Medicare Part C and Part D Reporting Requirements

Data Validation Procedure Manual

Appendix B: Data Validation Standards

Version 3.0

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Table of Contents

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 (~~also~~ identical for each reporting section), and reporting section criteria that are based on the applicable *Part C/Part D Reporting Requirements Technical Specifications*.

Please note that the reporting section criteria in this document <u>for the reporting sections listed below</u> are based on the 201~~0~~1 *Part C~~/Part D~~ Reporting Requirements Technical Specifications* <u>(December 2011 version) and the</u> *Part D <u>Reporting Requirements Technical Specifications</u>* <u>(January 2012 version), which have</u> ~~(~~reporting period<u>s</u> of 1/1/11<u>0</u> - 12/31/11<u>0) for the following data measures</u>:
~~Procedure Frequency (Part C)~~
Serious Reportable Adverse Events (Part C)
Special Needs Plans (SNPs) Care Management (Part C)
Long-Term Care (LTC) Utilization (Part D)

The reporting section criteria in this document for all other reporting sections are based on the 201<u>2</u>~~1~~ *Part C/Part D Reporting Requirements Technical Specifications* <u>(Part C: October 2012 version; Part D: December 2012 version).</u> ~~(~~The reporting period varies by reporting section~~)~~.

All revisions to the reporting section criteria since the ~~March May 2011~~<u>April – June 2012</u> data validation cycle are identified by underlined and/or strikethrough text.<u>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."</u>

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 use 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.

2   PART C DATA VALIDATION STANDARDS

2.1   PROCEDURE FREQUENCY

Note to reviewer: If the organization reports this measure's applicable data elements (per the starred notation in the *Part C Technical Specifications Document*) in HEDIS, then it is appropriate for the contract to report "0" for these applicable data elements, and data validation for those elements is not required.

To determine compliance with the standards for Procedure Frequency, 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).

2.1 PROCEDURE FREQUENCY	
Note to reviewer: If the organization reports this measure's applicable data elements (per the starred notation in the *Part C Technical Specifications Document)* in HEDIS, then it is appropriate for the contract to report "0" for these applicable data elements, and data validation for those elements is not required.	
5	Organization implements appropriate policies and procedures for archiving and restoring data in each data system (e.g., disaster recovery plan).
6	*If organization's data systems underwent any changes during the reporting period (e.g., as a result of a merger, acquisition, or upgrade):* Organization provided documentation on the data system changes and, upon review, there were no issues that adversely impacted data reported.
7	*If data collection and/or reporting for this data 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.
MEASURE SPECIFIC CRITERIA (for 2010 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 5/31 and (for organizations that submit HEDIS data) reports applicable procedure frequency data elements in accordance with NCQA's timetable for data submission. *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 calculates the number of members receiving the specified procedures, including the following criteria: a. Includes all members with paid claims for the specified procedures with dates of service that occur during the reporting period (if a member received the same procedure multiple times within the reporting period, includes that member only once for the applicable data element). b. Properly uses all code types (i.e., CPT, ICD-9-CM Procedure, ICD-9-CM Diagnosis, MS-DRG) to identify procedures in a non-duplicative manner. c. Accurately maps non-standard codes to the standard codes provided by CMS in Appendix 4 of the *Part C Reporting Requirements Technical Specifications* Document. d. Properly sorts by each of the following procedures: Cardiac Catheterization; Open Coronary Angioplasty; PTCA or Coronary Atherectomy with CABG; PTCA or Coronary Atherectomy with insertion of drug-eluting coronary artery stent(s); PTCA or Coronary Atherectomy with insertion of non-drug-eluting coronary artery stent(s); PTCA or Coronary Atherectomy without insertion of Coronary Artery Stent; Total Hip Replacement; Total Knee Replacement; Bone Marrow Transplant; Heart Transplant; Heart/Lung Transplant; Kidney Transplant; Liver Transplant; Lung Transplant; Pancreas Transplant; Pancreas/Kidney Transplant; CABG; Gastric Bypass; Excision or Destruction of Lesion or Tissue of Lung; Excision of Large Intestine; Mastectomy; Lumpectomy; and Prostatectomy. e. For Data Elements 2.3 through 2.6, includes members that received the applicable procedures during the same admission (i.e., procedures do not need to occur on the same date of service). f. For Data Elements 2.7 and 2.8, if a member receives a procedure identified by MS-DRG 461-462 or 466-470 with no accompanying CPT or ICD-9 procedure code, and no other information is available to distinguish between Total Hip Replacement and Total Knee Replacement procedures, then the member is reported for Data Element 2.8 as receiving Total Knee Replacement procedure. g. For Data Element 2.9, includes all members that received the procedure regardless of whether or not that member had a cancer diagnosis. h. For Data Elements 2.12 and 2.13, if a member receives a kidney and liver transplant, then the member is reported for Data Element 2.13 as receiving Liver Transplant. i. For Data Elements 2.19 through 2.23, includes only members with the specified cancer diagnosis that received the following procedures: Excision or Destruction of Lesion or Tissue of Lung; Excision of Large Intestine; Mastectomy; Lumpectomy; and Prostatectomy. [Data Elements 2.1 – 2.23]

2.2 SERIOUS REPORTABLE ADVERSE EVENTS (SRAES)

To determine compliance with the standards for Serious Reportable Adverse Events (SRAEs), 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~~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~~if~~ 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 ~~appropriate~~ policies and procedures for data submission, including the following:
	    a. Data elements are accurately entered / uploaded into ~~the HPMS tool~~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 ~~HPMS~~CMS systems 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).

2.2   SERIOUS REPORTABLE ADVERSE EVENTS (SRAES)

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 2011 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 5/31. *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 total number of surgeries, including the following criteria:
	    a. Includes all surgeries with dates of service that occur during the reporting period. If a date of service is not available, date of discharge is acceptable.
	    b. Includes only surgeries that occur in an acute inpatient hospital setting.
	[Data Element 3.1]

5	Organization accurately calculates the number of surgical SRAEs, including the following criteria:
	    a. Accurately maps SRAEs to the codes provided by CMS in Appendix 5̶2 of the *Part C Reporting Requirements Technical Specifications* Document, Table 2. *Note to reviewer: Organizations may map non-standard, homegrown codes, or events/conditions that are typically documented by hospital review personnel to the applicable SRAE. It is not necessary for an SRAE claim to contain every qualifier to be counted.*
	    b. Includes all specified SRAEs that are confirmed during the reporting period ~~(even if the event actually occurred during a previous reporting period~~. If date of service is not available, date of discharge is acceptable.
	    c. Includes only surgical SRAEs that occur in an acute inpatient hospital setting (i.e., during the hospital stay).
	    d. Excludes surgical SRAEs acquired after admission to Long Term Acute Care facilities.
	    e. ~~Includes any supplemental information provided by the hospital regarding SRAEs that are confirmed during the reporting period (even if the event actually occurred during a previous reporting period)~~ Includes SRAEs identified by paid claims as well as claims denied only due to being a non-reimbursable SRAE ("Never Events").
	    f. Excludes any patient admitted with an SRAE and/or hospital acquired condition (HAC) and only counts acute care in-patients who suffer an SRAE and/or HAC *after* admission, but during their hospital stay (if an SRAE is reported on a claim and there is an "n" (No) in the Present on Admission (POA) field, this is considered a "confirmation" that the SRAE was acquired during the hospital stay).
	    g. Properly assigns each event to a single applicable SRAE data element unless multiple SRAEs occur during that single episode; if multiple events are associated with multiple procedures, organization appropriately reports each SRAE associated with all of those procedures.
	    h. Properly sorts by each of the following events: Surgeries on wrong body part; Surgeries on wrong patient; Wrong surgical procedures on a patient; and Surgeries with post-operative death in normal health patient.
	    i. Properly counts each unique event.
	[Data Elements 3.2 – 3.5]

2.2   SERIOUS REPORTABLE ADVERSE EVENTS (SRAES)

6	Organization accurately calculates the number of HACs, including the following criteria: a. Accurately maps HACs to the codes provided by CMS in Appendix 5̶2 of the *Part C Reporting Requirements Technical Specifications* Document, Table 3 and Table 4. *Note to reviewer:* Organizations may map non-standard, homegrown codes, or events/conditions that are typically documented by hospital review personnel to the applicable SRAE. It is not necessary for a HAC claim to contain every qualifier to be counted. b. Includes all specified HACs that are confirmed during the reporting period (even if the event actually occurred during a previous reporting period). If date of service is not available, date of discharge is acceptable. The diagnosis code and procedure code may be on the same claim or on different claims, and may or may not be on the same date of service. c. For Data Elements 3.6-3.14, includes only HACs that occur in an acute inpatient hospital setting (i.e., during the hospital stay). d. For Data Elements 3.15 – 3.16, includes only those HACs that occur in an acute inpatient hospital setting and are diagnosed during the hospital stay. e. Excludes HACs acquired after admission to Long Term Acute Care facilities. e. Includes any supplemental information provided by the hospital regarding HACs that are confirmed during the reporting period (even if the event actually occurred during a previous reporting period). f. Includes HACs identified by paid claims as well as claims denied only due to being a non-reimbursable HAC ("Never Events"). g. Excludes any patient admitted with an SRAE and/or HAC and only counts acute care inpatients who suffer an SRAE and/or HAC *after* admission, but during their hospital stay (if an SRAE is reported on a claim and there is an "n" (No) in the Present on Admission (POA) field, this is considered a "confirmation" that the SRAE was acquired during the hospital stay). h. Properly assigns each HAC to a single applicable HAC data element unless multiple HACs occur during that single episode; if multiple HACs are associated with multiple procedures, organization appropriately reports each HAC associated with all of those procedures. i. Properly sorts by each of the following HACs: Foreign object retained after surgery; Air embolism events; Blood incompatibility events; Stage III & IV pressure ulcers; Fractures; Dislocations; Intracranial injuries; Crushing injuries; Burns; Vascular catheter-associated infections; and Catheter-associated UTIs. j. Properly counts each unique event. [Data Elements 3.6 – 3.16]

2.2   SERIOUS REPORTABLE ADVERSE EVENTS (SRAES)

7	Organization accurately calculates the number of HACs, including the following criteria: a. Accurately maps HACs to the codes provided by CMS in Appendix ~~5~~2 of the *Part C Reporting Requirements Technical Specifications* Document, Table 4. *Note to reviewer: Organizations may map non-standard, homegrown codes, or events/conditions that are typically documented by hospital review personnel to the applicable SRAE. It is not necessary for an HAC claim to contain every qualifier to be counted.* b. Includes all specified HACs that are confirmed during the reporting period ~~(even if the event actually occurred during a previous reporting period).~~ If date of service is not available, date of discharge is acceptable. The diagnosis code and procedure code may be on the same claim or on different claims, and may or may not be on the same date of service. c. Excludes HACs acquired after admission to Long Term Acute Care facilities. d. For Data Element 3.17, includes only those HACs that occur in an acute inpatient hospital setting and are diagnosed during the hospital stay. e. For Data Element 3.18, includes SSI diagnosis codes with a date of service that extends 30 days from the date of ~~the procedure~~service. f. For Data Element 3.19, includes SSI diagnosis codes with a date of service that extends 365 days from the date of ~~the procedure~~service. g. For Data Element 3.20, includes SSI diagnosis codes with a date of service that extends 30 days from the date of ~~the procedure~~service. ~~g. Includes any supplemental information provided by the hospital regarding HACs that are confirmed during the reporting period (even if the event actually occurred during a previous reporting period).~~ h. Includes HACs identified by paid claims as well as claims denied only due to being a non-reimbursable HAC ("Never Events"). i. Excludes any patient admitted with an SRAE and/or HAC and only counts acute care in-patients who suffer an SRAE and/or HAC *after* admission, but during their hospital stay (if an SRAE is reported on a claim and there is an "n" (No) in the Present on Admission (POA) field, this is considered a "confirmation" that the SRAE was acquired during the hospital stay). j. Properly assigns each HAC to a single applicable HAC data element unless multiple HACs occur during that single episode; if multiple HACs are associated with multiple procedures, organization appropriately reports each HAC associated with all of those procedures. k. Properly sorts by each of the following HACs: Manifestations of poor glycemic control; SSI (mediastinitis) after CABG; SSI after certain orthopedic procedures; SSI following bariatric surgery for obesity; and DVT and pulmonary embolism following certain orthopedic procedures. l. Properly counts each unique event. [Data Elements 3.17 – 3.21]

2.3   PROVIDER NETWORK ADEQUACY

To determine compliance with the standards for Provider Network Adequacy, 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).
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.

2.3   PROVIDER NETWORK ADEQUACY
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.
MEASURE-SPECIFIC CRITERIA (for 2011 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 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 calculates the number of primary care physicians (PCPs) in the network on the first day of the reporting period, including the following criteria: a. Includes only physicians that are contracted in the network as of the first day of the reporting period, using the contracting date, not the credentialing date. b. Includes all physicians that are identified as able to serve as a member's primary care physician (regardless of whether or not they are considered a PCP and a specialist). *Note to reviewer: If the organization does not recognize one or more of the PCP types listed below as a primary care physician, it must still include that type as a PCP for the purposes of this reporting.* c. Properly defines PCPs as persons. d. Properly sorts by each of the following PCP types: General Medicine; Family Medicine; Internal Medicine (includes Geriatricians as Internal Medicine); Obstetricians; Pediatricians; and State Licensed Nurse Practitioners. [Data Elements 4.1 – 4.6]
5	Organization accurately calculates the number of PCPs in the network continuously through the reporting period, including the following criteria: a. Includes only physicians that are defined as having been continuously in the network through the reporting period, using the contracting date, not the credentialing date. b. Includes all physicians that are identified as able to serve as a member's primary care physician (regardless of whether or not they are considered a PCP and a specialist). *Note to reviewer: If the organization does not recognize one or more of the PCP types listed below as a primary care physician, it must still include that type as a PCP for the purposes of this reporting.* c. Properly defines PCPs as persons. d. Properly sorts by each of the following PCP types: General Medicine; Family Medicine; Internal Medicine (includes Geriatricians as Internal Medicine); Obstetricians; Pediatricians; and State Licensed Nurse Practitioners. [Data Elements 4.7 – 4.12]
6	Organization accurately calculates the number of PCPs added to the network during the reporting period, including the following criteria: a. Includes only physicians whose effective date of contracted network participation occurs after the first day of the reporting period, using the contracting date, not the credentialing date. b. Includes all physicians that are identified as able to serve as a member's primary care physician (regardless of whether or not they are considered a PCP and a specialist). *Note to reviewer: If the organization does not recognize one or more of the PCP types listed below as a primary care physician, it must still include that type as a PCP for the purposes of this reporting.* c. Properly defines PCPs as persons. d. Properly sorts by each of the following PCP types: General Medicine; Family Medicine; Internal Medicine (includes Geriatricians as Internal Medicine); Obstetricians; Pediatricians; and State Licensed Nurse Practitioners. [Data Elements 4.13 – 4.18]

2.3 PROVIDER NETWORK ADEQUACY

7	Organization accurately calculates the number of PCPs accepting new patients at the beginning of the reporting period, including the following criteria: a. Includes only physicians who are contracted in the network and identified as accepting new patients as of the first day of the reporting period, using the contracting date, not the credentialing date. b. Includes all physicians that are identified as able to serve as a member's primary care physician (regardless of whether or not they are considered a PCP and a specialist). Note to reviewer: If the organization does not recognize one or more of the PCP types listed below as a primary care physician, it must still include that type as a PCP for the purposes of this reporting. c. Properly defines PCPs as persons. d. Properly sorts by each of the following PCP types: General Medicine; Family Medicine; Internal Medicine (includes Geriatricians as Internal Medicine); Obstetricians; Pediatricians; and State Licensed Nurse Practitioners. [Data Elements 4.19 – 4.24]
8	Organization accurately calculates the number of PCPs accepting new patients at the end of the reporting period, including the following criteria: a. Includes only physicians who are contracted in the network and identified as accepting new patients as of the last day of the reporting period, using the contracting date, not the credentialing date. b. Includes all physicians that are identified as able to serve as a member's primary care physician (regardless of whether or not they are considered a PCP and a specialist). Note to reviewer: If the organization does not recognize one or more of the PCP types listed below as a primary care physician, it must still include that type as a PCP for the purposes of this reporting. c. Properly defines PCPs as persons. d. Properly sorts by each of the following PCP types: General Medicine; Family Medicine; Internal Medicine (includes Geriatricians as Internal Medicine); Obstetricians; Pediatricians; and State Licensed Nurse Practitioners. [Data Elements 4.25 – 4.30]
9	Organization accurately calculates the number of PCPs in the network on the last day of the reporting period, including the following criteria: a. Includes only physicians that are contracted in the network as of the last day of the reporting period, using the contracting date, not the credentialing date. b. Includes all physicians that are identified as able to serve as a member's primary care physician (regardless of whether or not they are considered a PCP and a specialist). Note to reviewer: If the organization does not recognize one or more of the PCP types listed below as a primary care physician, it must still include that type as a PCP for the purposes of this reporting. c. Properly defines PCPs as persons. d. Properly sorts by each of the following PCP types: General Medicine; Family Medicine; Internal Medicine (includes Geriatricians as Internal Medicine); Obstetricians; Pediatricians; and State Licensed Nurse Practitioners. [Data Elements 4.31 – 4.36]
10	Organization accurately calculates the number of specialists/facilities in the network on the first day of the reporting period, including the following criteria: a. Includes only specialists/facilities defined as having been in network on the first day of the reporting period, using the contracting date, not the credentialing date. b. Includes all applicable specialists (regardless of whether or not they have dual specialties or are considered a PCP and a specialist). c. Properly defines specialists as persons, not as specialty facilities. d. Properly sorts by each of the following specialty/facility types: Hospitals (includes Psychiatric Hospitals and Inpatient Substance Abuse Facilities); Home Health Agencies; Cardiologist; Oncologist; Pulmonologist; Endocrinologist; Skilled Nursing Facilities; Rheumatologist; Ophthalmologist; and Urologist. [Data Elements 4.37 – 4.46]

	2.3 PROVIDER NETWORK ADEQUACY
11	Organization accurately calculates the number of specialists/facilities continuously in the network through the reporting period, including the following criteria: a. Includes only specialists/facilities defined as having been continuously in the network through the reporting period, using the contracting date, not the credentialing date. b. Includes all applicable specialists (regardless of whether or not they have dual specialties or are considered a PCP and a specialist). c. Properly defines specialists as persons, not as specialty facilities. d. Properly sorts by each of the following specialty/facility types: Hospitals (includes Psychiatric Hospitals and Inpatient Substance Abuse Facilities); Home Health Agencies; Cardiologist; Oncologist; Pulmonologist; Endocrinologist; Skilled Nursing Facilities; Rheumatologist; Ophthalmologist; and Urologist. [Data Elements 4.47 – 4.56]
12	Organization accurately calculates the number of specialists/facilities added to the network during the reporting period, including the following criteria: a. Includes only specialists/facilities whose effective date of network participation occurs after the first day of the reporting period, using the contracting date, not the credentialing date. b. Includes all applicable specialists (regardless of whether or not they have dual specialties or are considered a PCP and a specialist). c. Properly defines specialists as persons, not as specialty facilities. d. Properly sorts by each of the following specialty/facility types: Hospitals (includes Psychiatric Hospitals and Inpatient Substance Abuse Facilities); Home Health Agencies; Cardiologist; Oncologist; Pulmonologist; Endocrinologist; Skilled Nursing Facilities; Rheumatologist; Ophthalmologist; and Urologist. [Data Elements 4.57 – 4.66]
13	Organization accurately calculates the number of specialists/facilities in the network accepting new patients at the start of the reporting period, including the following criteria: a. Includes only specialists/facilities that are contracted in the network as of the last day of the reporting period, using the contracting date, not the credentialing date. b. Includes all applicable specialists (regardless of whether or not they have dual specialties or are considered a PCP and a specialist). c. Properly defines specialists as persons, not as specialty facilities. d. Properly sorts by each of the following specialty/facility types: Hospitals (includes Psychiatric Hospitals and Inpatient Substance Abuse Facilities); Home Health Agencies; Cardiologist; Oncologist; Pulmonologist; Endocrinologist; Skilled Nursing Facilities; Rheumatologist; Ophthalmologist; and Urologist. [Data Elements 4.67 – 4.76]
14	Organization accurately calculates the number of specialists/facilities in the network accepting new patients at the end of the reporting period, including the following criteria: a. Includes only specialists/facilities that are contracted in the network as of the last day of the reporting period, using the contracting date, not the credentialing date. b. Includes all applicable specialists (regardless of whether or not they have dual specialties or are considered a PCP and a specialist). c. Properly defines specialists as persons, not as specialty facilities. d. Properly sorts by each of the following specialty/facility types: Hospitals (includes Psychiatric Hospitals and Inpatient Substance Abuse Facilities); Home Health Agencies; Cardiologist; Oncologist; Pulmonologist; Endocrinologist; Skilled Nursing Facilities; Rheumatologist; Ophthalmologist; and Urologist. [Data Elements 4.77 – 4.86]

2.3 PROVIDER NETWORK ADEQUACY

15 Organization accurately calculates the number of specialists/facilities in the network on the last day of the reporting period, including the following criteria:
    a. Includes only specialists/facilities that are contracted in the network as of the last day of the reporting period, using the contracting date, not the credentialing date.
    b. Includes all applicable specialists (regardless of whether or not they have dual specialties or are considered a PCP and a specialist).
    c. Properly defines specialists as persons, not as specialty facilities.
    d. Properly sorts by each of the following specialty/facility types: Hospitals (includes Psychiatric Hospitals and Inpatient Substance Abuse Facilities); Home Health Agencies; Cardiologist; Oncologist; Pulmonologist; Endocrinologist; Skilled Nursing Facilities; Rheumatologist; Ophthalmologist; and Urologist.
[Data Elements 4.87 – 4.96]

2.4 GRIEVANCES (PART C)

Note to reviewer: Aggregate all quarterly data submitted within the reporting year 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 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~~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~~if~~ 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 ~~appropriate~~ policies and procedures for data submission, including the following:
	    a. Data elements are accurately entered / uploaded into ~~the HPMS tool~~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 ~~HPMS~~CMS systems 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).

2.4   GRIEVANCES (PART C)

Note to reviewer: Aggregate all quarterly data submitted within the reporting year 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 2012 reported data)

1	Organization reports data based on the required reporting 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 and plan benefit package.
3	Organization meets deadlines for reporting quarterly data to CMS by 5/31, 8/31, 11/30, 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 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 ~~1~~ and 20 ~~2~~. This includes applying all relevant guidance properly when performing its calculations and categorizations. Requests for organization determinations or appeals are not improperly categorized as grievances.
5	Organization 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 ~~by~~under a single complainant, each issue is calculated as a separate grievance. d. If a ~~beneficiary~~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 ~~beneficiary~~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, 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). [Data Elements 5.1 – ~~5.7~~5.10]
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: Fraud ~~and Abuse~~; Enrollment/Disenrollment; ~~Access/~~Benefit Package; Access; Marketing; Customer Service; ~~Confidentiality and~~ Privacy Issues; Quality of Care; and ~~Expedited Grievances~~Appeals. b. Assigns all additional categories tracked by the organization that are not listed above as Other. [Data Elements 5.1 – ~~5.7~~5.10]

2.4   GRIEVANCES (PART C)

Note to reviewer: Aggregate all quarterly data submitted within the reporting year 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.

7	Organization accurately calculates the number of grievances for which it provided timely notification of the decision, including the following criteria:
	    a. Includes only grievances for which the member is notified of decision according to the following timelines:
	          i. For standard grievances: no later than 30 days after receipt 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 5.11 – 5.18]

~~7~~	~~Organization accurately categorizes all expedited grievances based on the following criteria:~~
	    ~~a. Complaints involving an MAO's decision to invoke an extension in an organization determination or reconsideration.~~
	    ~~b. Complaints involving an MAO's refusal to grant a request for an expedited organization determination or reconsideration.~~
	~~[Data Element 5.6]~~

2.5 ORGANIZATION DETERMINATIONS / RECONSIDERATIONS

Note to reviewer: Aggregate all quarterly data submitted within the reporting year 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 ~~and output~~ are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via ~~HPMS~~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~~if~~ 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 ~~appropriate~~ policies and procedures for data submission, including the following: a. Data elements are accurately entered / uploaded into ~~the HPMS tool~~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 ~~HPMS~~CMS systems 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).

	2.5 ORGANIZATION DETERMINATIONS / RECONSIDERATIONS
	Note to reviewer: Aggregate all quarterly data submitted within the reporting year 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 2012 reported data)
1	Organization reports data based on the required reporting 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 quarterly data to CMS by 5/31, 8/31, 11/30, 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 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) fort the rest of the reporting section criteria for this reporting section.*

4	Organization accurately calculates the total number of organization determinations, in accordance with CMS guidance and criteria 5-7 below, 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, 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 or~~ withdrawals.
	    j. Excludes Quality Improvement Organization (QIO) reviews of a member's request to continue Medicare-covered services (e.g., a SNF stay).
	    k. Excludes duplicate payment requests concerning the same service or item.
	    l. Excludes payment requests returned to a provider/supplier in which a substantive decision (~~F~~fully ~~F~~favorable, ~~P~~partially ~~F~~favorable or ~~A~~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).
	    ~~l. Excludes all organization determinations that involve services provided to Medicaid-only members.~~
	 [Data Elements 6.1 – 6.3]

	2.5 ORGANIZATION DETERMINATIONS / RECONSIDERATIONS
	Note to reviewer: Aggregate all quarterly data submitted within the reporting year before applying the 90% threshold.

5	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.
	    b. Includes all fully favorable payment (claim) organization determinations for contract and non-contract providers/suppliers.
	    ~~c. Properly defines contract and non-contract providers/suppliers based on whether the provider/supplier is under contract for the plan in which the member is enrolled on the date of service.~~
	    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.
	[Data Element 6.1]

6	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 ~~with a "part" that has been approved~~) organization determinations, including the following criteria:
	    a. Includes all partially favorable pre-service organization determinations for contract and non-contract providers/suppliers.
	    b. ~~Excludes~~Includes all partially favorable payment organization determinations for contract and non-contract providers/suppliers.
	    ~~c. Properly defines contract and non-contract providers/suppliers based on whether the provider/supplier is under contract for the plan in which the member is enrolled on the date of service.~~
	[Data Element 6.2]

7	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.
	    b. Includes all adverse payment (claim) organization determinations that result in zero payment being made to contract and non-contract providers.
	    ~~c. Excludes all adverse payment (claim) organization determinations that result in zero payment being made to contract providers/suppliers.~~
	    ~~d. Properly defines contract and non-contract providers/suppliers based on whether the provider/supplier is under contract for the plan in which the member is enrolled on the date of service.~~
	[Data Element 6.3]

8	Organization properly defines the term "Reconsideration" in accordance with the Medicare Managed Care Manual Chapter 13, Sections 10~~.1~~ and 70. This includes applying all relevant guidance properly when performing its calculations and categorizations.

	2.5 ORGANIZATION DETERMINATIONS / RECONSIDERATIONS
	Note to reviewer: Aggregate all quarterly data submitted within the reporting year before applying the 90% threshold.
9	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, 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 QIO reviews of a member's request to continue Medicare-covered services (e.g., a SNF stay). i. Excludes duplicate payment requests concerning the same service or item. j. 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). j. Excludes all reconsiderations that involve services provided to Medicaid only members. [Data Elements 6.4 – 6.6]
10	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. b. Includes all fully favorable payment (claim) reconsideration determinations for contract and non-contract providers/suppliers. c. Properly defines contract and non-contract providers/suppliers based on whether the provider/supplier is under contract for the plan in which the member is enrolled on the date of service. [Data Element 6.4]
11	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 with a "part" that has been approved) reconsiderations, including the following criteria: a. Includes all partially favorable pre-service reconsideration determinations for contract and non-contract providers/suppliers. b. ExcludesIncludes all partially favorable payment reconsideration determinations for contract and non-contract providers/suppliers. c. Properly defines contract and non-contract providers/suppliers based on whether the provider/supplier is under contract for the plan in which the member is enrolled on the date of service. [Data Element 6.5]
12	Organization accurately calculates the number of adverse (e.g., denial of entire request resulting in no coverage of the item or service) reconsiderations, including the following criteria: a. Includes all adverse pre-service reconsideration determinations for contract and non-contract providers/suppliers. b. Includes all adverse payment (claim) reconsideration determinations that result in zero payment being made to contract and non-contract providers. c. Excludes all adverse payment (claim) reconsideration determinations that result in zero payment being made to contract providers/suppliers. d. Properly defines contract and non-contract providers/suppliers based on whether the provider/supplier is under contract for the plan in which the member is enrolled on the date of service. [Data Element 6.6]

2.6 EMPLOYER GROUP PLAN SPONSORS (PART C)

To determine compliance with the standards for Employer Group Plan Sponsors (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
- 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).
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.

2.6 EMPLOYER GROUP PLAN SPONSORS (PART C)	
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.
MEASURE-SPECIFIC CRITERIA (for 2011 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 and 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 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 identifies data on each employer group plan and uploads it into the HPMS submission tool, including the following criteria: a. Includes the following information for each plan benefit package reported: Employer Legal Name; Employer DBA Name; Employer Federal Tax ID; Employer Address; Type of Group Sponsor (employer, union, trustees of a fund); Organization Type (State Government, Local Government, Publicly Traded Organization, Privately Held Corporation, Non-Profit, Church Group, Other); Type of Contract (insured, ASO, other); Employer Plan Year Start Date; and Current Enrollment. b. Follows the specified file format provided by CMS in the *Part C Reporting Requirements Technical Specifications* Document (Appendix 6). [Data Elements 7.1 – 7.9]
5	The organization's "Employer Address" data field accurately reflects the employer's headquarters address. [Data Element 7.4]
6	The organization's "Organization Type" data field accurately reflects data based on how the organization files its taxes. [Data Element 7.6]
7	The organization's "Type of Contract" data field accurately captures the type of contract that the organization holds with the employer group that binds it to offer benefits to group retirees. [Data Element 7.7]
8	The organization's "Employer Plan Year Start Date" data field accurately reflects the month and year in which the employer's benefit year with the plan begins. [Data Element 7.8]
9	The organization accurately calculates the number of currently enrolled members, including the following criteria: a. Includes all enrollments from a particular employer group into the specific PBP. b. Includes all members that are enrolled in the employer group plan as of the last day of the reporting period. c. Enrollment number for contracts that were cancelled during the reporting period is reported as zero. [Data Element 7.9]

2.7 PLAN OVERSIGHT OF AGENTS (PART C)

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 reporting section, 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~~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~~if~~ 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 ~~appropriate~~ policies and procedures for data submission, including the following:
	    a. Data elements are accurately entered / uploaded into ~~the HPMS tool~~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 ~~HPMS~~CMS systems 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).

2.7   PLAN OVERSIGHT OF AGENTS (PART C)

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 reporting section, 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 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 2012 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 criteria for this reporting section.*

4	Organization accurately calculates the total number of agents who are licensed to sell on behalf of the Parent Organization during the applicable reporting period, including the following criteria:
	    a. Includes all direct employees of the organization who were licensed to sell on behalf of the Parent Organization, regardless of whether or not the agent was actively selling during the reporting period.
	    b. Includes all licensed agents who were under a contractual agreement to sell on behalf of the Parent Organization, regardless of whether or not the agent was actively selling during the reporting period.
	Note to reviewer: If the organization has multiple contracts, it should report the same number of agents for Data Element 12.1 for each contract, since this number is based on the Parent Organization.
	[Data Element 12.1]

5	Organization accurately calculates the number of agents investigated based on complaints, including the following criteria:
	    a. Includes all agents with investigations that were completed during the applicable reporting period, regardless of when the complaint was received and whether the member remained enrolled, disenrolled, or declined enrollment during the enrollment process.
	    b. Includes agents with investigations based on complaints filed directly with the organization as well as those from the HPMS Complaint Tracking Module (CTM).
	    c. Includes all agents with investigations based on complaints against the agent under the applicable plan contract. If a complaint cannot be tied to a specific contract, then the complaint is included under all contracts that the agent is licensed to sell.
	    d. Excludes investigations in which the member or agent could be not contacted.
	    e. The number calculated for Data Element 12.2 is a subset of the total number of agents calculated for Data Element 12.1.
	[Data Element 12.2]

2.7 PLAN OVERSIGHT OF AGENTS (PART C)

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 reporting section, and data validation is not required.

6	Organization accurately calculates the number of agents receiving disciplinary action resulting from a complaint filed against an agent, including the following criteria:
	a. Includes all agents with disciplinary actions that were taken during the applicable reporting period, regardless of when the complaint was received.
	b. Includes agents wth any disciplinary action taken by the organization, including manager-coaching, documented verbal warning, re-training, documented corrective action plan, suspension, termination of employment/contract, and short-term revocation.
	c. Includes agents with disciplinary actions based on complaints filed directly with the organization as well as those from the HPMS Complaint Tracking Module (CTM).
	d. Includes all agents with disciplinary actions based on complaints against the agent under the applicable plan contract. If a complaint cannot be tied to a specific contract, then the disciplinary action is included under all contracts that the agent is licensed to sell.
	e. The number calculated for Data Element 12.3 is a subset of the total number of agents calculated for Data Element 12.1.
	[Data Element 12.3]
7	Organization accurately calculates the number of complaints filed against an agent that the organization reported to the governing State, including the following criteria:
	a. Includes all complaints against a contracted agent received and reported to the State during the applicable reporting period.
	b. Includes only complaints 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).
	c. Includes all complaints against an agent and reported to the governing State under the applicable plan contract. If a complaint that is reported to the governing State cannot be tied to a specific contract, then the complaint is included under all contracts that the agent is licensed to sell.
	Note to reviewer: If organization does not voluntarily report complaints against a contracted agent to the State, then it is appropriate to report a zero for this data element.
	[Data Element 12.4]
8	Organization accurately calculates the number of agents whose selling privileges were revoked by the organization based on conduct or discipline, including the following criteria:
	a. Includes all agents with revocations initiated during the applicable reporting period, regardless of when the conduct causing the revocation occurred.
	b. The number calculated for Data Element 12.5 is a subset of the total number of agents calculated for Data Element 12.1.
	[Data Element 12.5]
9	Organization accurately calculates the number of "agent assisted enrollments" during the applicable reporting period, including the following criteria:
	a. Includes all agent assisted enrollments that became effective during the reporting period but excludes cancelled enrollments.
	b. Defines "agent assisted enrollments" as enrollments involving a member who used a licensed agent that is compensated (employee or independent) to complete the enrollment process (e.g., includes enrollments completed through a call center staffed by licensed agents, in person sales appointments, and public sales meetings where a licensed agent collects enrollment forms).
	c. Includes agent assisted enrollments from both the individual and group enrollment process.
	d. Includes enrollments that are as a direct result of the participation of the group of agents reported in Data Element 12.1.
	e. Excludes agent assisted enrollments that involve only a member's change from one benefit package to another within the same contract.
	[Data Element 12.6]

2.8 SPECIAL NEEDS PLANS (SNP) CARE MANAGEMENT

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 ~~and output~~ are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via ~~HPMS~~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~~if~~ 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 ~~appropriate~~ policies and procedures for data submission, including the following:
	   a. Data elements are accurately entered / uploaded into ~~the HPMS tool~~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 ~~HPMS~~CMS systems 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).
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.

2.8   SPECIAL NEEDS PLANS (SNP) CARE MANAGEMENT

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 2011 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 and plan benefit package.
3	Organization meets deadline for reporting annual data to CMS by 5/31. *Note to reviewer: If the organization has, for any reason, re-submitted its data to CMS for this reporting section, the reviewer should verify that the organization's original data submission met the CMS deadline in order to have a finding of "yes" for this reporting section criterion. However, if the organization re-submits data for any reason and if the re-submission was completed by 3/31 of the data validation year, the reviewer should use the organization's corrected data submission for the rest of the reporting section criteria for this reporting section*
4	Organization accurately calculates the number of new members, including the following criteria: a. Includes all members who were eligible for an initial assessment during the current reporting period.whose effective date of enrollment occurred during the reporting period. [Data Element 13.1]
5	Organization accurately calculates the number of existing members who were eligible for an annual health risk reassessment during the reporting period, including the following criteria: a. Excludes cancelled enrollments. all members whose reassessments were completed during the following plan year (e.g., member was eligible for reassessment in plan year 2010 and reassessment was completed in plan year 2011). [Data Element 13.2]

6	Organization accurately calculates the number of initial health risk assessments performed on new members, including the following criteria:
	     a. Includes all initial assessments that were confirmed completed (within 90 days of enrollment) during the reporting period (even if the event actually occurred during a previous reporting period).
	     b. The number of initial assessments calculated for Data Element 13.3 is a subset of 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 members eligible for a reassessment, including the following criteria:
	     a. Includes all annual reassessments that were completed during the reporting period (even if the event actually occurred during a previous reporting period).
	     b. Includes annual reassessments that were completed during the plan year prior to the year the member was eligible for a reassessment (e.g., member was eligible for reassessment in plan year 2011 and reassessment was completed in plan year 2010).
	     b. The number of annual reassessments calculated for Data Element 13.4 is a subset of 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]

3 PART D DATA VALIDATION STANDARDS

3.1 RETAIL, HOME INFUSION, AND LONG TERM CARE PHARMACY ACCESS

To determine compliance with the standards for Retail, Home Infusion, and Long Term Care Pharmacy Access, 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
- 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).

3.1	RETAIL, HOME INFUSION, AND LONG TERM CARE PHARMACY ACCESS
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.
MEASURE SPECIFIC CRITERIA (for 2011 reported data)	
1	Organization reports data based on the required reporting periods of 1/1 through 3/31 (Data Elements A and B) and 1/1 through 12/31 (Data Elements C and D). *Note to reviewer: All criteria that reference Data Element C are applicable only to contracts that own and operate their own pharmacies and received a CMS waiver of the any willing pharmacy requirement for the reporting period. All criteria that reference Data Element D are applicable only to contracts that own and operate their own retail pharmacies and received a CMS waiver of the retail pharmacy convenient access standards for the reporting period.*
2	Organization properly assigns data to the applicable CMS contract number (Data Elements A and B) and plan benefit package (Data Elements C and D). *Note to reviewer: All criteria that reference Data Element C are applicable only to contracts that own and operate their own pharmacies and received a CMS waiver of the any willing pharmacy requirement for the reporting period. All criteria that reference Data Element D are applicable only to contracts that own and operate their own retail pharmacies and received a CMS waiver of the retail pharmacy convenient access standards for the reporting period.*
3	Organization meets deadlines for reporting data to CMS by 5/31 (Data Elements A and B) and by 2/28 (Data Elements C and D). *Note to reviewer: All criteria that reference Data Element C are applicable only to contracts that own and operate their own pharmacies and received a CMS waiver of the any willing pharmacy requirement for the reporting period. All criteria that reference Data Element D are applicable only to contracts that own and operate their own retail pharmacies and received a CMS waiver of the retail pharmacy convenient access standards for the reporting period.* *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 submissions met each 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(s) for rest of the measure-specific criteria for this data measure.*
4	Organization maintains appropriate documentation to support submitted pharmacy access data elements (e.g., Geo-Access reports).
5	Organization accurately calculates retail pharmacy access percentages, including the following criteria: a. Uses either the Quest Analytics Suite™ or GeoNetworks® software or another alternative method that has been approved by CMS to calculate the ratios. b. Uses the CMS reference file that provides counts of Medicare beneficiaries by state, region, and zip code for the appropriate year. c. Bases the calculated ratios on the "total Medicare beneficiary count" and not plan member counts. d. Bases the calculated ratios on pharmacies that are contracted in the network as of the last day of the reporting period. e. Calculates the ratios by state for PDPs and RPPOs. f. Calculates the ratios by service area for local MA-PDs, Employer Group "800 Series Only" contracts, Employer/Union Direct contracts, and Part D sponsors that offer both individual plans and "800 series" plans. [Data Element A1 – A3]
6	Organization accurately calculates the number of contracted retail pharmacies in the contract's service area, including the following criteria: a. Includes only pharmacies that are contracted in the network as of the last day of the reporting period. b. Includes only retail pharmacies. c. Includes the number of contracted retail pharmacies by state for PDPs and RPPOs, and by service area for local MA-PDs. [Data Element A4]

3.1	RETAIL, HOME INFUSION, AND LONG TERM CARE PHARMACY ACCESS
7	Organization accurately calculates data for each home infusion network pharmacy and uploads it into the HPMS submission tool, including the following criteria: a. Includes only pharmacies that are contracted in the network as of the last day of the reporting period. b. Includes only home infusion pharmacies. c. Includes data for the contract's entire service area, even if there are no home infusion pharmacies in specific territories/states. d. For the States_Licensed field, includes all states in the contract's service area. *Note to reviewer: A contract with both individual contracts in particular states and 800 series plans with national coverage will be required to report data only for the states in the individual contract's service area. If a contract only includes 800 series plans, it will be required to report data for all states.* e. Follows the specified file format provided by CMS in the *Part D Reporting Requirements Technical Specifications* Document. [Data Element B1]
8	Organization accurately calculates data for each long-term care (LTC) pharmacy and uploads it into the HPMS submission tool, including the following criteria: a. Includes only pharmacies that are contracted in the network as of the last day of the reporting period. b. Includes only long term care pharmacies. c. Includes data for the contract's entire service area, even if there are no LTC pharmacies in specific territories/states. d. For the States_Licensed field, includes all states in the contract's service area. *Note to reviewer: A contract with both individual contracts in particular states and 800 series plans with national coverage will be required to report data only for the states in the individual contract's service area. If a contract only includes 800 series plans, it will be required to report data for all states.* e. Follows the specified file format provided by CMS in the *Part D Reporting Requirements Technical Specifications* Document. [Data Element B2]
9	Organization accurately calculates the number of prescriptions provided, including the following criteria: a. For Data Element C1: Includes only pharmacy claims with dates of service within the reporting period that are identified as provided by a pharmacy that is owned and operated by the plan. b. For Data Element C2: Includes all pharmacy claims with dates of service within the reporting period. c. Number calculated for Data Element C1 is a subset of the number of prescriptions provided at all pharmacies calculated for Data Element C2. *Note to reviewer: All criteria that reference Data Element C are applicable only to contracts that own and operate their own pharmacies and received a CMS waiver of the any willing pharmacy requirement for the reporting period.* [Data Element C]
10	Organization accurately calculates the number of prescriptions provided by retail pharmacies, including the following criteria: a. For Data Element D1: Includes only pharmacy claims with dates of service within the reporting period that are identified as provided by a retail pharmacy that is owned and operated by the plan. b. For Data Element D2: Includes all retail pharmacy claims with dates of service within the reporting period. c. Number calculated for Data Element D1 is a subset of the number of prescriptions provided at all retail pharmacies calculated for Data Element D2. *Note to reviewer: All criteria that reference Data Element D are applicable only to contracts that own and operate their own pharmacies and received a CMS waiver of the retail pharmacy convenient access standards for the reporting period.* [Data Element D]

3.2   MEDICATION THERAPY MANAGEMENT (MTM) PROGRAMS

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

To determine compliance with the standards for Medication Therapy Management (MTM) Programs, the data validation contractor (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~~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~~if~~ 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 ~~appropriate~~ policies and procedures for data submission, including the following:
	   a. Data elements are accurately entered / uploaded into ~~the HPMS tool~~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 ~~HPMS~~CMS systems 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).

3.2 MEDICATION THERAPY MANAGEMENT (MTM) PROGRAMS

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

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 2012 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 42 CFR §423.153(d), the Prescription Drug Benefit Manual Chapter 7 section 30 and the CY2013 Medication Therapy Management Program Guidance and Submission Instructions. This includes applying all relevant guidance properly when performing its calculations and categorizations.
4̶5	Organization accurately identifies data on MTM program participation and uploads it into Gentran ~~calculates the number of members identified to be eligible and auto-enrolled in the MTM program~~, including the following criteria: a. Properly identifies and includes members who met the organization's MTM program targeting criteria based on CMS requirements and were automatically enrolled in the MTM program 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 ~~identified beneficiary~~ targeted member ~~only once~~, reported once per contract year per contract file, based on the member's most current HICN. e. Excludes members deceased prior to their MTM identification date. f. Excludes members who receive MTM services outside of the CMS-required 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. 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. [Data Elements ~~A~~B – F, H]
6	Organization accurately identifies MTM eligible long-term care facility residents and uploads it into Gentran, including the following criteria: a. Properly identifies and includes whether each member was a resident in a long-term care facility for the entire time s/he was enrolled in the MTM program during the reporting period or on the date the member opted-out of MTM program enrollment. [Data Element G]

	3.2 MEDICATION THERAPY MANAGEMENT (MTM) PROGRAMS
	Note to reviewer: If the Part D sponsor has no MTM members, then it is not required to report this data and data validation is not required for this reporting section.
5~~7~~	Organization accurately identifies~~calculates the number of~~ 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'~~ with a~~ 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). ~~b. The number calculated for Data Element B is a subset of the number of members reported for Data Element A.~~ [Data Elements ~~BI~~, J]
~~6~~	~~Organization accurately calculates the number of members who opted-out of MTM program enrollment by reason for opt-out, including the following criteria:~~ ~~a. Properly sorts the total number of members who opted out of MTM program by each of the following opt-out reasons: death, disenrollment, request by member, other reason.~~ ~~b. Each number calculated for Data Elements C through F is a subset of the total number of members who opted out of MTM program enrollment calculated for Data Element B.~~ ~~c. The sum of the numbers calculated for Data Elements C through F is equal to the total number of members who opted out of MTM program enrollment calculated for Data Element B.~~ ~~[Data Elements C – F]~~
~~7~~	~~Organization accurately calculates the total prescription cost of all covered Part D medications for MTM program members on a per member per month (PMPM) basis, including the following criteria:~~ ~~a. Rounding the currency value to the nearest dollar.~~ ~~b. The numerator is the total prescription drug costs for all members enrolled in the MTM program for the time they were enrolled in the contract (not just the MTM program) during the reporting period and and is calculated using gross drug costs, which equals Ingredient Cost Paid + Dispensing Fee + Sales Tax + Vaccine Administration Fee).~~ ~~c. The numerator includes the costs of covered Part D prescriptions dispensed in the reporting period.~~ ~~d. The numerator includes both beneficiary and plan costs.~~ ~~e. The denominator is the sum of the total number of months these members were enrolled in the Part D contract during the reporting period, not only the months the member was enrolled in the MTM program.~~ ~~f. The number calculated for Data Element G is a subset of the members reported for Data Element A, and includes only the members reported for Data Element A who are still enrolled as of the last day of the reporting period. The members' enrollment in the MTM program may have started at any time in the reporting period. The members do not have to be enrolled in the MTM program for the entire reporting period to be included in Data Element G, but they have to still be enrolled in the MTM program as of the last day of the reporting period.~~ ~~[Data Element G]~~
~~8~~	~~Organization accurately calculates the number of covered Part D prescriptions on a per member per month (PMPM) basis to a 30-day equivalent, including the following criteria:~~ ~~a. The numerator is the sum of the total days supply of all covered Part D drugs dispensed for all members enrolled in MTM program for the time they were enrolled in the contract (not just the MTM program) divided by 30.~~ ~~b. The denominator is the sum of the total number of months these members were enrolled in the Part D contract during the reporting period, not only the months the member was enrolled in MTM program.~~ ~~c. The number calculated for Data Element H is a subset of the members reported for Data Element A, and includes only the members reported for Data Element A who are still enrolled as of the last day of the reporting period. The members' enrollment in the MTM program may have started at any time in the reporting period. The members do not have to be enrolled in the MTM program for the entire reporting period to be included in Data Element H, but they have to still be enrolled in the MTM program as of the last day of the reporting period.~~ ~~[Data Element H]~~

3.2 MEDICATION THERAPY MANAGEMENT (MTM) PROGRAMS

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

9~~8~~	Organization accurately identifies data on CMR offers~~calculates the number of MTM program members offered an interactive, person-to-person comprehensive medication review~~ and uploads it into Gentran, including the following criteria:
	
	   a. Properly identifies and includes MTM program members who were offered an interactive, person-to-person CMR during the reporting period.
	   b. Properly identifies and i~~I~~ncludes ~~all MTM program~~ members' ~~with a~~ date of initial offer of a ~~comprehensive medication review~~CMR that occurs within the reporting period.
	   ~~c. Excludes MTM members who the organization cannot confirm received the offer (e.g., returned mail or incorrect phone numbers).~~
	   ~~c. The number calculated for Data Element I should be a subset of the members reported Data Element A.~~
	
	[Data Element ~~I~~K, L]

10 9	Organization accurately identifies data on CMR dates ~~correctly calculates the number of MTM program members who received an interactive, person-to-person comprehensive medication review~~ and uploads it into Gentran, including the following criteria:
	
	   a. ~~Includes all MTM program members with a comprehensive medication review with date of service that occurs within the reporting period.~~ Properly identifies and includes the date(s) (up to three) 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 comprehensive medication review," and if more than one comprehensive medication review occurred, includes the date of the first CMR.
	   ~~b. The number calculated for Data Element J should be equal to or a subset of the number of members offered a comprehensive medication review calculated for Data Element I.~~
	
	[Data Element~~s~~ ~~J~~M, N]

~~11~~	~~Organization accurately identifies data on MTM program participation for each member identified as being eligible for the MTM program and uploads it into the HPMS submission tool, including the following criteria:~~
	   ~~a. Each of the data elements requested in Section II is based on the same members counted for Data Element A.~~
	   ~~b. For Section II (g)/Field Name "LTC Enrollment": Properly identifies whether each member was a resident in a long-term care facility for the entire time s/he was enrolled in the MTM program during the reporting period or on the date the member opted out of MTM program enrollment.~~
	   ~~c. For Section II (i)/Field Name "Date of MTM Opt-out, if applicable": The date of MTM program opt-out, if applicable, is completed for the same members counted for Data Element B.~~
	   ~~d. For Section II (j)/Field Name "Reason Participant Opted-out of MTM, if applicable": The reason participant opted-out of the MTM program is completed for every member with a date of opt-out completed, and is completed for the same members counted for Data Elements C through F.~~

3.2 MEDICATION THERAPY MANAGEMENT (MTM) PROGRAMS

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

12 10	Organization accurately identifiescalculates data on MTM program interventions for each member identified as being eligible for the MTM program and uploads it into Gentran the HPMS submission tool, including the following criteria:

a. For Section II (k)/Field Name "Received annual comprehensive medication review": Properly identifies whether each member received an interactive, person-to-person comprehensive medication review during the reporting period, and completes this field for the same members counted for Data Element J.

b. For Section II (l)/Field Name "Date of annual comprehensive medication review, if applicable": The date the member received an interactive, person-to-personof comprehensive medication review, if applicable, occurs within the reporting period, is completed for every member with a "Y" entered for Section II (k)/Field Name "Received annual comprehensive medication review," and if more than one comprehensive medication review occurred, includes the date of the first CMR.

a. For Section II (m)/Field Name "Number of targeted medication reviews": Properly identifies and iIncludes all targeted medication reviews within the reporting period for each applicable member.

b. For Section II (n)/Field Name "Number of prescriber interventions": Properly identifies and iIncludes the number ofall prescriber interventions within the reporting period for each applicable member, regardless of the success or result of the intervention, and counts these interventions based on the number of unique interventions made to prescribers (e.g., the number is not equal to the total number of prescribers that received intervention recommendations from the organization). Organization does not count each individual problem identified per prescriber intervention (e.g., if the organization sent a prescriber a fax identifying 3 drug therapy problems for a member, this should beis reported as 1 intervention).

c. For Section II (o)/Field Name "Number of changes to drug therapy made as a result of MTM interventions": Properly identifies and iIncludes the number of all changes to drug therapy made as a result of MTM program interventions within the reporting period for each applicable member (includes, but is not limited to, dosage changes, therapeutic or generic substitutions, and discontinuation or addition of therapy). *Note to reviewer: If the change was observed in the calendar year after the current reporting period, but was the result of an MTM intervention and drug therapy recommendation made within the current reporting period, the change may be reported for the current reporting period. However, this change to drug therapy cannot be reported again in the following reporting period.*

[Data Elements O – Q]

3.3   GRIEVANCES (PART D)

Note to reviewer: Aggregate all quarterly data submitted within the reporting year 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 ~~and output~~ are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via ~~HPMS~~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~~if~~ 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 ~~appropriate~~ policies and procedures for data submission, including the following:
	    a. Data elements are accurately entered / uploaded into ~~the HPMS tool~~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 ~~HPMS~~CMS systems 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).

3.3 GRIEVANCES (PART D)

Note to reviewer: Aggregate all quarterly data submitted within the reporting year 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 2012 reported data)

1	Organization reports data based on the required reporting 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 and plan benefit package.
3	Organization meets deadlines for reporting quarterly data to CMS by 5/~~15~~31, 8/~~15~~31, 11/~~15~~30, and 2/~~15~~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~~.1~~ and 20~~.2~~. 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 the number of members who filed a grievance, including the following criteria:~~ ~~a. Includes all members who filed a grievance with a date of receipt that occurs during the reporting period.~~ ~~b. Properly sorts by member's low income subsidy (LIS) eligibility status as of the date the grievance was received. [Data Elements A and B]~~

	3.3 GRIEVANCES (PART D)
	Note to reviewer: Aggregate all quarterly data submitted within the reporting year 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~~5	Organization accurately calculates the total number of grievances, including the following criteria:
	    a. Includes all grievances with a date of decision that occurs ~~that were received~~ 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 ~~beneficiary~~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 ~~beneficiary~~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. ~~Includes only grievances that are filed directly with the organization (e.g., excludes all complaints that are received by 1-800 Medicare or are only forwarded to the organization from the CMS Complaint Tracking Module (CTM) and not filed directly with the organization).~~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 plan ID 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 ~~C and D~~A – H]

~~7~~	~~Organization accurately sorts all grievances received during the reporting period according to the member's LIS eligibility status on the date the grievance was received.~~
	    ~~a.~~ ~~The number calculated for Data Element C1 (Total number of grievances filed by LIS beneficiaries) should be at least equal to the number calculated for Data Element A (Number of LIS beneficiaries who filed grievances). Note to reviewer: If organization reports zero for Data Element A (Number of LIS beneficiaries who filed grievances), then it is appropriate to report zero for Data Element C1 (Total number of grievances filed by LIS beneficiaries).~~
	    ~~b.~~ ~~The number calculated for Data Element C3 (Total number of grievances filed by non-LIS beneficiaries) should be at least equal to the number calculated for Data Element B (Number of non-LIS beneficiaries who filed grievances). Note to reviewer: If organization reports zero for Data Element B (Number of non-LIS beneficiaries who filed grievances), then it is appropriate to report zero for Data Element C3 (Total number of grievances filed by non-LIS beneficiaries).~~
	    ~~c.~~ ~~The number calculated for Data Elements C1 + C3 (total number of grievances filed by LIS and non-LIS beneficiaries) should equal the total number of grievances by category calculated for Data Elements D1 (enrollment, plan benefits, or pharmacy access) + D3 (customer service) + D5 (coverage determinations/exceptions and appeals process) + D7 (other).~~
	   ~~[Data Element C]~~

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/Plan Benefits/Pharmacy Access; Customer Service; and Coverage determinations/Exceptions/Appeals Process (which includes expedited grievances (e.g., untimely decisions) and any grievance about the exceptions and appeals process).
	    b. Assigns all additional categories tracked by organization that are not listed above as Other.
	   [Data Elements A, C, E, G]

3.3 GRIEVANCES (PART D)

Note to reviewer: Aggregate all quarterly data submitted within the reporting year 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.

87	Organization accurately calculates the number of grievances which the Part D sponsor provided timely notification of the decision, including the following criteria: a. Includes only grievances for which the member is notified of decision according to the following timelines: ○ For standard grievances: no later than 30 days after receipt of grievance. ○ For standard grievances with an extension taken: no later than 44 days after receipt of grievance. ○ 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 ~~beneficiary status and~~ category. [Data Elements ~~C and D~~B, D, F, H]
~~9~~	~~Organization accurately calculates the number of grievances by category, including the following criteria:~~ ~~c. Properly sorts the total number of grievances by grievance category: Enrollment/Plan Benefits/Pharmacy Access; Customer Service; and Coverage determinations/Exceptions/Appeals Process (which includes expedited grievances (e.g., untimely decisions) and any grievance about the exceptions and appeals process).~~ ~~d. Assigns all additional categories tracked by organization that are not listed above as Other.~~ ~~[Data Element D]~~

3.4   COVERAGE DETERMINATIONS AND EXCEPTIONS

Note to reviewer: Aggregate all quarterly data submitted within the reporting year 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 ~~and output~~ are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via ~~HPMS~~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~~if~~ 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 ~~appropriate~~ policies and procedures for data submission, including the following:
	   a. Data elements are accurately entered / uploaded into ~~the HPMS tool~~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 ~~HPMS~~CMS systems 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).

3.4 COVERAGE DETERMINATIONS AND EXCEPTIONS

Note to reviewer: Aggregate all quarterly data submitted within the reporting year 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 2012 reported data)

1	Organization reports data based on the required reporting 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 and plan benefit package.
3	Organization meets deadlines for reporting quarterly data to CMS by 5/~~15~~31, 8/~~15~~31, 11/~~15~~30, and 2/~~15~~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-~~1~~ and 30-~~1~~. 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.

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 in-network and out-of-network transactions.~~
	    b. Includes transactions with a final disposition of reversed.
	    c. Excludes pharmacy transactions for drugs assigned to an excluded drug category.~~and enhanced alternative drugs~~.
	    d. If a prescription drug claim contains multiple transactions, each transaction is calculated as a separate pharmacy transaction.
	  [Data Element A]

6	Organization accurately calculates the number of pharmacy transactions rejected due to formulary restrictions, including the following criteria:
	    a. Includes rejections due to non-formulary status, prior authorization (PA) requirements, step therapy and quantity limits.
	    b. Excludes rejections due to early refill requests.
	    c. Includes all types of quantity limit 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).
	    d. If a prescription drug claim contains multiple rejections, each rejection is calculated as a separate pharmacy transaction.
	    e. Number calculated for Data Element B is a subset of the number of pharmacy transactions calculated for Data Element A.
	  [Data Element B]

	3.4 COVERAGE DETERMINATIONS AND EXCEPTIONS
	Note to reviewer: Aggregate all quarterly data submitted within the reporting year before applying the 90% threshold.
7	Organization accurately calculates the number of coverage determinations and exceptions (Part D only), including the following criteria: a. Includes all coverage determinations/exceptions with a date of ~~receipt~~ decision that occurs during the reporting period, regardless of when the ~~final decision was made~~ request for coverage determination or exception was received. b. Includes all methods of receipt (e.g., telephone, letter, fax, in-person). c. Includes all coverage determinations/exceptions regardless of who filed the request (e.g., ~~beneficiary~~member, appointed representative, or prescribing physician). d. Includes coverage determinations/exceptions from delegated entities. e. Includes both standard and expedited coverage determinations/exceptions. f. ~~Excludes coverage determinations/exceptions that were forwarded to the IRE because the organization failed to make a timely decision on a standard or expedited request.~~ f. Excludes requests for coverage determinations or exceptions that are withdrawn. g. Excludes coverage determinations/ exceptions regarding drugs assigned to an excluded drug category. ~~excluded drugs~~ h. Excludes ~~beneficiaries that~~members who have UM requirements waived based on an exception decision made in a previous plan year or reporting period~~are "grand fathered" on drugs, and thus have UM requirements waived~~. [Data Elements C – ~~J~~N]
8	Organization accurately calculates the total number of PA~~s~~ decisions made~~requested and approved~~, including the following criteria: a. ~~Data Element C: Includes all requests for a decision on whether a member has, or has not, satisfied a PA requirement.~~ a. Includes all decisions made (both favorable and unfavorable) on whether a member has, or has not, satisfied a PA requirement. b. ~~Data Element C:~~ Includes PA decisions~~requests~~ that relate to Part B versus Part D coverage (drugs covered under Part B are considered denials under Part D). c. Includes PA requests that were forwarded to the Independent Review Entity (IRE) because the organization failed to make a timely decision. d. Includes PA requests that were approved soon after the adjudication timeframes expired (i.e., within 24 hours) and were not auto-forwarded to the IRE. e. ~~Data Element C:~~ Excludes exception requests (i.e., requests for a decision where a member/ prescribing physician is seeking an exception to a PA or other UM requirement). d. ~~Data Element D: Includes all favorable decisions on requests for PAs.~~ e. ~~Number calculated for approved requests (Data Element D) is a subset of the number of requests calculated for Data Element C.~~ [Data Element~~s~~ C~~and D~~]

	3.4 COVERAGE DETERMINATIONS AND EXCEPTIONS
	Note to reviewer: Aggregate all quarterly data submitted within the reporting year before applying the 90% threshold.

9	Organization accurately calculates the number of PA decisions for which it provided a timely notification of the decision, including the following criteria:
	   a. Includes only PA determinations 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 PA requests that were forwarded to the IRE because the organization failed to make a timely decision.
	   d. Number calculated for timely PA decisions (Data Element D) is a subset of the number of PA decisions made (Data Element C).
	[Data Element D]

10	Organization accurately calculates the number of PA decisions made that were approved, including the following criteria:
	   a. Includes all favorable decisions on requests for PAs.
	   b. Excludes decisions that are only partially favorable.
	   c. Excludes decisions made by the IRE.
	   d. Number calculated for approved PA decisions (Data Element E) is a subset of the number of PA decisions made (Data Element C).
	[Data Element E]

~~9~~11	Organization accurately calculates the number of <u>decisions made on</u> exceptions to the organization's utilization management (UM) tools (PAs, quantity limits, step therapy requirements) ~~requested and approved~~, including the following criteria:
	   ~~a. Data Element E: Includes all requests for a decision where a member/prescribing physician is seeking an exception to a PA or other UM requirement (e.g., a physician indicates that the member would suffer adverse effects if he or she were required to satisfy the PA requirement).~~
	   a. <u>Includes all decisions made (both favorable and unfavorable) where a member/prescribing physician is seeking an exception to a PA or other UM requirement (e.g., a physician indicates that the member would suffer adverse effects if he or she were required to satisfy the PA requirement).</u>
	   b. ~~Data Element E:~~ Excludes PA requests (i.e., requests for a decision on whether a member has, or has not, satisfied a PA requirement).
	   c. <u>Includes UM exception requests that were forwarded to the Independent Review Entity (IRE) because the organization failed to make a timely decision.</u>
	   d. <u>Includes UM exception requests that were approved soon after the adjudication timeframes expired (i.e., within 24 hours) and were not auto-forwarded to the IRE.</u>
	   ~~c. Data Element F: Includes all favorable decisions on requests for exceptions to the organization's UM tools.~~
	   ~~d. Number calculated for approved requests (Data Element F) is a subset of the number of decisions calculated for Data Element E.~~
	[Data Element~~s E and~~ F]

	3.4 COVERAGE DETERMINATIONS AND EXCEPTIONS
	Note to reviewer: Aggregate all quarterly data submitted within the reporting year before applying the 90% threshold.

12	Organization accurately calculates the number of UM exception decisions for which it provided a timely notification of the decision, including the following criteria:
	a. Includes only exception decisions for which the member (and the prescribing physician or other prescriber involved, as appropriate) is notified of the decision according to the following timelines:
	    o For standard exceptions: as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement.
	    o For expedited exceptions: as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the physician's or other prescriber's supporting statement.
	b. Excludes favorable exception decisions in which the organization did not authorize or provide the benefit or payment under dispute according to the following timelines:
	    o For standard exceptions: as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement.
	    o For expedited exceptions: as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the physician's or other prescriber's supporting statement.
	c. Excludes exception requests that were forwarded to the IRE because the organization failed to make a timely decision.
	d. Number calculated for timely exception decisions (Data Element G) is a subset of the number of exception decisions made (Data Element F).
	[Data Element G]

13	Organization accurately calculates the number of UM exception decisions made that were approved, including the following criteria: a. Includes all favorable decisions on requests for exceptions to the organization's UM tools. b. Excludes decisions that are only partially favorable. c. Excludes decisions made by the IRE. d. Number calculated for favorable UM exception decisions (Data Element H) is a subset of the number of UM exception decisions made (Data Element F). [Data Element H]
~~10~~ 14	Organization accurately calculates the number of decisions made on tier exceptions ~~requested and approved~~, including the following criteria: a. ~~Data Element G:~~ Includes all ~~requests for a~~ decisions (both favorable and unfavorable) on whether to permit a member to obtain a non-preferred drug at the more favorable cost-sharing terms applicable to drugs in the preferred tier. b. Includes tier exception requests that were forwarded to the Independent Review Entity (IRE) because the organization failed to make a timely decision. c. Includes tier exception requests that were approved soon after the adjudication timeframes expired (i.e., within 24 hours) and were not auto-forwarded to the IRE. ~~b. Data Element H: Includes all favorable decisions on requests for tier exceptions.~~ ~~c. Number calculated for approved requests (Data Element H) is a subset of the number of requests calculated for Data Element G.~~ [Data Element~~s [G and~~ H]

3.4 COVERAGE DETERMINATIONS AND EXCEPTIONS	
Note to reviewer: Aggregate all quarterly data submitted within the reporting year before applying the 90% threshold.	

15	Organization accurately calculates the number of tier exception decisions for which it provided a timely notification of the decision, including the following criteria:
	  a. Includes only exception decisions for which the member (and the prescribing physician or other prescriber involved, as appropriate) is notified of the decision according to the following timelines:
	    o For standard exceptions: as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement.
	    o For expedited exceptions: as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the physician's or other prescriber's supporting statement.
	  b. Excludes favorable exception decisions in which the organization did not authorize or provide the benefit or payment under dispute according to the following timelines:
	    o For standard exceptions: as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement.
	    o For expedited exceptions: as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the physician's or other prescriber's supporting statement.
	  c. Excludes exceptions requests that were forwarded to the IRE because the organization failed to make a timely decision.
	  d. Number calculated for timely exception decisions (Data Element J) is a subset of the number of exception decisions made (Data Element I).
	[Data Element J]

16	Organization accurately calculates the number of tier exception decisions made that were approved, including the following criteria:
	  a. Includes all favorable decisions on requests for tier exceptions.
	  b. Excludes decisions that are only partially favorable.
	  c. Excludes decisions made by the IRE.
	  d. Number calculated for favorable tier exception decisions (Data Element K) is a subset of the number tier exception decisions (Data Element I).
	[Data Element K]

~~11~~ 17	Organization accurately calculates the number of decisions made on formulary exceptions ~~for non-formulary medications requested and approved~~, including the following criteria:
	  a. ~~Data Element I:~~ Includes all ~~requests for a~~ decisions (both favorable and unfavorable) on whether to permit a member to obtain a Part D drug that is not included on the formulary.
	  b. Includes formulary exception requests that were forwarded to the Independent Review Entity (IRE) because the organization failed to make a timely decision.
	  c. Includes formulary exception requests that were approved soon after the adjudication timeframes expired (i.e., within 24 hours) and were not auto-forwarded to the IRE.
	  ~~b. Data Element J: Includes all favorable decisions on requests for non-formulary medications.~~
	  ~~c. Number calculated for approved requests (Data Element J) is a subset of the number of requests calculated for Data Element I.~~
	[Data Element~~s~~ L~~I and J~~]

3.4 COVERAGE DETERMINATIONS AND EXCEPTIONS

Note to reviewer: Aggregate all quarterly data submitted within the reporting year before applying the 90% threshold.

18	Organization accurately calculates the number of formulary exception decisions for which it provided a timely notification of the decision, including the following criteria:
	a. Includes only exception decisions for which the member (and the prescribing physician or other prescriber involved, as appropriate) is notified of the decision according to the following timelines:
	   o For standard exceptions: as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement.
	   o For expedited exceptions: as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the physician's or other prescriber's supporting statement.
	b. Excludes favorable exception decisions in which the organization did not authorize or provide the benefit or payment under dispute according to the following timelines:
	   o For standard exceptions: as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement.
	   o For expedited exceptions: as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the physician's or other prescriber's supporting statement.
	c. Excludes exceptions requests that were forwarded to the IRE because the organization failed to make a timely decision.
	d. Number calculated for timely exception decisions (Data Element M) is a subset of the number of exception decisions made (Data Element L).
	[Data Element M]

19	Organization accurately calculates the number of formulary exception decisions made that were approved, including the following criteria: a. Includes all favorable decisions on requests for non-formulary medications. b. Excludes decisions that are only partially favorable. c. Excludes decisions made by the IRE. d. Number calculated for favorable formulary exception decisions (Data Element N) is a subset of the number of formulary exception decisions (Data Element L). [Data Element N]

3.5 ~~APPEALS~~ REDETERMINATIONS

Note to reviewer: Aggregate all quarterly data submitted within the reporting year before applying the 90% threshold.

To determine compliance with the standards for Appeals, 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~~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~~if~~ 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 ~~appropriate~~ policies and procedures for data submission, including the following:
	    a. Data elements are accurately entered / uploaded into ~~the HPMS tool~~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 ~~HPMS~~CMS systems 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).

	3.5 ~~APPEALS~~ REDETERMINATIONS
	Note to reviewer: Aggregate all quarterly data submitted within the reporting year 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 2012 reported data)	
1	Organization reports data based on the required reporting 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 and plan benefit package.
3	Organization meets deadlines for reporting quarterly data to CMS by 5/~~15~~31, 8/~~15~~31, 11/~~15~~30, and 2/~~15~~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 "~~Appeal~~Redetermination" in accordance with Title ~~1~~42, Part 423, Subpart ~~B~~MM §423.560, §423.580, §423.582, §423.584, and §423.590 and the Prescription Drug Benefit Manual Chapter 18, Section 10~~.1~~, 70, and 130. This includes applying all relevant guidance properly when performing its calculations and categorizations.

5	Organization accurately calculates the total number of redeterminations (Part D only), including the following criteria:
	    a. Includes all redetermination~~s~~ 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. ~~reviews of partially favorable and adverse coverage determinations.~~
	    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. If a redetermination request contains multiple distinct disputes (i.e., multiple drugs), each dispute is calculated as a separate redetermination.
	    h. Excludes dismissals or withdrawals.
	    i. Excludes IRE decisions, as they are considered to be the second level of appeal.
	    j. Excludes redeterminations regarding excluded drugs.
	    k. ~~Correctly defines appeals, and l~~Limits reporting ~~to just the first level of appeals (redeterminations) done by the plan~~just the redetermination level.
	 [Data Element A]

3.5 ~~APPEALS~~ REDETERMINATIONS *Note to reviewer: Aggregate all quarterly data submitted within the reporting year before applying the 90% threshold.*

<u>6</u>	<u>Organization accurately calculates the number of redeterminations for which the Part D sponsor provided timely notification of the decision, including the following criteria:</u>
	    a. <u>Includes only redeterminations for which the member is notified of the decision according to the following timelines:</u>
	        o <u>For standard redeterminations: no later than 7 calendar days after receipt of the request.</u>
	        o <u>For expedited redeterminations: no later than 72 hours after receipt of the request.</u>
	    b. <u>Excludes approvals in which the sponsor did not authorize or provide the benefit or payment under dispute according to the following timelines:</u>
	        o <u>For standard redeterminations: no later than 7 calendar days after receipt of the request.</u>
	        o <u>For expedited redeterminations: no later than 72 hours after receipt of the request.</u>
	    c. <u>Excludes redeterminations that were forwarded to the IRE because the organization failed to make a timely decision.</u>
	    d. <u>The number calculated for Data Element B is a subset of the total number of redeterminations calculated for Data Element A.</u>
	<u>[Data Element B]</u>

~~6~~<u>7</u>	Organization accurately calculates the number of redeterminations by final decision, including the following criteria:
	    a. Properly ~~sorts~~<u>categorizes</u> the total number of redeterminations by final decision: <u>partially favorable (e.g., denial with a "part" that has been approved) and fully favorable (e.g., fully favorable decision reversing the original coverage determination).</u> ~~Full Reversal (e.g., fully favorable decision reversing the original coverage determination) and Partial Reversal (e.g., denial with a "part" that has been approved).~~
	    b. Each number calculated for Data Elements ~~B and C~~<u>C and D</u> is a subset of the total number of redeterminations calculated for Data Element A.
	    c. <u>Excludes redetermination decisions made by the IRE.</u>
	[Data Elements ~~B and C~~<u>C, D</u>]

3.6   LONG-TERM CARE UTILIZATION

Note to reviewer: This reporting section applies to data reported in 2011 and 2012.

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 ~~and output~~ are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via ~~HPMS~~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~~if~~ 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 ~~appropriate~~ policies and procedures for data submission, including the following:
	a. Data elements are accurately entered / uploaded into ~~the HPMS tool~~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 ~~HPMS~~CMS systems are archived.
4	Organization implements ~~appropriate~~ policies and procedures for periodic data system updates (e.g., changes in enrollment, provider/pharmacy status, claims adjustments).

3.6   LONG-TERM CARE UTILIZATION

Note to reviewer: This reporting section applies to data reported in 2011 and 2012.

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 ~~appropriate~~ policies and procedures for archiving and restoring data in each data system (e.g., disaster recovery plan).
6	*If organization's data systems underwent any changes during the reporting period (e.g., as a result of a merger, acquisition, or upgrade):* Organization provided documentation on the data system changes and, upon review, there were no issues that adversely impacted data reported.
7	*If data collection and/or reporting for this 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 2011 and 2012 reported data)

1	Organization reports data based on the required reporting period of 1/1 through 12/31 for 2011 reported data and the periods of 1/1 through 6/30 and 7/1 through 12/31 for 2012 reported data.
2	Organization properly assigns data to the applicable CMS contract.
3	Organization meets deadline for reporting annual data to CMS by 6/30 for 2011 reported data and for reporting biannual data to CMS by 8/31 and 2/28 for 2012 reported data. *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 ~~by state~~at the state level for PDPs and RPPOs, and ~~by service area for MA-PDs.~~at the contract level for MA-PDs.
	    b. Includes any LTC pharmacy that is active in the network for one (1) or more days in the reporting period.
	    c. Includes LTC pharmacies that do not have utilization.
	    d. Includes LTC pharmacies holding license for the state(s) in the sponsor's service area, including those without a physical location/address in the service area.
	 [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 ~~by state~~at the state level for PDPs and RPPOs, and ~~by service area for MA-PDs.~~at the contract level for MA-PDs.
	    b. Includes any retail pharmacy that is active in the network 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, including the following criteria:
	    a. Includes the number of members at the state level for PDPs and RPPOs, and at the contract level for MA-PDs.
	    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 ~~location~~patient residence code 03 or the LTI report may be used to identify applicable members. ~~Claims with location code 04 or 07 should not be included.~~*
	 [Data Element C]

3.6 LONG-TERM CARE UTILIZATION

Note to reviewer: This reporting section applies to data reported in 2011 and 2012.

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 ~~following~~ data below for each network LTC pharmacy in the service area and uploads it into the HPMS submission tool~~:~~.
	    a. PDPs, RPPOs, and MA-PDs report for the entire service area.
	    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 for one or more days in the reporting period.
	    d. Includes LTC pharmacies holding a license for the state(s) in the sponsor's service area, including those without a physical location/address in the service area.
	    e. Includes LTC pharmacies that do not have utilization (zeroes are entered for number and cost of prescriptions).
	    f. 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. PDPs, RPPOs, and MA-PDs report for the entire service area.
	    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 ~~drug claims~~prescriptions dispensed with a fill date (not batch date) that falls within the reporting period.
	    e. Includes LTC pharmacies holding a license for the state(s) in the sponsor's service area, including those without a physical location/address in the service area.
	    f. Includes LTC pharmacies that do not have utilization (zeroes are entered for number and cost of prescriptions).
	    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. PDPs, RPPOs, and MA-PDs report for the entire service area.
	    b. Prescription cost is the sum of the ingredient cost, dispensing fee, ~~and~~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 ~~drug claims~~prescriptions dispensed with a fill date (not batch date) that falls within the reporting period.
	    f. Includes LTC pharmacies holding a license for the state(s) in the sponsor's service area, including those without a physical location/address in the service area.
	    g. Includes LTC pharmacies that do not have utilization (zeroes are entered for number and cost of prescriptions).
	    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]

3.6   LONG-TERM CARE UTILIZATION

Note to reviewer: This reporting section applies to data reported in 2011 and 2012.

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. PDPs, and RPPOs report at the state level; and MA-PDs 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 drug claimsprescriptions 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 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. PDPs, and RPPOs report at the state level; MA-PDs report at the contract level.
	b. Prescription cost is the sum of the ingredient cost, dispensing fee, and 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 drug claimsprescriptions 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 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]

3.7 EMPLOYER/UNION-SPONSORED GROUP HEALTH PLAN SPONSORS

Note to reviewer: If the Part D sponsor also has one or more MA-PD contracts for which it reported data under the Part C Employer Group Plan Sponsors data measure, then it is not required to report this data measure for its PDP (S contracts) and data validation is not required for this measure. Additionally, Part D sponsors with only employer group contracts are not required to report this data measure and data validation is not required for this measure.

To determine compliance with the standards for Employer/Union-Sponsored Group Health Plan Sponsors, 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
- 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).

3.7 ~~EMPLOYER/UNION-SPONSORED GROUP HEALTH PLAN SPONSORS~~ Note to reviewer: If the Part D sponsor also has one or more MA-PD contracts for which it reported data under the Part C Employer Group Plan Sponsors data measure, then it is not required to report this data measure for its PDP (S contracts) and data validation is not required for this measure. Additionally, Part D sponsors with only employer group contracts are not required to report this data measure and data validation is not required for this measure.	
~~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.
~~MEASURE-SPECIFIC CRITERIA (for 2011 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 and 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 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 identifies data on each employer/union-sponsored group health plan and uploads it into the HPMS submission tool, including the following criteria: a. Includes the following information for each plan benefit package reported: Employer Legal Name; Employer DBA Name; Employer Federal Tax ID; Employer Address; Type of Group Sponsor (employer, union, trustees of a fund); Organization Type (State Government, Local Government, Publicly Traded Organization, Privately Held Corporation, Non-Profit, Church Group, Other); Type of Contract (insured, ASO, other); Employer Plan Year Start Date; and Current/Anticipated Enrollment. b. Follows the specified file format provided by CMS in the *Part D Reporting Requirements Technical Specifications* Document. [Data Elements A – I]
~~5~~	The organization's "Employer Address" data field accurately reflects the employer's headquarters address. [Data Element D]
~~6~~	The organization's "Organization Type" data field accurately reflects data based on how the organization files its taxes. [Data Element F]
~~7~~	The organization's "Type of Contract" data field accurately captures the type of contract that the organization holds with the employer group that binds it to offer benefits to group retirees. [Data Element G]
~~8~~	The organization's "Employer Plan Year Start Date" data field accurately reflects the month and year in which the employer's benefit year with the plan begins. [Data Element H]
~~9~~	The organization accurately calculates the number of currently enrolled members, including the following criteria: a. Includes all enrollments from a particular employer group into the specific PBP. b. Includes all members that are enrolled in the employer group plan as of the last day of the reporting period. c. Enrollment number for contracts that were cancelled during the reporting period is reported as zero. [Data Element I]

3.8   PLAN OVERSIGHT OF AGENTS (PART D)

Note to reviewer: If the Part D sponsor also has one or more MA-PD contracts for which it reported data under the Part C Plan Oversight of Agents reporting section, then it is not required to report this data for its PDP (S contracts) and data validation is not required for this reporting section.

Note to reviewer: 800 series plans and employer/union group contracts are not required to report this data. For contracts with both non-800 series and 800-series plans, data for the 800-series plan(s) may be excluded.

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 reporting section, 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~~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~~if~~ 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.

3.8   PLAN OVERSIGHT OF AGENTS (PART D)

Note to reviewer: If the Part D sponsor also has one or more MA-PD contracts for which it reported data under the Part C Plan Oversight of Agents reporting section, then it is not required to report this data for its PDP (S contracts) and data validation is not required for this reporting section.

Note to reviewer: 800 series plans and employer/union group contracts are not required to report this data. For contracts with both non-800 series and 800-series plans, data for the 800-series plan(s) may be excluded.

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 reporting section, and data validation is not required.

3	Organization implements ~~appropriate~~ policies and procedures for data submission, including the following: a. Data elements are accurately entered / uploaded into ~~the HPMS tool~~CMS systems and entries match corresponding source documents. b. All source, intermediate, and final stage data sets <u>and other outputs</u> relied upon to enter data into ~~HPMS~~CMS systems 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).
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 2012 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 criteria for this reporting section.*
4	Organization accurately calculates the total number of agents who are licensed to sell on behalf of the Parent Organization during the applicable reporting period, including the following criteria: a. Includes all direct employees of the Part D sponsor who were licensed to sell on behalf of the Parent Organization, regardless of whether or not the agent was actively selling during the reporting period. b. Includes all licensed agents who are under a contractual agreement to sell on behalf of the Parent Organization, regardless of whether or not the agent was actively selling during the reporting period. *Note to reviewer: If the organization has multiple contracts, it should report the same number of agents for Data Element A for each contract, since this number is based on the Parent Organization.* [Data Element A]

3.8 PLAN OVERSIGHT OF AGENTS (PART D)

Note to reviewer: If the Part D sponsor also has one or more MA-PD contracts for which it reported data under the Part C Plan Oversight of Agents reporting section, then it is not required to report this data for its PDP (S contracts) and data validation is not required for this reporting section.

Note to reviewer: 800 series plans and employer/union group contracts are not required to report this data. For contracts with both non-800 series and 800-series plans, data for the 800-series plan(s) may be excluded.

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 reporting section, and data validation is not required.

5	Organization accurately calculates the number of agents investigated based on complaints, including the following criteria:
	a. Includes all agents with investigations that were completed during the applicable reporting period, regardless of when the complaint was received and whether the member remained enrolled, disenrolled, or declined enrollment during the enrollment process.
	b. Includes agents with investigations based on complaints filed directly with the organization as well as those from the HPMS Complaint Tracking Module (CTM).
	c. Includes all agents with investigations based on complaints against the agent under the applicable contract. If a complaint cannot be tied to a specific contract, then the complaint is included under all contracts that the agent is licensed to sell.
	d. Excludes investigations in which the member or agent could be not contacted.
	e. The number calculated for Data Element B is a subset of the total number of agents calculated for Data Element A.
	[Data Element B]
6	Organization accurately calculates the number of agents receiving disciplinary action resulting from a complaint filed against an agent, including the following criteria:
	a. Includes all agents with disciplinary actions that were taken during the applicable reporting period, regardless of when the complaint was received.
	b. Includes any agents with disciplinary action taken by the Part D sponsor, including manager-coaching, documented verbal warning, re-training, documented corrective action plan, suspension, termination of employment/contract, and short-term revocation.
	c. Includes agents with disciplinary actions based on complaints filed directly with the organization as well as those from the HPMS Complaint Tracking Module (CTM).
	d. Includes all agents with disciplinary actions based on complaints against the agent under the applicable contract. If a complaint cannot be tied to a specific contract, then the disciplinary action is included under all contracts that the agent is licensed to sell.
	e. The number calculated for Data Element C is a subset of the total number of agents calculated for Data Element B.
	[Data Element C]
7	Organization accurately calculates the number of complaints filed against an agent that the Part D sponsor reported to the governing State, including the following criteria:
	a. Includes all complaints against a contracted agent received and reported to the State during the applicable reporting period.
	b. Includes only complaints 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).
	c. Includes all complaints against an agent and reported to the governing State under the applicable plan contract. If a complaint that is reported to the governing State cannot be tied to a specific contract, then the complaint is included under all contracts that the agent is licensed to sell.
	Note to reviewer: If organization does not voluntarily report complaints against a contracted agent to the State, then it is appropriate to report a zero for this data element.
	[Data Element D]

3.8   PLAN OVERSIGHT OF AGENTS (PART D)

Note to reviewer: If the Part D sponsor also has one or more MA-PD contracts for which it reported data under the Part C Plan Oversight of Agents reporting section, then it is not required to report this data for its PDP (S contracts) and data validation is not required for this reporting section.

Note to reviewer: 800 series plans and employer/union group contracts are not required to report this data. For contracts with both non-800 series and 800-series plans, data for the 800-series plan(s) may be excluded.

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 reporting section, and data validation is not required.

8	Organization accurately calculates the number of agents whose selling privileges were revoked by the organization based on conduct or discipline, including the following criteria:
	   a. Includes all agents with revocations initiated during the applicable reporting period, regardless of when the conduct causing the revocation occurred.
	   b. The number calculated for Data Element E is a subset of the total number of agents calculated for Data Element A.
	 [Data Element E]

9	Organization accurately calculates the number of "agent assisted enrollments" during the applicable reporting period, including the following criteria:
	   a. Includes all agent assisted enrollments that became effective during the reporting period, but excludes cancelled enrollments.
	   b. Defines "agent assisted enrollments" as enrollments involving member who used a licensed agent that is compensated (employee or independent) to complete the enrollment process (e.g., includes enrollments completed through a call center staffed by licensed agents, in person sales appointments, and public sales meetings where a licensed agent collects enrollment forms).
	   c. Includes agent assisted enrollments from both the individual and group enrollment process.
	   d. Includes enrollments that are as a direct result of the participation of the group of agents reported in Data Element A.
	   e. Excludes agent-assisted enrollments that involve only a member's change from one benefit package to another within the same contract.
	 [Data Element F]

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
ESRD	End Stage Renal Disease
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
PCP	Primary Care Physician
PDP	Prescription Drug Plan
POA	Present on Admission
PTCA	Percutaneous Transluminal Coronary Angioplasty
QA	Quality Assurance
QIO	Quality Improvement Organization
RPPO	Regional Preferred Provider Organization
Rx	Prescription
SNF	Skilled Nursing Facility
SNP	Special Needs Plan
SRAE	Serious Reportable Adverse Event
SSI	Surgical Site Infections
TBD	To Be Determined
TMR	Targeted Medication Review
UM	Utilization Management
UTI	Urinary Tract Infection