edit from the same pharmacy for the same beneficiary, prescription (drug, quantity and prescriber) and DOS, this would count as one rejected claim. On the other hand, if a beneficiary attempted to fill the same prescription at 3 different pharmacies, either the same day or on different days, and the prescription was rejected each time for the same formulary-level cumulative opioid MED POS edit this would count as 3 rejected claims.

VI. Coverage Determinations and Redeterminations

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 uploaded into HPMS at the Contract level. Please refer to HPMS layouts and templates for more information.

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

- CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.
- The rate of exception requests per 1,000 enrollees will be examined for outlier data. After accounting for enrollment, plans with values above the 95th percentile for their plan type or below the 5th percentile for their plan type will be flagged as outliers.
- The percent of coverage determinations requests approved by the contract will be examined for outlier data. Contracts with values above the 95th percentile or below the 5th percentile will be flagged as outliers.
- CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.
- The rate of redeterminations per 1,000 enrollees will be examined for outlier data. After accounting for enrollment, contracts with values above the 95th percentile or below the 5th percentile will be flagged as outliers.
- The percent of redeterminations resulting in a full or partial reversal of the original decision will be examined for outlier data. After accounting for the number of redeterminations filed, contracts with values above the 95th percentile or below the 5th percentile will be flagged as outliers.
- The percent of redeterminations resulting in upholding the original decision will be examined for analysis purposes.
- The rate of reopenings per 1,000 enrollees will be examined for outlier data. After accounting for enrollment, contracts with values above the 95th percentile or below the 5th percentile will be flagged as outliers. CMS will also identify outliers in the percent of coverage determinations and redeterminations that are reopened.

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

- Contracts should validate that "All Coverage Determinations" under timeliness and disposition equal "Total Number of Coverage Determinations".
- Contracts should validate that the Case_Reopened_Date field is later than or equal to the Original_Disposition_Date field and that Reopening_Disposition_Date field is later than or equal to Case_Reopened_Date field.

- 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.
   - CMS will evaluate exception rates per 1,000 enrollees and will trend rates from quarter to quarter and from previous years.
   - 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.

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

E. Notes – additional clarifications to a reporting section.

1. Rejected Pharmacy Transactions:

1. All types of quantity limit rejects should be included 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).
2. Part D Sponsors should report the total number of pharmacy transactions for Part D drugs by fill date (not batch date), including approved, rejected, and those with final disposition of reversed. Rejections for early refills or safety edits should be excluded. CMS understands these numbers may include multiple transactions for the same prescription drug claim.
3. If there are multiple cost thresholds in place for non-compounds, Sponsors should report the lowest threshold value. Part D Sponsors should report the total number of claims rejected by the plan due to high cost edits for non-compounds. CMS understands these numbers may include multiple transactions for the same prescription drug claim.
4. Sponsors should report the counts of all rejected claims due to high cost edits for non-compounds, even those with different threshold values.
5. Multiple transactions for the same claim should be counted individually.

2. Coverage Determinations and Exceptions:

6. Sponsors should refer to 42 CFR §423.566, §423.568, §423.570, §423.572, §423.576, and §423.578 and Chapter 18, Sections 10, 30, 40, 50 and 130 of the Prescription Drug Benefit Manual for additional information regarding Part D coverage determinations, including exceptions.
7. If a sponsor decides not to provide or pay for a required benefit, in whole or in part, then the decision is an adverse coverage determination and the Sponsor must provide the enrollee with a written denial notice. To ensure consistent reporting by all sponsors, CMS has included data fields to report partially favorable decisions and expects decisions that are only partially favorable are not reported as favorable decisions.

8. Requests for coverage determinations, including exceptions, are reported based on the decision date.
9. Coverage determination requests that relate to Part B versus Part D coverage are included in this reporting. Point of Sale (POS) claims adjudications (e.g., a rejected claim for a drug indicating a B v. D PA is required) are NOT included unless the plan subsequently processed a coverage determination. A drug that is ultimately covered under Part B should be considered for this reporting as an adverse decision under Part D.
10. Drug or classes of drugs, or their medical uses which are statutorily excluded from coverage under Part D should not be included in this reporting. This exclusion is in place for the context of reporting, and is not related to Sponsors' requirements for processing such requests.
11. In the event that a beneficiary files one coverage determination request containing multiple distinct disputes (i.e., multiple drugs), each dispute should be counted as a separate request.
12. A request for an exception to a sponsor's PA criteria could be processed as a coverage determination or as a redetermination, depending if the sponsor has received the beneficiary's initial PA request, and denied it. Reporting should be based on the manner in which each request for exception to a sponsor's PA criteria is processed.
13. Beneficiaries who have Utilization Management (UM) requirements waived based on an exception decision made in a previous plan year or reporting period are not considered as exception requests; and therefore, should not be reported.
14. A coverage determination is timely only when the sponsor makes a decision and appropriately notifies the enrollee and physician (if applicable) of the decision within the applicable adjudication timeframe. For favorable decisions, sponsors must also authorize or provide the benefit (or payment) under dispute within the applicable adjudication timeframe. Sponsors should refer to Chapter 18, Sections 40, 50, and 130 of the Prescription Drug Benefit Manual.
15. Untimely cases forwarded to the Independent Review Entity (IRE) are included in this reporting, and should be included as untimely coverage determinations as well as adverse decisions. Sponsors should include the cases auto-forwarded to the IRE based on the date notification was sent to the member informing him/her that their case has been referred to the IRE.
16. If a sponsor does not provide notice of a coverage determination within the required timeframe, then the case must be forwarded to the IRE, and the sponsor must send a notice to the enrollee informing him or her that their case has been referred to the IRE. Sponsors should refer to Chapter 18, Sections 40.4 and 50.6 of the Prescription Drug Benefit Manual.
17. Untimely cases that were approved (fully favorable to the enrollee) and the enrollee notified within 24 hours of the expiration of the adjudication timeframe are not required to be auto-forwarded to the IRE. These should be reported in element D under Timeliness.

18. While CMS does not currently prescribe the manner in which Part D plans should process invalid or withdrawn coverage determination requests, as a best practice, we do expect plans to develop policies and procedures for processing and responding to coverage determinations that are either withdrawn by the requestor or dismissed by the plan. CMS expects that coverage requests that are withdrawn or dismissed represent a very small percentage of total Part D coverage requests a plan receives. However, these elements have been added to provide plans with a means to report requests that are received and processed but are not adjudicated as either favorable or adverse by the plan.
    - Generally, a dismissal would occur when the procedural requirements for a valid request are not met and the plan is unable to cure the defect. For example, a coverage determination request is received from a purported representative of the enrollee. The plan has been unable to obtain the required documentation within a reasonable amount of time and therefore dismisses the request. Sponsors should refer to Chapter 18, section 10.4.1 for guidance on processing coverage determination, redetermination and grievance requests from enrollee representatives.
    - An example of a withdrawn request: a coverage determination is requested by an enrollee for a drug that requires step therapy. Before the plan issues the coverage determination, and before the timeframe expires and the plan loses jurisdiction of the case and must forward to the IRE, the enrollee speaks to her prescriber and learns that she can take the covered alternative, then calls her plan and asks them not to process her coverage request.

    CMS strongly encourages plans to document withdrawn coverage requests in their systems, including the date and the reason the request was withdrawn.

19. Please review the following two examples about differentiating between coverage determinations and exceptions:

    - Mary's doctor prescribes drug X for Mary; however, Mary's Part D plan has established Step Therapy (ST) criteria to be met for drug X to be covered. Mary would not satisfy the plan's ST criteria, but Mary would suffer adverse effects if she were required to satisfy the ST requirement. Therefore, Mary's doctor submits a request for an exception to the ST criteria along with supporting documentation of the drug's medical necessity. The plan will process this as an exception to ST criteria.
    - John's doctor prescribes drug X for John; however, John's Part D plan has established Step Therapy (ST) criteria to be met for drug X to be covered. John's doctor submits supporting documentation

that John has attempted to satisfy the plan's ST criteria. The plan will process this as a coverage determination (not exception).

20. As mentioned in the July 18, 2014 final guidance, CMS strongly encourages sponsors to place beneficiary-level PA requirements on only four categories of prescription drugs: analgesics, antinauseants (antiemetics), laxatives, and antianxiety drugs (anxiolytics). Part D sponsors are not expected to place hospice PA requirements on other categories of drugs or take special measures beyond their normal compliance and utilization review activities to retrospectively review paid claims for purposes of determining whether drugs in the other categories were unrelated to the hospice beneficiary's terminal illness and related conditions. Sponsors should include hospice-related coverage determinations in this reporting.
21. Direct Member Reimbursements (DMRs) should be reported under the appropriate exception type.
22. Cumulative opioid MED POS edit coverage determination exceptions should be categorized as Utilization Management (Elements H-J)
23. Exclude IRE decisions from this reporting.
24. Exclude duplicate requests.

3. Redeterminations:

25. Refer to 42 CFR §423.580, §423.582, §423.584, and §423.590 and Chapter 18, Sections 10, 70 and 130 of the Prescription Drug Benefit Manual for additional information regarding Part D redeterminations.
26. Redetermination requests are reported based on the decision date.
27. Redetermination requests that relate to Part B versus Part D coverage are included in this reporting if they are processed under the plan's Part D redetermination process. Point of Sale (POS) claims adjudications (e.g., a rejected claim for a drug indicating a B v. D PA is required) are NOT included unless the plan subsequently processed a coverage determination. A drug that is ultimately covered under Part B should be considered for this reporting as an adverse decision Part D.
28. Drug or classes of drugs, or their medical uses which are statutorily excluded from coverage under Part D should not be included in this reporting.
29. In the event that a beneficiary files one redetermination request containing multiple distinct disputes (i.e., multiple drugs), plans should count each dispute as a separate request.
30. A redetermination is timely only when the sponsor makes a decision and appropriately notifies the enrollee of the decision within the applicable adjudication timeframe. For favorable decisions, sponsors must also authorize or provide the benefit (or payment) under dispute within the applicable adjudication timeframe. Sponsors should refer to Chapter 18, of the Prescription Drug Benefit Manual.

31. Untimely cases forwarded to the Independent Review Entity (IRE) are included in this reporting, and should be included as untimely redeterminations as well as adverse decisions. Sponsors should include the cases auto-forwarded to the IRE based on the date notification was sent to the member informing him/her that their case has been referred to the IRE.
32. If a Sponsor does not provide notice of a decision within the required timeframe, then the case should be forwarded to the IRE, and the Sponsor must send a notice to the enrollee informing him or her that their case has been referred to the IRE. Sponsors should refer to Chapter 18, Sections 70.7.1 and 70.8.2 of the Part D Manual.
33. While CMS does not currently prescribe the manner in which Part D plans should process invalid or withdrawn redetermination requests, as a best practice, we do expect plans to develop policies and procedures for processing and responding to redetermination requests that are either withdrawn by the requestor or dismissed by the plan. CMS expects that coverage requests that are withdrawn or dismissed represent a very small percentage of total Part D coverage requests a plan receives. However, these elements were added to provide plans with a means to report requests that are received and processed but are not adjudicated as either favorable or adverse by the plan.
    - Generally, a dismissal would occur when the procedural requirements for a valid request are not met and the plan is unable to cure the defect. For example, a redetermination request is received from a purported representative of the enrollee. The plan has been unable to obtain the required documentation within a reasonable amount of time and therefore dismisses the request. Sponsors should refer to Chapter 18, section 10.4.1 for guidance on processing coverage determination, redetermination and grievance requests from enrollee representatives.
    - An example of a withdrawn request: a redetermination is requested by an enrollee for a drug that requires step therapy. Before the plan issues the redetermination, and before the timeframe expires and the plan loses jurisdiction of the case and must forward to the IRE, the enrollee speaks to her prescriber and learns that she can take the covered alternative, then calls her plan and asks them not to process her coverage request.
    - CMS strongly encourages plans to document withdrawn coverage requests in their systems, including the date and the reason the request was withdrawn.
34. Exclude duplicate requests.

4. Reopenings (Coverage Determinations and Redeterminations):

35. A reopening is a remedial action taken to change a binding determination or decision even though the determination or decision may have been correct at the time it was made based on the evidence of record.

36. Refer to 42 CFR §423.1978-1986 and Chapter 18, section 120 of the Medicare Prescription Drug Benefit Manual for additional information and CMS requirements related to reopenings.
37. Any revisions to a previously issued binding decision that is made through the reopening process, including a revision to the rationale on which that binding decision was based, is subject to the beneficiary notification requirements at 42 CFR §423.1982, and should be included in this reporting.
38. "Other" refers to cases that would not be considered a "clerical error", "other error", "new and material evidence", "fraud or similar fault". Examples of "other" may include policy/procedure change, business configuration change, provider update, other adjustments etc.
39. If an enrollee requests a redetermination (and the request is valid), the contract has no jurisdiction to reopen the coverage determination and must instead process the request as an appeal.
40. Sponsors should exclude Point of Sale (POS) claims transactions which were subsequently revised for purposes of this reopening reporting element, because plans are not required to treat the presentation of a prescription at the pharmacy counter as a request for a coverage determination. All reopened coverage determinations and redeterminations should be included.
41. For cases that are in a reopening status across multiple reporting periods, contracts should report those cases in each applicable reporting period. For example, if a plan reopened a coverage determination on 3/15/2018 and sent the notice of the revised decision on 4/22/2018, that case should be reported as "pending" in the Q1 data file and then as resolved in Q2 (either Fully Favorable, Partially Favorable or Adverse).
42. Case ID is the unique internal tracking number the contract assigned to the case that is being reopened.
43. If the plan assigns a new case ID when it reopens a case, the plan should populate the case ID for the original coverage determination or redetermination in this field.
44. Original Disposition Date: If the contract reopened a coverage determination, this is the date of the original coverage determination. If the contract reopened a redetermination, it is the date of the original redetermination.
45. Case Reopened Date: This may be the same as the date of the reopening disposition, and should fall in the quarter for which the data are being reported. If the Reopening Disposition is resolved (fully favorable, partially favorable, or adverse), the date of reopening disposition is expected to fall in the quarter for which the data is being reported.
46. Reopening Disposition Date is the date the plan revised the original disposition in its system and sent written notification to the enrollee. See 42 CFR §423.1982.

VII. Employer/Union-Sponsored Group Health Plan Sponsors

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

   Data elements to be uploaded into HPMS at the Plan (PBP) and contract level. Please refer to HPMS layouts and templates for more information.

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
   - CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.
   - 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.
   - To be determined.

E. Notes - additional clarifications to a reporting section. This section incorporates previously answered frequently asked questions.
   1. This reporting requirement applies only to individual PDPs and "800 series" PDPs offered to employers. MA-PD plans already report these data as part of the Part C reporting requirements and are therefore exempt from this Part D reporting. Individual PDPs and "800 series" PDPs that have been identified as having the same parent organization as a MA-PD plan are also exempt from this Part D reporting.
   2. HPMS displays one module for reporting both Part C and Part D Employer/Union-Sponsored Group Health Plan Sponsors data.
   3. Each Part D contract will upload a file containing plan level data.
   4. Refer to Part C Technical Specifications for additional guidance.

VIII. Summary of CY2018 Part D Reporting Requirements

Section	Report Level	Frequency	Report Period(s)	Data Due date(s)
Enrollment and Disenrollment	Contract	Biannually	1/1/2018 - 6/30/2018; 7/1/2018 - 12/31/2018	Last Monday of August Last Monday of February
Retail, Home Infusion, and Long-Term Care Pharmacy Access	Subsection I: Contract; Subsections II and III: PBP	Annually	Subsection I: 1/1/2018 - 3/31/2018; Subsections II and III: 1/1/2018 - 12/31/2018	Subsection I: First Monday of May Subsections II and III: First Monday of February
Medication Therapy Management Programs	Contract	Annually	1/1/2018 - 12/31/2018	Last Monday of February
Grievances	Contract	Annually	1/1/2018 - 3/31/2018; 4/1/2018 - 6/30/2018; 7/1/2018 - 9/30/2018; 10/1/2018 - 12/31/2018	First Monday of February

Section	Report Level	Frequency	Report Period(s)	Data Due date(s)
Improving Drug Utilization Review Controls	PBP	Annually	1/1/2018 - 3/31/2018; 1/1/2018 - 6/30/2018; 1/1/2018 - 9/30/2018; 1/1/2018 - 12/31/2018	Last Monday of February
Coverage Determinations and Redeterminations	Contract	Annually	1/1/2018 - 3/31/2018; 4/1/2018 - 6/30/2018; 7/1/2018 - 9/30/2018; 10/1/2018 - 12/31/2018	Last Monday of February
Employer/Union-Sponsored Group Health Plan Sponsors	PBP	Annually	1/1/2018 - 12/31/2018	First Monday of February