Medicare Part C and Part D Reporting Requirements
Data Validation Procedure Manual

Appendix B: Data Validation Standards

For Data Validation Occurring in 2023

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

Last Updated: July 2022

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1. OVERVIEW

The *Data Validation Standards* include general standards and reporting section criteria that the data validation contractor must use to determine whether the organization's data reported to Centers for Medicare & Medicaid Services (CMS) per the *Part C/Part D Reporting Requirements* are accurate, valid, and reliable. Each reporting section's *Data Validation Standards* include identical instructions relating to the types of information that will be reviewed, a set of validation standards (identical for each reporting section), and reporting section criteria that are based on the applicable *Part C/Part D Reporting Requirements and Technical Specifications*.

The DV contractor must use these standards in conjunction with the Data Extraction and Sampling Instructions and Appendix J, the Excel version of the Findings Data Collection Form (FDCF) to upload into the Health Plan Management System (HPMS) Plan Reporting Data Validation Module (PRDVM) in order to evaluate the organization's processes for producing and submitting the reporting sections. It is strongly recommended that the DV contractor and report owner/data provider review the Data Validation Standards documentation before and during the review of a reporting section to ensure that all applicable data fields are extracted for each reporting section.

For the Part C reporting sections, the Medicare Part C Plan Reporting Requirements Document is used as the basis for the data validation standards. For the Part D reporting sections, the Medicare Part D Plan Reporting Requirements Document is used as the basis for the data validation standard.

2. PART C DATA VALIDATION STANDARDS

GRIEVANCES (PART C)

To determine compliance with the standards for Grievances (Part C), the data validation contractor will assess the following information:

- Written response to *OAI* Sections 3 and 4, and documentation requested per *OAI* Sections 5 and 6
- Outlier/data integrity notification(s)- See OAI 4.3.3 for instructions on how to retrieve notices
- Results of interviews with organization staff
- Census and/or sample data
- Data file created for submission to CMS and copy of HPMS screen shots of data entered
- Other relevant information provided by organization

VALIDATION STANDARDS

1. A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) indicates that all source documents accurately capture required data fields and are properly documented.

Criteria for Validating Source Documents:

a. Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS.
b. Source documents create all required data fields for reporting requirements.
c. Source documents are error-free (e.g., programming code and spreadsheet formulas have no messages or warnings indicating errors, use correct fields, have appropriate data selection, etc.).
d. All data fields have meaningful, consistent labels (e.g., label field for patient ID as Patient ID, rather than Field1 and maintain the same field name across data sets).
e. Data file locations are referenced correctly.
f. If used, macros are properly documented.
g. Source documents are clearly and adequately documented.
h. Titles and footnotes on reports and tables are accurate.
i. Version control of source documents is appropriately applied.

2. A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) and census or sample data, whichever is applicable, indicates that data elements for each reporting section are accurately identified, processed, and calculated.

Criteria for Validating Reporting Section Criteria (Refer to reporting section criteria section below):

a. The appropriate date range(s) for the reporting period(s) is captured.
b. Data are assigned at the applicable level (e.g., plan benefit package or contract level).
c. Appropriate deadlines are met for reporting data.
d. Terms used are properly defined per CMS regulations, guidance, Reporting Requirements, and Technical Specifications.
e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; Quality Assurance (QA) checks/thresholds are applied to detect outlier or erroneous data prior to data submission.

3. Organization implements policies and procedures for data submission, including the following:
   a. Data elements are accurately entered / uploaded into HPMS and entries match corresponding source documents. [Data Elements A – E]
   b. All sources, intermediate, and final stage data sets and other outputs relied upon to enter data into HPMS are archived.

4. Organization implements policies and procedures for periodic data system updates (e.g., changes in enrollment, provider/pharmacy status, and claims adjustments).

5. Organization implements policies and procedures for archiving and restoring data in each data system (e.g., disaster recovery plan).

GRIEVANCES (PART C)

6. If organization's data systems underwent any changes during the reporting period (e.g., because of a merger, acquisition, or upgrade): Organization provided documentation on the data system changes and, upon review, there were no issues that adversely impacted data reported.

7. If data collection and/or reporting for this reporting section is delegated to another entity: Organization regularly monitors the quality and timeliness of the data collected and/or reported by the delegated entity or first tier/downstream contractor.

REPORTING SECTION CRITERIA

1. Organization reports data based on the periods of 1/1 through 3/31, 4/1 through 6/30, 7/1 through 9/30, and 10/1 through 12/31.
2. Organization properly assigns data to the applicable CMS contract.
3. Organization meets deadlines for reporting data to CMS by 2/6/2023.

Note to reviewer: If the organization has, for any reason, re-submitted its data to CMS for this reporting section, the reviewer should verify that the organization's original data submissions met each CMS deadline in order to have a finding of "yes" for this reporting section criterion. However, if the organization re-submits data for any reason and if the re-submission was completed by 3/31 of the data validation year, the reviewer should use the organization's corrected data submission for the review of this reporting section.

4. Organization properly defines the term "Grievance" in accordance with 42 Code of Federal Regulations (CFR) §422.564 and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Manual. This includes applying all relevant guidance properly when performing its calculations.
5. Organization accurately reports data by applying data integrity checks listed below and uploads it into HPMS.
   a. Number of total grievances in which timely notification was given (Data Element B) does not exceed number of total grievances (Data Element A).
   b. Number of expedited grievances in which timely notification was given (Data Element D) does not exceed number of total grievances in which timely notification was given (Data Element B).
   c. Number of expedited grievances (Data Element C) does not exceed total grievances (Data Element A).
   d. Number of expedited grievances in which timely notification was given (Data Element D) does not exceed total expedited grievances (Data Element C).
   e. Number of dismissed grievances (Data Element E) are excluded from the total.
   f. If the organization received a CMS outlier/data integrity notice, validate whether or not an internal procedure change was warranted or resubmission through HPMS. (Data Elements A - E)

[Data Elements A – E]

6. Organization accurately calculates the total number of grievances, including the following criteria:
   a. Includes all grievances that were completed (i.e., organization has notified member of its decision) during the reporting period, regardless of when the grievance was received.
   b. Includes all grievances reported by or on behalf of members who were previously eligible, regardless of whether the member was eligible on the date that the grievance was reported to the organization.
   c. If a grievance contains multiple issues filed under a single complainant, each issue is calculated as a separate grievance.
   d. If a member files a grievance and then files a subsequent grievance on the same issue prior to the organization's decision or the deadline for decision notification (whichever is earlier), then the issue is counted as one grievance.
   e. If a member files a grievance and then files a subsequent grievance on the same issue after the organization's decision or deadline for decision notification (whichever is earlier), then the issue is counted as a separate grievance.
   f. Includes all methods of grievance receipt (e.g., telephone, letter, fax, and in-person).
   g. Includes all grievances regardless of who filed the grievance (e.g., member or appointed representative)
   h. Includes only grievances that are filed directly with the organization (e.g., excludes all complaints that are only forwarded to the organization from the CMS Complaint Tracking Module (CTM) and not filed directly with the organization). If a member files the same complaint both directly with the organization and via the CTM, the organization includes only the grievance that was filed directly with the organization and excludes the identical CTM complaint.
   i. For MA-PD contracts: Includes only grievances that apply to the Part C benefit (If a clear distinction cannot be made for an MA-PD, cases are reported as Part C grievances).
   j. Excludes withdrawn grievances.

[Data Elements A –E]

GRIEVANCES (PART C)

7. Organization accurately calculates the number of grievances for which it provided timely notification of the decision, including the following criteria:
   a. Includes only grievances for which the member is notified of decision according to the following timelines:
      i. For standard grievances: no later than 30 days after receipt ofgrievance.
      ii. For standard grievances with an extension taken: no later than 44 days after receipt of grievance.
      iii. For expedited grievances: no later than 24 hours after receipt of grievance.

[Data Element B]

ORGANIZATION DETERMINATIONS / RECONSIDERATIONS

To determine compliance with the standards for Organization Determinations/Reconsiderations, the data validation contractor will assess the following information:

- Written response to *OAI* Sections 3 and 4, and documentation requested per *OAI* Sections 5 and 6
- Outlier/data integrity notification(s)- See OAI 4.3.3 for instructions on how to retrieve notices
- Results of interviews with organization staff
- Census and/or sample data
- Data file created for submission to CMS and copy of HPMS screen shots of data entered
- Other relevant information provided by organization

VALIDATION STANDARDS

1. A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) indicates that all source documents accurately capture required data fields and are properly documented.

Criteria for Validating Source Documents:

   a. Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS.
   b. Source documents create all required data fields for reporting requirements.
   c. Source documents are error-free (e.g., programming code and spreadsheet formulas have no messages or warnings indicating errors, use correct fields, have appropriate data selection, etc.).
   d. All data fields have meaningful, consistent labels (e.g., label field for patient ID as Patient ID, rather than Field1 and maintain the same field name across data sets).
   e. Data file locations are referenced correctly.
   f. If used, macros are properly documented.
   g. Source documents are clearly and adequately documented.
   h. Titles and footnotes on reports and tables are accurate.
   i. Version control of source documents is appropriately applied.

2. A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) and census or sample data, whichever is applicable, indicates that data elements for each reporting section are accurately identified, processed, and calculated.

Criteria for Validating Reporting Section Criteria (Refer to reporting section criteria section below):

   a. The appropriate date range(s) for the reporting period(s) is captured.
   b. Data are assigned at the applicable level (e.g., plan benefit package or contract level).
   c. Appropriate deadlines are met for reporting data (e.g., quarterly).
   d. Terms used are properly defined per CMS regulations, guidance, Reporting Requirements and Technical Specifications.
   e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.

3. Organization implements policies and procedures for data submission, including the following:
   a. Data elements are accurately entered/uploaded into HPMS and entries match corresponding source documents. [Subsection #1, Data Elements A – G, Subsection #2, Data Elements I – L, Subsection #3, Data Elements A – G, Subsection #4, Data Elements I – L, Subsection #5, Data Elements A – B, E – O]
   b. All source, intermediate, and final stage data sets and other outputs relied upon to enter data into HPMS are archived.

4. Organization implements policies and procedures for periodic data system updates (e.g., changes in enrollment, provider/pharmacy status, and claims adjustments).

5. Organization implements policies and procedures for archiving and restoring data in each data system (e.g., disaster recovery plan).

6. If organization's data systems underwent any changes during the reporting period (e.g., because of a merger, acquisition, or upgrade): Organization provided documentation on the data system changes and, upon review, there were no issues that adversely impacted data reported.

ORGANIZATION DETERMINATIONS / RECONSIDERATIONS

7. If data collection and/or reporting for this reporting section is delegated to another entity: Organization regularly monitors the quality and timeliness of the data collected and/or reported by the delegated entity or first tier/downstream contractor.

REPORTING SECTION CRITERIA

1. Organization reports data based on the periods of 1/1 through 3/31, 4/1 through 6/30, 7/1 through 9/30, and 10/1 through 12/31.
2. Organization properly assigns data to the applicable CMS contract.
3. Organization meets deadlines for reporting data to CMS by 02/27/2023.

Note to reviewer: If the organization has, for any reason, re-submitted its data to CMS for this reporting section, the reviewer should verify that the organization's original data submissions met each CMS deadline in order to have a finding of "yes" for this reporting section criterion. However, if the organization re-submits data for any reason and if the re-submission was completed by 3/31 of the data validation year, the reviewer should use the organization's corrected data submission for the review of this reporting section.

4. Organization properly defines the term "Organization Determinations" in accordance with 42 C.F.R. Part 422, Subpart M, and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Manual. This includes applying all relevant guidance properly when performing its calculations and categorizations.

   Organization properly defines the term "Reconsideration" in accordance with 42 C.F.R. Part 422, Subpart M, and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Manual. This includes applying all relevant guidance properly when performing its calculations and categorizations.

5. Organization accurately reports data by applying data integrity checks listed below and uploads it into HPMS.
   a. The total number of organization determinations (Subsection #1, Data Element A) is equal to sum of organization determinations by outcome (Subsection #2, Data Elements A-L).
   b. The total number of reconsiderations (Subsection#3, Data Element A) is equal to sum of reconsiderations by outcome (Subsection #4, Data Elements A-L).
   c. The total number of reopened decisions (Subsection #5, Data Element A) is equal to the number of records reported in the data file with a disposition of reopened.
   d. The date each case was reopened (Subsection #5, Data Element K) is after the date of its original disposition (Subsection #5 Data Element F).
   e. The date of disposition for each reopening (Subsection #5, Data Element N) is after the date of the original disposition (Subsection #5, Data Element F).
   f. The date of disposition for each reopening (Subsection #5, Data Element N) is after the date the case was reopened (Subsection #5, Data Element K).
   g. The date of disposition of each reopening (Subsection #5, Data Element N) is within the reporting quarter.
   h. Verify that there is a valid value submitted for date of original disposition as MM/DD/YYYY format (Subsection #5, Data Element F).
   i. Verify that there is a valid value submitted for case level (Organization Determination or Reconsideration) (Subsection #5, Data Element E).
   j. Verify that there is a valid value submitted for reopening disposition (Fully Favorable; Partially Favorable; Adverse or Pending) (Subsection #5, Data Element O).
   k. If the organization received a CMS outlier/data integrity notice validate whether or not an internal procedure change was warranted or resubmission through HPMS (Subsection #1, Data Elements A-G; Subsection #2, Data Elements A-L; Subsection #3, Data Elements A-G; Subsection #4, Data Elements A-L; Subsection #5, Data Elements A, E, F, G, N, and O).
6. Organization accurately calculates the total number of organization determinations, including the following criteria:
   a. Includes all completed organization determinations (Part C only) for services requested by an enrollee/representative, a provider on behalf of the enrollee, or a non-contract provider, and all organization determinations for claims submitted by enrollee/representative or non-contract provider with a date of member notification of the final decision that occurs during the reporting period, regardless of when the request for organization determination was received.
   b. Includes adjudicated claims with a date of adjudication that occurs during the reporting period.
   c. Includes all claims submitted for payment including those that pass through the adjudication system that may

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not require determination by the staff of the organization or its delegated entity.
d. Includes decisions made on behalf of the organization by a delegated entity.
e. Includes organization determinations that are filed directly with the organization or its delegated entities for services requested by an enrollee/representative, or a provider on behalf of the enrollee, or non-contract provider, and claims submitted either by an enrollee/representative or non-contract provider. If a member requests an organization determination directly with the organization and files an identical complaint via the CTM, the organization includes only the organization determination that was filed directly with the organization and excludes the identical CTM complaint.
f. Includes all methods of organization determination request receipt (e.g., telephone, letter, fax, and in-person).
g. Includes all organization determinations for services requested by an enrollee/representative, or provider on behalf of the enrollee, or non-contract provider, and claims submitted by either enrollee/representative or non-contract provider.
h. Includes supplement benefits (i.e., non- Medicare covered item or service) provided as part of a plan's Medicare benefit package.
i. Excludes dismissals and withdrawals.
j. Excludes Independent Review Entity (IRE) Decisions.
k. Excludes Quality Improvement Organization (QIO) reviews of a member's request to continue Medicare- covered services (e.g., a Skilled Nursing Facility (SNF) stay).
l. Excludes duplicate payment requests concerning the same service or item.
m. Excludes payment requests returned to an enrollee/representative or non-contract provider in which a substantive decision (fully favorable, partially favorable or adverse) has not yet been made due to error (e.g., payment requests or forms that are incomplete, invalid or do not meet the requirements for a Medicare claim).

[Subsection #1, Data Elements A, D-G, and Subsection #2, Data Elements I-L]

7. Organization accurately calculates the number of organization determinations, including the following criteria:
   a. Includes all service organization determinations requested by enrollee/representative, provider on behalf of enrollee, or non-contract provider (Subsection #1, Data Elements D and F).
   b. Includes all payment (claim) organization determinations submitted by enrollee/representative or non-contract provider (Subsection #1, Data Elements E and G).

8. Organization accurately calculates the number of adverse (e.g., denial of entire request resulting in no coverage of the item or service) organization determinations, including the criteria below. All non-adverse organization determinations must be either partially or fully favorable organization determinations:
   a. Includes all adverse service organization determinations requested by enrollee/representative, a provider on behalf of the enrollee, or non-contract provider (Subsection #2, Data Elements I and J).
   b. Includes all adverse payment (claim) organization determinations submitted by enrollee/representative or non-contract provider that result in zero payment (Subsection #2 Data Elements K and L).

9. Organization accurately calculates "Withdrawn Organization Determination" according to the following criteria:
   a. Includes an organization determination that is withdrawn upon the enrollee's request, the enrollee representative's request, or the enrollee provider's request but excludes appeals that the organization forwards to the IRE for dismissal (Subsection #1, Data Element B).

10. Organization accurately calculates "Organization Determinations - Dismissals" according to the following criteria:
    a. Includes dismissals that were processed in accordance with the Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Manual (Subsection #1, Data element C).

11. Organization accurately calculates the total number of reconsiderations, including the following criteria:
    a. Includes all completed reconsiderations (Part C only) both for services requested by an enrollee/representative, or provider on behalf of the enrollee, or non-contract provider, and claims submitted either by enrollee/representative or non-contract provider with a date of member notification of the final decision that occurs during the reporting period, regardless of when the request for reconsideration was received.
    b. Includes decisions made on behalf of the organization by a delegated entity.
    c. Includes all methods of reconsideration request receipt (e.g., telephone, letter, fax, and in-person).
    d. Includes all reconsiderations for services requested by an enrollee/representative, or provider on behalf of the enrollee, or non-contract provider, and claims submitted either by enrollee/representative or non-contract provider.
    e. Includes reconsiderations that are filed directly with the organization or its delegated entities for services

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requested by an enrollee/representative, or provider on behalf of the enrollee, or non-contract provider, and claims submitted either by enrollee/representative or non-contract provider. If a member requests a reconsideration directly with the organization and files an identical complaint via the CTM, the organization includes only the reconsideration that was filed directly with the organization and excludes the identical CTM complaint. f. Includes supplemental benefits (i.e., non- Medicare covered item or service) provided as a part of a plan's Medicare benefit package. g. Excludes dismissals and withdrawals. h. Excludes IRE Decisions. i. Excludes QIO reviews of a member's request to continue Medicare-covered services (e.g., a SNF stay). j. Excludes duplicate payment requests concerning the same service or item. k. Excludes payment requests returned to an enrollee/representative or non-contract provider in which a substantive decision (Fully Favorable, Partially Favorable or Adverse) has not yet been made due to error (e.g., payment requests or forms that are incomplete, invalid or do not meet the requirements for a Medicare claim). [Subsection #3 Data Elements A, D-G and Subsection #4 Data Elements I-L]
12. Organization accurately calculates the number of adverse (e.g., denial of entire request resulting in no coverage of the item or service) reconsiderations, including the criteria below. All non-adverse organization reconsiderations must be either partially or fully favorable organization determinations: a. Includes all adverse service reconsideration determinations requested by enrollee/representative, or provider on behalf of the enrollee, or non-contract provider (Subsection #4, Data Elements I and J). b. Includes all adverse payment (claim) reconsideration determinations submitted by enrollee/representative or non-contract provider that result in zero payment being made (Subsection #4, Data Elements K and L). c. For instances when a reconsideration request for payment is submitted to an organization concerning an item or service, and the organization has already made an adverse service reconsideration determination, includes the reconsideration request for payment for the same item or service as another, separate, adverse reconsideration determination (Subsection #4, Data Elements I-L).
13. Organization accurately calculates "Withdrawn Reconsiderations" according to the following criteria: a. Includes a Reconsideration that is withdrawn upon the enrollee's request, the enrollee representative's request, or the enrollee provider's request (Subsection #3, Data Element B).
14. Organization accurately calculates "Reconsiderations Dismissals" according to the following criteria: a. Includes reconsiderations dismissals that were processed in accordance with the Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Manual (Subsection #3, Data Element C).
15. Organization accurately calculates the total number of reopened decisions according to the following criteria: a. Includes a remedial action taken to change a final determination or decision even though the determination or decision was correct based on the evidence of record (Subsection #5, Data Element A).
16. Organization accurately reports the following information for each reopened case. a. Contract Number b. Date of original disposition c. Original disposition (Fully Favorable; Partially Favorable; or Adverse) d. Case Level (Organization Determination or Reconsideration) e. Date case was reopened f. Reason (s) for reopening (Clerical Error, Other Error, New and Material Evidence, Fraud or Similar Fault, or Other) g. Date of reopening disposition (revised decision) h. Reopening disposition (Fully Favorable; Partially Favorable; Adverse or Pending) [Subsection #5, Data Elements B, E, F, G, K, L, N, and O]

SPECIAL NEEDS PLANS (SNPs) CARE MANAGEMENT

To determine compliance with the standards for Special Needs Plans (SNPs) Care Management, the data validation contractor will assess the following information:

- Written response to *OAI* Sections 3 and 4, and documentation requested per *OAI* Sections 5 and 6
- Outlier/data integrity notification(s)- See OAI 4.3.3 for instructions on how to retrieve notices
- Results of interviews with organization staff
- Census and/or sample data
- Data file created for submission to CMS and copy of HPMS screen shots of data entered
- Other relevant information provided by organization

VALIDATION STANDARDS

1. A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) indicates that all source documents accurately capture required data fields and are properly documented.

Criteria for Validating Source Documents:

a. Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS.
b. Source documents create all required data fields for reporting requirements.
c. Source documents are error-free (e.g., programming code and spreadsheet formulas have no messages or warnings indicating errors, use correct fields, have appropriate data selection, etc.).
d. All data fields have meaningful, consistent labels (e.g., label field for patient ID as Patient ID, rather than Field1 and maintain the same field name across data sets).
e. Data file locations are referenced correctly.
f. If used, macros are properly documented.
g. Source documents are clearly and adequately documented.
h. Titles and footnotes on reports and tables are accurate.
i. Version control of source documents is appropriately applied.

2. A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) and census or sample data, whichever is applicable, indicates that data elements for each reporting section are accurately identified, processed, and calculated.

Criteria for Validating Reporting Section Criteria (Refer to reporting section criteria section below):

a. The appropriate date range(s) for the reporting period(s) is captured.
b. Data are assigned at the applicable level (e.g., plan benefit package or contract level).
c. Appropriate deadlines are met for reporting data (e.g., quarterly).
d. Terms used are properly defined per CMS regulations, guidance, Reporting Requirements and Technical Specifications.
e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.

3. Organization implements policies and procedures for data submission, including the following:
   a. Data elements are accurately entered / uploaded into HPMS and entries match corresponding source documents. [Data Elements A – H]
   b. All source, intermediate, and final stage data sets and other outputs relied upon to enter data into HPMS are archived.

4. Organization implements policies and procedures for periodic data system updates (e.g., changes in enrollment, provider/pharmacy status, and claims adjustments).

5. Organization implements policies and procedures for archiving and restoring data in each data system (e.g., disaster recovery plan).

SPECIAL NEEDS PLANS (SNPs) CARE MANAGEMENT

6. If organization's data systems underwent any changes during the reporting period (e.g., because of a merger, acquisition, or upgrade): Organization provided documentation on the data system changes and, upon review, there were no issues that adversely impacted data reported.

7. If data collection and/or reporting for this reporting section is delegated to another entity: Organization regularly monitors the quality and timeliness of the data collected and/or reported by the delegated entity or first tier/downstream contractor.

REPORTING SECTION CRITERIA

1. Organization reports data based on the required reporting period of 1/1 through 12/31.

2. Organization properly assigns data to the applicable CMS plan benefit package.

3. Organization meets deadline for reporting annual data to CMS by 2/27/2023.
   Note to reviewer: If the organization has, for any reason, re-submitted its data to CMS for this reporting section, the reviewer should verify that the organization's original data submission met the CMS deadline in order to have a finding of "yes" for this reporting section criterion. However, if the organization re-submits data for any reason and if the re-submission was completed by 3/31 of the data validation year, the reviewer should use the organization's corrected data submission for the review of this reporting section.

4. Organization properly defines the term Health Risk Assessment (HRA) as defined in 42 CFR § 422.101 (f). This includes applying all relevant guidance properly when performing its HRA.

5. Organization accurately calculates the number of new members who are eligible for an initial health risk assessment (HRA), including the following criteria:
   a. Includes all new members who enrolled during the measurement year. Includes those members who have an effective enrollment date that falls within the measurement year, and are continuously enrolled for at least 90 days during the measurement year. These members will be considered eligible for an initial HRA for the year in which the effective enrollment date falls.
   b. Includes members who have an effective enrollment date that falls within the measurement year, are continuously enrolled for fewer than 90 days, and complete an initial HRA.
   c. Includes members who have an effective enrollment date that falls in the previous measurement year, but a 90- day deadline for initial HRA completion that falls in this measurement year, if no initial HRA was completed in the previous measurement year.
   d. Includes members who have enrolled in the plan after dis-enrolling from another plan (different sponsor or organization).
   e. Includes members who dis-enrolled from and re-enrolled into the same plan if an initial HRA was not performed prior to dis-enrollment and calculates the member's eligibility date starting from the date of re-enrollment.
   f. Excludes continuously enrolled members with a documented initial HRA that occurred under the plan during the previous year. These members, and their HRAs, should be counted as new in the previous year.
   g. Excludes members who received an initial HRA but were subsequently deemed ineligible because they were never enrolled in the plan.
   h. Excludes members who disenroll from the plan prior to the effective enrollment date or within the first 90 days after the effective enrollment date, if an initial HRA was not completed prior to disenrolling.
   i. Excludes enrollees who receive an initial or reassessment HRA and remain continuously enrolled under a Medicare Advantage Organization (MAO) whose contract was part of a consolidation of merger under the same legal entity during the member's continuous enrollment, where the consolidated SNP is still under the same Model of Care (MOC) as the enrollee's previous SNP.

   [Data Element A]

SPECIAL NEEDS PLANS (SNPs) CARE MANAGEMENT

6. Organization accurately reports data by applying data integrity checks listed below and uploads it into HPMS.
   a. The number of initial HRAs performed on new enrollees (Data Element C) does not exceed the number of new enrollees (Data Element A).
   b. The number of annual re-assessments performed (Data Element F) does not exceed number of enrollees eligible for annual HRA (Data Element B).
   c. Number of initial HRAs refusals (Data Element D) does not exceed number of new enrollees (Data Element A).
   d. Number of annual reassessment refusals (Data Element G) does not exceed the number of enrollees eligible for an annual reassessment HRA (Data Element B).
   e. Number of initial HRAs where SNP is unable to reach enrollees (Data Element E) does not exceed number of new enrollees (Data Element A).
   f. Number of annual reassessments where SNP is unable to reach enrollee (Data Element H) does not exceed number of enrollees eligible for annual HRA (Data Element B).
   g. If the organization received a CMS outlier/data integrity notice, validate whether or not an internal procedure change was warranted or resubmission through HPMS. (Data Element A-H)

   [Data Elements A-H]

7. Organization accurately calculates the number of members eligible for an annual health risk reassessment during the reporting period, including the following criteria:
   a. Includes members who remained continuously enrolled in the same plan for 365 days, starting from their initial enrollment date if no initial HRA had been performed, or from the date of their previous HRA.
   b. Includes members who received a reassessment during the measurement year within 365 days after their last HRA.
   c. Includes new enrollees who missed both the deadline to complete an initial HRA and the deadline to complete a reassessment HRA, and are enrolled for all 365 days of the measurement year.
   d. Includes new enrollees who missed an initial HRA, but completed a reassessment HRA by the 365-day deadline (even if the enrollee was covered for fewer than 365 days).
   e. Includes members who dis-enrolled from and re-enrolled into the same plan if an initial HRA was performed within 90 days of re-enrollment and the member has continuously enrolled in the same plan for up to 365 days since the initial HRA.
   f. Includes members who dis-enrolled from and re-enrolled into the same plan if an initial HRA or reassessment was not performed within 90 days of re-enrollment. The enrollee becomes eligible for a reassessment HRA the day after the 90-day initial period expires.
   g. Excludes enrollees for whom the initial HRA was completed within the current measurement year.
   h. Excludes new enrollees who miss the deadline to complete an initial HRA, and have not yet completed their reassessment HRA, but whose 365-day reassessment deadline is not until the following calendar year.
   i. Excludes members who received a reassessment but were subsequently deemed ineligible because they were never enrolled in the plan.
   j. Excludes members who were not continuously enrolled in their same health plan for 365 days after their last HRA and did not receive a reassessment HRA.

   [Data Element B]

SPECIAL NEEDS PLANS (SNPs) CARE MANAGEMENT

8. Organization accurately calculates the number of initial health risk assessments performed on new members, including the following criteria:
   a. Includes only initial HRAs performed on new members within 90 days before or after the effective date of enrollment/re-enrollment.
   b. The initial HRA is counted in the year that the effective date of enrollment occurred. For members who dis-enrolled from and re-enrolled into the same plan, excludes any HRAs (initial or reassessment) performed during their previous enrollment unless the re-enrollment occurred the day after the disenrollment.
   c. For members who dis-enrolled from and re-enrolled into the same plan, includes HRAs (initial or reassessment) performed during their previous enrollment if the HRAs are not more than 365 days old.
   d. Counts only one HRA for members who have multiple HRAs within 90 days before or after the effective date of enrollment.
   e. Excludes HRAs completed for members who were subsequently deemed ineligible because they were never enrolled in the plan.

   Note to reviewer: CMS has not identifie*d a standard tool that SNPs must use to complete initial and annual health risk assessments. The information will not be captured by designated CPT or ICD-10 Procedure codes. Reviewer should confirm that the SNP maintained documentation for each reported assessment.*

   [Data Element C]

9. Organization accurately calculates the number of initial health risk assessments refusals, including the following criteria:
   a. Includes only initial HRAs that were not performed within 90 days before or after the effective date of enrollment/re-enrollment due to enrollee refusal.
   b. Includes only initial HRA refusals for which the SNP has documentation of enrollee refusal.

   [Data Element D]

10. Organization accurately calculates the number of initial health risk assessments not performed due to SNP not being able to reach the enrollee, including the following criteria:
    a. Includes only initial HRAs not performed for which the SNP has documentation showing that enrollee did not respond to the SNP's attempts to reach him/her. Documentation must show that the SNP made at least 3 phone calls and sent a follow-up letter in its attempts to reach the enrollee.
    b. Includes only those initial HRAs not performed where the SNP made an attempt to reach the enrollee at least within 90 days after the effective enrollment date.

    [Data Element E]

11. Organization accurately calculates the number of annual health risk reassessments performed on members eligible for a reassessment, including the following criteria:
    a. Includes annual HRA reassessments that were completed within 365 days of the member becoming eligible for a reassessment.
    b. Includes annual HRA reassessments within 365 days of the member's initial date of enrollment if the member did not receive an initial HRA within 90 days before or after the effective date of enrollment.
    c. Includes only HRAs that were performed between 1/1 and 12/31 of the measurement year.
    d. Counts only one HRA for members who have multiple reassessments within 365 days of becoming eligible for a reassessment.
    e. Excludes HRAs completed for members who were subsequently deemed ineligible because they were never enrolled in the plan.

    Note to reviewer: CMS has not identified a standard tool that SNPs must use to complete initial and annual health risk assessments. The information will not be captured by designated CPT or ICD-10 Procedure codes. Reviewer should confirm that the SNP maintained documentationfor each reported assessment.

    [Data Element F]

SPECIAL NEEDS PLANS (SNPs) CARE MANAGEMENT

12. Organization accurately calculates the number of annual health risk reassessments not performed on members eligible for a reassessment due to enrollee refusal.
    a. Only includes annual reassessments not performed due to enrollee refusal.
    b. Includes only annual reassessments refusals for which the SNP has documentation of enrollee refusal.

    [Data Element G]

13. Organization accurately calculates the number of annual health risk reassessments not performed on members eligible for a reassessment due to SNP not being able to reach enrollee.
    a. Only includes annual reassessments not performed for which the SNP has documentation showing that the enrollee did not respond to the plan's attempts to reach him/her. Documentation must show that the SNP made at least 3 phone calls and sent a follow-up letter in its attempts to reach the enrollee.

    [Data Element H]

3. PART D DATA VALIDATION STANDARDS

MEDICATION THERAPY MANAGEMENT (MTM) PROGRAMS

Note to reviewer: If the Part D sponsor has no MTM members, then it is not required to report this data and data validation is not required for this reporting section.

To determine compliance with the standards for Medication Therapy Management (MTM) Programs, the data validation contractor will assess the following information:

- Written response to *OAI* Sections 3 and 4, and documentation requested per *OAI* Sections 5 and 6
- Outlier/data integrity notification(s)- See OAI 4.3.3 for instructions on how to retrieve notices
- Results of interviews with organization staff
- Census and/or sample data
- Data file created for submission to CMS and copy of HPMS screen shots of data entered
- Other relevant information provided by organization

VALIDATION STANDARDS

1. A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) indicates that all source documents accurately capture required data fields and are properly documented.

Criteria for Validating Source Documents:

a. Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS.
b. Source documents create all required data fields for reporting requirements.
c. Source documents are error-free (e.g., programming code and spreadsheet formulas have no messages or warnings indicating errors, use correct fields, have appropriate data selection, etc.).
d. All data fields have meaningful, consistent labels (e.g., label field for patient ID as Patient ID, rather than Field1 and maintain the same field name across data sets).
e. Data file locations are referenced correctly.
f. If used, macros are properly documented.
g. Source documents are clearly and adequately documented.
h. Titles and footnotes on reports and tables are accurate.
i. Version control of source documents is appropriately applied.

2. A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) and census data, whichever is applicable, indicates that data elements for each reporting section are accurately identified, processed, and calculated.

Criteria for Validating Reporting Section Criteria (Refer to reporting section criteria section below):

a. The appropriate date range(s) for the reporting period(s) is captured.
b. Data are assigned at the applicable level (e.g., plan benefit package or contract level).
c. Appropriate deadlines are met for reporting data (e.g., quarterly).
d. Terms used are properly defined per CMS regulations, guidance, Reporting Requirements and Technical Specifications.
e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.

3. Organization implements policies and procedures for data submission, including the following:
   a. Data elements are accurately uploaded into HPMS and entries match corresponding source documents. [Data Elements A – Z]
   b. All source, intermediate, and final stage data sets and other outputs relied upon to enter data into HPMS are archived.

4. Organization implements policies and procedures for periodic data system updates (e.g., changes in enrollment, provider/pharmacy status, and claims adjustments).

MEDICATION THERAPY MANAGEMENT (MTM) PROGRAMS

5. Organization implements policies and procedures for archiving and restoring data in each data system (e.g., disaster recovery plan).

6. If organization's data systems underwent any changes during the reporting period (e.g., because of a merger, acquisition, or upgrade): Organization provided documentation on the data system changes and, upon review, there were no issues that adversely impacted data reported.

7. If data collection and/or reporting for this reporting section is delegated to another entity; Organization regularly monitors the quality and timeliness of the data collected and/or reported by the delegated entity or first tier/downstream contractor.

REPORTING SECTION CRITERIA

1. Organization reports data based on the required reporting period of 1/1 through 12/31.

2. Organization properly assigns data to the applicable CMS contract.

3. Organization meets deadline for reporting annual data to CMS by 2/27/2023.

Note to reviewer: If the organization has, for any reason, re-submitted its data to CMS for this reporting section, the reviewer should verify that the organization's original data submission met the CMS deadline in order to have a finding of "yes" for this reporting section criterion. However, if the organization re-submits data for any reason and if the resubmission was completed by 3/31 of the data validation year, the reviewer should use the organization's corrected data submission for the review of this reporting section

4. Organization properly defines the MTM program services per CMS definitions, such as Comprehensive Medication Review (CMR) with written summary and Targeted Medication Review (TMR) in accordance with the annual MTM Program Guidance and Submission memo posted on the CMS MTM web page. This includes applying all relevant guidance properly when performing its calculations and categorizations.

5. Organization accurately reports data by applying data integrity checks listed below and uploads it into HPMS:
   a. Date of MTM program enrollment (Data Element H) is within the reporting period (between 1/1/2022 and 12/31/2022).
   b. One record is entered for each unique beneficiary i.e., only one record exists for a unique MBI number (Data Element B).
   c. Only reports beneficiaries enrolled in the contract during the reporting period, i.e., MBI (Data Element B) maps to a beneficiary enrolled at any point during the reporting year for the given Contract Number (Data Element A).
   d. CMR received date (Data Element P) is within the beneficiary's MTM enrollment period.
   e. If the beneficiary was identified as cognitively impaired at time of CMS offer or delivery (Data Element F = Yes), the beneficiary should have been offered a CMR (Data Element M = Yes).
   f. If the beneficiary was offered or received a CMR (Data Element M = Yes or Data Element O = Yes), the contract should report if beneficiary was cognitively impaired at time of CMR offer or delivery (Data Element F ≠ missing).
   g. If the beneficiary was offered or received a CMR (Data Element M = Yes or Data Element O = Yes), the contract should report if beneficiary was in a long-term care facility at time of CMR offer or delivery (Data Element G≠ missing).
   h. If the beneficiary met the specified targeting criteria per CMS-Part D Requirements in § 423.153(d)(2). (Data Element I ≠ missing), then the contract should report the date the beneficiary met the specified targeting criteria (Data Element J ≠ missing).
   i. If the beneficiary did not meet the specified targeting criteria per CMS-Part D Requirements in § 423.153(d)(2). (Data Element I = missing), then the field for 'date meets the specified targeting criteria' (Data Element J) should be missing.
   j. If a contract reports beneficiaries that were not eligible according to CMS-Part D Requirements in § 423.153(d)(2). (Data Element I = missing), then Contract's MTM program submission information should indicate that contract uses expanded eligibility (Targeting Criteria for Eligibility in the MTMP ≠ Only enrollees who meet the specified targeting criteria per CMS requirements).
   k. If the beneficiary opted out (Data Element K ≠ missing) then contract should provide an opt-out reason (Data Element L should not be missing).
   l. If the beneficiary did not opt-out (Data Element K = missing), the field for opt-out reason should be missing (Data Element L = missing).
   m. Date of MTM program opt-out (Data Element K) should not be before the date of MTM program enrollment (Data Element H).
   n. Date of (initial) CMR offer (Data Element N) should either be between the beneficiary's MTM enrollment date (Data Element H) and 12/31/2021 or the beneficiary's opt out date (Data Element K).
   o. If a CMR was offered (Data Element M = Yes), there is also a reported offer date (Data Element N ≠ missing).
   p. If a CMR was not offered (Data Element M = No), there is no reported offer date (Data Element N = missing).
   q. If a CMR was received (Data Element O = Yes), there is a reported date of initial CMR (Data Element P ≠ missing).
   r. If a CMR was received (Data Element O = Yes), there is a reported delivery date(s) (Data Element Q ≠ missing).

MEDICATION THERAPY MANAGEMENT (MTM) PROGRAMS

s. If a CMR was not received (Data Element O = No), there are no reported delivery date(s) (Data Element Q = missing) unless the CMR summary was returned via mail, then the reported delivery date should be the date that the written summary was sent (Data Element Q ≠ missing).
t. If records indicate that beneficiary received CMR (Data Element O = Yes), then indicator for CMR offered (Data element M ≠ No).
u. CMR offer date (Data Element N) is before the CMR received date (Data Element P).
v. If a CMR was received (Data Element O = Yes), there is a reported method of delivery (Data Element R ≠ missing).
w. If a CMR was not received (Data Element O = No), there is no reported method of CMR delivery (Data Element R = missing).
x. If a CMR was received (Data Element O = Yes), there is a reported provider who performed the CMR (Data Element S ≠ missing).
y. If a CMR was not received (Data Element O = No), there is no reported provider who performed the CMR (Data Element S = missing).
z. If a CMR was received (Data Element O = Yes), there is reported recipient of CMR (Data Element T ≠ missing).
aa. If a CMR was not received (Data Element O = No), there is no reported recipient of CMR (Data Element T = missing).
bb. Properly identifies and includes members' date of first TMR (Data Element V) if the number of targeted medication reviews (Data Element U) >0.
cc. If the organization received a CMS outlier/data integrity notice validate whether or not an internal procedure change was warranted or resubmission through HPMS (Data Elements A-Z).

6. Organization accurately identifies data on MTM program participation and uploads it into HPMS, including the following criteria:
   a. Properly identifies and includes members who either met the specified targeting criteria per CMS Part D requirements in § 423.153(d)(2) or other expanded plan-specific targeting criteria at any time during the reporting period (Data Elements B, C, D, E, F, G, H, I, J).
   b. Includes the ingredient cost, dispensing fee, sales tax, and the vaccine administration fee (if applicable) when determining if the total annual cost of a member's covered Part D drugs is likely to equal or exceed the specified annual cost threshold for MTM program eligibility (Data Element I).
   c. Includes continuing MTM program members as well as members who were newly identified and auto-enrolled in the MTM program at any time during the reporting period (Data Elements B, C, D, E, F, G, H, I, J).
   d. Includes and reports each targeted member, reported once per contract year per contract file, based on the member's most current MBI (Data Elements B, C, D, E, F, G, H, I, J).
   e. Excludes members deceased prior to their MTM eligibility date (Data Elements B, C, D, E, F, G, H, I, J).
   f. Includes members who receive MTM services based on plan-specific MTM criteria defined by the plan (Data Elements B, C, D, E, F, G, H, I, J).
   g. Properly identifies and includes members' date of MTM program enrollment (i.e., date they were automatically enrolled) that occurs within the reporting period (Data Element H).
   h. For those members who met the specified targeting criteria per CMS Part D requirements in § 423.153(d)(2), properly identifies the date the member met the specified targeting criteria (Data Element J).
   i. Includes members who moved between contracts in each corresponding file uploaded to HPMS. Dates of enrollment, disenrollment elements, and other elements (e.g., TMR/CMR data) are specific to the activity that occurred for the member within each contract (Data Elements B, C, D, E, F, G, H, I, J).
   j. Counts each member who disenrolls from and re-enrolls in the same contract once (Data Elements B, C, D, E, F, G, H, I, J).

7. Organization accurately identifies MTM eligible members who are cognitively impaired at the time of CMR offer or delivery of CMR and uploads it into HPMS, including the following criteria:
   a. Properly identifies and includes whether each member was cognitively impaired and reports this status as of the date of the CMR offer or delivery of CMR (Data Element F).

MEDICATION THERAPY MANAGEMENT (MTM) PROGRAMS
8. Organization accurately identifies data on members who opted-out of enrollment in the MTM program and uploads it into HPMS, including the following criteria: a. Properly identifies and includes members' date of MTM program opt-out that occurs within the reporting period, but prior to 12/31 (Data Element K). b. Properly identifies and includes the reason participant opted-out of the MTM program for every applicable member with an opt-out date completed (death, disenrollment, request by member, other reason) (Data Element L). c. Excludes members who refuse or decline individual services without opting-out (disenrolling) from the MTM program (Data Elements K, L). d. Excludes members who disenroll from and re-enroll in the same contract regardless of the duration of the gap of MTM program enrollment (Data Elements K, L).
9. Organization accurately identifies data on CMR offers and uploads it into HPMS, including the following criteria: a. Properly identifies and includes MTM program members who were offered a CMR per CMS Part D requirements in § 423.153(d)(2) during the reporting period (Data Element M). b. Properly identifies and includes members' date of initial offer of a CMR that occurs within the reporting period (Data Element N).
10. Organization accurately identifies data on CMR dates and uploads it into HPMS, including the following criteria: a. Properly identifies and includes the date the member received the initial CMR, if applicable. The date occurs within the reporting period, is completed for every member with a "Y" entered for Field Name "Received annual CMR with written summary in CMS standardized format," and if more than one comprehensive medication review occurred, includes the date of the first CMR (Data Element P). b. Properly identifies and includes the method of delivery for the initial CMR received by the member; if more than one CMR is received, the method of delivery for only the initial CMR is reported. The method of delivery must be reported as one of the following: Face-to-Face, Telephone, Telehealth Consultation, or Other (Data Element R). c. Properly identifies and includes the qualified provider who performed the initial CMR; if more than one CMR is received, the qualified provider for only the initial CMR is reported. The qualified provider must be reported as one of the following: Physician; Registered Nurse; Licensed Practical Nurse; Nurse Practitioner; Physician's Assistant; Local Pharmacist; Long-Term Care (LTC) Consultant Pharmacist; Plan Sponsor Pharmacist; Plan Benefit Manager (PBM) Pharmacist; MTM Vendor Local Pharmacist; MTM Vendor In-house Pharmacist; Hospital Pharmacist; Pharmacist – Other; Supervised Pharmacy Intern; or Other). Required if received annual CMR (Data Element S). d. Properly identifies the recipient of the annual CMR; if more than one CMR is received; only the recipient of the initial CMR is reported. The recipient of the CMR interaction must be reported, not the recipient of the CMR documentation. The recipient must be reported as one of the following: Beneficiary, Beneficiary's Prescriber, Caregiver, or Other Authorized Individual (Data Element T).

MEDICATION THERAPY MANAGEMENT (MTM) PROGRAMS

11. Organization accurately identifies data on MTM medication therapy problem recommendations and uploads it into HPMS, including the following criteria:
    a. Properly identifies and includes all targeted medication reviews within the reporting period for each applicable member (Data Element U).
    b. Properly identifies and includes the number of medication therapy problem recommendations made to the beneficiary's prescriber(s) as a result of MTM services within the reporting period for each applicable member, regardless of the success or result of the recommendations, and counts these recommendations based on the number of unique recommendations made to prescribers (e.g., the number is not equal to the total number of prescribers that received medication therapy problem recommendations from the organization). Organization counts each individual medication therapy problem identified per prescriber recommendation (e.g., if the organization sent a prescriber a fax identifying 3 medication therapy problems for a member, this is reported as 3 recommendations) (Data Element W).
    c. Properly identifies and includes the number of medication therapy problem resolutions resulting from recommendations made to beneficiary's prescriber(s) as a result of MTM program services within the reporting period for each applicable member. For reporting purposes, a resolution is defined as a change or variation from the beneficiary's previous medication therapy. Examples include, but are not limited to, initiate medication, change medication (such as product in different therapeutic class, dose, dosage form, quantity, or interval), discontinue or substitute medication (such as discontinue medication, generic substitution, or formulary substitution), and medication compliance/adherence (Data Element X).

Note to reviewer: If the resolution was observed in the calendar year after the current reporting period, but was the result of an MTM recommendation made within the current reporting period, the resolution may be reported for the current reporting period. However, this resolution cannot be reported again in the following reporting period.

GRIEVANCES (Part D)

To determine compliance with the standards for Grievances (Part D), the data validation contractor will assess the following information:

- Written response to *OAI* Sections 3 and 4, and documentation requested per *OAI* Sections 5 and 6
- Outlier/data integrity notification(s)- See OAI 4.3.3 for instructions on how to retrieve notices
- Results of interviews with organization staff
- Census and/or sample data
- Data file created for submission to CMS and copy of HPMS screen shots of data entered
- Other relevant information provided by organization

VALIDATION STANDARDS

1. A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) indicates that all source documents accurately capture required data fields and are properly documented.

Criteria for Validating Source Documents:

   a. Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS.
   b. Source documents create all required data fields for reporting requirements.
   c. Source documents are error-free (e.g., programming code and spreadsheet formulas have no messages or warnings indicating errors, use correct fields, have appropriate data selection, etc.).
   d. All data fields have meaningful, consistent labels (e.g., label field for patient ID as Patient ID, rather than Field1 and maintain the same field name across data sets).
   e. Data file locations are referenced correctly.
   f. If used, macros are properly documented.
   g. Source documents are clearly and adequately documented.
   h. Titles and footnotes on reports and tables are accurate.
   i. Version control of source documents is appropriately applied.

2. A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) and census or sample data, whichever is applicable, indicates that data elements for each reporting section are accurately identified, processed, and calculated.

Criteria for Validating Reporting Section Criteria (Refer to reporting section criteria section below):

   a. The appropriate date range(s) for the reporting period(s) is captured.
   b. Data are assigned at the applicable level (e.g., plan benefit package or contract level).
   c. Appropriate deadlines are met for reporting data (e.g., quarterly).
   d. Terms used are properly defined per CMS regulations, guidance, Reporting Requirements and Technical Specifications.
   e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.

3. Organization implements policies and procedures for data submission, including the following:
   a. Data elements are accurately uploaded into HPMS and entries match corresponding source documents. [Data Elements A – E]
   b. All source, intermediate, and final stage data sets and other outputs relied upon to enter data into HPMS are archived.

4. Organization implements policies and procedures for periodic data system updates (e.g., changes in enrollment, provider/pharmacy status, and claims adjustments).

5. Organization implements policies and procedures for archiving and restoring data in each data system (e.g., disaster recovery plan).

6. If organization's data systems underwent any changes during the reporting period (e.g., because of a merger, acquisition, or upgrade): Organization provided documentation on the data system changes and, upon review, there were no issues that adversely impacted data reported.

GRIEVANCES (Part D)

7. If data collection and/or reporting for this reporting section is delegated to another entity; Organization regularly monitors the quality and timeliness of the data collected and/or reported by the delegated entity or first tier/downstream contractor.

REPORTING SECTION CRITERIA

1. Organization reports data based on the periods of 1/1 through 3/31, 4/1 through 6/30, 7/1 through 9/30, and 10/1 through 12/31.
2. Organization properly assigns data to the applicable CMS contract.
3. Organization meets deadline for reporting data to CMS by 2/6/2023.

Note to reviewer: If the organization has, for any reason, re-submitted its data to CMS for this reporting section, the reviewer should verify that the organization's original data submissions met each CMS deadline in order to have a finding of "yes" for this reporting section criterion. However, if the organization re-submits data for any reason and if the re-submission was completed by 3/31 of the data validation year, the reviewer should use the organization's corrected data submission for the review of this reporting section.

4. Organization properly defines the term "Grievance" in accordance with 42 CFR §422.564 and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Manual. This includes applying all relevant guidance properly when performing its calculations.
5. Organization accurately reports data by applying data integrity checks listed below and uploads it into HPMS:
   a. Number of total grievances in which timely notification was given (Data Element B) does not exceed number of total grievances (Data Element A).
   b. Number of expedited grievances in which timely notification was given (Data Element D) does not exceed number of total grievances in which timely notification was given (Data Element B).
   c. Number of expedited grievances (Data Element C) does not exceed total grievances (Data Element A).
   d. Number of expedited grievances in which timely notification was given (Data Element D) does not exceed total expedited grievances (Data Element C).
   e. Number of dismissed grievances (Data Element E) are excluded from the total.
   f. If the organization received a CMS outlier/data integrity notice, validate whether or not an internal procedure change was warranted or resubmission through HPMS.

[Data Elements A – E]

6. Organization accurately calculates and uploads into HPMS the total number of grievances, including the following criteria:
   a. Includes all grievances that were completed (i.e., organization has notified member of its decision) during the reporting period, regardless of when the grievance was received.
   b. If a grievance contains multiple issues filed by a single complainant, each issue is calculated as a separate grievance.
   c. If a member files a grievance and then files a subsequent grievance on the same issue prior to the organization's decision or deadline for decision notification (whichever is earlier), then the issue is counted as one grievance.
   d. If a member files a grievance and then files a subsequent grievance on the same issue after the organization's decision or deadline for decision notification (whichever is earlier), then the issue is counted as a separate grievance.
   e. Includes all methods of grievance receipt (e.g., telephone, letter, fax, and in-person).
   f. Includes all grievances regardless of who filed the grievance (e.g., member or appointed representative).
   g. Excludes complaints received only by 1-800 Medicare or recorded only in the CMS Complaint Tracking Module (CTM); however, complaints filed separately as grievances with the organization are included.
   h. Excludes withdrawn Part D grievances.
   i. For MA-PD contracts: Includes only grievances that apply to the Part D benefit and were processed through the Part D grievance process. If a clear distinction cannot be made for an MA-PD, cases are calculated as Part C grievances.
   j. Counts grievances for the contract to which the member belongs at the time the grievance was filed, even if the beneficiary enrolled in a new contract before the grievance is resolved (e.g., if a grievance is resolved within the reporting period for a member that has disenrolled from a plan and enrolled in a new plan, then the member's previous plan is still responsible for investigating, resolving, and reporting the grievance).

[Data Elements A – E]

GRIEVANCES (Part D)

7. Organization accurately calculates the number of grievances which the Part D sponsor provided timely notification of the decision, including the following criteria:
   a. Includes only grievances for which the member is notified of decision according to the following timelines:
      i. For standard grievances: no later than 30 days after receipt of grievance.
      ii. For standard grievances with an extension taken: no later than 44 days after receipt of grievance.
      iii. For expedited grievances: no later than 24 hours after receiptof grievance.

[Data Element B]

COVERAGE DETERMINATIONS AND REDETERMINATIONS

To determine compliance with the standards for Coverage Determinations and Exceptions, the data validation contractor will assess the following information:

- Written response to *OAI* Sections 3 and 4, and documentation requested per *OAI* Sections 5 and 6
- Outlier/data integrity notification(s)- See OAI 4.3.3 for instructions on how to retrieve notices
- Results of interviews with organization staff
- Census and/or sample data
- Data file created for submission to CMS and copy of HPMS screen shots of data entered
- Other relevant information provided by organization

VALIDATION STANDARDS

1. A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) indicates that all source documents accurately capture required data fields and are properly documented.

Criteria for Validating Source Documents:

a. Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS.
b. Source documents create all required data fields for reporting requirements.
c. Source documents are error-free (e.g., programming code and spreadsheet formulas have no messages or warnings indicating errors, use correct fields, have appropriate data selection, etc.).
d. All data fields have meaningful, consistent labels (e.g., label field for patient ID as Patient ID, rather than Field 1 and maintain the same field name across data sets).
e. Data file locations are referenced correctly.
f. If used, macros are properly documented.
g. Source documents are clearly and adequately documented.
h. Titles and footnotes on reports and tables are accurate.
i. Version control of source documents is appropriately applied.

2. A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) and census or sample data, whichever is applicable, indicates that data elements for each reporting section are accurately identified, processed, and calculated.

Criteria for Validating Reporting Section Criteria (Refer to reporting section criteria section below):

a. The appropriate date range(s) for the reporting period(s) is captured.
b. Data are assigned at the applicable level (e.g., plan benefit package or contract level).
c. Appropriate deadlines are met for reporting data (e.g., quarterly).
d. Terms used are properly defined per CMS regulations, guidance, Reporting Requirements and Technical Specifications.
e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.

3. Organization implements policies and procedures for data submission, including the following:
   a. Data elements are accurately uploaded into HPMS and entries match corresponding source documents. [Data Elements 1.A – 1.R, 2.A – 2.V, 3.A, 3.B.1-3.B.12]
   b. All source, intermediate, and final stage data sets and other outputs relied upon to enter data into HPMS are archived.

COVERAGE DETERMINATIONS AND REDETERMINATIONS

4. Organization implements policies and procedures for periodic data system updates (e.g., changes in enrollment, provider/pharmacy status, and claims adjustments).
5. Organization implements policies and procedures for archiving and restoring data in each data system (e.g., disaster recovery plan).
6. If organization's data systems underwent any changes during the reporting period (e.g., because of a merger, acquisition, or upgrade): Organization provided documentation on the data system changes and, upon review, there were no issues that adversely impacted data reported.
7. If data collection and/or reporting for this reporting section is delegated to another entity; Organization regularly monitors the quality and timeliness of the data collected and/or reported by the delegated entity or first tier/downstream contractor.

REPORTING SECTION CRITERIA

1. Organization reports data based on the periods of 1/1 through 3/31, 4/1 through 6/30, 7/1 through 9/30, and 10/1 through 12/31.
2. Organization properly assigns data to the applicable CMS contract.
3. Organization meets deadlines for reporting data to CMS by 2/27/2023.
   Note to reviewer: If the organization has, for any reason, re-submitted its data to CMS for this reporting section, the reviewer should verify that the organization's original data submissions met each CMS deadline in order to have a finding of "yes" for this reporting section criterion. However, if the organization re-submits data for any reason and if the re- submission was completed by 3/31 of the data validation year, the reviewer should use the organization's corrected data submission for the review of this reporting section.
4. Organization properly defines the term "Coverage Determinations" in accordance with 42 C.F.R. Part 423, Subpart M, and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance. This includes applying all relevant guidance properly when performing its calculations and categorizations.

   Organization properly defines the term "Redetermination" in accordance with 42 C.F.R. Part 423, Subpart M, and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance. This includes applying all relevant guidance properly when performing its calculations and categorizations.
5. Organization accurately reports data by applying data integrity checks listed below and uploads it into HPMS:
   a. Number of coverage determination decisions by outcome (Data Elements (1.D + 1.E + 1.F) + (1.H + 1.I + 1.J) + (1.L + 1.M + 1.N) + (1.P + 1.Q + 1.R) does not exceed the total number of processed coverage determinations that include exceptions (Data Element 1.A).
   b. Number of exception decisions by outcome made in the reporting period (Data Elements (1.H + 1.I + 1.J) + (1.L + 1.M + 1.N) + (1.P + 1.Q + 1.R)) does not exceed the total number of processed coverage determination decisions that include exceptions (Data Element 1.A).
   c. Number of redetermination decisions by outcome (Data Elements (2.D + 2.E + 2.F) + (2.H + 2.I + 2.J) + (2.L + 2.M + 2.N) + (2.P + 2.Q + 2.R) + (2.T + 2.U + 2.V)) is equal to total number of processed redetermination decisions that include exception redeterminations and at-risk redeterminations (Data Element 2.A).
   d. Total number of reopened (revised) decisions (Data Element 3.A) is equal to the number of records reported in data file.
   e. Verify that the date of each reopening disposition (Data Element 3.B.11) is in the reporting quarter.
   f. Verify that the date of disposition for each reopening (Data Element 3.B.11) is equal to or later than the date of original disposition (Data Element 3.B.5).
   g. Verify that the date of each reopening disposition (Data Element 3.B.11) is equal to or later than the date the case was reopened (Data Element 3.B.9).
   h. Verify that the date each case was reopened (Data Element 3.B.9) is after the date of original disposition (Data Element 3.B.5).
   i. If the organization received a CMS outlier/data integrity notice, validate whether or not an internal procedure change was warranted or resubmission through HPMS (Data Elements 1.A−1.R, 2.A−2.V, 3.A−3.B.12).[1]

COVERAGE DETERMINATIONS AND REDETERMINATIONS

6. Organization accurately calculates the number of coverage determination (Part D only) decisions made in the reporting period, including the following criteria:
   a. Includes all coverage determinations (fully favorable, partially favorable, and adverse), including exceptions,[2] with a date of decision that occurs during the reporting period. Date of the final decision is based on the date the enrollee/enrollee's representative is notified in writing of the coverage determination decision.
   b. Includes hard morphine milligram equivalent dose (MME) edit coverage determinations.
   c. Includes opioid naïve days supply edit coverage determinations.
   d. Includes hospice-related coverage determinations.
   e. Includes all methods of receipt (e.g., telephone, letter, fax, and in-person).
   f. Includes all coverage determinations (including exceptions) regardless of who filed the request (e.g., member, appointed representative, or prescribing physician).
   g. Includes coverage determinations (including exceptions) from delegated entities.[3]
   h. Includes both standard and expedited coverage determinations (including exceptions).
   i. Excludes requests for coverage determinations (including exceptions) that are withdrawn or dismissed.
   j. Includes each distinct dispute (i.e., multiple drugs) contained in one coverage determination request as a separate coverage determination request.
   k. Includes adverse coverage determination cases that were forwarded to the IRE because the organization made an untimely decision.
   l. Includes all coverage determination decisions that relate to Part B versus Part D coverage (drugs covered under Part B are considered as adverse decisions under Part D).
      i. Point of Sale (POS) claims adjudications (e.g., a rejected claim for a drug indicating a B vs. D prior authorization (PA) is required) are not included unless the plan subsequently processed a coverage determination.
   m. Includes Direct Member Reimbursements (DMRs) part of the total number of exceptions if the plan processed the request under the tiering or formulary exceptions process. Verify that all DMRs regardless of request disposition type that were processed under the tiering or formulary exception process should be included in the count of the total number of coverage determination decisions made in the reporting period.
   n. Excludes coverage determinations (including exceptions) regarding drugs assigned to an excluded drug category.
   o. Excludes members who have Utilization Management (UM) requirements waived based on an exception decision made in a previous plan year or reporting period.
   p. Confirm that a coverage determination was denied for lack of medical necessity based on review by a physician or other appropriate health care professional.

   [Data Elements 1.A, 1.G, 1.K, 1.O]

7. Organization accurately calculates the total number of UM, Formulary, and Tier exceptions decisions made in the reporting period, including the following criteria:
   a. Includes all decisions made (fully favorable, partially favorable, and adverse) with a date of decision that occurs during the reporting period. Date of the final decision is based on the date the enrollee/enrollee's representative is notified in writing of the exception decision.
   b. Includes all methods of receipt (e.g., telephone, letter, fax, in-person).
   c. Includes exception requests that were forwarded to the IRE because the organization failed to make a timely decision.
   d. Includes requests for exceptions from delegated entities.
   e. Includes both standard and expedited exceptions.
   f. Excludes requests for exceptions that are withdrawn or dismissed.

[1] Note that Data Elements 1.A – 1.R relate to Coverage Determinations, Data Elements 2.A – 2V relate to Redeterminations, and Data Elements 3.A and 3.B.1 – 3.B.12 relate to Re-openings.
[2] Exception requests include tiering exceptions, formulary exceptions, and UM exceptions, such as prior authorization, step therapy, quantity limits, etc.
[3] Delegated entities are contractors to Part D sponsors.

COVERAGE DETERMINATIONS AND REDETERMINATIONS

g. Excludes requests for exceptions regarding drugs assigned to an excluded drug category.
h. Excludes members who have utilization management requirements waived based on an exception decision made in a previous plan year or reporting period.

[Data Element 1.G, 1.K, 1.O]

8. Organization accurately calculates the number of coverage determination decisions made by final decision, including the following criteria:
   a. Properly categorizes the number of coverage determinations (excluding exceptions) by final decision: fully favorable, partially favorable, or adverse. Verify that all cases included in the count for the total number of processed coverage determinations made in the reporting period are identified as one of the accepted disposition types.
   b. Includes untimely coverage determination decisions, regardless if they were auto-forwarded to the IRE.

[Data Elements 1.D, 1.E, 1.F]

9. Organization accurately calculates the number of coverage determinations that were withdrawn or dismissed, including the following criteria:
   a. Includes all withdrawals and dismissals on requests for coverage determinations (including exceptions). This includes expedited coverage determinations and exceptions that were withdrawn or dismissed for any reason.
   b. Includes dismissals that are made where the procedural requirements for a valid request are not met within the stipulated timeframe. The plan should issue a dismissal only when the required documentation was not received within a reasonable amount of time.

[Data Elements 1.B, 1.C]

10. Organization accurately calculates the total number of redeterminations (Part D only), including the following criteria:
    a. Includes all redetermination final decisions for Part D drugs with a date of final decision that occurs during the reporting period. Date of the final decision is based on the date the enrollee/enrollee's representative is notified in writing of the redetermination decision.
    b. Includes all redetermination decisions, including fully favorable, partially favorable, and adverse decisions.
    c. Includes redetermination requests that were forwarded to the IRE because the organization failed to make a timely decision.
    d. Includes both standard and expedited redeterminations.
    e. Includes t-risk determination appeals (beneficiary-specific Point of Sale (POS) edit, prescriber or pharmacy coverage limitation appeals, sharing information for subsequent Part D enrollments) made under a drug management program.
    f. Includes all methods of receipt (e.g., telephone, letter, fax, in-person).
    g. Includes all redeterminations regardless of who filed the request (e.g., member, appointed representative, or prescribing physician).
    h. Includes Direct Member Reimbursements (DMRs) part of the total number of redeterminations if the plan processed the request under the tiering or formulary exceptions process.
    i. Includes all redetermination decisions that relate to Part B versus Part D coverage (drugs covered under Part B are considered as adverse decisions under Part D).
        a. Point of Sale (POS) claims adjudications (e.g., a rejected claim for a drug indicating a B vs. D PA is required) are not included unless the plan subsequently processed a redetermination.
    j. Includes each distinct dispute contained in one redetermination request (i.e., multiple drugs) as a separate redetermination request.
    k. Excludes dismissals and withdrawals.
    l. Excludes IRE decisions.
    m. Excludes redeterminations regarding excluded drugs.
    n. Limits reporting to just the redetermination level.

[Data Element 2.A, 2.G, 2.K, 2.O, 2.S]

COVERAGE DETERMINATIONS AND REDETERMINATIONS

11. Organization accurately calculates the total number of UM, Formulary, and Tier exception redetermination decisions made in the reporting period, including the following criteria:
    a. Includes all decisions made (fully favorable, partially favorable, and adverse) with a date of decision that occurs during the reporting period. Date of the final decision is based on the date the enrollee/enrollee's representative is notified in writing of the exception redetermination decision.
    b. Includes all methods of receipt (e.g., telephone, letter, fax, in-person).
    c. Includes exception redetermination requests that were forwarded to the IRE because the organization failed to make a timely decision.
    d. Includes requests for exception redeterminations from delegated entities.
    e. Includes both standard and expedited exception redeterminations.
    f. Excludes requests for exception redeterminations that are withdrawn or dismissed.
    g. Excludes requests for exception redeterminations regarding drugs assigned to an excluded drug category.

[Data Element 2.G, 2.K, 2.O]

12. Organization accurately calculates the number of redeterminations by final decision, including the following criteria:
    a. Properly categorizes the total number of redeterminations by final decision: fully favorable (e.g., fully favorable decision reversing the original coverage determination), partially favorable (e.g., denial with a "part" that has been approved), and adverse (e.g., the original coverage determination decision was upheld).
    b. Excludes redetermination decisions made by the IRE.

[Data Elements 2.D–2.F]

13. Organization accurately calculates the number of requests for redeterminations that were withdrawn or dismissed, including the following criteria:
    a. Includes all withdrawals and dismissals on requests for redeterminations.
    b. Includes dismissals that are made when the procedural requirements for a valid request are not met within the stipulated timeframe. The plan should issue a dismissal only when the required documentation has not been received within a reasonable amount of time.

[Data Element 2.B and 2.C]

14. Organization accurately calculates the total number of reopened decisions according to the following criteria:
    a. Includes a remedial action taken to change a final determination or decision even though the determination or decision was correct based on the evidence of record.

[Data Element 3.A]

15. Organization accurately reports the following information for each reopened case.
    a. Contract Number
    b. Plan ID
    c. Case ID
    d. Case level (Coverage Determination or Redetermination)
    e. Date of original disposition
    f. Original disposition (Fully Favorable; Partially Favorable; or Adverse)
    g. Was case processed under expedited timeframe (Y/N)
    h. Case type (Pre-Service; Payment)
    i. Date case was reopened
    j. Reason(s) for reopening (Clerical Error, Other Error, New and Material Evidence, Fraud or Similar Fault, or Other)
    k. Date of reopening disposition (revised decision)
    l. Reopening disposition (Fully Favorable; Partially Favorable; Adverse; or Pending).

[Data Elements 3.B.1–3.B.12]

IMPROVING DRUG UTILIZATION REVIEW CONTROLS

Note to reviewer: Access to the CY 2022 cumulative opioid MME POS edits and the attestation opioid naïve days supply edit submissions is in HPMS. Consider implementation dates of all CMS approved changes to the organization's drug utilization management program policies and procedures.

To determine compliance with the standards for Improving Drug Utilization Review Controls, the data validation contractor will assess the following information:

- Written response to *OAI* Sections 3 and 4, and documentation requested per *OAI* Sections 5 and 6
- Outlier/data integrity notification(s)- See OAI 4.3.3 for instructions on how to retrieve notices
- Results of interviews with organization staff
- Census and/or sample data
- Data file created for submission to CMS and copy of HPMS screen shots of data entered
- Other relevant information provided by organization

VALIDATION STANDARDS

1. A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) indicates that all source documents accurately capture required data fields and are properly documented.

Criteria for Validating Source Documents:

a. Source documents and output are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS.
b. Source documents create all required data fields for reporting requirements.
c. Source documents are error-free (e.g., programming code and spreadsheet formulas have no messages or warnings indicating errors).
d. All data fields have meaningful, consistent labels (e.g., label field for patient ID as Patient ID, rather than Field1 and maintain the same field name across data sets).
e. Data file locations are referenced correctly.
f. If used, macros are properly documented.
g. Source documents are clearly and adequately documented.
h. Titles and footnotes on reports and tables are accurate.
i. Version control of source documents is appropriately applied.

2. A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) and census or sample data, whichever is applicable, indicates that data elements for each reporting section are accurately identified, processed, and calculated.

Criteria for Validating Reporting Section Criteria (Refer to reporting section criteria section below):

a. The appropriate date range(s) for the reporting period(s) is captured.
b. Data are assigned at the applicable level (e.g., plan benefit package or contract level).
c. Appropriate deadlines are met for reporting data (e.g., quarterly).
d. Terms used are properly defined per CMS regulations, guidance, Reporting Requirements, and Technical Specifications.
e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.

IMPROVING DRUG UTILIZATION REVIEW CONTROLS

3. Organization implements appropriate policies and procedures for data submission, including the following:
   a. Data elements are accurately uploaded into the HPMS tool, and entries match corresponding source documents. [Data Elements A-FF]
   b. All source, intermediate, and final stage data sets relied upon to enter data into HPMS are archived.

4. Organization implements appropriate policies and procedures for periodic data system updates (e.g., changes in enrollment, provider/pharmacy status, and claims adjustments).

5. Organization implements appropriate policies and procedures for archiving and restoring data in each data system (e.g., disaster recovery plan).

6. If organization's data systems underwent any changes during the reporting period (e.g., because of a merger, acquisition, or upgrade): Organization provided documentation on the data system changes and, upon review, there were no issues that adversely impacted data reported.

7. If data collection and/or reporting for this data reporting section is delegated to another entity: Organization regularly monitors the quality and timeliness of the data collected and/or reported by the delegated entity or first tier/downstream contractor.

REPORTING SECTION CRITERIA

1. Organization reports data based on the required reporting period of 1/1 through 3/31, 1/1 through 6/30, 1/1 through 9/30, 1/1 through 12/31.

2. Organization properly assigns data to the applicable CMS contract and plan.

3. Organization meets deadline for reporting annual data to CMS by 2/27/2023.

Note to reviewer: If the organization has, for any reason, re-submitted its data to CMS for this reporting section, the reviewer should verify that the organization's original data submission met the CMS deadline in order to have a finding of "yes" for this reporting section criterion. However, if the organization re-submits data for any reason and if the re-submission was completed by 3/31 of the data validation year, the reviewer should use the organization's corrected data submission for the review of this reporting section.

4. Organization complies with drug utilization management (DUM) requirements of 42 C.F.R §423.153 et seq. to prevent overutilization of opioids as well as other DUM requirements according to guidelines specified by CMS. This includes but is not limited to:
   a. Applying all relevant guidance to properly establish and implement a care coordination formulary-level cumulative opioid morphine milligram equivalent (MME) threshold point of sale (POS) edit, an opioid naïve days supply POS edit, and if applicable, a hard formulary-level cumulative opioid MME threshold POS edit.
   b. Organization provides documentation that its care coordination safety POS edit, an opioid naïve days supply POS edit, and if applicable, a hard formulary-level cumulative opioid MME threshold POS edit were properly tested and validated prior to its implementation date.
   c. For the care coordination safety edit,
      i. Properly reports the opioid MME threshold, provider count, and pharmacy count criteria from the Reporting Requirements submission matches the CY 2022 care coordination safety edit formulary-level cumulative opioid MME threshold submission report in HPMS.
   d. For the hard MME edit,
      i. Properly reports opioid MME threshold, provider count, and pharmacy count criteria from the Reporting Requirements submission matches the CY 2022 hard MME safety edit formulary-level cumulative opioid MME threshold submission report in HPMS.
   e. For the opioid naïve days supply safety edit,
      i. Properly reports that the opioid naïve days supply safety edit look-back period reported matches the CY 2022 look-back period submission report in HPMS.

IMPROVING DRUG UTILIZATION REVIEW CONTROLS

5. Organization accurately reports data by applying data integrity checks listed below and uploads it into HPMS.
   a. For the care coordination safety edit, the following is true:
      i. The prescriber count criterion used and the pharmacy count criterion used must be reported (Data Elements A, B ≠ blank).
      ii. The number of claims rejected due to the care coordination safety edit (Element C) should be greater than or equal to each of the following:
         - The number of claim rejections overridden by the pharmacy (Element D);
         - The number of claim rejections overridden by the pharmacy within 24 hours of the initial claim rejection (Element E);
         - The number of claim rejections overridden by the pharmacy due to an exemption (Element F); and
         - The number of claim rejections overridden by the pharmacy as a result of prescriber consultation (Element G).
      iii. The number of unique beneficiaries with at least one claim rejected due to the care coordination safety edit (Element H) should be greater than or equal to each of the following:
         - the number of unique beneficiaries with at least one claim rejection overridden by the pharmacy (Element I)
         - The number of unique beneficiaries with at least one claim rejection overridden by the pharmacy within 24 hours of the initial claim rejection (Element J)
         - The number of unique beneficiaries with at least one claim rejection overridden by the pharmacy due to an exemption (Element K)
         - The number of unique beneficiaries with at least one claim rejection overridden by the pharmacy as a result of prescriber consultation (Element L)

   b. If the organization had a hard MME safety edit (Data Element M =Yes), the following is true:

      i. The number of unique beneficiaries with at least one claim rejected due to the hard MME safety edit (Element R) should be greater than or equal to each of the following:
         - the number of unique beneficiaries with at least one claim rejection overridden by the pharmacy due to an exemption (Element S);
         - the number of unique beneficiaries who requested a coverage determination for the prescription(s) subject to the edit (Element T); and
         - the number of unique beneficiaries that had a favorable (either full or partial) coverage determination for the prescription(s) subject to the edit (Element U).

      ii. The cumulative MME threshold (Element N) must be reported (Data Element N≠ blank).

   c. If the organization does not have hard MME safety POS edits (Data Element M=No), Data Elements N, O, P Q, R, S, T and U should equal 0.

IMPROVING DRUG UTILIZATION REVIEW CONTROLS

d. For the opioid naïve days supply safety edit, the following is true:
   i. The look-back period used to identify an initial opioid prescription fill for the treatment of acute pain (Element V) must be reported (Data Element V ≠ blank).
   ii. The number of claims rejected due to the opioid naïve days supply edit (Element W) should be greater than or equal to each of the following:
      - the number of claim rejections overridden by the pharmacy due to an exemption (Element X);
      - the number of claim rejections overridden by the pharmacy because the beneficiary was not opioid naive (Element Y); and
      - the number of rejected claims for which up to a 7-day supply (covered by the plan) was dispensed by the pharmacy (Element Z).
   iii. The number of unique beneficiaries with at least one claim rejected due to the opioid naïve days supply edit (Element AA) should be greater than or equal to:
      - the number of unique beneficiaries with at least one rejected claim overridden by the pharmacy due to an exemption (Element BB);
      - the number of unique beneficiaries with at least one rejected claim overridden by the pharmacy because the beneficiary was not opioid naïve (Element CC);
      - the number of unique beneficiaries for whom up to a 7-day supply (covered by the plan) was dispensed by the pharmacy (Element DD);
      - the number of unique beneficiaries with an opioid naïve days supply edit claim rejection who requested a coverage determination for the prescription(s) subject to the edit (Element EE); and
      - the number of unique beneficiaries with an opioid naïve days supply edit claim rejection who had a favorable (either full or partial) coverage determination for the prescription(s) subject to the edit (Element FF)

e. If the organization received an outlier/data integrity notice for the Improving Drug Utilization Review Controls section validate whether or not an internal procedure change was warranted or resubmission through HPMS. Data Elements: A-L, N-U, and V-FF.

[Data Elements A-FF]

IMPROVING DRUG UTILIZATION REVIEW CONTROLS

6. Organization can accurately identify and create a Part D data set of POS claim rejects related to its care coordination safety edit, hard MME safety edit, and/or opioid naïve days supply safety edit and correctly calculate and report counts to CMS via HPMS, including the following criteria:

   a. Properly identifies and counts the number of POS rejects triggered and unique beneficiaries related to the care coordination safety edit and if applicable, a provider and pharmacy criterion.
      i. Includes pharmacy transactions for Part D opioid drugs with a fill date (not batch date) that falls within the reporting period.
      ii. The rejected opioid claim due to the care coordination safety edit is not associated with an early refill rejection transaction.
      iii. Rejected opioid claims are counted at the unique plan, beneficiary, prescriber, pharmacy, drug (strength and dosage form), quantity, date of service (DOS), and formulary-level opioid MME POS edit.
      iv. Properly counts the number of unique beneficiaries by plan that triggered the care coordination safety edit and, if applicable, a provider and/or pharmacy criterion.

   b. Properly identifies and counts the number of POS rejects triggered and unique beneficiaries related to the established hard MME safety edit threshold and, if applicable, a provider and pharmacy criterion.
      i. Includes pharmacy transactions for Part D opioid drugs with a fill date (not batch date) that falls within the reporting period.
      ii. The rejected opioid claim due to the hard MME safety edit is not associated with an early refill rejection transaction.
      iii. Rejected opioid claims are counted at the unique plan, beneficiary, prescriber, pharmacy, drug (strength and dosage form), quantity, DOS, and formulary-level opioid MME POS edit.
      iv. Properly counts the number of unique beneficiaries by plan that triggered the established hard MME safety edit threshold and, if applicable, a provider and/or pharmacy criterion.

   c. Properly identifies and counts the number of POS rejects triggered and unique beneficiaries related to the opioid naïve days supply safety edit.
      i. Includes pharmacy transactions for Part D opioid drugs with a fill date (not batch date) that falls within the reporting period.
      ii. The rejected opioid claim due to opioid naïve days supply safety edit is not associated with an early refill rejection transaction.
      iii. Rejected opioid claims are counted at the unique plan, beneficiary, prescriber, pharmacy, drug (strength and dosage form), quantity, and DOS.
      iv. Properly counts the number of unique beneficiaries by plan that triggered the opioid naïve days supply safety edit.

[Data Elements C, H, Q, R, W, AA]

IMPROVING DRUG UTILIZATION REVIEW CONTROLS

7. From the data set of POS rejects (RSC 6a) related to the care coordination safety edit the organization accurately identifies and counts the number of overridden rejected claims and correctly uploads the counts into HPMS, including the following criteria:

   a. Properly identifies and counts the number of pharmacist-overridden care coordination safety edit POS rejected claims.
      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 MME POS edit. For example, if multiple transactions are submitted and rejected by the sponsor for the same formulary-level cumulative opioid MME POS edit from the same pharmacy for the same beneficiary, prescription (drug, quantity and prescriber) and DOS, this would count as one rejected claim. However, if a beneficiary attempted to fill the same prescription at 3 different pharmacies, either on the same day or on different days, and the prescription was rejected each time for the same formulary-level cumulative opioid MME POS edit, this would count as 3 rejected claims. The same claim and beneficiary should be reported in multiple reporting sections of the opioid safety edits, if a claim triggers multiple safety edits at POS.

   b. Properly identifies and counts the number of unique beneficiaries per plan with at least one claim rejection due to its care coordination safety POS edit and a pharmacist overridden care coordination safety POS edit rejected claim.

      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 MME POS edit. For example, if multiple transactions are submitted and rejected by the sponsor for the same formulary-level cumulative opioid MME POS edit from the same pharmacy for the same beneficiary, prescription (drug, quantity and prescriber) and DOS, this would count as one rejected claim. However, if a beneficiary attempted to fill the same prescription at 3 different pharmacies, either on the same day or on different days, and the prescription was rejected each time for the same formulary-level cumulative opioid MME POS edit, this would count as 3 rejected claims. The same claim and beneficiary should be reported in multiple reporting sections of the opioid safety edits, if a claim triggers multiple safety edits at POS.

[Data Elements D, H , I]

8. The organization accurately identifies claims leading to a coverage determination request and correctly uploads the count into HPMS including the following criteria:

   a. From the data set (RSC6b) of POS rejects related to the hard MME safety edits,
      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 MME POS edit. For example, if multiple transactions are submitted and rejected by the sponsor for the same formulary-level cumulative opioid MME POS edit from the same pharmacy for the same beneficiary, prescription (drug, quantity and prescriber) and DOS, this would count as one rejected claim. However, if a beneficiary attempted to fill the same prescription at 3 different pharmacies, either on the same day or on different days, and the prescription was rejected each time for the same formulary-level cumulative opioid MME POS edit, this would count as 3 rejected claims. The same claim and beneficiary should be reported in multiple reporting sections of the opioid safety edits, if a claim triggers multiple safety edits at POS.
      ii. Includes all methods of coverage determination receipt (e.g., telephone, letter, fax, in-person).
      iii. Includes all coverage determination requests.

   b. From the data set (RSC6c) of POS rejects related to the opioid naïve days supply safety edits,
      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 MME POS edit. For example, if multiple transactions are submitted and rejected by the sponsor for the same formulary-level cumulative opioid MME POS edit from the same pharmacy for the same beneficiary, prescription (drug, quantity and prescriber) and DOS, this would count as one rejected claim. However, if a beneficiary attempted to fill the same prescription at 3 different pharmacies, either on the same day or on different days, and the prescription was rejected each time for the same formulary-level cumulative opioid MME POS edit, this would count as 3 rejected claims. The same claim and beneficiary should be reported in multiple reporting sections of the opioid safety edits, if a claim triggers multiple safety edits at POS.
      ii. Includes all methods of coverage determination receipt (e.g., telephone, letter, fax, in-person).
      iii. Includes all coverage determination requests subject to the opioid naïve edit.

[Data Elements T, EE]

IMPROVING DRUG UTILIZATION REVIEW CONTROLS

9. The organization accurately identifies the number of unique beneficiaries with at least one POS claim rejection related to a hard MME safety edit and/or opioid naïve days supply safety edit who had a favorable (either full or partial) coverage determination for the prescription(s) subject to the edit. Correctly uploads the count, if the data set of POS rejects includes the complete reporting period, into HPMS including the following criteria:

    a. From the subset of POS rejects (RSC 6b) related to the hard MME safety POS edits,
        i. The beneficiary's opioid claim is also included in data element R. [Data Element U]

    b. From the subset of POS rejects (RSC 6c) related to the opioid naïve days supply safety POS edits,
        i. The beneficiary's opioid claim is also included in data element AA. [Data Element FF]

10. The organization accurately identifies the number of unique beneficiaries with at least one POS claim rejection related to a hard MME safety edit and/or opioid naïve days supply safety edit that was overridden due to an exemption (Elements S, BB), because the beneficiary was not opioid naïve (Element CC), or for whom up to a 7-day supply (covered by the plan) was dispensed by the pharmacy (Element DD). Correctly uploads the count, if the data set of POS rejects includes the complete reporting period, into HPMS, including the following criteria:

    a. From the subset of POS rejects (RSC 6b) related to the hard MME safety POS edits,
        i. The beneficiary's opioid claim is also included in data element R.

    [Data Element S]

    b. From the subset of POS rejects (RSC 6c) related to the opioid naïve days supply safety POS edits,
        i. The beneficiary's opioid claim is also included in data element AA.

    [Data Elements BB, CC, DD]

APPENDIX: ACRONYMS

Acronym	Description
CFR	Code of Federal Regulations
CMR	Comprehensive Medication Review
CMS	Centers for Medicare & Medicaid Services
CPT	Current Procedural Terminology
CTM	Complaint Tracking Module
DOS	Date of Service
DUM	Drug Utilization Management
HPMS	Health Plan Management System
ICD-9	International Classification of Diseases, 9th Revision
ICD-10	International Classification of Diseases, 10th Revision
IRE	Independent Review Entity
LTC	Long-Term Care
MAO	Medicare Advantage Organization
MA-PD	Medicare Advantage Prescription Drug Plan
MME	Morphine Equivalent Dose
MTM	Medication Therapy Management
OAI	Organizational Assessment Instrument
PA	Prior Authorization
PBM	Pharmacy Benefit Management
POS	Point of Sale
QA	Quality Assurance
QIO	Quality Improvement Organization
SNF	Skilled Nursing Facility
SNPs	Special Needs Plans
TMR	Targeted Medication Review
UM	Utilization Management