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

Appendix 1: Data Validation Standards

Version 5.0

For Data Validation Occurring in 2015

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1   OVERVIEW

The *Data Validation Standards* include general standards and reporting section criteria that the data validation contractor (reviewer) 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*.

All revisions to the reporting section criteria since the April – June 2014 data validation cycle are identified by underlined and/or strikethrough text. The terms "section" and "measure" that previously appeared in the Part C and Part D Reporting Requirement Technical Specifications have been replaced with the term "reporting section." To ensure alignment with this new terminology, all references in the data validation documents to the term "measure" have been replaced with the term "reporting section." In addition, the term "measure-specific criteria" has also been revised and replaced with "reporting section criteria."

The reviewer must use these standards in conjunction with the Data Extraction and Sampling Instructions and the Excel-version of the Findings Data Collection Form (FDCF) or the version of the FDCF in the Health Plan Management System Plan Reporting Data Validation Module to evaluate the organization's processes for producing and reporting the reporting sections. It is strongly recommended that the reviewer 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 2014* (version date April 2014) 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 2014* (February 2014) is used as the basis for the data validation standards.

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2 PART C DATA VALIDATION STANDARDS

2.1 GRIEVANCES (PART C) – 2014 REPORTED DATA

Note to reviewer: Aggregate all quarterly data before applying the 90% threshold.

Note to reviewer: Apply the 90% threshold to the total count of grievances calculated. Do not apply the 90% threshold to individual grievance categories.

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

- Written response to *OAI* Sections 3 and 4, and documentation requested per *OAI* Sections 5 and 6
- 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.

2.1 GRIEVANCES (PART C) – 2014 REPORTED DATA

Note to reviewer: Aggregate all quarterly data before applying the 90% threshold.

Note to reviewer: Apply the 90% threshold to the total count of grievances calculated. Do not apply the 90% threshold to individual grievance categories.

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 2014 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 plan benefit package.
3	Organization meets deadlines for reporting data to CMS by 2/28. *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.

2.1 GRIEVANCES (PART C) – 2014 REPORTED DATA

Note to reviewer: Aggregate all quarterly data before applying the 90% threshold.

Note to reviewer: Apply the 90% threshold to the total count of grievances calculated. Do not apply the 90% threshold to individual grievance categories.

5	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 5.1 – 5.22]

6	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 5.1 – 5.22]

7	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.
	    b. Each number calculated is a subset of the total number of grievances received for the applicable category.
	[Data Elements 5.12 – 5.22]

2.3 ORGANIZATION DETERMINATIONS / RECONSIDERATIONS – 2014 REPORTED DATA

Note to reviewer: Aggregate all quarterly data before applying the 90% threshold.

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

- Written response to *OAI* Sections 3 and 4, and documentation requested per *OAI* Sections 5 and 6
- 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).

2.3 ORGANIZATION DETERMINATIONS / RECONSIDERATIONS – 2014 REPORTED DATA

Note to reviewer: Aggregate all quarterly data before applying the 90% threshold.

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 2014 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 2/28. *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 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.
	    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]

2.3 ORGANIZATION DETERMINATIONS / RECONSIDERATIONS – 2014 REPORTED DATA

Note to reviewer: Aggregate all quarterly data before applying the 90% threshold.

6	Organization accurately calculates the number of fully favorable organization determinations, including the following criteria:
	    a. Includes all pre-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]

7	Organization accurately calculates the total number of organization determinations that were processed in a timely manner including the following criteria:
	    a. Includes all pre-service organization determinations for contract and non-contract providers/suppliers.
	    b. <u>Includes</u> all payment (claim) organization determinations for contract and non-contract providers/suppliers
	
	[Data Element 6.2]

8	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 pre-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 pre-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.

9	Organization accurately calculates the number of partially favorable (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 pre-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]
	    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 partially favorable organization determination (i.e., issued a partially favorable pre-service decision), includes the request for payment for the same item or service as another, separate, partially favorable organization determination.

10	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 pre-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]
	    c. For instances when a request for payment is submitted to an organization concerning an item or service, and the organization has already made an adverse organization determination (i.e., issued an adverse pre-service decision), includes the request for payment for the same item or service as another, separate, adverse organization determination.

2.3 ORGANIZATION DETERMINATIONS / RECONSIDERATIONS – 2014 REPORTED DATA

Note to reviewer: Aggregate all quarterly data before applying the 90% threshold.

11	Organization accurately calculates "Withdrawn Organization Determination" according to the following criteria: a. Includes an organization determination that is withdrawn upon the enrollee's request, but excludes appeals that the organization forwards to the IRE for dismissal. [Data Element 6.9]

12	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 or 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 6.10]

13	Organization accurately calculates the total number of reconsiderations processed timely according to the following criteria: a. Includes all filings of requests for reconsideration within 60 calendar days from the date of the notice of the organization determination. I [Data Element 6.11]

14	Organization accurately calculates the number of fully favorable (e.g., approval of entire request resulting in full coverage of the item or service) reconsiderations, including the following criteria:
	   a. Includes all fully favorable pre-service reconsideration determinations for contract and non-contract providers/suppliers. [Data Element 6.12]
	   b. Includes all fully favorable payment (claim) reconsideration determinations for contract and non-contract providers/suppliers. [Data Element 6.13]
	   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 pre-service reconsideration determination, includes the reconsideration request for payment for the same item or service as another, separate, fully favorable reconsideration determination.

2.3 ORGANIZATION DETERMINATIONS / RECONSIDERATIONS – 2014 REPORTED DATA

Note to reviewer: Aggregate all quarterly data before applying the 90% threshold.

15	Organization accurately calculates the number of partially favorable (e.g., coverage denial of some items and coverage approval of some items in a claim that has multiple line items reconsiderations, including the following criteria:
	    a. Includes all partially favorable pre-service reconsideration determinations for contract and non-contract providers/suppliers. [Data Element 6.14]
	    b. Includes all partially favorable payment (claim) reconsideration determinations for contract and non-contract providers/suppliers. [Data Element 6.15]
	    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 partially favorable pre-service reconsideration determination, includes the reconsideration request for payment for the same item or service as another, separate, partially favorable reconsideration determination.

16	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 pre-service reconsideration determinations for contract and non-contract providers/suppliers. [Data Element 6.16]
	    b. Includes all adverse payment (claim) reconsideration determinations that result in zero payment being made to contract and non-contract providers. [Data Element 6.17]
	    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 pre-service reconsideration determination, includes the reconsideration request for payment for the same item or service as another, separate, adverse reconsideration determination.

17	Organization accurately calculates "Withdrawn Reconsiderations" according to the following criteria: a. Includes a Reconsideration that is withdrawn upon the enrollee's request. [Data Element 6.18]
18	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 6.19]

19	a. Organization accurately reports the following information for each reopened case. 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, New and Material Evidence, or Other)
	    i. Date of reopening disposition (revised decision)
	    j. Reopening disposition (Fully Favorable; Partially Favorable; or Adverse)
	
	[Data Elements 6.20 – 6.29]

2.1

2.2 SPECIAL NEEDS PLANS (SNP) CARE MANAGEMENT - 2014 REPORTED DA

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

- Written response to *OAI* Sections 3 and 4, and documentation requested per *OAI* Sections 5 and 6
- 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, claims adjustments).
5	Organization implements policies and procedures for archiving and restoring data in each data system (e.g., disaster recovery plan).

	2.2 SPECIAL NEEDS PLANS (SNP) CARE MANAGEMENT - 2014 REPORTED DA
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 2014 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 2/28. *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	a. Organization accurately calculates the number of new members who are eligible for an initial health risk assessment (HRA), including the following criteria: Includes all new members who enrolled during the measurement year and those members who may have enrolled as early as 90 days prior to the measurement year if no initial HRA had been performed prior to 1/1. 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 members who dis-enrolled from and re-enrolled into the same plan if an initial HRA or reassessment was performed prior to dis-enrollment. e. Excludes 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. f. Excludes members who received an initial HRA but were subsequently deemed ineligible because they were never enrolled in the plan. g. Excludes new members who dis-enrolled from the plan within 90 days of enrollment, if they did not receive an initial HRA prior to dis-enrolling. [Data Element 13.1]
5	a. Organization accurately calculates the number of members eligible for an annual health risk reassessment during the reporting period, including the following criteria: Includes members who were enrolled for more than 90 days in the same plan without receiving an initial HRA. b. Includes members who remained continuously enrolled in the same plan for 365 days, starting from either the 91st day of enrollment 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 or reassessment was performed prior to dis-enrollment and calculates the member's reassessment eligibility date starting from the date of re-enrollment. e. Excludes members who dis-enrolled from and re-enrolled into the same plan if an initial HRA was not performed prior to dis-enrollment. f. Excludes members who received a reassessment but were subsequently deemed ineligible because they were never enrolled in the plan. g. Excludes members who did not remain enrolled in their same health plan for at least 365 days after their last HRA and did not receive a reassessment HRA. [Data Element 13.2]

	2.2 SPECIAL NEEDS PLANS (SNP) CARE MANAGEMENT - 2014 REPORTED DA

6	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 of enrollment/re-enrollment.
	  b. Includes only HRAs that were performed between 1/1 and 12/31 of the measurement year even if the new member enrolled prior to the start of the measurement year.
	  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.
	  d. Counts only one HRA for members who have multiple HRAs within 90 days of enrollment.
	  e. Excludes HRAs completed for members who were subsequently deemed ineligible because they were never enrolled in the plan.
	  f. The number of initial assessments calculated for Data Element 13.3 is a subset of the number of new members calculated for Data Element 13.1.
	
	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]

7	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 (i.e., within 365 days of their previous HRA, or within 365 days of their 91st day of enrollment (for new members who did not receive an initial HRA), or within 365 days of re-enrollment (for members who dis-enrolled from and re-enrolled into the same plan)).
	  b. Includes only HRAs that were performed between 1/1 and 12/31 of the measurement year.
	  c. Counts only one HRA for members who have multiple reassessments within 365 days of becoming eligible for a reassessment.
	  d. Excludes HRAs completed for members who were subsequently deemed ineligible because they were never enrolled in the plan.
	  e. The number of annual reassessments calculated for Data Element 13.4 is a subset of the number of eligible members calculated for Data Element 13.2.
	
	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 13.4]

2.5 PLAN OVERSIGHT OF AGENTS (PART C) – 2014 REPORTED DATA

Note to reviewer: If the contract did not use licensed agents directly employed by the organization or licensed independent agents/brokers to conduct marketing for its Medicare products during the reporting period, then it is appropriate for the contract to report "0" for each data element in this measure, and data validation is not required.

To determine compliance with the standards for Plan Oversight of Agents (Part C), the data validation contractor (reviewer) will assess the following information:

- Written response to *OAI* Sections 3 and 4, and documentation requested per *OAI* Sections 5 and 6
- Results of interviews with organization staff
- Census and/or sample data
- Data file created for submission to CMS and copy of HPMS screen shots of data entered
- Other relevant information provided by organization

VALIDATION STANDARDS

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

2	A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) and census or sample data, if applicable, indicates that data elements for each measure are accurately identified, processed, and calculated.
	
	Criteria for Validating Measure-Specific Criteria (Refer to measure-specific 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 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

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).

2.5 PLAN OVERSIGHT OF AGENTS (PART C) – 2014 REPORTED DATA

Note to reviewer: If the contract did not use licensed agents directly employed by the organization or licensed independent agents/brokers to conduct marketing for its Medicare products during the reporting period, then it is appropriate for the contract to report "0" for each data element in this measure, and data validation is not required.

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 measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected and/or reported by the delegated entity or first tier/downstream contractor.

REPORTING SECTION CRITERIA

1	Organization reports data based on the required reporting period of 1/1 through 12/31.
2	Organization properly assigns data to the applicable CMS contract.
3	Organization meets deadline for reporting annual data to CMS by 2/28. *Note to reviewer: If the organization has, for any reason, re-submitted its data to CMS for this measure, 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 measure-specific 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 rest of the measure-specific criteria for this data measure.*

4	Organization accurately includes and uploads into HPMS data for all Agents/Brokers who earned compensation during the reporting period, including the following criteria:
	    a. Properly identifies and includes Agents/Brokers who earned and received compensation, including commission and salary, for initial enrollments and renewals for reporting purposes, compensation is further defined as any payment made to an agent/broker for purposes of enrolling beneficiaries into health plans.
	    b. Includes the appropriate Agent/Broker type as Captive, Employed, Independent, or None.
	    c. Includes all appropriate states where the Agent/Broker is licensed. For agents licensed in multiple states, all states are identified.
	    d. Properly identifies and includes the Agent/Broker Identification Number.
	    e. Properly identifies and includes the Agent/Broker current license effective date.
	    f. Properly identifies and includes the Agent/Broker appointment date.
	    g. Properly identifies and includes the Agent/Broker training completion date.
	    h. Properly identifies and includes the Agent/Broker testing completion date.
	    i. Properly identifies and includes the Agent/Broker termination date, if applicable.
	    j. Properly identifies and includes whether there was termination for cause.
	    k. Properly identities and includes the name of the associated Third-party Marketing Organization (TMO)/Field Marketing Organization (FMO), if applicable.
	
	[Data Elements 12.1.A – 12.1.R)

5	Organization accurately identifies and uploads into HPMS data on Agent/Broker complaints filed by the beneficiary, including the following criteria:
	
	    a. Properly calculates and includes the aggregate number of Agent/Broker marketing complaints from any source reported during the reporting period.
	    b. Properly calculates and includes the aggregate number of Agent/Broker disciplinary actions taken in the reporting period (related to Marketing).
	    c. Properly calculates and includes the number of new enrollments in the reporting period. If the Agent/Broker is licensed in multiple states, then enrollment numbers should be calculated and included by state.
	
	[Data Elements 12.1.M, 12.1.N and 12.1.R]

2.5 PLAN OVERSIGHT OF AGENTS (PART C) – 2014 REPORTED DATA

Note to reviewer: If the contract did not use licensed agents directly employed by the organization or licensed independent agents/brokers to conduct marketing for its Medicare products during the reporting period, then it is appropriate for the contract to report "0" for each data element in this measure, and data validation is not required.

6	Organization accurately identifies and uploads into Gentran data for all new enrollments during the reporting period for which an Agent/Broker is associated, including the following criteria:
	
	    a. Properly identifies and includes all beneficiaries who an Agent/Broker assisted in enrolling in the plan.
	    b. Includes all new enrollments and renewals. New enrollments for reporting purposes as new to the organization. A change from one Plan Benefit Package (PBP) to another PBP, within the same organization, is not considered "new enrollment" for purposes of these reporting requirements. In addition, Plans should report on all agents/brokers, not just independent agent/brokers.
	    c. Includes and reports each Agent/Broker assisted beneficiary, based on beneficiary's HICN or RRB Number.
	    d. Defines "Agent/Broker assisted enrollments" as enrollments involving a beneficiary who used a licensed Agent/Broker that is compensated to complete the enrollment process (e.g., includes enrollments completed through the designated enrollment mechanisms.
	    e. Properly identifies and includes the Agent/Broker National Producer Number (NPN).
	    f. Properly identifies and includes the Agent/Broker Identification Number assigned by the plan.
	    g. Properly identifies and includes the enrollment mechanism as Plan Representative Online; CMS Online Enrollment Center; Plan Call Center; 1-800-MEDICARE; Paper Application; Auto-Assigned/Facilitated; Other.
	    h. Properly identifies and includes the beneficiary's enrollment application date.
	    i. Properly identifies and includes the beneficiary's enrollment effective date.
	    j. Excludes enrollment/renewal cancellations.
	    k. Includes Agent/Broker assisted enrollments that involve a beneficiary's change from one plan benefit package to another within the same contract.
	
	[Data Elements:12.2.A-12.2.P]

7	Organization accurately identifies data on Agent/Broker complaints filed by the beneficiary and uploads it into Gentran, including the following criteria:
	    a. Properly calculates and includes the number of all Agent/Broker complaints received within the reporting period for each applicable beneficiary.
	    b. Properly calculates and includes the number of all Agent/Broker complaints that are Marketing related.
	    c. The number of Marketing related complaints (Data Element P) is a subset of the number of Agent/Broker complaints filed by the beneficiary (Data Element O).
	
	[Data Elements – 12.2.O, 12.2.P]

PART D DATA VALIDATION STANDARDS

2.5 MEDICATION THERAPY MANAGEMENT (MTM) PROGRAMS – 2014 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 (reviewer) will assess the following information:

- Written response to *OAI* Sections 3 and 4, and documentation requested per *OAI* Sections 5 and 6
- Results of interviews with organization staff
- Census data
- Data file created for submission to CMS
- 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 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, claims adjustments).

2.5 MEDICATION THERAPY MANAGEMENT (MTM) PROGRAMS – 2014 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.

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 2014 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 2/28. *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 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 – G, –I - J]

	2.5 MEDICATION THERAPY MANAGEMENT (MTM) PROGRAMS – 2014 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.
6	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]
7	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 if the gap of MTM program enrollment is equal to 60 days or less. [Data Elements K, L]
8	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 per CMS Part D requirements that occurs within the reporting period. [Data Element M, N]
9	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 five) 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, last CMR, and then other CMR dates based upon the significance of the CMR purpose or findings. 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, or Other. 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]

**2.5 MEDICATION THERAPY MANAGEMENT (MTM) PROGRAMS – 2014 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.*
10	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]
11	Organization accurately identifies topics discussed with the beneficiary during the CMR and uploads it into Gentran, including the following criteria: a. Properly identifies and includes the topics discussed with the beneficiary during the CMR (up to 5), including the medication or care issue to be resolved or behavior to be encouraged. This includes descriptions of the topics listed on the beneficiary's written summary in CMS standardized format in the Medication Action Plan under 'What we talked about." Topics should be reported in English. [Data Element X]

2.6 GRIEVANCES (PART D) – 2014 REPORTED DATA

Note to reviewer: Aggregate all quarterly data before applying the threshold.

Note to reviewer: Do not apply the 90% threshold to individual grievance categories; 100% correct records are required for individual grievance categories.

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

- Written response to *OAI* Sections 3 and 4, and documentation requested per *OAI* Sections 5 and 6
- 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, claims adjustments).
5	Organization implements policies and procedures for archiving and restoring data in each data system (e.g., disaster recovery plan).

2.6   GRIEVANCES (PART D) – 2014 REPORTED DATA

Note to reviewer: Aggregate all quarterly data before applying the threshold.

Note to reviewer: Do not apply the 90% threshold to individual grievance categories; 100% correct records are required for individual grievance categories.

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 2014 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 plan benefit package.
3	Organization meets deadline for reporting data to CMS by 2/28. *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 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 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, 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 is resolved, regardless of where the grievance originated (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 new plan should report the grievance regardless of where the grievance originated, if they actually resolve the grievance).
	
	[Data Elements B – W]

	2.6 GRIEVANCES (PART D) – 2014 REPORTED DATA
	Note to reviewer: Aggregate all quarterly data before applying the threshold. *Note to reviewer: Do not apply the 90% threshold to individual grievance categories; 100% correct records are required for individual grievance categories.*

6	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: Expedited; 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 D, F, H, J, L, N, P, R, T, V]

7	Organization accurately calculates and uploads into HPMS 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:
	        o For standard grievances: no later than 30 days after receipt of grievance.
	        o For standard grievances with an extension taken: no later than 44 days after receipt of grievance.
	        o 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 C, E, G, I, K, M, O, Q, S, U, W]

2.7 COVERAGE DETERMINATIONS AND REDETERMINATIONS – 2014 REPORTED DATA

Note to reviewer: Aggregate all quarterly data before applying the 90% threshold.

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

- Written response to *OAI* Sections 3 and 4, and documentation requested per *OAI* Sections 5 and 6
- 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, claims adjustments).
5	Organization implements policies and procedures for archiving and restoring data in each data system (e.g., disaster recovery plan).

**2.7 COVERAGE DETERMINATIONS AND REDETERMINATIONS – 2014 REPORTED DATA**
*Note to reviewer: Aggregate all quarterly data before applying the 90% threshold.*
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 2014 reported data) for Coverage Determinations (subsection 1)**
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 2/28. *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 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 and 30. 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. 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.

5	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]

6	Organization accurately calculates the number of pharmacy transactions rejected due to non-formulary status, 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.
	    c. Number calculated for Data Element 1.B is a subset of the number of pharmacy transactions calculated for Data Element 1.A.
	  [Data Element 1.B]

7	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.
	    c. Number calculated for Data Element 1.C is a subset of the number of pharmacy transactions calculated for Data Element 1.A.
	  [Data Element 1.C]

	2.7 COVERAGE DETERMINATIONS AND REDETERMINATIONS – 2014 REPORTED DATA
	Note to reviewer: Aggregate all quarterly data before applying the 90% threshold.

8	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.
	    c. Number calculated for Data Element 1.D is a subset of the number of pharmacy transactions calculated for Data Element 1.A.
	[Data Element 1.D]

9	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.
	    d. Number calculated for Data Element 1.E is a subset of the number of pharmacy transactions calculated for Data Element 1.A.
	[Data Element 1.E]

10	Organization accurately reports data on high cost edits, including the following criteria:
	    a. Indicates whether or not high cost edits for compounds were in place during the reporting period.
	    b. If high cost edits for compounds were in place during the reporting period, reports the cost threshold used.
	    c. Indicates whether or not high cost edits for non-compounds were in place during the reporting period.
	    d. If high cost edits for non-compounds were in place during the reporting period, reports the cost threshold used.
	    e. Includes the number of claims rejected due to high cost edits for compounds.
	    f. Includes the number of claims rejected due to high cost edits for non-compounds.
	    g. If a prescription drug claim contains multiple rejections, each rejection is calculated as a separate pharmacy transaction.
	[Data Elements 1.F – 1.K]

11	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, with a date of decision that occurs during the reporting period, regardless of when the request for coverage determination was received.
	    b. Includes all methods of receipt (e.g., telephone, letter, fax, in-person).
	    c. Includes all coverage determinations (including exceptions) regardless of who filed the request (e.g., member, appointed representative, or prescribing physician).
	    d. Includes coverage determinations (including exceptions) from delegated entities.
	    e. Includes both standard and expedited coverage determinations (including exceptions).
	    f. Includes requests for coverage determinations (including exceptions) that are withdrawn or dismissed.
	    g. Includes all coverage determination decisions that relate to Part B versus Part D coverage (drugs covered under Part B are considered denials under Part D).
	    h. Excludes coverage determinations (including exceptions) regarding drugs assigned to an excluded drug category.
	    i. Excludes members who have UM requirements waived based on an exception decision made in a previous plan year or reporting period.
	[Data Elements 1.L]

	2.7 COVERAGE DETERMINATIONS AND REDETERMINATIONS – 2014 REPORTED DATA
	Note to reviewer: Aggregate all quarterly data before applying the 90% threshold.

12	Organization accurately calculates the total number of exceptions decisions made in the reporting period, including the following criteria:
	    a. Includes all decisions made (fully favorable, partially favorable, and adverse) with a date of decision that occurs during the reporting period, regardless of when the exception decision was received.
	    b. Includes all methods of receipt (e.g., telephone, letter, fax, in-person).
	    c. Includes all requests for exceptions, regardless of who filed the request (e.g., member, appointed representative, or prescribing physician).
	    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.
	    g. Excludes requests for exceptions regarding drugs assigned to an excluded drug category.
	    h. Excludes members who have UM requirements waived based on an exception decision made in a previous plan year or reporting period.
	    i. Number calculated for exception decisions made (Data Element 1.M) is a subset of the number of coverage determinations decisions made (Data Element 1.L).
	  [Data Element 1.M]

13	Organization accurately calculates the number of coverage determinations decisions processed timely , including the following criteria:
	    a. Includes only coverage determinations (including exceptions) for which the member is notified of the decision according to the following timelines:
	        o For standard coverage determinations: as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request.
	        o For expedited coverage determinations: as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the request.
	    b. Excludes favorable determinations in which the organization did not authorize or provide the benefit or payment under dispute according to the following timelines:
	        o For standard coverage determinations: as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request.
	        o For expedited coverage determinations: as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the request.
	    c. Excludes coverage determination requests that were forwarded to the IRE because the organization failed to make a timely decision.
	    d. Number calculated for coverage determinations decisions processed timely (Data Element 1.N) is a subset of the number of coverage determinations decisions made (Data Element 1.L).
	  [Data Element 1.N]

14	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.
	    b. Excludes coverage determinations decisions made by the IRE.
	    c. Each number calculated for coverage determinations decisions that were fully favorable (Data Element 1.O), coverage determinations decisions that were partially favorable (Data Element 1.P), and coverage determinations decisions made that were adverse (Data Element 1.Q) is a subset of the number of coverage determinations decisions made (Data Element 1.L).
	  [Data Element 1.O, 1.P, and 1.Q]

	2.7 COVERAGE DETERMINATIONS AND REDETERMINATIONS – 2014 REPORTED DATA
	Note to reviewer: Aggregate all quarterly data before applying the 90% threshold.

15	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).
	    b. Excludes withdrawals and dismissals input by the IRE.
	    c. Each number calculated for coverage determinations that were withdrawn (Data Element1.R) and coverage determinations that were dismissed (Data Element 1.S) is a subset of the number of coverage determinations decisions made (Data Element 1.L).
	[Data Element 1.R and 1.S]

16	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 all redetermination decisions that relate to Part B versus Part D coverage (drugs covered under Part B are considered denials under Part D).
	    h. If a redetermination request contains multiple distinct disputes (i.e., multiple drugs), each dispute is calculated as a separate redetermination.
	    i. Excludes dismissals and withdrawals.
	    j. Excludes IRE decisions, as they are considered to be the second level of appeal.
	    k. Excludes redeterminations regarding excluded drugs.
	    l. Limits reporting to just the redetermination level.
	[Data Element 2.A]

17	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:
	        o For standard redeterminations: no later than 7 calendar days after receipt of the request.
	        o For expedited redeterminations: no later than 72 hours 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:
	        o For standard redeterminations: no later than 7 calendar days after receipt of the request.
	        o For expedited redeterminations: no later than 72 hours after receipt of the request.
	    c. Excludes redeterminations that were forwarded to the IRE because the organization failed to make a timely decision.
	    d. The number calculated for redeterminations decisions processed timely (Data Element 2.B) is a subset of the total number of redeterminations decisions made (Data Element 2.A).
	[Data Element 2.B]

	2.7 COVERAGE DETERMINATIONS AND REDETERMINATIONS – 2014 REPORTED DATA
	Note to reviewer: Aggregate all quarterly data before applying the 90% threshold.

18	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.
	   c. Each number calculated for redeterminations that were fully favorable (Data Elements 2.C), redeterminations that were partially favorable (Data Element 2.D), and redeterminations that were adverse (Data Element 2.E) D is a subset of the total number of redeterminations decisions made (Data Element 2.A).
	[Data Elements 2.C, 2.D, 2.E]

19	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. Excludes withdrawals and dismissals input by the IRE.
	   c. Each number calculated requests for redeterminations that were withdrawn (Data Element 2.F) and requests for redeterminations that were dismissed (Data Element 2.G) is not included in the number of redeterminations decisions made (Data Element 2.A).
	[Data Element 2.F and 2.G]

	2.8 LONG-TERM CARE UTILIZATION – 2013 REPORTED DATA

Note to reviewer: Employer-Direct PDPs, Employer-Direct PFFS, and any other contracts that have only 800 series plans are excluded from this reporting. For contracts with both non-800 series and 800-series plans, data for the 800-series plan(s) may be excluded.

To determine compliance with the standards for Long-Term Care Utilization, the data validation contractor (reviewer) will assess the following information:

- Written response to *OAI* Sections 3 and 4, and documentation requested per *OAI* Sections 5 and 6
- 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, claims adjustments).

	2.8 LONG-TERM CARE UTILIZATION – 2013 REPORTED DATA
*Note to reviewer: Employer-Direct PDPs, Employer-Direct PFFS, and any other contracts that have only 800 series plans are excluded from this reporting. For contracts with both non-800 series and 800-series plans, data for the 800-series plan(s) may be excluded.*
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 SPECIFIC CRITERIA (for 2014 reported data)**
1	Organization reports data based on the required reporting periods of 1/1 through 6/30 and 7/1 through 12/31.
2	Organization properly assigns data to the applicable CMS contract.
3	Organization meets deadline for reporting biannual data to CMS by 8/31 and 2/28. *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 network LTC pharmacies in the service area, including the following criteria:
	    a. Includes the number of contracted LTC pharmacies at the contract level for MA-PDs, PDPs, and RPPOs.
	    b. Includes any LTC pharmacy that is active in the network (i.e., contracted with the Part D organization) for one (1) or more days in the reporting period.
	    c. Includes LTC pharmacies that do not have utilization.
	 [Data Element A]

5	Organization accurately calculates the number of network retail pharmacies in the service area, including:
	    a. Includes the number of contracted retail pharmacies at the contract level for MA-PDs, PDPs, and RPPOs.
	    b. Includes any retail pharmacy that is active in the network (i.e., contracted with the Part D organization) for one (1) or more days in the reporting period.
	    c. Includes retail pharmacies that do not have utilization.
	 [Data Element B]

6	Organization accurately calculates the total number of distinct members in LTC facilities for whom Part D drugs have been provided under the contract, including the following criteria:
	    a. Includes the number of members at the contract level for MA-PDs, PDPs, and RPPOs.
	    b. Counts each member only once in each reporting period.
	    c. Includes only members with covered Part D drug claims at network pharmacies with dates of service within the reporting period.
	    d. Includes only members who resided in a long-term care facility on the date of service for that Part D drug at the time the Part D claim for that member was processed. *Note to reviewer: Claims with patient residence code 03 or the LTI report may be used to identify applicable members.*
	    e. Includes all covered members regardless if the LTC pharmacy is located in the service area.
	 [Data Element C]

2.8 LONG-TERM CARE UTILIZATION – 2013 REPORTED DATA

Note to reviewer: Employer-Direct PDPs, Employer-Direct PFFS, and any other contracts that have only 800 series plans are excluded from this reporting. For contracts with both non-800 series and 800-series plans, data for the 800-series plan(s) may be excluded.

7	Organization accurately identifies the data below for each network LTC pharmacy in the service area and uploads it into the HPMS submission tool.
	a. MA-PDs, PDPs, and RPPOs report at the contract level.
	b. LTC pharmacy name, LTC pharmacy NPI, contract entity name of LTC pharmacy, chain code of LTC pharmacy ("Not Available" is specified in the chain code field if the pharmacy chain code is unknown or does not exist).
	c. Includes all LTC pharmacies that were active in the network (i.e., contracted with the Part D sponsor) for one or more days in the reporting period.
	d. Includes LTC pharmacies that do not have utilization (zeroes are entered for number and cost of prescriptions).
	e. Number calculated for Data Element D is a subset of the total number of network LTC pharmacies calculated for Data Element A.
	[Data Element D: a-d]
8	Organization accurately calculates the number of 31-day equivalent prescriptions dispensed for each network LTC pharmacy in the service area and uploads it into the HPMS submission tool, including the following criteria:
	a. MA-PDs, PDPs, and RPPOs report at the contract level.
	b. Sums days supply of all covered Part D prescriptions dispensed and divides this by 31 days.
	c. Performs the calculations separately for formulary prescriptions and non-formulary prescriptions.
	d. Includes only covered Part D prescriptions dispensed with a fill date (not batch date) that falls within the reporting period.
	e. Includes LTC pharmacies that do not have utilization (zeroes are entered for number and cost of prescriptions).
	f. Includes any pharmacy that services a LTC facility; claims with patient residence code 03 may be used to identify LTC pharmacies.
	g. Number calculated for Data Element D is a subset of the total number of network LTC pharmacies calculated for Data Element A.
	[Data Element D: e-f]
9	Organization accurately calculates prescription costs for each network LTC pharmacy in the service area and uploads it into the HPMS submission tool, including the following criteria:
	a. MA-PDs, PDPs, and RPPOs report at the contract level.
	b. Prescription cost is the sum of the ingredient cost, dispensing fee, sales tax, and vaccine administration fee.
	c. Ingredient cost reflects Sponsor's negotiated price.
	d. Performs the calculations separately for formulary prescriptions and non-formulary prescriptions.
	e. Includes only covered Part D prescriptions dispensed with a fill date (not batch date) that falls within the reporting period.
	f. Includes LTC pharmacies that do not have utilization (zeroes are entered for number and cost of prescriptions).
	g. Includes any pharmacy that services a LTC facility; claims with patient residence code 03 may be used to identify LTC pharmacies.
	h. Number calculated for Data Element D is a subset of the total number of network LTC pharmacies calculated for Data Element A.
	[Data Element D: g-h]

2.8 LONG-TERM CARE UTILIZATION – 2013 REPORTED DATA

Note to reviewer: Employer-Direct PDPs, Employer-Direct PFFS, and any other contracts that have only 800 series plans are excluded from this reporting. For contracts with both non-800 series and 800-series plans, data for the 800-series plan(s) may be excluded.

10	Organization accurately calculates the number of 30-day equivalent prescriptions dispensed for each network retail pharmacy in the service area, including the following criteria:
	    a. MA-PDs, PDPs and RPPOs report at the contract level.
	    b. Sums days supply of all covered Part D prescriptions dispensed and divides this by 30 days.
	    c. Performs the calculations separately for formulary prescriptions and non-formulary prescriptions.
	    d. Includes only covered Part D prescriptions dispensed with a fill date (not batch date) that falls within the reporting period.
	    e. Includes all retail pharmacies that were active in the network (i.e., contracted with the Part D sponsor) for one or more days in the reporting period.
	    f. Number calculated for Data Element E is a subset of the total number of network retail pharmacies calculated for Data Element B.
	 [Data Element E: a-b]

11	Organization accurately calculates prescription costs for all network retail pharmacies in the service area, including the following criteria:
	    a. MA-PDs, PDPs and RPPOs report at the contract level.
	    b. Prescription cost is the sum of the ingredient cost, dispensing fee, sales tax, and vaccine administration fee.
	    c. Ingredient cost reflects Sponsor's negotiated price.
	    d. Performs the calculations separately for formulary prescriptions and non-formulary prescriptions.
	    e. Includes only covered Part D prescriptions dispensed with a fill date (not batch date) that falls within the reporting period.
	    f. Includes all retail pharmacies that were active in the network (i.e., contracted with the Part D sponsor) for one or more days in the reporting period.
	    g. Number calculated for Data Element E is a subset of the total number of network retail pharmacies calculated for Data Element B.
	 [Data Element E: c-d]

2.9 PLAN OVERSIGHT OF AGENTS (PART D) – 2014 REPORTED DATA

Note to reviewer: If the contract did not use licensed agents directly employed by the organization or licensed independent agents/brokers to conduct marketing for its Medicare products during the reporting period, then it is appropriate for the contract to report "0" for each data element in this measure, and data validation is not required.

To determine compliance with the standards for Plan Oversight of Agents (Part D), the data validation contractor (reviewer) will assess the following information:

- Written response to *OAI* Sections 3 and 4, and documentation requested per *OAI* Sections 5 and 6
- Results of interviews with organization staff
- Census and/or sample data

- Data file created for submission to CMS and copy of HPMS screen shots of data entered
- Other relevant information provided by organization

VALIDATION STANDARDS

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

2	A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) and census or sample data, if applicable, indicates that data elements for each measure are accurately identified, processed, and calculated.
	
	Criteria for Validating Measure-Specific Criteria (Refer to measure-specific 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 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

4	Organization implements appropriate policies and procedures for periodic data system updates (e.g., changes in enrollment, provider/pharmacy status, claims adjustments).
5	Organization implements appropriate policies and procedures for archiving and restoring data in each data system (e.g., disaster recovery plan).

2.9 PLAN OVERSIGHT OF AGENTS (PART D) – 2014 REPORTED DATA

Note to reviewer: If the contract did not use licensed agents directly employed by the organization or licensed independent agents/brokers to conduct marketing for its Medicare products during the reporting period, then it is appropriate for the contract to report "0" for each data element in this measure, and data validation is not required.

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 measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected and/or reported by the delegated entity or first tier/downstream contractor.

REPORTING SECTION CRITERIA	
1	Organization reports data based on the required reporting period of 1/1 through 12/31.
2	Organization properly assigns data to the applicable CMS contract.
3	Organization meets deadline for reporting annual data to CMS by 2/28. *Note to reviewer: If the organization has, for any reason, re-submitted its data to CMS for this measure, 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 measure-specific 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 rest of the measure-specific criteria for this data measure.*

4	Organization accurately includes and uploads into HPMS data for all Agents/Brokers who earned compensation during the reporting period, including the following criteria:
	    a. Properly identifies and includes Agents/Brokers who earned and received compensation, including commission and salary, for initial enrollments and renewals for reporting purposes, compensation is further defined as a payment made to an agent/broker for purposes of enrolling beneficiaries into health plans.
	    b. Includes the appropriate Agent/Broker type as Captive, Employed, Independent, or None.
	    c. Includes all appropriate states where the Agent/Broker is licensed. For agents licensed in multiple states, all states are identified.
	    d. Properly identifies and includes the Agent/Broker Identification Number.
	    e. Properly identifies and includes the Agent/Broker current license effective date.
	    f. Properly identifies and includes the Agent/Broker appointment date.
	    g. Properly identifies and includes the Agent/Broker training completion date.
	    h. Properly identifies and includes the Agent/Broker testing completion date.
	    i. Properly identifies and includes the Agent/Broker termination date, if applicable.
	    j. Properly identifies and includes whether there was termination for cause.
	    k. Properly identities and includes the name of the associated Third-party Marketing Organization (TMO)/Field Marketing Organization (FMO), if applicable.
	
	 [Data Elements 1.A – 1.R)

5	Organization accurately identifies and uploads into HPMS data on Agent/Broker complaints filed by the beneficiary, including the following criteria:
	
	    a. Properly calculates and includes the aggregate number of Agent/Broker marketing complaints from any source reported during the reporting period.
	    b. Properly calculates and includes the aggregate number of Agent/Broker disciplinary actions taken in the reporting period (related to Marketing).
	    c. Properly calculates and includes the number of new enrollments in the reporting period. If the Agent/Broker is licensed in multiple states, then enrollment numbers should be calculated and included by state.
	
	 [Data Elements 1.M, 1.N and 1.R]

2.9 PLAN OVERSIGHT OF AGENTS (PART D) – 2014 REPORTED DATA

Note to reviewer: If the contract did not use licensed agents directly employed by the organization or licensed independent agents/brokers to conduct marketing for its Medicare products during the reporting period, then it is appropriate for the contract to report "0" for each data element in this measure, and data validation is not required.

6	Organization accurately identifies and uploads into Gentran data for all new enrollments during the reporting period for which an Agent/Broker is associated, including the following criteria:
	
	    a. Properly identifies and includes all beneficiaries who an Agent/Broker assisted in enrolling in the plan.
	    b. Includes all new enrollments and renewals. New enrollments for reporting purposes as new to the organization. A change from one Plan Benefit Package (PBP) to another PBP, within the same organization, is not considered "new enrollment" for purposes of these reporting requirements. In addition, Plans should report on all agents/brokers, not just independent agent/brokers.
	    c. Includes and reports each Agent/Broker assisted beneficiary, based on beneficiary's HICN or RRB Number.
	    d. Defines "Agent/Broker assisted enrollments" as enrollments involving a beneficiary who used a licensed Agent/Broker that is compensated to complete the enrollment process (e.g., includes enrollments completed through the designated enrollment mechanisms.
	    e. Properly identifies and includes the Agent/Broker National Producer Number (NPN).
	    f. Properly identifies and includes the Agent/Broker Identification Number assigned by the plan.
	    g. Properly identifies and includes the enrollment mechanism as Plan/Plan Representative Online; CMS Online Enrollment Center; Plan Call Center; 1-800-MEDICARE; Paper Application; Auto-Assigned/Facilitated; Other.
	    h. Properly identifies and includes the beneficiary's enrollment application date.
	    i. Properly identifies and includes the beneficiary's enrollment effective date.
	    j. Excludes enrollment/renewal cancellations.
	    k. Includes Agent/Broker assisted enrollments that involve a beneficiary's change from one plan benefit package to another within the same contract.
	
	[Data Elements 2.A – 2.P

7	Organization accurately identifies data on Agent/Broker complaints filed by the beneficiary and uploads it into Gentran, including the following criteria:
	    a. Properly calculates and includes the number of all Agent/Broker complaints received within the reporting period for each applicable beneficiary.
	    b. Properly calculates and includes the number of all Agent/Broker complaints that are Marketing related.
	    c. The number of Marketing related complaints (Data Element P) is a subset of the number of Agent/Broker complaints filed by the beneficiary (Data Element O).
	
	[Data Elements – 2.O – 2.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
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
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
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
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