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

Appendix B: Data Validation Standards

For Data Validation Occurring in 2018

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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 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 Technical Specifications*.

The DV contractor must use these standards in conjunction with the Data Extraction and Sampling Instructions and the Excel-version of the Findings Data Collection Form (FDCF) to upload into the Health Plan Management System Plan Reporting Data Validation Module in order to evaluate the organization's processes for producing and reporting 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 Technical Specifications Document Contract Year 2017 (version date January 2017) is used as the basis for the data validation standards. For the Part D reporting sections, the Medicare Part D Plan Reporting Requirements: Technical Specifications Document Contract Year 2017 (version October 2017) is used as the basis for the data validation standards.

2. PART C DATA VALIDATION STANDARDS

GRIEVANCES (PART C) *(for 2017 REPORTED DATA)*	
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 CMS systems. 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 and Reporting Requirements 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 CMS systems and entries match corresponding source documents. b. All source, intermediate, and final stage data sets and other outputs relied upon to enter data into CMS systems 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

GRIEVANCES (PART C) *(for 2017 REPORTED DATA)*	
	recovery plan).
6	*If organization's data systems underwent any changes during the reporting period (e.g., as a result 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 (for 2017 reported data)	
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 2/5/2018. *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(s) for the rest of the reporting section criteria for this reporting section.*
4	Organization properly defines the term "Grievance" in accordance with 42 CFR §422.564 and the Medicare Managed Care Manual Chapter 13, Sections 10 and 20. This includes applying all relevant guidance properly when performing its calculations and categorizations. Requests for organization determinations or appeals are not improperly categorized as grievances.
5	Organization data passes data integrity checks listed below: a. Total grievances (Data Element A) is equal to the sum of grievances by reason (Data Element F + Data Element H+ Data Element J + Data Element L+ Data Element N+ Data Element P + Data Element R + Data Element T+ Data Element V). b. Total grievances in which timely notification was given (Data Element B) is equal to the sum of grievances in which timely notification was given by reason (Data Element G+ Data Element I + Data Element K + Data Element M + Data Element O + Data Element Q + Data Element S+ Data Element U + Data Element W.). 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 grievances (Data Element A). e. Number of dismissed grievances (Data Element E) does not exceed total grievances (Data Element A). f. Number of enrollment/disenrollment grievances in which timely notification was given (Data Element G) does not exceed total enrollment/disenrollment grievances (Data Element F). g. Number of benefit package grievances in which timely notification was given (Data Element I) does not exceed total benefit package grievances (Data Element H). h. Number of access grievances in which timely notification was given (Data Element K) does not exceed total access grievances (Data Element J). i. Number of marketing grievances in which timely notification was given (Data Element M) does not exceed total marketing grievances (Data Element L). j. Number of customer service grievances in which timely notification was given (Data Element O) does not exceed total customer service grievances (Data Element N). k. Number of organization determination and reconsideration process grievances in which timely notification was given (Data Element Q) does not exceed total organization determination and reconsideration process grievances (Data Element P). l. Number of quality of care grievances in which timely notification was given (Data Element S) does not exceed total quality of care grievances (Data Element R). m. Number of CMS issue grievances in which timely notification was given (Data Element U) does not exceed total CMS issue grievances (Data Element T). n. Number of other grievances in which timely notification was given (Data Element W) does not exceed total other grievances (Data Element V). o. 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, B,C,E, F-W) [Data Elements A – W]

GRIEVANCES (PART C) *(for 2017 REPORTED DATA)*	
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, F, H, J, L, N, P, R, T, V]
7	Organization accurately calculates the number of grievances by category, including the following criteria: a. Properly sorts the total number of grievances by grievance category: Enrollment/Disenrollment; Benefit Package; Access; Marketing; Customer Service; Organization Determination and Reconsideration Process; Quality of Care; "CMS Issues". b. Grievances not falling in a specific listed category are properly assigned to "Other Grievances." [Data Elements F, H, J, L, N, P, R, T, V]
8	Organization accurately calculates the number of grievances by category 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 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 receipt of grievance. [Data Elements [B, G, I, K, M, O, Q, S, U, W]

ORGANIZATION DETERMINATIONS / RECONSIDERATIONS

(for 2017 REPORTED DATA)

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. <u>Criteria for Validating Source Documents:</u> a. Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via CMS systems. 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. <u>Criteria for Validating Reporting Section Criteria (Refer to reporting section criteria section below):</u> 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 and Reporting Requirements 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 CMS systems and entries match corresponding source documents. b. All source, intermediate, and final stage data sets and other outputs relied upon to enter data into CMS systems 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., as a result 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

ORGANIZATION DETERMINATIONS / RECONSIDERATIONS *(for 2017 REPORTED DATA)*	
	the quality and timeliness of the data collected and/or reported by the delegated entity or first tier/downstream contractor.
REPORTING SECTION CRITERIA (for 2017 reported data)	
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 2/26/2018. *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(s) for the rest of the reporting section criteria for this reporting section*.
4a	Organization properly defines the term "Organization Determinations" in accordance with 42 C.F.R Part 422, Subpart M and the Medicare Managed Care Manual Chapter 13, Section 10. This includes applying all relevant guidance properly when performing its calculations and categorizations.
4b	Organization properly defines the term "Reconsideration" in accordance with 42 C.F.R Part 422, Subpart M and the Medicare Managed Care Manual Chapter 13, Sections 10 and 70. This includes applying all relevant guidance properly when performing its calculations and categorizations.
5	Organization data passes data integrity checks listed below: a. The number of organization determinations processed timely (Data Element 6.2) does not exceed the total number of organization determinations (Data Element 6.1). b. The total number of organization determinations (Data Element 6.1) is equal to sum of organization determinations by outcome (Data Element 6.3 + Data Element 6.4 + Data Element 6.5 + Data Element 6.6 + Data Element 6.7 + Data Element 6.8). c. Number of reconsiderations processed timely (Data Element 6.12) does not exceed total number of reconsiderations (Data Element 6.11). d. The total number of reconsiderations (Data Element 6.11) is equal to sum of reconsiderations by outcome (Data Element 6.13 + Data Element 6.14 + Data Element 6.15 + Data Element 6.16 + Data Element 6.17 + Data Element 6.18). e. The total number of reopened decisions (Data Element 6.21) is equal to the number of records reported in the data file with a disposition of reopened. f. The date each case was reopened (Data Element 6.31) is after the date of its original disposition (Data Element 6.26). g. The date of disposition for each reopening (Data Element 6.34) is after the date of the original disposition (Data Element 6.26). h. The date of disposition for each reopening (Data Element 6.34) is after the date the case was reopened (Data Element 6.31). i. The date of disposition of each reopening (Data Element 6.34) is within the reporting quarter. j. Verify that there is a valid value submitted for date of original disposition as MM/DD/YYYY format (Data Element 6.26). k. Verify that there is a valid value submitted for case level (Organization Determination or Reconsideration) (Data Element 6.25). l. Verify that there is a valid value submitted for reopening disposition (Fully Favorable; Partially Favorable, Adverse or Pending (Data Element 6.35). m. 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 6.1-6.21, 6.25,6.26, 6.27, 6.34, 6.35) [Data Elements 6.1 – 6.35)
6	Organization accurately calculates the total number of organization determinations, including the following criteria: a. Includes all completed organization determinations (Part C only) 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 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.

ORGANIZATION DETERMINATIONS / RECONSIDERATIONS *(for 2017 REPORTED DATA)*	
	e. Includes organization determinations that are filed directly with the organization or its delegated entities (e.g., excludes all organization determinations that are only forwarded to the organization from the CMS Complaint Tracking Module (CTM) and not filed directly with the organization or delegated entity). 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 regardless of who filed the request. 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 Decisions. k. Excludes Quality Improvement Organization (QIO) reviews of a member's request to continue Medicare-covered services (e.g., a SNF stay). l. Excludes duplicate payment requests concerning the same service or item. m. Excludes payment requests returned to a provider/supplier 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). [Data Elements 6.1 – 6.8]
7	Organization accurately calculates the number of organization determinations, including the following criteria: a. Includes all service organization determinations for contract and non-contract providers/suppliers. b. Includes all payment (claim) organization determinations for contract and non-contract providers/suppliers. [Data Element 6.1]
8	Organization accurately calculates the total number of organization determinations that were processed in a timely manner including the following criteria: a. Includes all service organization determinations for contract and non-contract providers/suppliers. b. Includes all payment (claim) organization determinations for contract and non-contract providers/suppliers. [Data Element 6.2]
9	Organization accurately calculates the number of fully favorable (e.g., approval of entire request resulting in full coverage of the item or service) organization determinations, including the following criteria: a. Includes all fully favorable service organization determinations for contract and non-contract providers/suppliers. [Data Element 6.3] b. Includes all fully favorable payment (claim) organization determinations for contract and non-contract providers/suppliers. [Data Element 6.4] c. For instances when a request for payment is submitted to an organization concerning an item or service, and the organization has already made a favorable organization determination (i.e., issued a fully favorable service decision), includes the request for payment for the same item or service as another, separate, fully favorable organization determination. d. For instances when the organization approves an initial request for an item or service (e.g., physical therapy services) and the organization approves a separate additional request to extend or continue coverage of the same item or service, includes the decision to extend or continue coverage of the same item or service as another, separate, fully favorable organization determination. e. Includes auto-adjudicated claims, service authorizations which include prior-authorization (authorization that is issued prior to the services being rendered), concurrent authorization for services rendered in an office setting (authorization that is issued at the time the service is being rendered) and post-authorization (authorization that is issued after the services has already been provided) for contract and non-contract providers [Data Elements 6.3-6.4].
10	Organization accurately calculates the number of partially favorable claim and favorable service organization determinations (e.g., coverage denial of some items and coverage approval of some items in a claim that has multiple line items organization determinations, including the following criteria: a. Includes all partially favorable service organization determinations for contract and non-contract providers/suppliers. [Data Element 6.5] b. Includes all partially favorable payment (claim) organization determinations for contract and non-contract providers/suppliers. [Data Element 6.6]

ORGANIZATION DETERMINATIONS / RECONSIDERATIONS *(for 2017 REPORTED DATA)*	
11	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 following criteria: a. Includes all adverse service organization determinations for contract and non-contract providers/suppliers. [Data Element 6.7] b. Includes all adverse payment (claim) organization determinations that result in zero payment being made to contract and non-contract providers. [Data Element 6.8]
12	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. [Data Element 6.9]
13	Organization accurately calculates "Organization Determinations - Dismissals" according to the following criteria: Includes dismissals that were processed according to Reconsideration Dismissal Procedure as stated in guidance provided in the September 10, 2013 HPMS memo regarding Part C reconsideration dismissal procedures prior to issuing the dismissal as well as guidance provided in Chapter 13 of the Medicare Managed Care Manual. [Data Element 6.10]
14	Organization accurately calculates the total number of reconsiderations, including the following criteria: a. Includes all completed reconsiderations (Part C only) 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 regardless of who filed the request. For example, if a non-contracted provider signs a waiver of liability and submits a reconsideration request, a plan is to report this reconsideration in the same manner it would report a member-filed reconsideration. e. Includes reconsiderations that are filed directly with the organization or its delegated entities (e.g., excludes all reconsiderations that are only forwarded to the organization from the CMS Complaint Tracking Module (CTM) and not filed directly with the organization or delegated entity). 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 Independent Review Entity 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 a provider/supplier 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). [Data Element 6.11-6.18]
15	Organization accurately calculates the total number of reconsiderations processed timely according to the following criteria: a. Includes all -service reconsiderations for contract and non-contract providers/suppliers. Includes all payment (claim) reconsiderations for contract and non-contract providers/suppliers. [Data Element 6.12] [Data Element 6.12]
16	Organization accurately calculates the number of fully favorable ((item or service was covered in full)) reconsiderations, including the following criteria: a. Includes all fully favorable service reconsideration determinations for contract and non-contract providers/suppliers. [Data Element 6.13] b. Includes all fully favorable payment (claim) reconsideration determinations for contract and non-contract providers/suppliers. [Data Element 6.14] 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 a favorable service reconsideration determination, includes the reconsideration request for payment for the same item or service as another, separate, fully favorable reconsideration determination. [Data Element 6.13-6.14]
17	Organization accurately calculates the number of partially favorable (e.g., coverage denial of some items and coverage

ORGANIZATION DETERMINATIONS / RECONSIDERATIONS *(for 2017 REPORTED DATA)*	
	approval of some items in a claim that has multiple line items reconsiderations, including the following criteria: a. Includes all partially favorable service reconsideration determinations for contract and non-contract providers/suppliers. [Data Element 6.15] b. Includes all partially favorable payment (claim) reconsideration determinations for contract and non-contract providers/suppliers. [Data Element 6.16]
18	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 following criteria: a. Includes all adverse service reconsideration determinations for contract and non-contract providers/suppliers. [Data Element 6.17] b. Includes all adverse payment (claim) reconsideration determinations that result in zero payment being made to contract and non-contract providers. [Data Element 6.18] 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. [Data Element 6.17-6.18]
19	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. [Data Element 6.19]
20	Organization accurately calculates "Reconsiderations Dismissals" according to the following criteria: a. Includes reconsiderations dismissals that were processed according to Reconsideration Dismissal p procedure as provided in the September 10, 2013 HPMS memo and according to guidance provided by Chapter 13 of the Medicare Managed Care Manual. [Data Element 6.20]
21	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 6.21]
22	Organization accurately reports the following information for each reopened case. a. Contract Number b. Plan ID c. Case ID d. Date of original disposition e. Original disposition (Fully Favorable; Partially Favorable; or Adverse) f. Case Level (Organization Determination or Reconsideration) g. Date case was reopened h. Reason (s) for reopening (Clerical Error, Other Error, New and Material Evidence, Fraud or Similar Fault, or Other) i. Date of reopening disposition (revised decision) j. Reopening disposition (Fully Favorable; Partially Favorable; Adverse or Pending) [Data Elements 6.22 – 6.35]

SPECIAL NEEDS PLANS (SNP) CARE MANAGEMENT

(for 2017 REPORTED DATA)

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. <u>Criteria for Validating Source Documents:</u> a. Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via CMS systems. 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. <u>Criteria for Validating Reporting Section Criteria (Refer to reporting section criteria section below):</u> 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 and Reporting Requirements 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 CMS systems and entries match corresponding source documents. b. All source, intermediate, and final stage data sets and other outputs relied upon to enter data into CMS systems are archived.
4	Organization implements policies and procedures for periodic data system updates (e.g., changes in enrollment, provider/pharmacy status, and claims adjustments).

SPECIAL NEEDS PLANS (SNP) CARE MANAGEMENT *(for 2017 REPORTED DATA)*	
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., as a result 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 (for 2017 reported data)	
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 2/26/2018. *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 rest of the reporting section criteria for this reporting section*
4	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 may have enrolled as early as 90 days prior to the effective enrollment date as they will be considered eligible for an initial HRA for the year in which the effective enrollment date falls. b. Includes members who have enrolled in the plan after dis-enrolling from another plan (different sponsor or organization). c. 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. d. 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. e. Excludes members who received an initial HRA but were subsequently deemed ineligible because they were never enrolled in the plan. [Data Element 13.1]
5	Organization data passes data integrity checks listed below: a. The number of initial HRAs performed on new enrollees (Data Element 13.3) does not exceed the number of new enrollees (Data Element 13.1). b. The number of annual re-assessments performed (Data Element 13.6) does not exceed number of enrollees eligible for annual HRA (Data Element 13.2). c. Number of initial HRAs refusals (Data Element 13.4) does not exceed number of new enrollees (Data Element 13.1). d. Number of annual reassessment refusals (Data Element 13.7) does not exceed the number of enrollees eligible for an annual reassessment HRA (Data Element 13.2). e. Number of initial HRAs where SNP is unable to reach enrollees (Data Element 13.5) does not exceed number of new enrollees (Data Element 13.1). f. Number of annual reassessments where SNP is unable to reach enrollee (Data Element 13.8) does not exceed number of enrollees eligible for annual HRA (Data Element 13.2). 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 13.1 -13.8) [Data Elements 13.1 - 13.8]
6	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 were enrolled in the same plan for more than 90 days after the effective date of enrollment without receiving an initial HRA.

SPECIAL NEEDS PLANS (SNP) CARE MANAGEMENT *(for 2017 REPORTED DATA)*	
	b. 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. c. Includes members who received a reassessment during the measurement year within 365 days after their last HRA. d. 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. e. 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. f. Excludes members who received a reassessment but were subsequently deemed ineligible because they were never enrolled in the plan. g. 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 13.2]
7	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, excludes any HRAs (initial or reassessment) performed during their previous enrollment unless the re-enrollment occurred the day after the disenrollment. 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* 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-9 Procedure codes. Reviewer should confirm that the SNP maintained documentation for each reported assessment.* [Data Element 13.3]
8	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 13.4]
9	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 13.5]

SPECIAL NEEDS PLANS (SNP) CARE MANAGEMENT *(for 2017 REPORTED DATA)*	
10	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-9 Procedure codes. Reviewer should confirm that the SNP maintained documentation for each reported assessment.* [Data Element 13.6]
11	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 13.7]
12	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 13.8]

3. PART D DATA VALIDATION STANDARDS

MEDICATION THERAPY MANAGEMENT (MTM) PROGRAMS *(for 2017 Reported Data)* 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. <u>Criteria for Validating Source Documents:</u> a. Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via CMS systems. 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. <u>Criteria for Validating Reporting Section Criteria (Refer to reporting section criteria section below):</u> 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 and *Reporting Requirements 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 CMS systems and entries match corresponding source documents. b. All source, intermediate, and final stage data sets and other outputs relied upon to enter data into CMS systems 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., as a result 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 (for 2017 reported data)	
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 2/26/2018. *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 rest of the reporting section specific criteria for 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 data passes data integrity checks listed below: a. Date of MTM program enrollment (Data Element I) is within the reporting period (between 1/1/2017 and 12/31/2017). b. One record is entered for each unique beneficiary i.e. only one record exists for a unique HICN or RRB number. c. Only reports beneficiaries enrolled in the contract during the reporting period, i.e. HICN or RRB Number (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 Q) 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 H = 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 H ≠ missing). g. If the beneficiary met the specified targeting criteria per CMS-Part D Requirements (Data Element G = Yes), then the contract should report the date the beneficiary met the specified targeting criteria (Data Element J ≠ missing). h. If the beneficiary did not meet the specified targeting criteria per CMS-Part D Requirements (Data Element G = No), then the field for 'date meets the specified targeting criteria' (Data Element J) should be missing. i. If a contract reports beneficiaries that were not eligible according to CMS-Part D Requirements (Data Element G = No), 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). j. If the beneficiary opted out (Data Element K ≠ missing) then contract should provide an opt-out reason (Data Element L should not be missing). k. If the beneficiary did not opt-out (Data Element K = missing), the field for opt-out reason should be missing (Data Element L = missing). l. Date of MTM program opt-out (Data Element K) should not be before the date of MTM program enrollment (Data Element I). m. Date of (initial) CMR offer (N) should either be between the beneficiary's MTM enrollment date (Data Element I) and 12/31/2017 or the beneficiary's opt out date (Data Element K). n. If a CMR was offered (Data Element M = Yes), there is also a reported offer date (Data Element N ≠ missing). o. If a CMR was not offered (Data Element M = No), there is no reported offer date (Data Element N = missing). p. If a CMR was received (Data Element O = Yes), there is a reported number of CMRs (Data Element P ≠ missing or > 0). q. If no CMRs were received (Data Element O = No), there are no reported number for CMRs (Data Element P = missing or 0). r. If a CMR was received (Data Element O = Yes), there is a reported delivery date(s) (Data Element Q ≠ missing)

	s. If a CMR was not received (Data Element O = No), there are no reported delivery date(s) (Data Element Q = missing). t. If a CMR was received, then the Number of CMRs received (Data Element P) aligns with number of reported dates of CMRs (Data Element Q) [ex: If Data Element P = 4 then Data Element Q reports 2 CMR dates]. u. If records indicate that beneficiary received CMR (Data Element O = Yes), then indicator for CMR offered (Data element M ≠ No). v. CMR offer date (Data Element N) is before the CMR received date (Data Element Q). w. If a CMR was received (Data Element O = Yes), there is a reported method of delivery (Data Element R ≠ missing). x. If a CMR was not received (Data Element O = No), there is no reported method of CMR delivery (Data Element R = missing). y. If a CMR was received Data Element (Data Element O = Yes), there is a reported provider who performed the CMR (Data Element S ≠ missing). z. If a CMR was not received (Data Element O = No), there is no reported provider who performed the CMR (Data Element S = missing). aa. If a CMR was received (Data Element O = Yes), there is reported recipient of CMR (Data Element T ≠ missing). bb. If a CMR was not received (Data Element O = No), there is no reported recipient of CMR (Data Element T = missing). 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-T]
6	Organization accurately identifies data on MTM program participation and uploads it into Gentran, including the following criteria: a. Properly identifies and includes members who either met the specified targeting criteria per CMS Part D requirements or other expanded plan-specific targeting criteria at any time during the reporting period. 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. 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 d. Includes and reports each targeted member, reported once per contract year per contract file, based on the member's most current HICN. e. Excludes members deceased prior to their MTM eligibility date. f. Includes members who receive MTM services based on plan-specific MTM criteria defined by the plan. g. Properly identifies and includes members' date of MTM program enrollment (i.e., date they were automatically enrolled) that occurs within the reporting period. h. For those members who met the specified targeting criteria per CMS Part D requirements, properly identifies the date the member met the specified targeting criteria. i. Includes members who moved between contracts in each corresponding file uploaded to Gentran. 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. j. Counts each member who disenrolls from and re-enrolls in the same contract once. [Data Elements B –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 Gentran, 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 H]
8	Organization accurately identifies data on members who opted-out of enrollment in the MTM program and uploads it into Gentran, 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. 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). c. Excludes members who refuse or decline individual services without opting-out (disenrolling) from the MTM

	program. d. Excludes members who disenroll from and re-enroll in the same contract regardless of the duration of if the gap of MTM program enrollment [Data Elements K, L]
9	Organization accurately identifies data on CMR offers and uploads it into Gentran, including the following criteria: a. Properly identifies and includes MTM program members who were offered a CMR per CMS Part D requirements during the reporting period. b. Properly identifies and includes members' date of initial offer of a CMR that occurs within the reporting period. [Data Element M, N]
10	Organization accurately identifies data on CMR dates and uploads it into Gentran, including the following criteria: a. Properly identifies and includes the number of CMRs the member received, if applicable, with written summary in CMS standardized format. b. Properly identifies and includes the date(s) (up to 2) the member received a 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 and last CMR. c. 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. d. 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; 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. e. 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 Elements O - T]
11	Organization accurately identifies data on MTM drug therapy problem recommendations and uploads it into Gentran, including the following criteria: a. Properly identifies and includes all targeted medication reviews within the reporting period for each applicable member. b. Properly identifies and includes the number of drug 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 drug therapy problem recommendations from the organization). Organization counts each individual drug therapy problem identified per prescriber recommendation (e.g., if the organization sent a prescriber a fax identifying 3 drug therapy problems for a member, this is reported as 3 recommendations). c. Properly identifies and includes the number of drug 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 drug therapy. Examples include, but is not limited to, Initiate drug, Change drug (such as product in different therapeutic class, dose, dosage form, quantity, or interval), Discontinue or substitute drug (such as discontinue drug, generic substitution, or formulary substitution), and Medication compliance/adherence. *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.* [Data Elements U - W]

GRIEVANCES (Part D)

(for 2017 Reported Data)

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 CMS systems. 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 and Reporting Requirements 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 CMS systems and entries match corresponding source documents. b. All source, intermediate, and final stage data sets and other outputs relied upon to enter data into CMS systems 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., as a result 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) *(for 2017 Reported Data)*	
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 (for 2017 reported data)	
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 2/5/2018. *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(s) for the rest of the reporting section criteria for this reporting section*.
4	Organization properly defines the term "Grievance" in accordance with 42 CFR §423.564 and the Prescription Drug Benefit Manual Chapter 18, Sections 10 and 20. This includes applying all relevant guidance properly when performing its calculations and categorizations. Requests for coverage determinations, exceptions, or redeterminations are not improperly categorized as grievances.
5	Organization data passes data integrity checks listed below: a. Total grievances (Data Element A) is equal to the sum of grievances by reason (Data Element F + Data Element H + Data Element J + Data Element L + Data Element N + Data Element P + Data Element R + Data Element T+ Data Element V). b. Total grievances in which timely notification was given (Data Element B) is equal to the sum of grievances in which timely notification was given by reason (Data Element G + Data Element I + Data Element K + Data Element M + Data Element O + Data Element Q + Data Element S + Data Element U + Data Element W). 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) f. Number of enrollment/disenrollment grievances in which timely notification was given (Data Element G) does not exceed total enrollment/disenrollment grievances (Data Element F). g. Number of plan benefit grievances in which timely notification was given (Data Element I) does not exceed total plan benefit grievances (Data Element H). h. Number of pharmacy access grievances in which timely notification was given (Data Element K) does not exceed total pharmacy access grievances (Data Element J). i. Number of marketing grievances in which timely notification was given (Data Element M) does not exceed total marketing grievances (Data Element L). j. Number of customer service grievances in which timely notification was given (Data Element O) does not exceed total customer service grievances (Data Element N). k. Number of coverage determination and redetermination process grievances in which timely notification was given (Data Element Q) does not exceed total coverage determination and redetermination process grievances (Data Element P). l. Number of quality of care grievances in which timely notification was given (Data Element S) does not exceed total quality of care grievances (Data Element R). m. Number of CMS issue grievances in which timely notification was given (Data Element U) does not exceed total CMS issue grievances (Data Element T). n. Number of other grievances in which timely notification was given (Data Element W) does not exceed total other grievances (Data Element V). o. 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 – W]
6	Organization accurately calculates and uploads into HPMS the total number of grievances, including the following criteria: a. Includes all grievances with a date of decision that occurs during the reporting period, regardless of when the grievance was received or completed (i.e., organization notified member of its decision). b. If a grievance contains multiple issues filed by a single complainant, each issue is calculated as a separate

GRIEVANCES (Part D) *(for 2017 Reported Data)*	
	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 – W]
7	Organization accurately calculates and uploads into HPMS the number of grievances by category, including the following criteria: a. Properly sorts the total number of grievances by grievance category: Enrollment/Disenrollment; Plan Benefit; Pharmacy Access; Marketing; Customer Service; Coverage Determination and Redetermination Process (e.g., untimely coverage decisions); Quality of Care; CMS Issues (which includes grievances related to issues outside of the organization's direct control); and other grievances that do not properly fit into the other listed categories. b. Assigns all additional categories tracked by organization that are not listed above as Other. [Data Elements F,H,J,L,N,P,R,T,V]
8	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 receipt of grievance. b. Each number calculated is a subset of the total number of grievances received for the applicable category. [Data Elements B,D,G,I,K,M,O,Q,S,U,W]

COVERAGE DETERMINATIONS AND REDETERMINATIONS

(for 2017 Reported Data)

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. <u>Criteria for Validating Source Documents:</u> a. Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via CMS systems. 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. <u>Criteria for Validating Reporting Section Criteria (Refer to reporting section criteria section below):</u> 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 and Reporting Requirements 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 CMS systems and entries match corresponding source documents. b. All source, intermediate, and final stage data sets and other outputs relied upon to enter data into CMS systems are archived.

COVERAGE DETERMINATIONS AND REDETERMINATIONS *(for 2017 Reported Data)*	
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., as a result 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 (for 2017 reported data)	
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 2/26/2018. *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(s) for the rest of the reporting section criteria for this reporting section.*
4	a. Organization properly determines whether a request is subject to the coverage determinations or the exceptions process in accordance with 42 CFR §423.566, §423.578, and the Prescription Drug Benefit Manual Chapter 18, Sections 10 and30. This includes applying all relevant guidance properly when performing its calculations and categorizations for the above-mentioned regulations in addition to 42 CFR §423.568, §423.570, §423.572, §423.576 and the Prescription Drug Benefit Manual Chapter 18, Sections 40, 50, and 130. b. Organization properly defines the term "Redetermination" in accordance with Title 42, Part 423, Subpart M §423.560, §423.580, §423.582, §423.584, and §423.590 and the Prescription Drug Benefit Manual Chapter 18, Section 10, 70, and 130. This includes applying all relevant guidance properly when performing its calculations and categorizations. c. Refer to 42 CFR §423.1978-1986 and Chapter 18, section 120 of the Medicare Prescription Drug Benefit Manual for additional information and CMS requirements related to reopenings.
5	Organization data passes data integrity checks listed below: a. The following numbers do not exceed the total number of pharmacy transactions (Data Element 1.A): i. Number of pharmacy transactions rejected due to non-formulary status (Data Element 1.B). ii. Number of pharmacy transactions rejected due to PA requirements (Data Element 1.C). iii. Number of pharmacy transactions rejected due to step therapy requirements (Data Element 1.D). iv. Number of pharmacy transactions rejected due to QL requirements (Data Element 1.E). b. If the plan reported high cost edits in place for non-compounds (Data Element 1.F = Yes), then the plan reported a corresponding cost threshold (Data Element 1. F) is greater than 0. c. If the plan did not have high cost edits in place for non-compounds (Data Element 1.F = No), then the plan did not report a corresponding cost threshold (Data Element 1.F= blank). d. If the plan did not have high cost edits in place for non-compounds (Data Element 1.F = No), then the plan did not report claims rejected due to high cost edits for non-compounds (Data Element 1.G = 0). e. The following numbers do not exceed the total number of pharmacy transactions rejected (Data Element 1.A): i. Number of claims rejected due to high cost edits for non-compounds (Data Element 1.G). f. The following numbers do not exceed the total number of coverage determination decisions (Data Element 2.A): i. Number of exception decisions made in the reporting period (Data Element 2.J-2.AA).

COVERAGE DETERMINATIONS AND REDETERMINATIONS *(for 2017 Reported Data)*	
	ii. Number of coverage determination decisions processed timely (Data Element 2.B). iii. Number of coverage determinations decisions by outcome (Data Element 2.E + Data Element 2.F + Data Element 2.G + Data Element 2.H + Data Element 2.I) is equal to total number of coverage determinations (Data Element 2.A). iv. Number of coverage determination decisions not processed timely (Data Element 2.C + Data Element 2.D) g. Number of redeterminations by outcome (Data Element 3.E + Data Element 3.F + Data Element 3.G + Data Element H + Data Element I) is equal to total number of redeterminations (Data Element 3.A). h. Number of redeterminations processed timely (Data Element 3.B) does not exceed the total number of redeterminations made during the reporting period (Data Element 3.A): i. Number of redetermination decisions not processed timely (Data Element 3.C + Data Element 3.D) j. Total number of reopened (revised) decisions (Data Element 4.A) is equal to the number of records reported in data file. k. Verify that the date of each reopening disposition (Data Element 4.B.11) is in the reporting quarter. l. Verify that the date of disposition for each reopening (Data Element 4.B.11) is after the date of original disposition (Data Element 4.B.5). m. Verify that the date of each reopening disposition (Data Element 4.B.11) is after the date that the case was reopened (Data Element 4.B.9). n. Verify that the date each case was reopened (Data Element 4.B.9) is after the date of original disposition (Data Element 4.B.5). o. 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.G, 2.A – 2.AA, 3.A-3.I, 4.A – 4.B.9] [1]
6	Organization accurately calculates the number of pharmacy transactions, including the following criteria: a. Includes pharmacy transactions for Part D drugs with a fill date (not batch date) that falls within the reporting period. b. Includes transactions with a final disposition of reversed. c. Excludes pharmacy transactions for drugs assigned to an excluded drug category. d. If a prescription drug claim contains multiple transactions, each transaction is calculated as a separate pharmacy transaction. [Data Element 1.A]
7	Organization accurately calculates the number of pharmacy transactions rejected due to formulary restrictions, including the following criteria: a. Excludes rejections due to early refill requests. b. If a prescription drug claim contains multiple rejections, each rejection is calculated as a separate pharmacy transaction. [Data Element 1.B]
8	Organization accurately calculates the number of pharmacy transactions rejected due to prior authorization (PA) requirements, including the following criteria: a. Excludes rejections due to early refill requests. b. If a prescription drug claim contains multiple rejections, each rejection is calculated as a separate pharmacy transaction.

[1] Note that Data Elements 1.A – 1. G relate to Rejected Pharmacy Transactions, Data Elements 2.A – 2.AA relate Coverage Determinations, Data Elements 3.A, - 3.I. relate to Redeterminations, and Data Elements 4.A, 4.B.1 – 4.B.12 related to reopenings.

COVERAGE DETERMINATIONS AND REDETERMINATIONS *(for 2017 Reported Data)*	
	[Data Element 1.C]
9	Organization accurately calculates the number of pharmacy transactions rejected due to step therapy requirements, including the following criteria: a. Excludes rejections due to early refill requests. b. If a prescription drug claim contains multiple rejections, each rejection is calculated as a separate pharmacy transaction. [Data Element 1.D]
10	Organization accurately calculates the number of pharmacy transactions rejected due to quantity limits (QL) requirements, including the following criteria: a. Excludes rejections due to safety edits and early refill requests. b. Includes all types of QL rejects, including but not limited to claim rejections due to quantity limits or time rejections (e.g., a claim is submitted for 20 tablets/10 days, but is only approved for 10 tablets/5 days). c. If a prescription drug claim contains multiple rejections, each rejection is calculated as a separate pharmacy transaction. [Data Element 1.E]
11	Organization accurately reports data on high cost edits, including the following criteria: a. Indicates whether or not high cost edits for non-compounds were in place during the reporting period. b. If high cost edits for non-compounds were in place during the reporting period, reports the cost threshold used. c. Includes the number of claims rejected due to high cost edits for non-compounds. d. If a prescription drug claim contains multiple rejections, each rejection is calculated as a separate pharmacy transaction. [Data Elements 1.F – 1.G]
12	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, regardless of when the request for coverage determination was received b. Includes hospice-related coverage determinations. c. Includes all methods of receipt (e.g., telephone, letter, fax, in-person). d. Includes all coverage determinations (including exceptions) regardless of who filed the request (e.g., member, appointed representative, or prescribing physician). e. Includes coverage determinations (including exceptions) from delegated entities[3]. f. Includes both standard and expedited coverage determinations g. Includes requests for coverage determinations (including exceptions) that are withdrawn or dismissed. h. Includes each distinct dispute (i.e., multiple drugs) contained in one coverage determination request as a separate coverage determination request. i. Includes adverse coverage determination cases that were forwarded to the Independent Review Entity (IRE) because the organization made an untimely decision. j. 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 v. D PA is required) are not included unless the plan subsequently processed a coverage determination.

[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 *(for 2017 Reported Data)*	
	k. 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. l. Excludes coverage determinations (including exceptions) regarding drugs assigned to an excluded drug category. m. Excludes members who have UM requirements waived based on an exception decision made in a previous plan year or reporting period. n. 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 2.A, 2.J, 2.P, 2.V]
13	Organization accurately calculates the total number of UM, Formulary, and Tier exceptions decisions made in the reporting period, including the following criteria: [4] : a. Includes all decisions made (fully favorable, partially favorable, and adverse) with a date of decision that occurs during the reporting period, regardless of when the exception request was received. 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. Includes requests for exceptions that are withdrawn or dismissed. Verify that all standard exceptions that are withdrawn or dismissed are included. Verify that all expedited exceptions that are withdrawn or dismissed are included. 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 2. J, 2. P, 2.V.]
14	Organization accurately calculates the number of coverage determinations decisions processed timely or not timely, including the following criteria: a. Included both standard coverage determinations and expedited coverage determinations. Includes only coverage determinations (including exceptions) for which the member is notified of the decision according to the following timelines:[5] i. For standard coverage determinations: as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request. ii. For expedited coverage determinations: as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the request. iii. For reimbursement requests: as expeditiously as the enrollee's health condition requires, but no later than 14 days after receipt of the request. b. Excludes favorable coverage determinations in which the organization did not authorize or provide the benefit or payment under dispute according to the following timelines: i. For standard coverage determinations: as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request. ii. For expedited coverage determinations: as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the request.

[4] Exception requests include tiering exceptions, formulary exceptions, and UM exceptions such as prior authorization, step therapy, quantity limits, etc.

[5] Sponsors should refer to Chapter 18, Sections 40.2, 50.4 and 50.6 of the Prescription Drug Benefit Manual for the timeframe for determination requests.

COVERAGE DETERMINATIONS AND REDETERMINATIONS *(for 2017 Reported Data)*	
	iii. For reimbursement requests: as expeditiously as the enrollee's health condition requires, but no later than 14 days after receipt of the request. iv. Includes fully favorable determinations where the enrollee was notified untimely but within 24 hours of the expiration of the adjudication timeframe and thus not auto-forwarded to the IRE. c. Reflects if untimely cases were auto-forwarded to the IRE, or not. [Data Element 2.B, 2.C, 2.D]
15	Organization accurately calculates the number of coverage determinations decisions made by final decision, including the following criteria: a. Properly categorizes the number of coverage determinations (including exceptions) by final decision: fully favorable, partially favorable, or adverse. Verify that all cases included in the count for the total number of coverage determinations made in the reporting period are identified as one of the accepted disposition types. b. Includes untimely coverage determinations decisions, regardless if they were auto-forwarded to the IRE. [Data Element 2. E, 2.F, 2.G,
16	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 Element 2.H, 2.I]
17	Organization accurately calculates the total number of redeterminations (Part D only), including the following criteria: a. Includes all redetermination decisions for Part D drugs with a date of final decision that occurs during the reporting period, regardless of when the request for redetermination was received or when the member was notified of the decision. b. Includes all redetermination decisions, including fully favorable, partially favorable, and unfavorable 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 all methods of receipt (e.g., telephone, letter, fax, in-person). f. Includes all redeterminations regardless of who filed the request (e.g., member, appointed representative, or prescribing physician). g. 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. Reference Medicare Part C and Part D Reporting Requirements Data Validation Procedure Manual, h. 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 v. D PA is required) are not included unless the plan subsequently processed a redetermination. i. Includes each distinct dispute contained in one redetermination request (i.e. multiple drugs) as a separate redetermination request. j. Includes dismissals and withdrawals. k. Excludes IRE decisions, as they are considered to be the second level of appeal. l. Excludes redeterminations regarding excluded drugs. m. Limits reporting to just the redetermination level. n. Includes untimely redeterminations, regardless if they were auto-forwarded to the IRE.

COVERAGE DETERMINATIONS AND REDETERMINATIONS *(for 2017 Reported Data)*	
	[Data Element 3.A]
18	Organization accurately calculates the number of redeterminations for which the Part D sponsor processed timely, including the following criteria: a. Includes only redeterminations for which the member is notified of the decision according to the following timelines: i. For standard redeterminations: no later than 7 calendar days after receipt of the request. ii. For expedited redeterminations: no later than 72 hours after receipt of the request. iii. For reimbursement requests: no later than 14 days after receipt of the request. b. Excludes approvals in which the sponsor did not authorize or provide the benefit or payment under dispute according to the following timelines: i. For standard redeterminations: no later than 7 calendar days after receipt of the request. ii. For expedited redeterminations: no later than 72 hours after receipt of the request. iii. For reimbursement requests: no later than 14 days after receipt of the request. c. Includes untimely redeterminations, regardless if they were auto-forwarded to the IRE. [Data Element 3.B-3.D]
19	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 3.E-3.G]
20	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. c. Each number calculated for requests for redeterminations that were withdrawn (Data Element 3.H) and requests for redeterminations that were dismissed (Data Element 3.I) is a subset of the number of redeterminations decisions made (Data Element 3.A). [Data Element 3.H and 3.I]
21	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 4.A]
22	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)

COVERAGE DETERMINATIONS AND REDETERMINATIONS *(for 2017 Reported Data)*	
	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 4.B.1 – 4.B.12]

IMPROVING DRUG UTILIZATION REVIEW CONTROLS

(2017 Reported Data)

Note to reviewer: Access to the CY 2017 cumulative opioid MED POS edit submissions in HPMS. Consider implementation dates of all CMS approved changes to the organization's drug utilization management program polies 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
- Technical specifications for CY 2017 Part D Improving Drug Utilization Review Controls File Record Layout in HPMS
- CY 2017 POS soft and/or hard formulary-level cumulative opioid POS edit MED threshold submission report in HPMS

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, if applicable, indicates that data elements for each reporting section are accurately identified, processed, and calculated. <u>Criteria for Validating Reporting Section Criteria (Refer to reporting section criteria section below):</u> 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 and *Reporting Requirements 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 appropriate policies and procedures for data submission, including the following: a. Data elements are accurately entered / uploaded into the HPMS tool and entries match corresponding source documents. b. All source, intermediate, and final stage data sets relied upon to enter data into HPMS are archived

IMPROVING DRUG UTILIZATION REVIEW CONTROLS *(2017 Reported Data)* Note to reviewer: Access to the CY 2017 cumulative opioid MED POS edit submissions in HPMS. Consider implementation dates of all CMS approved changes to the organization's drug utilization management program polies and procedures.	
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., as a result 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 (for 2017 reported data)	
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 2/26/2018. *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.*

IMPROVING DRUG UTILIZATION REVIEW CONTROLS *(2017 Reported Data)* Note to reviewer: Access to the CY 2017 cumulative opioid MED POS edit submissions in HPMS. Consider implementation dates of all CMS approved changes to the organization's drug utilization management program polies and procedures.	
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: i. This includes applying all relevant guidance to properly establish and implement a soft and/or hard formulary-level cumulative opioid morphine equivalent dose (MED) threshold edit at point of sale. ii. Organization provides documentation that its soft and/or hard formulary-level cumulative opioid MED POS edit was properly tested and validated prior to its implementation date. iii. Properly reports the soft formulary-level cumulative opioid edit MED threshold reported matches the approved CY 2017 soft formulary-level cumulative opioid POS edit MED threshold submission to CMS via HPMS. iv. Properly reports the soft formulary cumulative opioid MED POS edit provider matches the approved CY 2017 soft formulary-level cumulative opioid POS edit provider count submission. v. Properly reports the soft formulary cumulative opioid MED POS edit pharmacy count criteria matches the approved CY 2017 soft formulary-level cumulative opioid POS edit pharmacy count submission to CMS via HPMS. vi. Properly reports the hard formulary-level cumulative opioid edit with morphine equivalent dose (MED) threshold reported matches the approved CY 2017 POS hard formulary-level cumulative opioid POS edit MED threshold submission to CMS via HPMS. vii. Properly reports the hard formulary-level cumulative opioid MED POS edit provider matches the approved CY 2017 hard formulary-level cumulative opioid POS edit provider count submission to CMS via HPMS. viii. Properly reports the hard formulary-level cumulative opioid MED POS edit pharmacy count matches the approved CY 2017 hard formulary-level cumulative opioid POS edit pharmacy count submission to CMS via HPMS.

IMPROVING DRUG UTILIZATION REVIEW CONTROLS *(2017 Reported Data)* Note to reviewer: Access to the CY 2017 cumulative opioid MED POS edit submissions in HPMS. Consider implementation dates of all CMS approved changes to the organization's drug utilization management program polies and procedures.	
5	Organization data passes data integrity checks listed below: a. The organization has either a soft and/or hard formulary cumulative opioid MED POS edit in place (At least one of Data Elements A and I must be 1 (Yes)). b. If the organization has a soft formulary cumulative opioid MED POS edit (Data Element A = 1), the following is true: i. The number of soft edit claim rejections overridden by the pharmacist at the pharmacy (G) does not exceed the number of claims rejected due to the soft formulary-level cumulative opioid MED edit at POS (E) ii. The cumulative MED threshold, the number of claims rejected due to soft edits, and the number of unique beneficiary rejected due to the soft formulary edits must be reported (Elements B, E, F ≠ blank). iii. The number of unique beneficiaries with at least one soft edit claim rejection overridden by the pharmacist at the pharmacy (H) does not exceed the number of unique beneficiaries with at least one claim rejected due to the soft formulary-level cumulative opioid MED edit at POS (F) iv. The number of unique beneficiaries with at least one claim rejected due to the soft formulary-level cumulative opioid MED edit at POS (data element F) is a value less than or equal to the number of claims rejected (data element E). c. If the organization does not have soft formulary cumulative opioid MED POS edits (Data Element A = 2), data elements B, C, D, E, F, G, and H should equal 0. d. If the organization had a hard formulary cumulative opioid MED POS edit (Data Element I = 1), the following is true: i. The number of unique beneficiaries with coverage determinations from hard edit rejections (Data Element O) does not exceed the number of unique beneficiaries with hard edit rejections (Data Element N). ii. The number of unique beneficiaries that had a claim successfully processed (paid) (Data Element P) does not exceed the number of unique beneficiaries with hard edit rejections (Data Element N). iii. The cumulative MED threshold, the number of claims rejected due to hard edits, and the number of unique beneficiary rejected due to the hard formulary edit must be reported (Elements J, M, N, ≠ blank). iv. The number of unique beneficiaries with at least one claim rejected due to the hard formulary-level cumulative opioid MED edit at POS (data element N) is a value less than or equal to the number of claims rejected due to the hard formulary-level cumulative opioid MED edit at POS (data element M). v. The number of unique beneficiaries with at least one claim rejected that also had a claim successfully processed (paid) for an opioid drug subject to the hard opioid MED edit such as, but not limited to, through favorable coverage determination (data element P) is a value less than or equal to the number of unique beneficiaries with at least one hard edit claim rejection that also had a coverage determination request (data element O). e. If the organization does not have hard formulary cumulative opioid MED POS edits (Data Element I = 2), data elements J, K, L M, N, O, and P should equal 0. f. If the organization received a CMS outlier/data integrity notice based on their soft/hard/provider/pharmacy formulary-level cumulative opioid morphine equivalent dose (MED) threshold, validate whether or not an internal procedure change was warranted or resubmission through HPMS. Data elements: B-H and J-P [Data Elements A-P]

IMPROVING DRUG UTILIZATION REVIEW CONTROLS *(2017 Reported Data)* Note to reviewer: Access to the CY 2017 cumulative opioid MED POS edit submissions in HPMS. Consider implementation dates of all CMS approved changes to the organization's drug utilization management program polies and procedures.	
6	Organization can accurately identify and create a Part D data set of POS claim rejects related to its soft and/or hard formulary-level cumulative opioid morphine equivalent dose (MED) edit(s) 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 by the established soft formulary-level cumulative MED 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 soft formulary-level cumulative opioid MED POS edit is not associated with an early refill rejection transaction. iii. Rejected opioid claims are counted at the unique contract, beneficiary, prescriber, pharmacy, drug (strength and dosage form), quantity, and date of service (DOS). iv. Properly counts the number of unique beneficiaries by contract that triggered the established soft formulary-level cumulative MED threshold and if applicable, a provider and pharmacy criterion. b. Properly identifies and counts the number of POS rejects triggered and unique beneficiaries by the established hard formulary-level cumulative MED 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 formulary-level cumulative opioid MED POS edit is not associated with an early refill rejection transaction. iii. Rejected opioid claims are counted at the unique contract, beneficiary, prescriber, pharmacy, drug (strength and dosage form), quantity, and date of service (DOS). iv. Properly counts the number of unique beneficiaries by contract that triggered the established hard formulary-level cumulative MED threshold and if applicable, a provider and pharmacy criterion. [Data Elements E, F, M, N]
7	From the data set of POS rejects (RSC 6a) related to the soft formulary-level cumulative opioid MED 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 soft formulary-level cumulative opioid MED edit POS rejected claims. i. If a prescription drug claim contains multiple POS rejections, each rejection is considered as a separate pharmacy transaction and included in the data set. b. Properly identifies and counts the number of unique beneficiaries per contract with at least one claim rejection due to its soft formulary-level cumulative opioid MED POS edit and a pharmacist overridden soft formulary-level cumulative opioid MED POS edit rejected claim (RSC 6a). i. If a prescription drug claim contains multiple POS rejections, each rejection is considered as a separate pharmacy transaction and included in the data set. [Data Elements G,H]

IMPROVING DRUG UTILIZATION REVIEW CONTROLS *(2017 Reported Data)* Note to reviewer: Access to the CY 2017 cumulative opioid MED POS edit submissions in HPMS. Consider implementation dates of all CMS approved changes to the organization's drug utilization management program polies and procedures.	
8	From the data set of POS rejects (RSC 6b) related to the hard formulary-level cumulative opioid morphine equivalent doses (MED) edits, the organization accurately identifies claims leading to a coverage determination and correctly uploads the count into HPMS including the following criteria: a. If a prescription drug claim contains multiple POS rejections, each rejection is considered as a separate pharmacy transaction. b. Includes all methods of coverage determination receipt (e.g., telephone, letter, fax, in-person). c. Includes all coverage determinations (fully favorable, partially favorable, and adverse). [Data Element O]
9	From the subset of POS rejects (RSC 6b) related to the hard formulary-level cumulative opioid morphine equivalent doses (MED) POS edits, the organization accurately identifies the number of unique beneficiaries with at least one hard edit claim rejection due to its hard formulary-level cumulative opioid MED POS edit that also had a claim successfully processed (paid) for an opioid drug subject to the hard opioid MED edit such as, but not limited to, through a favorable coverage determination or process and correctly uploads the count, if the data set of POS rejects includes the complete reporting period, into HPMS including the following criteria: a. The beneficiary's opioid claim is also included in data element O. [Data Element P]

APPENDIX: ACRONYMS

Acronym	Description
ASO	Administrative Services Only
CABG	Coronary Artery Bypass Surgery
CFR	Code of Federal Regulations
CMR	Comprehensive Medication Review
CMS	Centers for Medicare & Medicaid Services
CPT	Current Procedural Terminology
CTM	Complaint Tracking Module
DBA	Doing Business As
DME	Durable Medical Equipment
DOS	Date of Service
DUM	Drug Utilization Management
DVT	Deep Vein Thrombosis
FFS	Fee for Service
HAC	Hospital Acquired Condition
HEDIS	Healthcare Effectiveness Data and Information Set
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
LIS	Low Income Subsidy
LTC	Long-Term Care
MA	Medicare Advantage
MAO	Medicare Advantage Organization
MA-PD	Medicare Advantage Prescription Drug Plan
MED	Morphine Equivalent Dose
MTM	Medication Therapy Management
OAI	Organizational Assessment Instrument
OP	Outpatient
PA	Prior Authorization
PBM	Pharmacy Benefit Management
PBP	Plan Benefit Package
PDP	Prescription Drug Plan
POA	Present on Admission
POS	Point of Sale
QA	Quality Assurance
QIO	Quality Improvement Organization
RPPO	Regional Preferred Provider Organization
Rx	Prescription
SNF	Skilled Nursing Facility
SNP	Special Needs Plan
SSI	Surgical Site Infections
TBD	To Be Determined
TMR	Targeted Medication Review
UM	Utilization Management