APPENDIX 3: Medicare Part C and Part D Measure Data Validation Standards

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DRAFT

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1.0 OVERVIEW

The Data Validation Standards include general standards and measure-specific criteria that the data validation contractor (reviewer) will 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 measure'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 measure), and measure-specific criteria that are based on the applicable Part C/Part D Reporting Requirements.

The reviewer must use these standards in conjunction with the Data Extraction and Sampling Instructions for Data Validation Contractors and the Findings Data Collection Form for Data Validation Contractors to evaluate the organization's processes for producing and reporting the measures. 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 measure to ensure that all applicable data fields are extracted for each measure. Upon review of the information and documentation provided by the organization and completion of the review, the reviewer will determine compliance with each of the standards and, using the Findings Data Collection Form, record the appropriate finding to each standard and criteria.

2.0 PART C DATA VALIDATION STANDARDS

2.1 BENEFIT UTILIZATION

To determine compliance with the standards for Benefit 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. 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 into the HPMS tool and entries match corresponding source documents. b. Data files are properly uploaded into HPMS according to any HPMS templates provided. c. 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 significantly impacted data reported.
7	*If data collection, validation, and/or reporting for this data measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected, validated, and/or reported by the delegated entity or first tier/downstream contractor.
MEASURE-SPECIFIC CRITERIA Note: Columns referenced below correspond to the HPMS Upload Table provided in Appendix 1 of the Medicare Part C Plan Reporting Requirements Technical Specifications Document.	
1	Organization reports data based on the required reporting period of 1/1 through 12/31 and includes claims paid through 6/30 of the following year.
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 8/31.
4	Organization accurately maps Plan Benefit Package (PBP) Service Category services to the Corresponding MA Medical Utilization and Expenditure Experience Category per the chart provided in Appendix 3 of the Medicare Part C Plan Reporting Requirements Technical Specifications Document, and includes all Part B services excluded from the other benefit categories in the "Other Medicare Part B" Service Category.
5	Organization accurately calculates the number of members with access to services, including the following criteria: a. Includes members who were enrolled for at least one month during the reporting period. b. Includes members who had access to each of the following services: Inpatient Facility; Skilled Nursing Facility; Home Health; Ambulance; DME/Prosthetics/Supplies; OP Facility-Emergency; OP Facility-Surgery; OP Facility-Other; Professional; Part B Rx; Other Medicare Part B; Transportation (Non-Covered); Dental (Non-Covered); Vision (Non-Covered); Hearing (Non-Covered); Health & Education (Non-Covered); Other (Non-Covered); and Medical. [Data Elements 1.3, 1.11, 1.19, 1.27, 1.35, 1.43, 1.51, 1.59, 1.67, 1.75, 1.83, 1.91, 1.97, 1.103, 1.109, 1.115, 1.121, 1.127 for reporting in Column C]
6	Organization accurately calculates member utilization of benefits, including the following criteria: a. Includes unique members that incurred a service in the specified category for each of the following services during the reporting period: Inpatient Facility; Skilled Nursing Facility; Home Health; Ambulance; DME/Prosthetics/Supplies; OP Facility-Emergency; OP Facility-Surgery; OP Facility-Other; Professional; Part B Rx; Other Medicare Part B; Transportation (Non-Covered); Dental (Non-Covered); Vision (Non-Covered); Hearing (Non-Covered); Health & Education (Non-Covered); Other (Non-Covered); and Medical. [Data Elements 1.4, 1.12, 1.20, 1.28, 1.36, 1.44, 1.52, 1.60, 1.68, 1.76, 1.84, 1.92, 1.98, 1.104, 1.110, 1.116, 1.122, 1.128] b. Correctly selects the appropriate code to identify how the organization captures utilization data for each service listed above. *Note to reviewer: The organization may determine which utilization type to use when categorizing services, but it must assign a consistent "utilization type" for each service category.* [Data Elements 1.5, 1.13, 1.21, 1.29, 1.37, 1.45, 1.53, 1.61, 1.69, 1.77, 1.85, 1.93, 1.99, 1.105, 1.111, 1.117, 1.123] c. Correctly sums the total utilization of each service listed above by calculating the total number of services used by members during the reporting period. [Data Elements 1.6, 1.14, 1.22, 1.30, 1.38, 1.46, 1.54, 1.62, 1.70, 1.78, 1.86, 1.94, 1.100, 1.106, 1.112, 1.118, 1.124] [For reporting in Columns D – F]
7	Organization accurately calculates the amounts of plan reimbursement, including the following criteria: a. Correctly sums the total amount reimbursed from the plan to providers during the reporting period for each of the following services: Inpatient Facility; Skilled Nursing Facility; Home Health; Ambulance; DME/Prosthetics/Supplies; OP Facility-Emergency; OP Facility-Surgery; OP Facility-Other; Professional; Part B Rx; Other Medicare Part B; Transportation (Non-Covered); Dental (Non-Covered); Vision (Non-Covered); Hearing (Non-Covered); Health & Education (Non-Covered); Other (Non-Covered); and Medical. b. Includes all benefits paid for whether they are covered by Medicare or not. c. Includes all benefits paid for with federal funding, state funding, group sponsor funding, and member premiums. d. Includes all benefits furnished during the reporting period, regardless of their representation in the approved bid. e. Includes benefits regardless of a member's ESRD status. [Data Elements 1.7, 1.15, 1.23, 1.31, 1.39, 1.47, 1.55, 1.63, 1.71, 1.79, 1.87, 1.95, 1.101, 1.107, 1.113, 1.119, 1.125, 1.129 for reporting in Column G]

8	Organization accurately calculates the amounts of member cost sharing, including the following criteria: a. Includes only cost sharing liability of the member (which may or may not be paid in full), and not the amount charged by the provider. b. Correctly sums the total cost-sharing amount that members paid directly to providers during the reporting period for each of the following services: Inpatient Facility; Skilled Nursing Facility; Home Health; Ambulance; DME/Prosthetics/Supplies; OP Facility-Emergency; OP Facility-Surgery; OP Facility-Other; Professional; Part B Rx; Other Medicare Part B; Transportation (Non-Covered); Dental (Non-Covered); Vision (Non-Covered); Hearing (Non-Covered); Health & Education (Non-Covered); Other (Non-Covered); and Medical. c. Includes all benefits paid for whether they are covered by Medicare or not. d. Includes all benefits paid for with federal funding, state funding, group sponsor funding, and member premiums. e. Includes all benefits furnished during the reporting period, regardless of their representation in the approved bid. f. Includes benefits regardless of a member's ESRD status. *Note to reviewer:* The organization must provide the reviewer and CMS with a brief narrative explaining how the cost-sharing amounts are derived. [Data Elements 1.8, 1.16, 1.24, 1.32, 1.40, 1.48, 1.56, 1.64, 1.72, 1.80, 1.88, 1.96, 1.102, 1.108, 1.114, 1.120, 1.126, 1.130 for reporting in Column H]
9	Organization accurately calculates the amounts of total payments to providers for Medicare covered services, including the following criteria: a. Correctly sums the total payments made to providers during the reporting period for services covered under original Medicare for each of the following services: Inpatient Facility; Skilled Nursing Facility; Home Health; Ambulance; DME/Prosthetics/Supplies; OP Facility-Emergency; OP Facility-Surgery; OP Facility-Other; Professional; Part B Rx; Other Medicare Part B; and Medical. [Data Elements 1.9, 1.17, 1.25, 1.33, 1.41, 1.49, 1.57, 1.65, 1.73, 1.81, 1.89, 1.131] b. Number calculated for total payments for each of the following non-covered services must be $0: Transportation (Non-Covered); Dental (Non-Covered); Vision (Non-Covered); Hearing (Non-Covered); Health & Education (Non-Covered); and Other (Non-Covered). *Note to reviewer:* The organization must provide the reviewer and CMS with a brief narrative explaining how the payment amounts for Medicare-covered services are derived. [For reporting in Column J]
10	Organization accurately calculates the amounts of Medicare actuarial equivalent (cost-sharing), including the following criteria: a. Uses appropriate actuarial equivalent factors (as based on the 2010 bid pricing tool) to calculate the cost sharing that would be required for covered services using original Medicare requirements for each of the following services: Inpatient Facility; Skilled Nursing Facility; Home Health; Ambulance; DME/Prosthetics/Supplies; OP Facility-Emergency; OP Facility-Surgery; OP Facility-Other; Professional; Part B Rx; Other Medicare Part B; and Medical. [Data Elements 1.10, 1.18, 1.26, 1.34, 1.42, 1.50, 1.58, 1.66, 1.74, 1.82, 1.90, 1.132] b. Number calculated for actuarial equivalent (cost-sharing) for each of the following non-covered services must be $0: Transportation (Non-Covered); Dental (Non-Covered); Vision (Non-Covered); Hearing (Non-Covered); Health & Education (Non-Covered); and Other (Non-Covered). *Note to reviewer:* The organization must provide the reviewer and CMS with a brief narrative explaining how the Medicare actuarial equivalent amounts are derived. [For reporting in Column L]
11	Organization accurately calculates the total number of members, including the following criteria: a. Includes all members who were enrolled for at least one month during the reporting period. [Data Element 1.133]
12	Organization accurately calculates the number of member months during the reporting period. a. Includes all plan members whether they used a service or not. [Data Element 1.134]
13	Organization accurately calculates the amount of premiums collected, including the following criteria: a. Includes all premium payments during the reporting period from members (regardless of ESRD status), employer/union groups, State Medicaid agencies, and other third parties. [Data Element 1.135]

14	Organization accurately calculates the amount of CMS revenue collected, including the following criteria: a. Includes all revenue received from CMS under the contract during the reporting period. b. Includes rebates applied to Part A and Part B services. c. Includes amounts received from CMS from final risk adjustment settlement to be included in the August MMR. [Data Element 1.136]
15	Organization accurately calculates the amount of CMS rebates for Part A and Part B services, including the following criteria: a. Includes all CMS rebates for Part A and Part B services and additional non-prescription drug benefits collected under the contract during the reporting period. b. Excludes rebates designated to reduce Part B and Part D premiums. [Data Element 1.137]
16	Organization accurately calculates the amount of reserves for outstanding claims, including the following criteria: a. Includes all reserves for outstanding claims from the reporting period. b. Includes claims that have not been submitted to the organization and claims that have been received but not yet processed. [Data Element 1.138]

2.2 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. <u>Criteria for Validating Source Documents:</u> 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. <u>Criteria for Validating Measure-Specific Criteria (Refer to measure-specific criteria section below):</u> a. The appropriate date range(s) for the reporting period(s) is captured. b. Data are assigned at the applicable level (e.g., plan benefit package or contract level). c. Appropriate deadlines are met for reporting data (e.g., quarterly). d. Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications. e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.
3	Organization implements appropriate policies and procedures for data submission, including the following: a. Data elements are accurately entered into the HPMS tool and entries match corresponding source documents. b. Data files are properly uploaded into HPMS according to any HPMS templates provided. c. 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 significantly impacted data reported.
7	*If data collection, validation, and/or reporting for this data measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected, validated, and/or reported by the delegated entity or first tier/downstream contractor.
MEASURE-SPECIFIC CRITERIA	
1	Organization reports data based on the required reporting period of 1/1 through 12/31.
2	Organization properly assigns data to the applicable CMS contract.
3	Organization meets deadline for reporting annual data to CMS by 5/31 and (for organizations that submit HEDIS data) reports applicable procedure frequency data elements in accordance with NCQA's timetable for data submission.
4	Organization accurately calculates the number of members receiving the specified procedures, including the following criteria: a. Includes all members that received 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 2.19 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]

2.3 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. <u>Criteria for Validating Source Documents:</u> 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. <u>Criteria for Validating Measure-Specific Criteria (Refer to measure-specific criteria section below):</u> a. The appropriate date range(s) for the reporting period(s) is captured. b. Data are assigned at the applicable level (e.g., plan benefit package or contract level). c. Appropriate deadlines are met for reporting data (e.g., quarterly). d. Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications. e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.
3	Organization implements appropriate policies and procedures for data submission, including the following: a. Data elements are accurately entered into the HPMS tool and entries match corresponding source documents. b. Data files are properly uploaded into HPMS according to any HPMS templates provided. c. 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 significantly impacted data reported.

7	*If data collection, validation, and/or reporting for this data measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected, validated, and/or reported by the delegated entity or first tier/downstream contractor.
MEASURE-SPECIFIC CRITERIA	
1	Organization reports data based on the required reporting period of 1/1 through 12/31.
2	Organization properly assigns data to the applicable CMS contract.
3	Organization meets deadline for reporting annual data to CMS by 5/31.
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. b. Includes only surgeries that occur in an acute 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 5 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). c. 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). d. Includes SRAEs identified by paid claims as well as claims denied only due to being a nonreimbursable SRAE. e. Excludes adverse health conditions present upon admission (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). f. Properly assigns each event to a single applicable SRAE category. g. 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. [Data Elements 3.2 – 3.5]
6	Organization accurately calculates the number of hospital acquired conditions (HACs), including the following criteria: a. Accurately maps HACs to the codes provided by CMS in Appendix 5 of the Part C Reporting Requirements Technical Specifications Document, Table 3. 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). 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. 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). d. Includes HACs identified by paid claims as well as claims denied only due to being a nonreimbursable HAC. e. Excludes adverse health conditions present upon admission (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). f. Properly assigns each HAC to a single applicable HAC category. g. 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. [Data Elements 3.6 – 3.16]

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 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). 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 Element 3.18, includes SSI diagnosis codes with a date of service that extends 30 days from the date of the procedure. d. For Data Element 3.19, includes SSI diagnosis codes with a date of service that extends 365 days from the date of the procedure. 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 nonreimbursable HAC. g. Excludes adverse health conditions present upon admission (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 category. i. 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. [Data Elements 3.17 – 3.21]

2.4 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. <u>Criteria for Validating Source Documents:</u> 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. <u>Criteria for Validating Measure-Specific Criteria (Refer to measure-specific criteria section below):</u> a. The appropriate date range(s) for the reporting period(s) is captured. b. Data are assigned at the applicable level (e.g., plan benefit package or contract level). c. Appropriate deadlines are met for reporting data (e.g., quarterly). d. Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications. e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.
3	Organization implements appropriate policies and procedures for data submission, including the following: a. Data elements are accurately entered into the HPMS tool and entries match corresponding source documents. b. Data files are properly uploaded into HPMS according to any HPMS templates provided. c. All source, intermediate, and final stage data sets relied upon to enter data into HPMS are archived
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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 significantly impacted data reported.

7	*If data collection, validation, and/or reporting for this data measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected, validated, and/or reported by the delegated entity or first tier/downstream contractor.
MEASURE-SPECIFIC CRITERIA	
1	Organization reports data based on the required reporting period of 1/1 through 12/31.
2	Organization properly assigns data to the applicable CMS contract.
3	Organization meets deadline for reporting annual data to CMS by 2/28.
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 sorts by each of the following PCP types: General Medicine; Family Medicine; 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 sorts by each of the following PCP types: General Medicine; Family Medicine; 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 sorts by each of the following PCP types: General Medicine; Family Medicine; Internal Medicine; Obstetricians; Pediatricians; and State Licensed Nurse Practitioners. [Data Elements 4.13 – 4.18]
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 sorts by each of the following PCP types: General Medicine; Family Medicine; 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 sorts by each of the following PCP types: General Medicine; Family Medicine; 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 sorts by each of the following PCP types: General Medicine; Family Medicine; 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. Property sorts by each of the following specialty/facility types: Hospitals; Home Health Agencies; Cardiologist; Oncologist; Pulmonologist; Endocrinologist; Skilled Nursing Facilities; Rheumatologist; Ophthalmologist; and Urologist. [Data Elements 4.37 – 4.46]
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 sorts by each of the following specialty/facility types: Hospitals; 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 sorts by each of the following specialty/facility types: Hospitals; 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 sorts by each of the following specialty/facility types: Hospitals; 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 sorts by each of the following specialty/facility types: Hospitals; Home Health Agencies; Cardiologist; Oncologist; Pulmonologist; Endocrinologist; Skilled Nursing Facilities; Rheumatologist; Ophthalmologist; and Urologist. [Data Elements 4.77 – 4.86]
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 sorts by each of the following specialty/facility types: Hospitals; Home Health Agencies; Cardiologist; Oncologist; Pulmonologist; Endocrinologist; Skilled Nursing Facilities; Rheumatologist; Ophthalmologist; and Urologist. [Data Elements 4.87 – 4.96]

2.5 GRIEVANCES (PART C)

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. <u>Criteria for Validating Source Documents:</u> 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. <u>Criteria for Validating Measure-Specific Criteria (Refer to measure-specific criteria section below):</u> a. The appropriate date range(s) for the reporting period(s) is captured. b. Data are assigned at the applicable level (e.g., plan benefit package or contract level). c. Appropriate deadlines are met for reporting data (e.g., quarterly). d. Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications. e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.
3	Organization implements appropriate policies and procedures for data submission, including the following: a. Data elements are accurately entered into the HPMS tool and entries match corresponding source documents. b. Data files are properly uploaded into HPMS according to any HPMS templates provided. c. 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 significantly impacted data reported.

7	*If data collection, validation, and/or reporting for this data measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected, validated, and/or reported by the delegated entity or first tier/downstream contractor.
MEASURE-SPECIFIC CRITERIA	
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.
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. Requests for organization determinations or appeals are not 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 grievances regardless of whether the event or incidence of the grievance was filed late (i.e., more than 60 calendar days after the event). c. If a grievance contains multiple issues filed by a single complainant, each issue is calculated as a separate grievance. d. If a beneficiary 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 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). i. Includes grievances regarding services covered under plan benefits, even if they are not services that would be covered under Fee For Service (FFS) Medicare. j. *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]
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; Marketing; Confidentiality and Privacy; Quality of Care; and Expedited Grievances. b. Assigns all additional categories tracked by the organization that are not listed above as Other. [Data Elements 5.1 – 5.7]
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]

2.6 ORGANIZATION DETERMINATIONS/ RECONSIDERATIONS

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. <u>Criteria for Validating Source Documents:</u> 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. <u>Criteria for Validating Measure-Specific Criteria (Refer to measure-specific criteria section below):</u> a. The appropriate date range(s) for the reporting period(s) is captured. b. Data are assigned at the applicable level (e.g., plan benefit package or contract level). c. Appropriate deadlines are met for reporting data (e.g., quarterly). d. Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications. e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.
3	Organization implements appropriate policies and procedures for data submission, including the following: a. Data elements are accurately entered into the HPMS tool and entries match corresponding source documents. b. Data files are properly uploaded into HPMS according to any HPMS templates provided. c. 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 significantly impacted data reported.

7	*If data collection, validation, and/or reporting for this data measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected, validated, and/or reported by the delegated entity or first tier/downstream contractor.
MEASURE-SPECIFIC CRITERIA	
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: Due to a revision to the technical specifications for this measure, the reviewer should confirm that the contract reported 1st quarter 2010 data for data elements 6.1 and 6.4, but it should not penalize the contract if the contract did not report these two data elements by 5/31.*
4	Organization properly defines the term "Organization Determination" in accordance with 42 CFR §422.566(b) and the Medicare Managed Care Manual Chapter 13, Sections 10.1 and 20.2.
5	Organization accurately calculates the total number of organization determinations, including the following criteria: a. Includes all organization determinations (Part C only) with a date of final decision that occurs during the reporting period, regardless of when the request for organization determination was received. b. Includes all organization determinations that involve services covered under Medicare only or Medicare and Medicaid. c. Includes all network and non-network organization determinations made as a result of a request being submitted to the plan (e.g., does not include a lab test covered during a physician's office visit). d. Includes payment denials that result in zero payment being made to non-contract providers. e. Includes organization determinations from delegated entities. f. Includes only 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). g. Includes all methods of organization determination request receipt (e.g., telephone, letter, fax, in-person). h. Includes all organization determinations regardless of who filed the request (e.g., member or appointed representative). i. Excludes decisions to continue coverage of a service that was already approved (i.e., includes initial requests only). j. Excludes dismissals or withdrawals. k. Excludes Quality Improvement Organization (QIO) reviews of a member's request to continue Medicare-covered services (e.g., a SNF stay). [Data Elements 6.1 – 6.3]
6	Organization accurately calculates the number of organization determinations by final decision, including the following criteria: a. Properly sorts the total number of organization determinations by final decision: Fully Favorable (e.g., decisions where the organization approves coverage or payment, in whole, for the service or item requested (including requested quantity or number of visits, if applicable)), Partially Favorable (e.g., denial with a "part" that has been approved), or Adverse (e.g., denial of entire request). [Data Elements 6.1 – 6.3]
7	Organization properly defines the term "Reconsideration" in accordance with the Medicare Managed Care Manual Chapter 13, Section 70.

8	Organization accurately calculates the total number of reconsiderations, including the following criteria: a. Includes all reconsiderations (Part C only) with a date of final decision that occurs during the reporting period, regardless of when the request for reconsideration was received. b. Includes all reconsiderations that involve services covered under Medicare only or Medicare and Medicaid. c. Includes all network and non-network reconsiderations made as a result of a request being submitted to the plan (e.g., does not include a lab test covered during a physician's office visit). d. Includes payment denials that result in zero payment being made to non-contract providers. e. Includes all reviews of partially favorable and adverse organization determinations. f. Includes reconsiderations made by or forwarded from delegated entities. g. Includes all reviews of a member's request to continue Medicare-covered services (e.g., if a member misses the QIO's deadline). h. Excludes dismissals or withdrawals. i. Excludes QIO reviews. j. Includes reconsideration cases forwarded to the Independent Review Entity (IRE). k. Includes all methods of reconsideration request receipt (e.g., telephone, letter, fax, in-person). l. Includes all reconsiderations regardless of who filed the request (e.g., member, appointed representative, provider). m. Includes only 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). [Data Elements 6.4 – 6.6]
9	Organization accurately calculates the number of reconsiderations by final decision, including the following criteria: a. Properly sorts the total number of reconsiderations by final decision: Fully Favorable (e.g., decisions where the organization approves coverage or payment, in whole, for the service or item requested (including requested quantity or number of visits, if applicable)); Partially Favorable (e.g., denial with a "part" that has been approved); or Adverse (e.g., denial of entire request). [Data Elements 6.4 – 6.6]

2.7 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. <u>Criteria for Validating Source Documents:</u> 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. <u>Criteria for Validating Measure-Specific Criteria (Refer to measure-specific criteria section below):</u> a. The appropriate date range(s) for the reporting period(s) is captured. b. Data are assigned at the applicable level (e.g., plan benefit package or contract level). c. Appropriate deadlines are met for reporting data (e.g., quarterly). d. Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications. e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.
3	Organization implements appropriate policies and procedures for data submission, including the following: a. Data elements are accurately entered into the HPMS tool and entries match corresponding source documents. b. Data files are properly uploaded into HPMS according to any HPMS templates provided. c. 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 significantly impacted data reported.

7	*If data collection, validation, and/or reporting for this data measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected, validated, and/or reported by the delegated entity or first tier/downstream contractor.
MEASURE-SPECIFIC CRITERIA	
1	Organization reports data based on the required reporting period of 1/1 through 12/31.
2	Organization properly assigns data to the applicable CMS contract and plan benefit package.
3	Organization meets deadline for reporting annual data to CMS by 2/28.
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 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]

2.8 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 measure, and data validation is not required.

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

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

VALIDATION STANDARDS	
1	A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) indicates that all source documents accurately capture required data fields and are properly documented. <u>Criteria for Validating Source Documents:</u> 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. <u>Criteria for Validating Measure-Specific Criteria (Refer to measure-specific criteria section below):</u> a. The appropriate date range(s) for the reporting period(s) is captured. b. Data are assigned at the applicable level (e.g., plan benefit package or contract level). c. Appropriate deadlines are met for reporting data (e.g., quarterly). d. Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications. e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.
3	Organization implements appropriate policies and procedures for data submission, including the following: a. Data elements are accurately entered into the HPMS tool and entries match corresponding source documents. b. Data files are properly uploaded into HPMS according to any HPMS templates provided. c. 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 significantly impacted data reported.
7	*If data collection, validation, and/or reporting for this data measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected, validated, and/or reported by the delegated entity or first tier/downstream contractor.
MEASURE-SPECIFIC CRITERIA	
1	Organization reports data based on the required reporting period of 1/1 through 12/31.
2	Organization properly assigns data to the applicable CMS contract.
3	Organization meets deadline for reporting annual data to CMS by 2/28.
4	Organization accurately calculates the total number of agents who are licensed to sell on behalf of the contract during the applicable reporting period, including the following criteria: a. Includes all direct employees of the organization who are licensed to sell on behalf of the contract. b. Includes all licensed agents who are under a contractual agreement to sell on behalf of the contract, regardless of whether or not the agent was actively selling during the reporting period. [Data Element 12.1]
5	Organization accurately calculates the number of agents investigated based on complaints, including the following criteria: a. Includes all investigations that were completed during the applicable reporting period, regardless of when the complaint was received. b. Includes investigations based on complaints filed directly with the organization as well as those from the HPMS Complaint Tracking Module (CTM). c. Includes all investigations based on complaints against an 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. 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]
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 disciplinary actions that were taken during the applicable reporting period, regardless of when the complaint was received. b. Includes 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 disciplinary actions based on complaints filed directly with the organization as well as those from the HPMS Complaint Tracking Module (CTM). d. Includes all disciplinary actions based on complaints against an 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 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. b. Defines "agent assisted enrollments" as enrollments where the member 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. [Data Element 12.6]

2.9 SPECIAL NEEDS PLANS (SNPs) 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. <u>Criteria for Validating Source Documents:</u> 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. <u>Criteria for Validating Measure-Specific Criteria (Refer to measure-specific criteria section below):</u> a. The appropriate date range(s) for the reporting period(s) is captured. b. Data are assigned at the applicable level (e.g., plan benefit package or contract level). c. Appropriate deadlines are met for reporting data (e.g., quarterly). d. Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications. e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.
3	Organization implements appropriate policies and procedures for data submission, including the following: a. Data elements are accurately entered into the HPMS tool and entries match corresponding source documents. b. Data files are properly uploaded into HPMS according to any HPMS templates provided. c. 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 significantly impacted data reported.

7	*If data collection, validation, and/or reporting for this data measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected, validated, and/or reported by the delegated entity or first tier/downstream contractor.
MEASURE-SPECIFIC CRITERIA	
1	Organization reports data based on the required reporting period of 1/1 through 12/31.
2	Organization properly assigns data to the applicable CMS contract and plan benefit package.
3	Organization meets deadline for reporting annual data to CMS by 5/31.
4	Organization accurately calculates the number of new members, including the following criteria: a. Includes all members 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 a reassessment during the reporting period. [Data Element 13.2]
6	Organization accurately calculates the number of initial assessments performed on new members, including the following criteria: a. Includes all initial assessments that were completed with a date of service that occurs within the 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 reassessments performed on members eligible for a reassessment, including the following criteria: a. Includes all annual reassessments that were completed with a date of service that occurs within the reporting period. 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]

3.0 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. <u>Criteria for Validating Source Documents:</u> 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. <u>Criteria for Validating Measure-Specific Criteria (Refer to measure-specific criteria section below):</u> a. The appropriate date range(s) for the reporting period(s) is captured. b. Data are assigned at the applicable level (e.g., plan benefit package or contract level). c. Appropriate deadlines are met for reporting data (e.g., quarterly). d. Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications. e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.
3	Organization implements appropriate policies and procedures for data submission, including the following: a. Data elements are accurately entered into the HPMS tool and entries match corresponding source documents. b. Data files are properly uploaded into HPMS according to any HPMS templates provided. c. 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 significantly impacted data reported.
7	*If data collection, validation, and/or reporting for this data measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected, validated, and/or reported by the delegated entity or first tier/downstream contractor.
MEASURE-SPECIFIC CRITERIA	
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.
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]

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. 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.* d. 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. 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. d. 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 <u>retail</u> 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 PROGRAMS

To determine compliance with the standards for Medication Therapy Management Programs (MTMP), 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. <u>Criteria for Validating Source Documents:</u> 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. <u>Criteria for Validating Measure-Specific Criteria (Refer to measure-specific criteria section below):</u> a. The appropriate date range(s) for the reporting period(s) is captured. b. Data are assigned at the applicable level (e.g., plan benefit package or contract level). c. Appropriate deadlines are met for reporting data (e.g., quarterly). d. Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications. e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.
3	Organization implements appropriate policies and procedures for data submission, including the following: a. Data elements are accurately entered into the HPMS tool and entries match corresponding source documents. b. Data files are properly uploaded into HPMS according to any HPMS templates provided. c. 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 significantly impacted data reported.

7	*If data collection, validation, and/or reporting for this data measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected, validated, and/or reported by the delegated entity or first tier/downstream contractor.
MEASURE-SPECIFIC CRITERIA	
1	Organization reports data based on the required reporting period of 1/1 through 12/31.
2	Organization properly assigns data to the applicable CMS contract.
3	Organization meets deadline for reporting annual data to CMS by 2/28.
4	Organization accurately calculates the number of members identified to be eligible and auto-enrolled in the MTMP, including the following criteria: a. Properly identifies members who met the eligibility criteria during the reporting period. b. Includes continuing MTMP members as well as members who were newly identified and auto-enrolled in the MTMP at any time during the reporting period. [Data Element A]
5	Organization accurately calculates the number of members who opted-out of enrollment in the MTMP, including: a. Properly identifies members with a date of MTMP opt-out that occurs within the reporting period. b. The number calculated for Data Element B is a subset of the number of members identified as eligible for and auto-enrolled in MTMP calculated for Data Element A. [Data Element B]
6	Organization accurately calculates the number of members who opted-out of MTMP enrollment by reason for opt-out, including the following criteria: a. Properly sorts the total number of members who opted-out of MTMP 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 MTMP 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 MTMP enrollment calculated for Data Element B. [Data Elements C – F]
7	Organization accurately calculates the total prescription cost of all covered Part D medications on a per MTMP member per month basis, including the following criteria: a. Rounding the currency value to the nearest dollar. b. The numerator is the sum of gross drug cost, which equals Ingredient Cost Paid + Dispensing Fee + Sales Tax. c. The numerator includes the costs of covered Part D prescriptions dispensed in the reporting period. d. The numerator includes both MTMP member cost sharing and Part D paid costs. e. The denominator is the total number of member months the member was enrolled in the Part D contract during the reporting period, not only the months the member was enrolled in the MTMP. [Data Element G]
8	Organization accurately calculates the number of covered Part D prescriptions on a per MTMP member per month basis to a 30-day equivalent, including the following criteria: a. The numerator is the sum of the days supply of all covered Part D prescriptions dispensed for all members enrolled in MTMP as of the last day of the reporting period divided by 30. b. The denominator is the total number of member months the member was enrolled in the Part D contract during the reporting period, not only the months the member was enrolled in MTMP. [Data Element H]
9	Organization accurately calculates the number of MTMP members offered a comprehensive medication review, including the following criteria: a. Includes all MTMP members with a date of offer of a comprehensive medication review that occurs within the reporting period. b. The number calculated for Data Element I should be a subset of the number of members identified to be eligible and auto-enrolled in the MTMP calculated for Data Element A. [Data Element I]

10	Organization correctly calculates the number of MTMP members who received a comprehensive medication review, including the following criteria: a. Includes all MTMP members with a comprehensive medication review with date of service that occurs within the reporting period. b. The number calculated for Data Element J should be a subset of the number of members offered a comprehensive medication review calculated for Data Element I. [Data Element J]
11	Organization accurately identifies data on MTMP participation for each member identified as being eligible for the MTMP 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): Properly identifies whether each member was a resident in a long-term care facility for the entire time s/he was enrolled in the MTMP or on the date the member opted-out of MTMP enrollment. c. For Section II (i): The date of MTMP opt-out, if applicable, is completed for the same members counted for Data Element B. d. For Section II (j): The reason participant opted-out of the MTMP 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.
12	Organization accurately calculates data on MTMP interventions for each member identified as being eligible for the MTMP and uploads it into the HPMS submission tool, including the following criteria: a. For Section II (k): Properly identifies whether each member received a 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): The date of comprehensive medication review, if applicable, occurs within the reporting period, is completed for every member with a "Y" entered for Section II (k). c. For Section II (m): Includes all targeted medication reviews within the reporting period for each applicable member. d. For Section II (n): Includes all prescriber interventions within the reporting period for each applicable member. e. For Section II (o): Includes all changes to drug therapy made as a result of MTMP interventions within the reporting period for each applicable member (includes dosage changes, therapeutic or generic substitutions, and discontinuation of therapy).

3.3 GRIEVANCES (PART D)

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. <u>Criteria for Validating Source Documents:</u> 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. <u>Criteria for Validating Measure-Specific Criteria (Refer to measure-specific criteria section below):</u> a. The appropriate date range(s) for the reporting period(s) is captured. b. Data are assigned at the applicable level (e.g., plan benefit package or contract level). c. Appropriate deadlines are met for reporting data (e.g., quarterly). d. Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications. e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.
3	Organization implements appropriate policies and procedures for data submission, including the following: a. Data elements are accurately entered into the HPMS tool and entries match corresponding source documents. b. Data files are properly uploaded into HPMS according to any HPMS templates provided. c. 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 significantly impacted data reported.

7	*If data collection, validation, and/or reporting for this data measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected, validated, and/or reported by the delegated entity or first tier/downstream contractor.
MEASURE-SPECIFIC CRITERIA	
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, 8/15, 11/15, and 2/15.
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. Requests for coverage determinations, exceptions, or redeterminations are not 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 quarterly Part D grievance data is reported to CMS. [Data Elements A and B]
6	Organization accurately calculates the total number of grievances, including the following criteria: a. Includes all grievances that were received during the reporting period, regardless of when the grievance was 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 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 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). h. *For MA-PD contracts:* Includes only grievances that apply to the Part D benefit. If a clear distinction cannot be made for an MA-PD, cases are calculated as Part C grievances. [Data Elements C and D]
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. [Data Element C]
8	Organization accurately calculates the number of grievances which the Part D sponsor provided timely notification of the decision, including the following criteria: a. Includes only grievances for which the member is notified of decision according to the following timelines: i. For standard grievances: no later than 30 days after receipt of grievance. ii. For standard grievances with an extension taken: no later than 44 days after receipt of grievance. iii. For expedited grievances: no later than 24 hours after receipt of grievance. b. Each number calculated is a subset of the total number of grievances received for the applicable beneficiary status and category. [Data Elements C and D]
9	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 Element D]

3.4 COVERAGE DETERMINATIONS AND EXCEPTIONS

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. <u>Criteria for Validating Source Documents:</u> 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. <u>Criteria for Validating Measure-Specific Criteria (Refer to measure-specific criteria section below):</u> a. The appropriate date range(s) for the reporting period(s) is captured. b. Data are assigned at the applicable level (e.g., plan benefit package or contract level). c. Appropriate deadlines are met for reporting data (e.g., quarterly). d. Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications. e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.
3	Organization implements appropriate policies and procedures for data submission, including the following: a. Data elements are accurately entered into the HPMS tool and entries match corresponding source documents. b. Data files are properly uploaded into HPMS according to any HPMS templates provided. c. 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 significantly impacted data reported.

7	*If data collection, validation, and/or reporting for this data measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected, validated, and/or reported by the delegated entity or first tier/downstream contractor.
MEASURE-SPECIFIC CRITERIA	
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, 8/15, 11/15, and 2/15.
4	Organization properly determines whether a request is subject to the coverage determinations or the exceptions process in accordance with the Prescription Drug Benefit Manual Chapter 18, Section 30.1.
5	Organization accurately calculates the number of pharmacy transactions, including the following criteria: a. Includes pharmacy transactions with dates of service within the reporting period. b. Includes in-network and out-of-network transactions. c. Includes transactions with a final disposition of reversed. d. Excludes pharmacy transactions for enhanced alternative drugs. [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. Number calculated for Data Element B is a subset of the number of pharmacy transactions calculated for Data Element A. [Data Element B]
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 that occurs during the reporting period, regardless of when the final decision was made. 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, 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. [Data Elements C – J]
8	Organization accurately calculates the total number of PAs 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. b. Data Element C: Includes requests that relate to Part B versus Part D coverage. c. Data Element D: Includes all favorable decisions on requests for PAs. d. Number calculated for approved requests (Data Element D) is a subset of the number of requests calculated for Data Element C. [Data Elements C and D]
9	Organization accurately calculates the number of 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). b. Data Element F: Includes all favorable decisions on requests for exceptions to the organization's UM tools. c. Number calculated for approved requests (Data Element F) is a subset of the number of decisions calculated for Data Element E. [Data Elements E and F]

10	Organization accurately calculates the number of tier exceptions requested and approved, including the following criteria: a. Data Element G: Includes all requests for a decision 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. 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 Elements G and H]
11	Organization accurately calculates the number of exceptions for non-formulary medications requested and approved, including the following criteria: a. Data Element I: Includes all requests for a decision on whether to permit a member to obtain a Part D drug that is not included on the formulary. 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 Elements I and J]

3.5 APPEALS

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. <u>Criteria for Validating Source Documents:</u> 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. <u>Criteria for Validating Measure-Specific Criteria (Refer to measure-specific criteria section below):</u> a. The appropriate date range(s) for the reporting period(s) is captured. b. Data are assigned at the applicable level (e.g., plan benefit package or contract level). c. Appropriate deadlines are met for reporting data (e.g., quarterly). d. Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications. e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.
3	Organization implements appropriate policies and procedures for data submission, including the following: a. Data elements are accurately entered into the HPMS tool and entries match corresponding source documents. b. Data files are properly uploaded into HPMS according to any HPMS templates provided. c. 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 significantly impacted data reported.

7	*If data collection, validation, and/or reporting for this data measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected, validated, and/or reported by the delegated entity or first tier/downstream contractor.
MEASURE-SPECIFIC CRITERIA	
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, 8/15, 11/15, and 2/15.
4	Organization properly defines the term "Appeal" in accordance with Title 1, Part 423, Subpart M §423.560 and the Prescription Drug Benefit Manual Chapter 18, Section 10.1.
5	Organization accurately calculates the total number of redeterminations (Part D only), including the following criteria: a. Includes all redeterminations with a date of final decision that occurs during the reporting period, regardless of when the request for redetermination was received. b. Includes all reviews of partially favorable and adverse coverage determinations. c. Includes both standard and expedited redeterminations. d. Includes all methods of receipt (e.g., telephone, letter, fax, in-person). e. Includes all redeterminations regardless of who filed the request (e.g., member, appointed representative, or prescribing physician). f. Excludes dismissals or withdrawals. g. Excludes IRE decisions, as they are considered to be the second level of appeal. [Data Element A]
6	Organization accurately calculates the number of redeterminations by final decision, including the following criteria: a. Properly sorts the total number of redeterminations by final decision: 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 is a subset of the total number of redeterminations calculated for Data Element A. [Data Elements B and C]

3.6 LONG-TERM CARE UTILIZATION

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. <u>Criteria for Validating Source Documents:</u> 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. <u>Criteria for Validating Measure-Specific Criteria (Refer to measure-specific criteria section below):</u> a. The appropriate date range(s) for the reporting period(s) is captured. b. Data are assigned at the applicable level (e.g., plan benefit package or contract level). c. Appropriate deadlines are met for reporting data (e.g., quarterly). d. Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications. e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.
3	Organization implements appropriate policies and procedures for data submission, including the following: a. Data elements are accurately entered into the HPMS tool and entries match corresponding source documents. b. Data files are properly uploaded into HPMS according to any HPMS templates provided. c. 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 significantly impacted data reported.

7	*If data collection, validation, and/or reporting for this data measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected, validated, and/or reported by the delegated entity or first tier/downstream contractor.
MEASURE-SPECIFIC CRITERIA	
1	Organization reports data based on the required reporting period of 1/1 through 12/31.
2	Organization properly assigns data to the applicable CMS contract.
3	Organization meets deadline for reporting annual data to CMS by 6/30.
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 for PDPs and RPPOs, and by service area for MA-PDs. b. Includes only LTC pharmacies that are contracted as of the last day of the reporting period. c. Includes LTC pharmacies that do not have utilization. [Data Element A]
5	Organization accurately calculates the number of network retail pharmacies in the service area, including: a. Includes the number of contracted retail pharmacies by state for PDPs and regional for PPOs, and by service area for local MA-PDs. b. Includes only retail pharmacies that are contracted as of the last day of the reporting period. c. Includes LTC pharmacies that do not have utilization. [Data Element B]
6	Organization accurately calculates the total number of members in LTC facilities for whom Part D drugs have been provided, including the following criteria: a. Counts each member only once in each reporting period. b. Includes only members with covered Part D drug claims with dates of service within the reporting period. c. 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 code 03 or the LTI report may be used to identify applicable members. Claims with location code 07 should not be included.* [Data Element C]
7	Organization accurately identifies the following data for each network LTC pharmacy in the service area and uploads it into the HPMS submission tool: a. LTC pharmacy name, LTC pharmacy NPI, contract entity name of LTC pharmacy, chain code of LTC pharmacy b. Includes all LTC pharmacies that were active in the network for one or more days in the reporting period. [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. Sums days supply of all covered Part D prescriptions dispensed and divides this by 31 days. b. Performs the calculations separately for formulary prescriptions and non-formulary prescriptions. c. Includes only covered Part D drug claims with dates of service within the reporting period. [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. Prescription cost is the sum of the ingredient cost, dispensing fee, and sales tax. b. Ingredient cost reflects Sponsor's negotiated price. c. Performs the calculations separately for formulary prescriptions and non-formulary prescriptions. d. Includes only covered Part D drug claims with dates of service within the reporting period. [Data Element D: g-h]
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. Sums days supply of all covered Part D prescriptions dispensed and divides this by 30 days. b. Performs the calculations separately for formulary prescriptions and non-formulary prescriptions. c. Includes only covered Part D drug claims with dates of service within the reporting period. [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. Prescription cost is the sum of the ingredient cost, dispensing fee, and sales tax. b. Ingredient cost reflects Sponsor's negotiated price. c. Performs the calculations separately for formulary prescriptions and non-formulary prescriptions. d. Includes only covered Part D drug claims with dates of service within the reporting period. [Data Element E: c-d]

3.7 EMPLOYER/UNION-SPONSORED GROUP HEALTH PLAN SPONSORS

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. <u>Criteria for Validating Source Documents:</u> 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. <u>Criteria for Validating Measure-Specific Criteria (Refer to measure-specific criteria section below):</u> a. The appropriate date range(s) for the reporting period(s) is captured. b. Data are assigned at the applicable level (e.g., plan benefit package or contract level). c. Appropriate deadlines are met for reporting data (e.g., quarterly). d. Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications. e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.
3	Organization implements appropriate policies and procedures for data submission, including the following: a. Data elements are accurately entered into the HPMS tool and entries match corresponding source documents. b. Data files are properly uploaded into HPMS according to any HPMS templates provided. c. 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 significantly impacted data reported.

7	*If data collection, validation, and/or reporting for this data measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected, validated, and/or reported by the delegated entity or first tier/downstream contractor.
MEASURE-SPECIFIC CRITERIA	
1	Organization reports data based on the required reporting period of 1/1 through 12/31.
2	Organization properly assigns data to the applicable CMS contract and plan benefit package.
3	Organization meets deadline for reporting annual data to CMS by 2/28.
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 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 contract did not use licensed agents directly employed by the organization or licensed independent agents/brokers to conduct marketing for its Medicare products during the reporting period, then it is appropriate for the contract to report "0" for each data element in this measure, and data validation is not required.

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

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

VALIDATION STANDARDS	
1	A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) indicates that all source documents accurately capture required data fields and are properly documented. <u>Criteria for Validating Source Documents:</u> 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. <u>Criteria for Validating Measure-Specific Criteria (Refer to measure-specific criteria section below):</u> a. The appropriate date range(s) for the reporting period(s) is captured. b. Data are assigned at the applicable level (e.g., plan benefit package or contract level). c. Appropriate deadlines are met for reporting data (e.g., quarterly). d. Terms used are properly defined per CMS regulations, guidance and Reporting Requirements Technical Specifications. e. The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.
3	Organization implements appropriate policies and procedures for data submission, including the following: a. Data elements are accurately entered into the HPMS tool and entries match corresponding source documents. b. Data files are properly uploaded into HPMS according to any HPMS templates provided. c. 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 significantly impacted data reported.
7	*If data collection, validation, and/or reporting for this data measure is delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected, validated, and/or reported by the delegated entity or first tier/downstream contractor.
MEASURE-SPECIFIC CRITERIA	
1	Organization reports data based on the required reporting period of 1/1 through 12/31.
2	Organization properly assigns data to the applicable CMS contract.
3	Organization meets deadline for reporting annual data to CMS by 2/28.
4	Organization accurately calculates the total number of agents who are licensed to sell on behalf of the contract during the applicable reporting period, including the following criteria: a. Includes all direct employees of the Part D sponsor who are licensed to sell on behalf of the contract. b. Includes all licensed agents who are under a contractual agreement to sell on behalf of the contract, regardless of whether or not the agent was actively selling during the reporting period. [Data Element A]
5	Organization accurately calculates the number of agents investigated based on complaints, including the following criteria: a. Includes all investigations that were completed during the applicable reporting period, regardless of when the complaint was received. b. Includes investigations based on complaints filed directly with the organization as well as those from the HPMS Complaint Tracking Module (CTM). c. Includes all investigations based on complaints against an 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. 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 disciplinary actions that were taken during the applicable reporting period, regardless of when the complaint was received. b. Includes any 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 disciplinary actions based on complaints filed directly with the organization as well as those from the HPMS Complaint Tracking Module (CTM). d. Includes all disciplinary actions based on complaints against an 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]
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 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. b. Defines "agent assisted enrollments" as enrollments where the member 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. [Data Element F]

APPENDIX: ACRONYMS

Acronym	Description
ASO	Administrative Services Only
CABG	Coronary Artery Bypass Surgery
CFR	Code of Federal Regulations
CMS	Centers for Medicare & Medicaid Services
CTM	Complaint Tracking Module
DBA	Doing Business As
DME	Durable Medical Equipment
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
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
MTMP	Medication Therapy Management Program
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
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
UM	Utilization Management
UTI	Urinary Tract Infection