Medicare Part C and Part D Reporting Requirements Data Validation

Procedure Manual
Version 2.0: December 2011

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1 INTRODUCTION

1.1 DATA VALIDATION REQUIREMENT

The Centers for Medicare & Medicaid Services (CMS) requires that organizations contracted to offer Medicare Part C and/or Part D benefits be subject to an independent yearly review to validate data reported to CMS on a variety of reporting requirements.[1] The purpose of the independent data validation is to ensure that Part C and Part D organizations (sponsoring organizations) are reporting health and drug plan data that are reliable, valid, complete, comparable, and timely.

The validated data improves reporting and provides CMS with assurance that data are credible and consistently collected and reported by Part C and Part D sponsoring organizations. CMS uses these reported data to respond to inquiries from Congress, oversight agencies, and the public about an organization's performance using indicators such as operations, costs, availability and use of services, provider network adequacy, and grievance rates. The validated data also allows CMS to more effectively monitor and compare the performance of sponsoring organizations over time. Additionally, sponsoring organizations can take advantage of the data validation process to more effectively assess their own performance and make improvements to their internal data, systems, and reporting processes.

The primary purpose of this *Procedure Manual* (*Manual*) is to provide sponsoring organizations, and the contractors they select to perform the data validation, with information regarding the Part C and Part D Reporting Requirements Data Validation program. The *Manual* provides background information and an overview of the data validation program, discusses the scope and timeframe required for the data validation, and describes the tools and processes used for conducting the data validation.

1.2 TYPES OF ORGANIZATIONS REQUIRED TO UNDERGO DATA VALIDATION

All Part C and Part D organizations that report Part C and/or Part D data to CMS per the *Part C/Part D Reporting Requirements*, regardless of enrollment size, are required to undergo an annual data validation review. The only organization types that the data validation requirement does not apply to are Program of All-Inclusive Care for the Elderly (PACE) organizations and Part C Health Care Prepayment Plans.

A sponsoring organization that terminates its contract(s) to offer Medicare Part C and/or Part D benefits, or that is subject to a CMS termination of its contract(s), is not required to undergo a data validation review for the final contract year's reported data. Similarly, for measures that are reported at the plan benefit package (PBP) level, PBPs that terminate are not required to undergo a data validation for the final year's reported data.

Any organization that delegates the data collection, calculation, and/or reporting for any data measure or data element to a Pharmacy Benefit Manager (PBM) or other type of delegated entity must have the data validation contractor it hires include the data and reporting processes for which the PBM/delegated entity is responsible in its data validation review for each applicable contract. For example, all entities that submit data to an organization that are used for any data measure should provide applicable policies, procedures, and source data to the reviewer for validation.

[1] See 42 CFR §422.516(g) and §423.514(g)

1.3 REQUIREMENT TO USE THIS MANUAL AND TOOLS

CMS requires that sponsoring organizations and their selected data validation contractors use the processes and tools contained in this *Procedure Manual* and its appendices to conduct the annual data validation. This includes each of the following documents:

1. *Standards for Selecting a Data Validation Contractor*
2. *Data Validation Standards*
3. *Organizational Assessment Instrument (OAI)*
4. *Interview Discussion Guide (IDG)*
5. *Data Extraction and Sampling Instructions*
6. *Findings Data Collection Form (FDCF)*[2]

The *Data Validation Standards* and other documentation associated with the implementation of the data validation program assess an organization's information systems capabilities and overall processes for collecting, storing, compiling, and reporting the required Part C and Part D data measures.[3] CMS expects to establish consistency in the data validation program by requiring that all entities use the same tools and follow the same process.

In order to ensure that the data validation documentation can incorporate periodic clarifications to the *Part C and Part D Reporting Requirements Technical Specifications*, CMS intends to update this *Procedure Manual* and the data validation tools contained in its appendices annually no later than February 28. CMS will post the most current version publicly at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/9_PartCDDataValidation.asp and within the Health Plan Management System (HPMS) Plan Reporting Data Validation Module (PRDVM). Prior to beginning each annual data validation, it is the responsibility of all sponsoring organizations and data validation reviewers to confirm that they are using the most recent data validation documentation available on the CMS Data Validation website.

In the event of a conflict between the *Part C and Part D Reporting Requirements Technical Specifications* and the *Data Validation Standards* measure-specific criteria, the *Data Validation Standards* supersede the *Technical Specifications*. Data validation reviewers must use the *Data Validation Standards* measure-specific criteria to determine data validation findings. CMS will take this conflict between the *Technical Specifications* and the *Data Validation Standards* into consideration when evaluating the results of the data validation review.

Exhibit 1 provides a revision history for this document.

Exhibit 1. Reporting Requirements Data Validation Procedure Manual Revision History

Version Number	Date	Description of Change
1.0	December 2010	Baseline Release for March-May 2011 data validation
2.0	December 2011	Updated Release for April-June 2012 data validation

[2] CMS recommends data validation reviewers work and enter findings directly in the Health Plan Management System Plan Reporting Data Validation Module. Alternatively, reviewers may also use the Excel version of the *FDCF* to record findings.

[3] Note: In order to streamline terms used, Part C measures and Part D sections are referred to as "measures" throughout the data validation documentation.

2 OVERVIEW OF THE DATA VALIDATION PROCESS

2.1 INTRODUCTION TO THE DATA VALIDATION STANDARDS

The *Data Validation Standards* (*Standards*) include general standards and measure-specific criteria that data validation reviewers must use to determine whether the data each organization reported to CMS per the *Part C/Part D Reporting Requirements* are accurate, valid, timely, and reliable.

The *Standards* assess an organization's information systems capabilities and its processes for collecting, storing, compiling, and reporting Part C and/or Part D data. They also assess whether sponsoring organizations follow the applicable *Part C/Part D Reporting Requirements Technical Specifications* to compile data, take into account appropriate data exclusions, and verify calculations, computer code, and algorithms.

2.2 DATA VALIDATION SCOPE

CMS requires that an annual, retrospective data validation be conducted once per year. For the 2012 data validation cycle and beyond, the data validation will take place during the April 1 – June 30 timeframe and will incorporate all data submitted to CMS by March 31st based on the previous calendar years' reporting requirements. Any data submitted or re-submitted by the sponsoring organization after March 31st cannot be used for purposes of the data validation. The data validation reviewer must submit findings from the annual data validation review to CMS by June 30 of each calendar year.

The data validation reviews must be conducted at the contract level. CMS believes the contract is the most appropriate unit of analysis in conducting this data validation, given that the Part C/D data are generally available at the contract level and that the contract is the basis of any legal and accountability issues concerning the rendering of services.

2.2.1 Part C and Part D Data Measures Requiring Data Validation in 2012

The 2012 data validation includes the 16 Part C and Part D data measures included in Exhibit 2. Please note that the 2012 data validation includes not only the 2011 data measures with a reporting deadline of 2/28/12 or before, but also four 2010 data measures that were not required to be submitted to CMS in time for the data validation performed in 2011. This schedule allows CMS to meet its goal of conducting a completely retrospective data validation for all required data.

Exhibit 2. Part C and Part D Data Measures Requiring Data Validation in 2012

2010 Measure	Reporting Period(s)	Data Submission Due Date(s) to CMS	Data Validation Findings Due to CMS*
Part C			
~~Benefit Utilization~~	~~1/1/10 - 12/31/10~~	~~8/31/11~~	~~5/31/12~~
Procedure Frequency	1/1/10 - 12/31/10	5/31/11	6/30/12
Serious Reportable Adverse Events	1/1/10 - 12/31/10	5/31/11	6/30/12
Special Needs Plans (SNPs) Care Management	1/1/10 - 12/31/10	5/31/11	6/30/12
Part D			
Long-Term Care (LTC) Utilization	1/1/10 - 12/31/10	6/30/11	6/30/12

2011 Measure	Reporting Period(s)	Data Submission Due Date(s) to CMS	Data Validation Findings Due to CMS*
Part C			
Provider Network Adequacy	1/1/11 - 12/31/11	2/28/12	6/30/12
Grievances	1/1/11 - 3/31/11 4/1/11 - 6/30/11 7/1/11 - 9/30/11 10/1/11 - 12/31/11	5/31/11 8/31/11 11/30/11 2/28/12	6/30/12
Organization Determinations/ Reconsiderations	1/1/11 - 3/31/11 4/1/11 - 6/30/11 7/1/11 - 9/30/11 10/1/11 - 12/31/11	5/31/11 8/31/11 11/30/11 2/28/12	6/30/12
Employer Group Plan Sponsors	1/1/11 - 12/31/11	2/28/12	6/30/12
Plan Oversight of Agents	1/1/11 - 12/31/11	2/28/12	6/30/12
2011 Measure (continued)	**Reporting Period(s)**	**Data Submission Due Date(s) to CMS**	**Data Validation Findings Due to CMS***
Part D			
Retail, Home Infusion, and LTC Pharmacy Access	1/1/11 - 3/31/11 (Sections A & B) 1/1/11 - 12/31/11 (Sections C & D)	5/31/11 (A & B) 2/28/12 (C & D)	6/30/12
Medication Therapy Management Programs	1/1/11 - 12/31/11	2/28/12	6/30/12
Grievances	1/1/11 - 3/31/11 4/1/11 - 6/30/11 7/1/11 - 9/30/11 10/1/11 - 12/31/11	5/15/11 8/15/11 11/15/11 2/15/12	6/30/12
Coverage Determinations and Exceptions	1/1/11 - 3/31/11 4/1/11 - 6/30/11 7/1/11 - 9/30/11 10/1/11 - 12/31/11	5/15/11 8/15/11 11/15/11 2/15/12	6/30/12
Appeals	1/1/11 - 3/31/11 4/1/11 - 6/30/11 7/1/11 - 9/30/11 10/1/11 - 12/31/11	5/15/11 8/15/11 11/15/11 2/15/12	6/30/12
Employer/Union-Sponsored Group Health Plan Sponsors	1/1/11 - 12/31/11	2/28/12	6/30/12
Plan Oversight of Agents	1/1/11 - 12/31/11	2/28/12	6/30/12

2.2.2 Part C and Part D Data Measures Requiring Data Validation in 2013

CMS is currently planning for the 2013 data validation to include the 17 Part C and Part D data measures included in

Exhibit 3. Please note that the 2013 data validation will include not only the 2012 data with a reporting deadline of 2/28/13 or before, but also four 2011 data measures that are not required to be submitted to CMS in time for the data validation performed in 2012.

Exhibit 3. Part C and Part D Data Measures Requiring Data Validation in 2013

2011 Measure	Reporting Period(s)	Data Submission Due Date(s) to CMS	Data Validation Findings Due to CMS*
Part C			
~~Benefit Utilization~~	~~1/1/11 - 12/31/11~~	~~8/31/12~~	~~5/31/13~~
Procedure Frequency	1/1/11 - 12/31/11	5/31/12	6/30/13
Serious Reportable Adverse Events	1/1/11 - 12/31/11	5/31/12	6/30/13
Special Needs Plans (SNPs) Care Management	1/1/11 - 12/31/11	5/31/12	6/30/13
Part D			
Long-Term Care (LTC) Utilization	1/1/11 - 12/31/11	6/30/12	6/30/13
2012 Measure	**Reporting Period(s)**	**Data Submission Due Date(s) to CMS**	**Data Validation Findings Due to CMS***
Part C			
Provider Network Adequacy	1/1/12 - 12/31/12	2/28/13	6/30/13
Grievances	1/1/12 - 3/31/12 4/1/12 - 6/30/12 7/1/12 - 9/30/12 10/1/12 - 12/31/12	5/31/12 8/31/12 11/30/12 2/28/13	6/30/13
Organization Determinations/ Reconsiderations	1/1/12 - 3/31/12 4/1/12 - 6/30/12 7/1/12 - 9/30/12 10/1/12 - 12/31/12	5/31/12 8/31/12 11/30/12 2/28/13	6/30/13
Employer Group Plan Sponsors	1/1/12 - 12/31/12	2/28/13	6/30/13
Plan Oversight of Agents	1/1/12 - 12/31/12	2/28/13	6/30/13
Part D			
Retail, Home Infusion, and LTC Pharmacy Access	1/1/12 - 3/31/12 (Sections A & B) 1/1/12 - 12/31/12 (Sections C & D)	5/31/12 (A & B) 2/28/13 (C & D)	6/30/13
Medication Therapy Management Programs	1/1/12 - 12/31/12	2/28/13	6/30/13
Grievances	1/1/12 - 3/31/12 4/1/12 - 6/30/12 7/1/12 - 9/30/12 10/1/12 - 12/31/12	5/31/12 8/31/12 11/30/12 2/28/13	6/30/13
Coverage Determinations and Exceptions	1/1/12 - 3/31/12 4/1/12 - 6/30/12 7/1/12 - 9/30/12 10/1/12 - 12/31/12	5/31/12 8/31/12 11/30/12 2/28/13	6/30/13
Redeterminations~~Appeals~~	1/1/12 - 3/31/12 4/1/12 - 6/30/12 7/1/12 - 9/30/12 10/1/12 - 12/31/12	5/31/12 8/31/12 11/30/12 2/28/13	6/30/13
Long-Term Care (LTC) Utilization	1/1/12 – 6/30/12 7/1/12 – 12/31/12	8/30/12 2/28/13[1]	6/30/13
Employer/Union-Sponsored Group Health Plan Sponsors	1/1/12 - 12/31/12	2/28/13	6/30/13
Plan Oversight of Agents	1/1/12 - 12/31/12	2/28/13	6/30/13

[1] *CMS expects to change the reporting deadline for this data measure to allow a completely retrospective data validation.*

2.2.3 Part C and Part D Data Measures Requiring Data Validation in 2014

CMS expects to modify the reporting deadlines for the calendar year 2013 reporting requirements so that all affected measures are reported to CMS prior to the start of the data validation timeframe, and all validations of calendar year 2013 data will be completed in 2014. This will require the 2014 data validation to include the 19 Part C and Part D data measures included in Exhibit 4. Please note that the 2014 data validation will include not only all 16 2013 data measures, but also three Part C 2012 data measures that were not required to be submitted to CMS in time for the data validation done in 2013.

Exhibit 4. Part C and Part D Data Measures Requiring Data Validation in 2014

2012 Measure	Reporting Period(s)	Data Submission Due Date(s) to CMS	Data Validation Findings Due to CMS*
Part C			
~~Benefit Utilization~~	~~1/1/12 - 12/31/12~~	~~8/31/13~~	~~5/31/14~~
Procedure Frequency	1/1/12 - 12/31/12	5/31/13	6/30/14
Serious Reportable Adverse Events	1/1/12 - 12/31/12	5/31/13	6/30/14
Special Needs Plans (SNPs) Care Management	1/1/12 - 12/31/12	5/31/13	6/30/14
~~**Part D**~~			
~~Long-Term Care (LTC) Utilization~~	~~1/1/12 - 12/31/12~~	~~6/30/13~~	~~5/31/14~~
2013 Measure	**Reporting Period(s)**	**Data Submission Due Date(s) to CMS**	**Data Validation Findings Due to CMS***
Part C			
~~Benefit Utilization~~	~~1/1/13 - 12/31/13~~	~~2/28/14~~[1]	~~5/31/14~~
Procedure Frequency	1/1/13 - 12/31/13	2/28/14[1]	6/30/14
Serious Reportable Adverse Events	1/1/13 - 12/31/13	2/28/14[1]	6/30/14
Provider Network Adequacy	1/1/13 - 12/31/13	2/28/14	6/30/14
Grievances	1/1/13 - 3/31/13 4/1/13 - 6/30/13 7/1/13 - 9/30/13 10/1/13 - 12/31/13	5/31/13 8/31/13 11/30/13 2/28/14	6/30/14
Organization Determinations/ Reconsiderations	1/1/13 - 3/31/13 4/1/13 - 6/30/13 7/1/13 - 9/30/13 10/1/13 - 12/31/13	5/31/13 8/31/13 11/30/13 2/28/14	6/30/14
Employer Group Plan Sponsors	1/1/13 - 12/31/13	2/28/14	6/30/14
Plan Oversight of Agents	1/1/13 - 12/31/13	2/28/14	6/30/14
Special Needs Plans (SNPs) Care Management	1/1/13 - 12/31/13	2/28/14[1]	6/30/14
Part D			
Retail, Home Infusion, and LTC Pharmacy Access	1/1/13 - 3/31/13 (Sections A & B) 1/1/13 - 12/31/13 (Sections C & D)	5/31/13 (A & B) 2/28/14 (C & D)	6/30/14
Medication Therapy Management Programs	1/1/13 - 12/31/13	2/28/14	6/30/14

2013 Measure	Reporting Period(s)	Data Submission Due Date(s) to CMS	Data Validation Findings Due to CMS*
Part D (continued)			
Grievances	1/1/13 - 3/31/13 4/1/13 - 6/30/13 7/1/13 - 9/30/13 10/1/13 - 12/31/13	5/31/13 8/31/13 11/30/13 2/28/14	6/30/14
Coverage Determinations and Exceptions	1/1/13 - 3/31/13 4/1/13 - 6/30/13 7/1/13 - 9/30/13 10/1/13 - 12/31/13	5/31/13 8/31/13 11/30/13 2/28/14	6/30/14
Redeterminations~~Appeals~~	1/1/13 - 3/31/13 4/1/13 - 6/30/13 7/1/13 - 9/30/13 10/1/13 - 12/31/13	5/31/13 8/31/13 11/30/13 2/28/14	6/30/14
Long-Term Care (LTC) Utilization	1/1/13 - 6/30/13 7/1/13 - 12/31/13	8/30/13 2/28/14	6/30/14
Employer/Union-Sponsored Group Health Plan Sponsors	1/1/13 - 12/31/13	2/28/14	6/30/14
Plan Oversight of Agents	1/1/13 - 12/31/13	2/28/14	6/30/14

2.3 REPORTING REQUIREMENTS THAT ARE EXCLUDED FROM THE VALIDATION REQUIREMENT AT THIS TIME

There are a number of Part C and Part D measures included in the *Reporting Requirements* that will not undergo validation at this time, as they have either been suspended from reporting, or will be used for monitoring purposes only. Exhibit 5 lists the measures excluded from the data validation process.

Exhibit 5. Part C and Part D Data Measures Excluded From Data Validation At This Time

Part C Data Measures	Part D Data Measures
• Benefit Utilization • PFFS Plan Enrollment Verification Calls • PFFS Provider Payment Dispute Resolution Process • Agent Compensation Structure • Agent Training and Testing	• Enrollment • Access to Extended Day Supplies at Retail Pharmacies • Prompt Payment by Part D Sponsors • Pharmacy Support of E-Prescribing • P & T Committees • Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions • Licensure and Solvency • Fraud, Waste and Abuse Compliance Programs

2.4 DATA VALIDATION TIMELINE

Exhibit 6 outlines the specific steps involved with the annual data validation review process, beginning with the selection of an appropriate data validation contractor and ending with CMS' decision on Pass or Not Pass determinations for the organization (tentatively scheduled for fall of each year) based on the findings from the data validation review. The data validation review process will largely entail a collaborative effort between the organization and its independent, external reviewer in terms of information sharing up to the point of the reviewer's final submission of data validation review findings to CMS. Each of these steps, including specific roles for the organization and reviewer, are summarized in Exhibit 6 and described in more detail in Sections 3 through 9 of this *Manual*.

Exhibit 6. Data Validation Annual Process and Timeline

Step Number	Step	Sponsoring Organization Action	Data Validation Reviewer Action	Date*
Planning for Data Validation Activities				
1	Select appropriate data validation contractor based on *Standards for Selecting a Data Validation Contractor*	X		December*-March
2	Complete the on-line Data Validation Training	X	X	December*-March
3	Review the *Data Validation Standards*	X	X	January-March
4	Notify CMS of Data Validation Contractor Selection / Request Access to Health Plan Management System (HPMS) PRDVM	X	X	January-April
5	Complete *OAI* and provide appropriate documentation to selected data validation contractor per *OAI*'s documentation request	X		Early April (allow minimum of 2 weeks)
6	Analyze *OAI* Responses		X	Mid-April
7	Prepare for the site visit (site visit agenda, resource needs, and logistics)**	X	X	Early April
Data Validation Activities				
8	Conduct site visit (Conduct interviews with sponsoring organization staff, observe organization's reporting processes, and obtain census and/or sample files)**	X	X	April-May (allow up to 1 week)
9	Determine compliance with *Data Validation Standards* and record findings in Excel-version of *FDCF* or directly into the HPMS PRDVM		X	June
10	~~(Optional)~~ Provide draft findings to sponsoring organization		X	June
11	~~(Optional)~~ Review draft findings and provide any additional documentation necessary to resolve issues	X		June
12	Submit data validation review findings to CMS via HPMS PRDVM		X	Must be complete by June 30
13	Compile archive of data validation work papers	X	X	After June 30
CMS Determination of Pass or Not Pass				
14	Receive CMS report of Pass or Not Pass determinations based on findings from data validation review	X		Fall***
15	(If applicable) Appeal CMS' data validation determination(s)	X		Fall***

** References to December refer to the calendar year before the data validation review; all other references to months refer to the same calendar year as the data validation review.*

*** CMS encourages sponsoring organizations and data validation contractors to include a physical site visit as part of the data validation review.*

**** Dates are tentative*

3 SELECTING A DATA VALIDATION CONTRACTOR

CMS requires that the data validation be conducted by an independent, external entity, and believes that this will ensure that the data used to develop plan performance measures are credible to other stakeholders, and that information used to respond to Congressional and public inquiries are reliable for monitoring plans. The sponsoring organization is responsible for acquiring the independent data validation contractor and for all other costs associated with completing the independent data validation and reporting the results to CMS.

3.1 TIMING OF DATA VALIDATION CONTRACTOR SELECTION

An organization may select a data validation contractor at any time, up to and during the April through June data validation review period. Organizations should implement the contract to allow sufficient time for the contractor to perform all of the requirements of the review during the required timeframe and submit findings to CMS via the PRDVM in HPMS by June 30.

3.2 STANDARDS FOR SELECTING A DATA VALIDATION CONTRACTOR

CMS has provided a set of *Standards for Selecting a Data Validation Contractor* (see Appendix A) as guidance for organizations to use in acquiring a data validation contractor. These standards describe the minimum qualifications, credentials, and resources that the selected data validation contractor must possess. Organizations must acquire one data validation contractor to conduct the data validation on reported data and if necessary, the data validation contractor may subcontract in order to ensure that it has the expertise required for each data validation area and to meet the minimum standards. Sponsoring organizations may use their own staff only to assist the data validation contractor in obtaining the information, data, and documents needed to complete the data validation review.

Sponsoring organizations may also contract with data validation reviewers to perform mock audits, pre-assessments, and any other types of review only during the formal data validation review period between April and June. At this time, sponsoring organizations may use the same contractor to perform the organization's formal data validation as long as there is no conflict of interest as described in the Organizational Conflict of Interest section of the *Standards for Selecting a Data Validation Contractor*. Sponsoring organizations and data validation reviewers should keep in mind that if they chose to perform a mock review, they must still have all findings for the formal review submitted to CMS no later than June 30. This provides more clarification from the previous version of the Procedural Manual (Version 1.0, December 2010). In that version, it did not specify in what time period the mock reviews were allowed. CMS continues its efforts to maintain a high level of independence with data validation; and therefore, will be developing further guidance pertinent to relationships between sponsoring organizations and data validation contractors for the 2013 data validation cycle. Any specific questions regarding whether or not a particular entity meets the organizational independence standard should be directed to PartCandD_Data_Validation@cms.hhs.gov.

3.3 DOCUMENTATION OF SELECTION PROCESS

Sponsoring organizations must document their data validation contractor selection process and be able to show, upon request by CMS, how their chosen data validation contractor meets the minimum qualifications, credentials, and resources set forth in the *Standards for Selecting a Data Validation Contractor*. This includes maintaining a copy of the documentation that all contractor staff assigned to the applicable data validation team completed the CMS Data Validation Training program (see Section 4.1).

CMS requires that the sponsoring organization retain this documentation for the 10-year retention period per federal regulations.[4]

If a sponsoring organization chooses to select the same data validation contractor it used for a previous year's data validation, it must still document the selection process as described above.

3.4 REQUESTING A CONTRACTOR CHANGE MID-REVIEW

A sponsoring organization may not change its data validation contractor during the formal review period (April-June) unless there are conditions that are unrelated to data validation findings such as negligence or malfeasance on the part of the contractor. If a change in contractor is required, the new contractor is required to complete the data validation review in its entirety (starting with the *OAI* submission through submitting findings to CMS) within the required April - June data validation review timeline.

CMS will consider mid-review contractor change requests on a case-by-case basis only. Requests must be in writing and be submitted to CMS via the PartCandD_Data_Validation@cms.hhs.gov email box.

4 GENERAL DATA VALIDATION PREPARATION ACTIVITIES

4.1 COMPLETE DATA VALIDATION TRAINING

CMS has developed a web-based Data Validation Training that provides an opportunity for sponsoring organizations and potential third-party data validation contractors to learn more about the data validation program and its specific requirements. CMS will post the links to register and take the training at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/9_PartCDDataValidation.asp.

During the data validation preparation phase, all sponsoring organization staff involved in the data validation should complete the CMS Data Validation training individually to familiarize themselves with the data validation process and requirements.

Additionally, all data validation contractor staff assigned to a data validation team must take the CMS Data Validation Training prior to working on the data validation project. The training will provide each participant with documentation that the training was completed, and the data validation contractor must provide this documentation to any hiring sponsoring organization for all staff assigned to the applicable data validation team before commencing work on the data validation.

Any data validation contractor staff that participated in a previous year's data validation must still take the current year's CMS Data Validation Training prior to working on the data validation project and provide documentation to the hiring sponsoring organization that the current year's training was completed before commencing work on the data validation.

4.2 REVIEW AND LEARN THE DATA VALIDATION STANDARDS

In preparation for the data validation process, both the sponsoring organization and the data validation contractor must review and learn the *Data Validation Standards*. Refer to Appendix B for the complete set of *Part C and Part D Measure Data Validation Standards*.

[4] See 42 CFR §422.504(d) and § 423.505(d)

4.2.1 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 must 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 Technical Specifications*.

The reviewer must use these standards in conjunction with the *Data Extraction and Sampling Instructions* and the Excel-version *FDCF* or the version of the *FDCF* in the PRDVM to evaluate the organization's processes for producing and reporting the measures. CMS strongly recommends that the reviewer and the sponsoring organization's leadership team and measure report owners/data providers review the *Data Validation Standards* documentation before and during the review of each measure to ensure that they thoroughly understand the standards and measure-specific criteria. This will also help to ensure all applicable data fields are extracted for each measure.

4.2.2 Data Validation Standards: General Instructions

The top portion of each set of data validation standards (which is identical for each measure) details the documents and reports that the data validation reviewer is required to use to determine compliance with the standards for each specific measure. The documents and reports are listed within the gray box underneath the name of the applicable data measure and are displayed in Exhibit 7.

Exhibit 7. General Instructions for Data Validation Standards

[NAME OF DATA MEASURE]	
To determine compliance with the standards for [name of data measure], 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 (if the measure is subject to the sampling process)	• Data file created for submission to CMS and copy of HPMS screen shots of data entered • Other relevant information provided by organization

Also contained within this section, if applicable, are notes to the data validation reviewer regarding a specific measure and any nuances or differences that may be encountered during the review of that measure. See Exhibit 8 for an example "Note to reviewer" for the Plan Oversight of Agents data measure.

Exhibit 8. Example "Note to Reviewer "in Data Validation Standards

PLAN OVERSIGHT OF AGENTS
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.

4.2.3 Data Validation Standards: Validation Standards

The second section of each set of data validation standards is identical for all Part C and Part D measures.

4.2.3.1 Standard 1

Standard 1 (see Exhibit 9) contains the general and specific criteria for validating source documentation that the sponsoring organization provides to the reviewer.

Exhibit 9. Standard 1: Required Data Fields Are Accurately Captured and Properly Documented

DATA VALIDATION STANDARD 1	
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.

4.2.3.2 Standard 2

Standard 2 (see Exhibit 10) provides an overview of the criteria for validating the measure-specific criteria. These processes are further detailed in the Measure-Specific Criteria section, located below the standards for each measure. The standard instructs the reviewer to validate the completeness of the underlying database and the accuracy of each reported data measure. For example, the measure-specific criteria assess whether the appropriate date ranges for the reporting period are captured by the data system, and whether the expected counts and calculations are accurate and match the corresponding source code and analysis plan. Additionally, one of these criteria is used to verify that the sponsoring organization has properly interpreted and defined key terms used to determine which data are applicable. For example, the organization must properly define the term “Appeal” in accordance with CMS regulations, guidance and the *Reporting Requirements Technical Specifications* in order to ensure the quality of the reported data for that measure.

Exhibit 10. Standard 2: Data Elements Are Accurately Identified, Processed, and Calculated

DATA VALIDATION STANDARD 2	
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.

4.2.3.3 Standard 3

Standard 3 (see Exhibit 11) is used to determine whether an organization implements appropriate policies and procedures for each measure's data submission. Not only should the reviewer validate that the reported data were correctly derived from the underlying database, but they should also verify that the data are accurately uploaded or entered into the HPMS Plan Reporting Module.

Exhibit 11. Standard 3: Appropriate Data Submission

DATA VALIDATION STANDARD 3	
3	Organization implements appropriate policies and procedures for data submission, including the following: a. Data elements are accurately entered / uploaded into the HPMS tool and entries match corresponding source documents. b. All source, intermediate, and final stage data sets relied upon to enter data into HPMS are archived.

4.2.3.4 Standards 4 and 5

For Standards 4 and 5 (see Exhibit 12), the reviewer must verify that the organization has, and implements, policies and procedures for regular database updates, and for data archiving and restoration. This ensures that data are kept up to date, and that systems are in place for timely data submission or re-submission in the event of data loss.

Exhibit 12. Standards 4 and 5: Appropriate Data System Updates and Archive/Restoration

DATA VALIDATION STANDARDS 4 AND 5	
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).

4.2.3.5 Standards 6 and 7

Standards 6 and 7 (see Exhibit 13) are applicable only in certain situations. Standard 6 is applicable if an organization's data systems underwent any changes during the reporting period. If this occurred, the data validation reviewer must examine documentation of the changes to ensure there were no issues that adversely impacted the reported data.

Standard 7 applies if any of the data collection or validation processes are outsourced to another entity. This validation standard assesses whether the organization routinely monitors the quality of the entity's work and processes related to the reporting requirements.

The reviewer should mark "Not Applicable" in the Excel-version *FDCF* or the version of the *FDCF* in the PRDVM if Standard 6 or 7 is not applicable to the measure or contract under review.

Exhibit 13. Standards 6 and 7: Data System Changes and Oversight of Delegated Entity Reporting

DATA VALIDATION STANDARDS 6 AND 7	
6	*If organization's data systems underwent any changes during the reporting period (e.g., as a result of a merger, acquisition, or upgrade):* Organization provided documentation on the data system changes and, upon review, there were no issues that adversely impacted data reported.
7	*If data collection and/or reporting for this data measure are delegated to another entity:* Organization regularly monitors the quality and timeliness of the data collected and/or reported by the delegated entity or first tier/downstream contractor.

4.2.4 Measure-Specific Criteria

The third section of each set of standards contains the measure-specific criteria, which vary for each Part C and Part D measure. Measure-specific criteria are used in conjunction with Standard 2 to determine if data elements are accurately identified, processed, and calculated. The first three measure-specific criteria for each measure (see Exhibit 14) are used to validate whether the organization is utilizing the appropriate reporting period, reporting level, and reporting deadline(s) per CMS requirements.

Exhibit 14. Measure-Specific Criteria for Appropriate Reporting Period, Reporting Level, and Reporting Deadline

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

Several of the data measure standards contain a measure-specific criterion to validate whether the organization properly defined key terms that it used to compile reported data per CMS regulations, guidance and the *Reporting Requirements Technical Specifications*.

Exhibit 15 shows an example of this criterion for the Part D Appeals data measure.

Exhibit 15. Measure-Specific Criterion for Defining Key Terms

MEASURE-SPECIFIC CRITERIA	
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.

The other measure-specific criteria reference the applicable data element from the *Reporting Requirements* when possible and differ considerably depending on the measure and data element. Exhibit 16 shows an example of selected measure-specific criteria applicable to the Part C and Part D Plan Oversight of Agents data measure. The exact criteria for each Part C and D measure are based on the *Part C and Part D Reporting Requirement Technical Specifications* documents.

Exhibit 16. Measure-Specific Criteria for Selected Plan Oversight of Agents Data Elements

MEASURE-SPECIFIC CRITERIA	
5	Organization accurately calculates the number of agents investigated based on complaints, including the following criteria: a. Includes all agents with investigations that were completed during the applicable reporting period, regardless of when the complaint was received. b. Includes agents with investigations based on complaints filed directly with the organization as well as those from the HPMS Complaint Tracking Module (CTM). c. Includes all agents with investigations based on complaints against the agent under the applicable plan contract. If a complaint cannot be tied to a specific contract, then the complaint is included under all contracts that the agent is licensed to sell. d. 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 (Part C)/Data Element B (Part D)]
6	Organization accurately calculates the number of agents receiving disciplinary action resulting from a complaint filed against an agent, including the following criteria: a. Includes all agents with disciplinary actions that were taken during the applicable reporting period, regardless of when the complaint was received. b. Includes agents with any disciplinary action taken by the organization/Part D sponsor, including manager-coaching, documented verbal warning, re-training, documented corrective action plan, suspension, termination of employment/contract, and short-term revocation. c. Includes agents with disciplinary actions based on complaints filed directly with the organization as well as those from the HPMS Complaint Tracking Module (CTM). d. Includes all agents with disciplinary actions based on complaints against the agent under the applicable 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 (Part C)/Data Element C (Part D)]

4.3 REQUEST ACCESS TO HPMS PLAN REPORTING DATA VALIDATION MODULE

Once the sponsoring organization has selected a data validation reviewer, the next step is for the reviewer to request access to the Plan Reporting Data Validation Module (PRDVM) in HPMS. This Module allows users to enter and review data validation findings and submit them to CMS. The credentials assigned to a user will allow that individual to access only the PRDVM and those sponsoring organization(s)/contract(s) with which they are associated. The reviewer will use these credentials to access the appropriate screen(s) to enter data validation findings within the PRDVM starting no earlier than April 1 of the calendar year.

4.3.1 Process for Sponsoring Organization

Each sponsoring organization is required to provide their data validation reviewer with an official letter from their organization in either hardcopy or an emailed .pdf format attachment. This letter must contain the following in order for individuals representing the data validation reviewer to gain access to the PRDVM:

- The sponsoring organization's acknowledgment that it has contracted with the selected data validation reviewer to complete the review,
- The name of each individual that requires access (up to 5 individuals),
- The type of functionality that each individual user requires,
- Acknowledgement that the individuals have completed the web-based Data Validation Training,
- The contract number(s) the data validation reviewer will need access to, and
- The sponsoring organization's Chief Executive Officer's (CEO) signature.

Model language for this letter can be found in Appendix C.

If a sponsoring organization chooses to select the same data validation contractor it used for a previous year's data validation, it must still provide the contractor with this signed letter for the current year's data validation activities.

4.3.2 Process for Data Validation Reviewer

Data validation reviewers must obtain individual access to the HPMS PRDVM. If the designated user(s) from the data validation reviewer do **not** have active access to HPMS, each user should download the *Application for Access to CMS Computer Systems* from http://www.cms.hhs.gov/InformationSecurity/Downloads/EUAaccessform.pdf and follow the instructions provided in Appendix D for requesting reviewer access to the HPMS PRDVM. CMS will allow up to 5 individuals from each data validation reviewer to have access to this Module on behalf of each sponsoring organization. One application must be completed for each user. The data validation reviewer must send the completed ~~original~~ application(s), along with the ~~original~~ letter from each sponsoring organization (signed by the CEO) for which they are under contract to complete the data validation review. These documents may be sent as email attachments to Kristy.Holtje@cms.hhs.gov or may be sent via traceable carrier to:

Ms. Kristy Holtje
Re: Plan Reporting Data Validation Reviewer HPMS Access
7500 Security Blvd.
Location: C4-18-14 / Mailstop: C4-18-13
Baltimore, MD 21244-1850

If a data validation reviewer is serving multiple organizations, only one CMS user access form is required for each of that reviewer's PRDVM users, however, a letter must be provided from each organization for which the individual reviewer will be serving as an agent in HPMS.

The process for gaining access to the PRDVM in HPMS can begin with the submission of only one application and the ~~original~~ letter from the sponsoring organization. The data validation reviewer can submit new applications as they are obtained, along with a copy of the sponsoring organization letter, until they have reached the limit of 5 individuals.

For individuals that already have active CMS Enterprise User Administration (EUA) User IDs and HPMS access, a new *Application for Access to CMS Computer Systems* is not necessary. Instead, their current credentials must be modified to allow access to the PRDVM. For this access, individuals need to ensure that the ~~original~~ letter from each sponsoring organization linking the reviewer to the organization (signed by the CEO) includes the individual's current User ID and an explanation that the user already has HPMS Access. This letter must be sent to CMS via email or traceable carrier to the address indicated above.

The findings from the annual data validation review must be submitted to CMS by June 30 of each calendar year. To assure timely access to the HPMS PRDVM to meet this annual data validation timeframe, CMS strongly recommends requests for HPMS PRDVM access be submitted by April 6. Any requests received after this date will be processed on a rolling basis. It will take approximately 4 weeks for the designated individuals to obtain the credentials (CMS EUA User IDs and passwords) to access the PRDVM.

For data validation contractor staff that participated in a previous year's data validation and already have an active CMS Enterprise User Administration (EUA) User ID and HPMS access, a new *Application for Access to CMS Computer Systems* is not necessary. However, these individuals must still follow the process described above to provide CMS with the letter from the sponsoring organization linking the reviewer to the organization in order to obtain access to the HPMS PRDVM for the current year's data validation activities.

5 PLANNING FOR DATA VALIDATION ACTIVITIES

5.1 COMPLETE AND SUBMIT ORGANIZATIONAL ASSESSMENT INSTRUMENT

The *Organizational Assessment Instrument* (*OAI*) (Appendix E) focuses on how the sponsoring organization collects, stores, and reports data. While completion of the *OAI* by the sponsoring organization is not mandatory, CMS strongly recommends that organizations complete this document in advance of the data validation, as the data validation review relies significantly on the information captured in this tool. The completed *OAI* may reduce required contractor resources, and make the data validation review more efficient and effective. Organizations should provide the completed *OAI* to their selected reviewer electronically. CMS estimates that the *OAI* should take a minimum of two weeks to complete and should be submitted to the data validation reviewer no later than early April. Sponsoring organizations may send their completed *OAI* along with source code, SOPs, etc. to their reviewer prior to the start of the data validation cycle; however, the reviewer should be using this documentation to help prepare for data validation and should not be assisting sponsoring organizations with data corrections and/or data resubmissions.

Each sponsoring organization must provide its data validation contractor basic information regarding its Medicare contracts and which Part C and/or Part D *Reporting Requirements* data each contract reports to CMS. Organizations that hold more than one contract with CMS only need to complete one version of the *OAI* that covers all its contracts. If the information provided in the *OAI* varies by contract, the document allows for the flexibility to identify the differences for the reviewer in applicable sections.

All documentation and responses to questions in the *OAI* should reflect the organization's systems and processes that were in place during the reporting period(s) undergoing the data validation review. For example, if the data being reviewed is for the 2011 reporting period, the organization should include only diagrams of the information systems in place in 2011 or the programming code used in 2011 to calculate the measures.

It is up to the organization and its contractor to work out mutually agreeable methods for sharing and protecting proprietary data, such as that requested in the *OAI*, and protected health information. The *Standards for Selecting a Data Validation Contractor* document includes minimum security requirements with which the contractor's facility, equipment, and processes must comply. The sponsoring organization is responsible for ensuring that the reviewer complies with all HIPAA privacy and security requirements.

The sponsoring organization must supply all the information required for the data validation review; otherwise, it will be out of compliance with CMS requirements and will be subject to compliance actions from CMS. If an organization contracts with delegated entities (e.g., PBMs) that are not cooperative in supplying required information, the sponsoring organization is still responsible for the required information and it is up to the organization to determine how to proceed. Additionally, if a sponsoring organization or its delegated entity does not provide the information required to determine if a Standard or Sub-Standard has been met, the data validation reviewer is required to select "No" in the PDVRM (and *FDCF*, if used) for that Standard or Sub-Standard.

5.2 ANALYZE OAI RESPONSES

CMS recommends data validation contractors perform a preliminary review of the documentation submitted in the *OAI* in advance of each site visit so that any follow-up regarding the documentation can be done during the site visit. The documentation submitted by the sponsoring organization when completing the *OAI* should be adequate and enabling of an effective review. The amount of detail provided in the documentation will determine the ease of the review process, especially for the review of programming code/source code.

Additionally, the *OAI* provides supplemental questions to help the reviewers better understand the processes used by the organization to compile and report its data measures. The organization's responses to these questions will provide insight as to who is responsible for the quality control and submission of the data, the processes for incorporating CMS updates to the *Reporting Requirements Technical Specifications* into the organization's systems, and descriptions of any past issues that may have occurred during the reporting process.

5.2.1 Perform OAI Gap Analysis

Upon receiving the completed *OAI*, the data validation contractor should review the document for completeness and accuracy. Sections of the *OAI* that are missing or incomplete should be noted and the data validation contractor should follow-up with the organization to complete. It is up to the data validation reviewer to determine whether any identified gaps in the organization's *OAI* responses require addressing prior to the site visit, or can be addressed during the site visit portion of the review.

5.2.2 Review Source Code and Other Documentation

Data dictionaries and source code are critical for allowing the reviewers to map ambiguous field names and internal status codes to meaningful descriptions. Well organized and structured documentation of the reporting and data extraction processes for the various measures will assist the data validation reviewer in gaining a more thorough understanding of the organization. Data validation reviewers should be familiar with data systems and processes detailed by the organization in the *OAI* to ensure thorough preparation for the site visit.

5.2.3 Prepare Interview Discussion Guide

The *Interview Discussion Guide* (*IDG*) (Appendix F) is intended to facilitate the discussion between the data validation reviewer and each organization's report owners and subject matter experts. The *IDG* is a dynamic tool containing both general and measure-specific questions that can guide an effective discussion regarding an organization's underlying data systems and reporting processes. If, during review of the documentation provided in response to the *OAI*, the data validation reviewer discovers evidence that may indicate errors in an organization's data or reporting processes, the reviewer should modify the *IDG* used for that organization with new questions that may identify any vulnerabilities or opportunities for repeated errors with data collection or reporting. Additionally, the *IDG* should serve as a "guide" for the reviewer; it is up to the reviewer's discretion to include additional questions and/or detail to the document to discuss during site visit interviews and to ensure the additional detail is documented accordingly.

5.3 SITE VISIT DATA VALIDATION PREPARATIONS

5.3.1 Select Dates and Appropriate Location(s) of Site Visit

CMS encourages sponsoring organizations and data validation contractors to include a physical site visit as part of the data validation review to conduct the following activities: (1) conduct interviews with sponsoring organization staff, (2) observe the organization's reporting processes, and (3) obtain census and/or sample files to support the validation of Part C and Part D measures. Sponsoring organizations and data validation contractors are responsible for determining mutually agreeable dates for performing the site visit. It is estimated that the site visit for a full Part C and Part D data validation review should take up to one week to complete.

It is up to the discretion of the review team to determine the most appropriate location(s) of the physical site visit (e.g., sponsoring organization's facility, PBM's facility, other delegated entity's facility).

If the data validation does not include a physical site visit, the review team should still conduct a "virtual" site visit using a virtual meeting tool or teleconference(s). CMS requires that the data validation contractor document in its work papers when a "virtual" site visit is used and explain the circumstances why an on-site review was not possible.

5.3.2 Develop Agenda for Site Visit

To further prepare for each organization's site visit, the data validation reviewer and sponsoring organization should work together to prepare a site visit agenda. Appendix G contains a sample agenda that can be used for the site visit portion of the data validation review. This agenda is structured to include an entrance and exit conference, and interviews and demonstrations of data systems for each measure included in the data validation. It is also recommended that the data validation reviewer create a sign-in sheet to be completed throughout the site visit in order to collect contact information for each organization's report owners and subject matter experts in case any follow-up is required.

It is important to note that the number of days required to complete the site visit may be contingent upon the size of the organization, efficiency of the organization's operations, level of reporting automation, and scope of the data validation review. The data validation reviewer must schedule sessions with the sponsoring organization's report owner(s) for each data measure and allow sufficient time for the sponsoring organization to provide an overview of each of the relevant data systems used in gathering data and producing reports, as well as to complete the data extraction/sampling process (see Section 6 for more information). Multiple sessions could be conducted concurrently during the site visit at the

discretion of the review team, or the agenda could be structured so that interviews and demonstrations of reporting processes are scheduled by each report owner in order to reduce repetitive discussions and demonstrations, especially in cases where one report owner oversees the processes for multiple data measures that use the same data system(s). This will ensure optimal time and resource management during the site visit.

5.3.3 Prepare for Data Extraction and Sampling

In preparation for the data extraction and sampling during the site visit, the data validation reviewer should review information provided in the completed *OAI* and, if necessary, hold conference calls with the sponsoring organization to discuss the organization's processes. Calls held specifically with each measure's report owner can also provide an opportunity for the data validation reviewer to review the *Data Extraction and Sampling Instructions* document in more detail and for the report owners to seek clarification as needed. These discussions can also inform the data validation reviewer about the organization's data systems and sources from which the sample data would be pulled.

There are two methodologies that can be used to extract data for each measure. The first is to extract the full census of data for a measure, meaning that every data record that is relevant to a measure is extracted. When possible, reviewers should attempt to extract the full census. Extracting the census will enable the reviewer to determine with the greatest precision whether reported measures were submitted accurately. If the size or complexity of a database presents an unusual time burden on the reviewer and/or sponsoring organization, then the second method, extraction of a random sample, which is a subset of the full census, can be used. Reviewers must use their best judgment to decide if extracting a full census is feasible, or if selecting a random sample will provide the data necessary for the data validation review. In addition, reviewers must determine if the sponsoring organization's staff requires supervision during the actual data extraction process, or if the sponsoring organization's staff are able to extract data without supervision. See Section 6.4 for additional requirements if the reviewer is unable to supervise the data extraction process.

6 SITE VISIT DATA VALIDATION ACTIVITIES

6.1 CONDUCT ENTRANCE CONFERENCE

The entrance conference provides an opportunity for the review team and the sponsoring organization's management and individual report owners to introduce themselves and discuss expectations for the site visit. At the entrance conference, the data validation reviewer should describe the objectives for the review and discuss any administrative needs of the review team. Optionally, the sponsoring organization may provide a high-level overview of its organization, focusing on its operations with respect to meeting the CMS reporting requirements. CMS recommends that the entire review team also meet briefly with the sponsoring organization's management and individual report owners at the beginning of each day of the site visit to go over administrative needs and review the day's agenda.

6.2 CONDUCT INTERVIEWS WITH ORGANIZATION STAFF

During the site visit, the data validation reviewer must conduct interviews with the subject matter experts and report owners for each data measure and reporting system. These interviews provide a first-hand opportunity for the data validation reviewer to gain a thorough understanding of each organization's data collection and reporting processes involved with meeting CMS reporting requirements. The reviewer should reference the *IDG* as needed to ensure that all key topics are addressed during the interviews.

Also, any outstanding questions and follow-up items identified during the analysis of *OAI* responses should be addressed during the interviews.

6.3 OBSERVE REPORTING PROCESSES

The site visit allows the opportunity for the sponsoring organization to provide a significant amount of useful information to the reviewer. Designated sponsoring organization staff (i.e., report owners) must provide visual demonstrations of the data systems and reporting processes including data extraction from originating data sources, data analysis, quality assurance processes, and processes for entering or uploading final data into the HPMS Plan Reporting Module. The following is a sample list of the parts of the process that should be demonstrated:

- Location of report owner and data providers
- Location and function of all data warehouses
- Types of data used (format, amount of tables)
- Links and joins to other areas/ departments/ data
- Types of programming used to create the reports
- Review processes and oversight
- Timeframes for the process (amount of time it takes to run specific parts of the report)
- Approximations of report volume
- Updates to the process and system changes
- Storage locations, security and access constraints

The visual demonstrations provide a clear illustration of the reporting processes, provide the reviewer with insight into the organization's ability to ensure accurate, valid and timely data, and allow an opportunity to get immediate responses to any questions or concerns about the reported data.

6.4 EXTRACT CENSUS OR SAMPLE DATA

The next step is for the data validation contractor to work with the report owners to draw a census or a random sample from each measure's final stage data set, following the *Data Extraction and Sampling Instructions* document (Appendix H). The sampling process involves using built-in random number generators in the applications used to display the data or perform the query (Microsoft Excel or SQL). Once a random number is assigned to each unique record ID, the data owner can sort the data by the random number field and chose the statistically appropriate number of records as the sample. A discussion of minimum sample sizes can be found in *Data Extraction and Sampling Instructions*. The unique IDs from the random sample in the final stage data set are then applied against the source data set to pull the corresponding source data records. For measures where it is more efficient to extract the entire data set (the "census"), there appears to be no benefit in creating the sample during the site visit. When providing the data validation findings to CMS in the PRDVM, the reviewer must report which data extraction method was used (full census or random sample) to validate data for each applicable measure.

The processes used to draw the random data samples vary considerably, depending on the report owner and measure. For example, some report owners may be able to easily draw the sample data for their measure without having to manually clean or manipulate the data, while other report owners may have to perform more extensive query programming and manual data cleaning in order to draw the sample data. During each of the sessions to demonstrate reporting processes, the sponsoring organization's report owners should brief the review team on the processes used to assemble the sample data files, including the source, intermediate, and final stage data sets.

It is mandatory that reviewers follow the *Data Extraction and Sampling Instructions* document (Appendix H). If the sponsoring organization's staff is extracting the data, it is highly recommended that the reviewer supervise the data extraction process to ensure these instructions are followed correctly. If the reviewer is unable to supervise the data extraction process, the reviewer should obtain documentation from the sponsoring organization describing how the extraction process was performed. For example, if a random sample is extracted, the reviewer should request and validate the programming code used to extract the sample data. If a full census is extracted, the reviewer should validate that the record counts match between the census extraction and the source and final stage data files.

CMS recommends that the data validation contractor record details about each measure's data set into a *Data File Inventory Log*. Appendix I contains an example log that the reviewer can use. It includes details such as the measure name, report owner, data file name, type of data file (e.g., source, intermediate, or final stage data file), number of rows or records, and a description of the file. By completing this log, the review team will be able to easily reference the data files during its post-site visit assessment of data.

The sponsoring organization should write all data files to tab-delimited or comma-delimited text files with variable names in the first row, and transfer these files to the reviewer's secure storage device for each measure's data. The organization must also provide the reviewer a file layout or data dictionary for the data files in either Word documents or Excel spreadsheets on the same secure storage device. The sponsoring organization and data validation contractor must ensure that they have established mutually agreeable methods for sharing protected health information and that the reviewer complies with all Health Insurance Portability and Accountability Act (HIPAA) privacy and security requirements.

6.5 CONDUCT EXIT CONFERENCE

CMS recommends that the entire review team meet briefly with the sponsoring organization's management and individual report owners at the end of each day of the site visit to go over any action items or outstanding documentation needs. The site visit should conclude with an exit conference, where the data validation reviewer should provide the organization with a summary of next steps and note any follow-up that may need to occur.

7 DETERMINING AND DOCUMENTING DATA VALIDATION FINDINGS

7.1 REQUEST ADDITIONAL DOCUMENTS (IF REQUIRED)

CMS recognizes that it may not be possible to obtain all of the required data and documentation during the scheduled site visit and follow-up conversations and requests may be required. The data validation reviewer should make every attempt to gather all required data and documentation during the site visit. In the event that not all information is available, or follow-up is required after the conclusion of the scheduled site visit, the reviewer should have additional conversations with the sponsoring organization and/or make requests for documentation. Data validation reviewers and sponsoring organizations should understand that the data validation is an iterative and collaborative effort, and organizations should be prepared to provide additional data and documentation after the site visit has been held.

7.2 DETERMINE DATA VALIDATION FINDINGS

Following the site visit, the data validation reviewer must assess the documentation and census/sample data received from the sponsoring organization, as well as the information gained during the interviews and demonstrations of the organization's reporting processes and information systems.

7.2.1 Using the PRDVM and Findings Data Collection Form

The data validation reviewer must complete the version of the *FDCF* in the applicable screens in the PRDVM as it determines the findings for each contract included in the scope of the review. CMS recommends data validation reviewers work and enter findings directly in the PRDVM, saving data periodically to avoid the system timing out. Alternatively, reviewers may also use the Excel version of the *FDCF* (Appendix J) torecord findings. The PRDVM data entry screens and *FDCF* mirror the content of the *Data Validation Standards* document, but allow the reviewer to record notes, data sources referenced, and findings for the different standards and criteria specified for a given measure. The reviewer will record measure-level, and in some cases data element-level, findings for each reported data measure. Most data validation standards (Standards 1, 4, 5, 6, and 7) are assessed at the measure-level, as they assess organization processes that are not likely to vary at the data element-level. The data validation reviewer may print the findings he/she entered in the PRDVM and share them with the sponsoring organization at any point during the review by accessing the HPMS report entitled "Review Data Validation Findings Report."

If using the *FDCF*, reviewers should only complete areas displayed in white for data sources, review results, and findings. Areas displayed in gray are not applicable and should not be completed. In the "Data Sources and Review Results:" column, the reviewer should enter the data sources used and review results for each Standard or Sub-Standard. Next to this column, in the "Findings" column, the reviewer must select "Y" if the requirements for the Standard or Sub-Standard have been completely met. If any requirement for the Standard or Sub-Standard has not been met, the reviewer must select "N." In instances where a Standard or Sub-Standard is not applicable, the reviewer must select "N/A" and must enter the reason for the "N/A" in the "Review Results" field.

Exhibit 17 illustrates an example of the *FDCF* for Standard 1. The reviewer will assess this standard at the measure-level and must determine a finding for each of the nine Sub-Standards contained in Standard 1.

Exhibit 17. Example Rows from *FDCF* for Standard 1

Standard / Sub-Standard ID	Measure-Specific Criteria ID	Standard/Sub-Standard Description	Data Sources and Review Results: Enter review results and/or data sources	Findings: Select "Y" "N" or "N/A" from Sections in White Only
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.	Data Sources:	
1.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.	Review Results:	
1.b		Source documents create all required data fields for reporting requirements.	Review Results:	
1.c		Source documents are error-free (e.g., programming code and spreadsheet formulas have no messages or warnings indicating errors).	Review Results:	
1.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).	Review Results:	
1.e		Data file locations are referenced correctly.	Review Results:	
1.f		If used, macros are properly documented.	Review Results:	
1.g		Source documents are clearly and adequately documented.	Review Results:	
1.h		Titles and footnotes on reports and tables are accurate.	Review Results:	
1.i		Version control of source documents is appropriately applied.	Review Results:	

Standard 2 requires the reviewer to assess measure-level findings for Sub-Standards 2.a through 2.c, which are based on measure-specific criteria 1 through 3 and, if applicable, Sub-Standard 2.d, which is based on measure-specific criterion 4. Exhibit 18 illustrates an example of the *FDCF* for Standard 2, Sub-Standards 2.a through 2.d. for the Part D Appeals data measure.

Exhibit 18. Example Rows from *FDCF* for Standard 2, Sub-Standards 2.a through 2.d for Part D Appeals Data Measure

Standard / Sub-Standard ID	Measure-Specific Criteria ID	Standard/Sub-Standard Description	Data Sources and Review Results: Enter review results and/or data sources	Findings: Select "Y" "N" or "N/A" from Sections in White Only
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.	Data Sources:	
2.a	MSC-1	The appropriate date range(s) for the reporting period(s) is captured. 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.	Review Results:	
2.b	MSC-2	Data are assigned at the applicable level (e.g., plan benefit package or contract level). Organization properly assigns data to the applicable CMS contract and plan benefit package.	Review Results:	
2.c	MSC-3	Appropriate deadlines are met for reporting data (e.g., quarterly). Organization meets deadlines for reporting quarterly data to CMS by 5/15, 8/15, 11/15, and 2/15. [*Note to reviewer*: If the organization has, for any reason, re-submitted its data to CMS for this measure, the reviewer should verify that the organization's original data submissions met each CMS deadline in order to have a finding of "yes" for this measure-specific criterion. However, if the organization re-submits data for any reason and if the re-submission was completed by 3/31 of the data validation year, the reviewer should use the organization's corrected data submission(s) for rest of the measure-specific criteria for this data measure.]	Review Results:	
2.d	MSC-4	Terms used are properly defined per CMS regulations, guidance and *Reporting Requirements Technical Specifications*. 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.	Review Results:	

The reviewer must also determine data element-level findings for Sub-Standard 2.e, which examines each data element for compliance with the applicable measure-specific criteria that varies across the data elements reported by the organization.

Exhibit 19 illustrates an example of the *FDCF* for Standard 2, Sub-Standard 2.e for the Part D Appeals data measure.

Exhibit 19. Example Rows from *FDCF* for Standard 2, Sub-Standard 2.e for Part D Appeals Data Measure

Standard / Sub-Standard ID	Measure-Specific Criteria ID	Standard/Sub-Standard Description		Data Sources and Review Results: Enter review results and/or data sources	Findings: Select "Y" "N" or "N/A" from Sections in White Only
2.e	MSC-5	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.	Data Element A	Review Results:	
		Applicable Measure-Specific Criteria: MSC-5: Organization accurately calculates the total number of redeterminations (Part D only), including the following criteria: MSC-5a: Includes all redeterminations for Part D drugs with a date of final decision that occurs during the reporting period, regardless of when the request for redetermination was received or when the member was notified of the decision. [Data Element A] MSC-5b: Includes all reviews of partially favorable and adverse coverage determinations. [Data Element A] MSC-5c: Includes both standard and expedited redeterminations. [Data Element A] MSC-5d: Includes all methods of receipt (e.g., telephone, letter, fax, in-person). [Data Element A] MSC-5e: Includes all redeterminations regardless of who filed the request (e.g., member, appointed representative, or prescribing physician). [Data Element A]	Data Element B	Review Results:	

Standard / Sub-Standard ID	Measure-Specific Criteria ID	Standard/Sub-Standard Description		Data Sources and Review Results: Enter review results and/or data sources	Findings: Select "Y" "N" or "N/A" from Sections in White Only
2.e (cont)	MSC-5 (cont)	MSC-5f: Excludes dismissals or withdrawals. [Data Element A]			
		MSC-5g: Excludes IRE decisions, as they are considered to be the second level of appeal. [Data Element A]	Data Element C	Review Results:	
		MSC-5h: Excludes redeterminations regarding excluded drugs. [Data Element A]			
	MSC-6	MSC-6: Organization accurately calculates the number of redeterminations by final decision, including the following criteria: MSC-6a: 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). [Data Elements B and C] MSC-6b: 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]			

Standard 3 contains two Sub-Standards. Sub-Standard 3.a requires the reviewer to assess data element-level findings and Sub-Standard 3.b requires measure-level findings. Sub-Standard 3.a is assessed at the data element-level for measures that CMS requires to be manually entered into the HPMS Plan Reporting Module because it confirms that there were no manual data entry errors for each data element, and for measures that are reported as file uploads, it confirms at the Sub-Standard level that the organization used the correct file layout. Exhibit 20 illustrates an example of the *FDCF* for Standard 3 for the Part D Appeals data measure.

Exhibit 20. Example Rows from *FDCF* for Standard 3 for Part D Appeals Data Measure

Standard / Sub-Standard ID	Measure-Specific Criteria ID	Standard/Sub-Standard Description		Data Sources and Review Results: Enter review results and/or data sources	Findings: Select "Y" "N" or "N/A" from Sections in White Only
3		Organization implements appropriate policies and procedures for data submission, including the following:		Data Sources:	
3.a		Data elements are accurately entered / uploaded into the HPMS tool and entries match corresponding source documents.	Data Element A	Review Results:	
			Data Element B	Review Results:	
			Data Element C	Review Results:	
3.b		All source, intermediate, and final stage data sets relied upon to enter data into HPMS are archived.		Review Results:	

Standards 4 through 7 do not have any Sub-Standards and are assessed at the measure-level. For example, Standard 4 assesses policies and procedures for periodic data system updates; an organization will most likely have these policies and procedures in place for an entire measure, as opposed to having them in place for only certain data elements. Exhibit 21 displays example rows from the *FDCF* for Standards 4 through 7.

Exhibit 21. Example Rows from *FDCF* for Standards 4 through 7

Standard / Sub-Standard ID	Measure-Specific Criteria ID	Standard/Sub-Standard Description	Data Sources and Review Results: Enter review results and/or data sources	Findings: Select "Y" "N" or "N/A" from Sections in White Only
4		Organization implements appropriate policies and procedures for periodic data system updates (e.g., changes in enrollment, provider/pharmacy status, claims adjustments).	Data Sources: Review Results:	
5		Organization implements appropriate policies and procedures for archiving and restoring data in each data system (e.g., disaster recovery plan).	Data Sources: Review Results:	
6		If organization's data systems underwent any changes during the reporting period (e.g., as a result of a merger, acquisition, or upgrade): Organization provided documentation on the data system changes and, upon review, there were no issues that adversely impacted data reported.	Data Sources: Review Results:	
7		If data collection and/or reporting for this data measure are delegated to another entity: Organization regularly monitors the quality and timeliness of the data collected and/or reported by the delegated entity or first tier/ downstream contractor.	Data Sources: Review Results:	

7.2.2 Sources and Criteria for Determining Findings

In order to ensure consistency with the review process, CMS has provided below a description of the data sources and criteria that data validation reviewers must use to determine findings for each of the data validation standards.

CMS expects that there will be situations when the data validation reviewer finds that a sponsoring organization is only in partial compliance with specific data validation standards. CMS does not believe that only a 100% score demonstrates compliance, and has established a minimum threshold value of 90 percent correct records (e.g., sample or census records, source documents, policies and procedures, data entry records) in order to record a "Yes" finding for any standard. Exhibit 22 provides examples of how to calculate this minimum threshold specifically for Standard 2, for which the data validation involves samples or the complete census of records and/or data values.

Exhibit 22. Examples of Calculations to Determine Minimum Threshold of Correct Sample/Census Records for "Yes" Finding

Sample/Census Size	Calculation for Minimum Threshold	Minimum Threshold of Correct Records for "Yes" Finding
150	0.90 x 150=135	At least 135 of the records are correct for the measure specific criteria to be recorded as "Yes".
205	0.90 x 205=184.5	At least 185 of the records are correct for the measure specific criteria to be recorded as "Yes" (round 184.5 to 185).

7.2.2.1 Standard 1

This validation standard is assessed at the measure-level and is used to determine that all source documents accurately capture required data fields and are properly documented. The data sources and criteria for evaluating Standard 1 are described in Exhibit 23.

Exhibit 23. Criteria for Evaluating Standard 1: Required Data Fields

SOURCE	CRITERIA
OAI Sections 4.1, 4.2, and 5 *IDG* Sections 2.2, 2.3, 2.4, 3 and 4	Determine if the organization's source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) accurately capture the data fields required for each measure under review and are properly documented. Ensure that all source documentation is legible, descriptive, and understandable, including each of the following: • Standard Operating Procedures (SOPs) reflect document handling procedures • Titles and footnotes used in programs and reported output are legible and correspond to HPMS reports and tables • SOPs, file-naming conventions, dates of source documents and output reports reflect application of version control • Data validation reviewer is using the documentation that is current and relevant to the time period of the reporting requirements • Dated HPMS entries match source document(s).

Please note that Standards 1 and 2 should be addressed concurrently given that an evaluation of source documents directly impacts the quality of the actual data and vice versa (that elements for each measure are accurately identified, processed, and calculated). For example, the data validation reviewer should

ensure that all source documentation (file layouts, data dictionaries, programming code, work instructions, SOPs etc.) is available and allows for the complete validation for each data measure's validation.

7.2.2.2 Standard 2

This validation standard assesses whether the data elements for each measure are accurately identified, processed, and calculated. Each data validation reviewer should ensure that it has staff fluent in the programming language (SQL, SAS, Microsoft VBA) used by the sponsoring organization. The data sources and criteria for evaluating Standard 2 are described in Exhibit 24.

Since the data validation reviews must be conducted at the contract level, for the data measures that require reporting at the plan benefit package (PBP)-level, if the reviewer finds that the organization incorrectly identified, processed, or calculated the data reported for any of the PBPs included under a contract, then the reviewer must assign a "No" finding in the PDVRM (and *FDCF*, if used) for the entire contract for the applicable Sub-Standard or data element (for Sub-Standard 2.e).

While careful inspection of the source code should detect most errors in the reported data, a careful review of the census or sample data gathered from the sponsoring organization will minimize the chance that a programming error was undetected by the reviewer. Many of the same items that will be checked in reviewing the source code can also be checked by analyzing the extracted data sets.

Exhibit 24. Criteria for Evaluating Standard 2: Accurate Data Elements

SOURCE	CRITERIA
OAI Sections 4.1, 4.2, and 5 *IDG* Sections 2.2, 2.3, 2.4, 3 and 4	Assess the programming code to determine if the data was extracted from the system properly and if the calculations used in reporting measure data to CMS is accurate according to the measure-specific criteria applicable to each measure under review. A thorough review of source code must examine every line of code to ensure the following for each measure under review: • Data is extracted from the appropriate source system; verify that all data sets found in the programming code can be traced back to the appropriate source data sets. • Data sets are filtered correctly; verify that data inclusion and exclusion criteria were applied according to the measure-specific criteria. For example, proper inclusion of records would ensure that source code indicates that only those records falling within the reporting period date range are included in the reported data. An example of correct exclusion would document source code that indicates beneficiaries are not eligible for a particular benefit (e.g., Medication Therapy Management Program). • Individual data sets are joined or merged correctly (this is especially important when moving data from source data sets to intermediate data sets); verify that the correct key data field was used to generate the new data set and that the correct type of join (or data merge) was used to avoid creating duplicate records or improperly combining records from various data sets. • Data set progression is accurate; verify that required data fields in both the source and final stage files allow for file comparison and understanding of data production from source system through the final stage file. • If full census data is not extracted, verify that the sample size is sufficient and representative of the population of interest. While the *Data Extraction and Sampling Instructions* provide minimum sample sizes, reviewers often will need larger data sets to check for errors that occur infrequently. Statisticians should rely on standard statistical practices when determining the proper sample size so that any estimates generated are statistically significant. • All data elements are calculated accurately; verify that the calculation of each of the data elements is consistent with the measure-specific criteria.

SOURCE	CRITERIA
Census/Sample Data	Assess the census/sample data provided by the sponsoring organization to determine each of the following for each measure under review: • Data records are selected properly. Perform frequency calculations to list all unique occurrences of data fields pertinent to the calculation of the data measure to verify they contain values within an acceptable range for the data field. Calculating frequency of occurrence for certain data fields might also alert the reviewer to obvious mistakes in the data extraction. Also verify that data has been selected at the proper level (e.g., either the contract or the plan benefit package level). Checking date ranges, demographic information, and eligibility information are other examples that examine proper data filtering. • Individual data sets are joined or merged correctly. When individual data sets are available (most likely for intermediate data sets), sample a few records from the individual data sets to confirm that they were joined properly. Also check for duplicate records and determine if record counts for the component data sets agree with those found in the merged data set. • All data elements are calculated accurately. Using the data fields that the organization used to calculate the data elements, refer to the measure-specific criteria for each reporting measure and recalculate the data elements to verify accuracy. Also calculate sums of the individual records within each reporting measure to ensure that they equal those reported to CMS.
Submission Activity Report from HPMS Plan Reporting Module	Request a copy of the contract's Submission Activity Report from the sponsoring organization. This report displays information about the original submission and all subsequent resubmissions for a particular contract or contracts. The report displays Reporting Period, Contract Number, Plan ID, Submission Version, Due Date and Date Submitted for each section. Assess this report to determine if appropriate deadlines were met for reporting data.

Exhibit 24 provides several examples of how to review source code and evaluate the integrity of the data. However, the data validation reviewer may use other methods of data validation to ensure a comprehensive and complete review of the source code and census/sample data. The reviewer must clearly document all errors found in programming code, referring to the program examined, the precise location in the program, the nature of the error, and the impact of the error in the "Data Sources and Review Results" section of the PDVRM (and *FDCF*, if used). Likewise, any evidence from the review of census/sample data that leads to a negative finding must be clearly documented in the applicable section of the PDVRM (and *FDCF*, if used).

When validating Sub-Standard 2.c, if the organization has, for any reason, re-submitted its data to CMS for a measure, the data validation reviewer should verify that the organization's original submission(s) met the CMS deadline. If the deadline was met, the reviewer must assess a "Yes" finding for this measure-specific criterion. However, if an organization re-submits data for any reason and if the re-submission was completed by March 31[5] of the calendar year of the data validation review (i.e., immediately prior to the data validation review timeframe), the data validation reviewer should use the organization's corrected data submission for performing the validation, not the original data. The March 31 deadline will give the reviewer enough time to include the corrected data in the scope of its review of data and determination of findings. Additionally, if the organization received CMS permission to submit data after the reporting deadline (i.e., its first submission), the reviewer must request that the organization show proof that it requested and was granted an extension by CMS. If this proof is valid, then the reviewer should consider the deadline as being met, and assess a "Yes" finding for this measure-specific criterion. For either of these scenarios, the reviewer must clearly document the circumstances in the "Data Sources and Review Results" section of the PDVRM (and *FDCF*, if used).

[5] These instructions should not discourage sponsoring organizations from re-submitting corrected data to CMS if necessary; however, re-submissions after March 31 will not be included in the scope of the data validation review and will not change a reviewer's "No" finding or a CMS determination of Not Pass.

7.2.2.3 Standard 3

This validation standard assesses whether the organization implements appropriate policies and procedures for entering or uploading each data submission to the HPMS Plan Reporting Module. The data sources and criteria for evaluating Standard 3 are described in Exhibit 25.

Since the data validation reviews must be conducted at the contract level, for the data measures that require reporting at the plan benefit package (PBP)-level, if the reviewer finds that the organization did not accurately enter or upload data reported for any of the PBPs included under a contract, then the reviewer must assign a "No" finding in the PDVRM (and *FDCF*, if used) for the entire contract for the applicable data element(s) for Sub-Standard 3.a or for Sub-Standard 3.b.

Exhibit 25. Criteria for Evaluating Standard 3: Appropriate Data Submission to CMS

SOURCE	CRITERIA
OAI Sections 4.3.1 and 5.4 *IDG* Sections 2.3 and 2.4	(Sub-Standard 3a) Determine who is responsible for entering/uploading data into the HPMS Plan Reporting Module for each measure under review and if the organization has appropriate written work instructions or policies and procedures for the entry or submission of the *Part C and Part D Reporting Requirements*.
OAI Section 5 Data file created for submission to CMS and HPMS screen shots of data entered	(Sub-Standard 3a) Compare the data file created for submission to CMS with a copy of the HPMS screen shots of data entered to confirm there were no manual data entry errors. For file uploads, confirm that the data file adheres to the record layout specified in the applicable *Part C or Part D Technical Specifications* document.
OAI Section 5.4 *IDG* Sections 2.2 and 2.3	(Sub-Standard 3b) Determine if the organization has a policy or procedure for archiving all source, intermediate, and final stage data sets relied upon to enter data into the HPMS Plan Reporting Module, and confirm that the organization implemented this policy for the measure under review.

7.2.2.4 Standard 4

This validation standard is assessed at the measure-level and is used to assess whether the organization has and implements appropriate policies and procedures for regular database updates. The data sources and criteria for evaluating Standard 4 are described in Exhibit 26.

Exhibit 26. Criteria for Evaluating Standard 4: Appropriate Data System Updates

SOURCE	CRITERIA
OAI Sections 4.3 and 5.4 *IDG* Sections 2.2, 2.3, and 2.4	Determine if the organization has a policy or procedure for performing periodic updates for each data system used for the measure under review that ensures reported data are accurate and timely.
OAI Section 4.3 *IDG* Sections 2.2, 2.3, and 2.4	Determine if the validity of the organization's data for the measure under review was negatively impacted by the failure to implement its data system update process during the reporting period.

7.2.2.5 Standard 5

This validation standard is assessed at the measure-level and is used to assess whether the organization has and implements appropriate policies and procedures for data archiving and restoration. The data sources and criteria for evaluating Standard 5 are described in Exhibit 27.

Exhibit 27. Criteria for Evaluating Standard 5: Appropriate Data System Archive/Restoration

SOURCE	CRITERIA
OAI Section 5.4	Determine if the organization has a policy or procedure for archiving and restoring data in each data system used for the measure under review that ensures that systems are in place for timely data submission or re-submission in the event of data loss.
IDG Section 2.4	Determine if the validity of the organization's data for the measure under review was negatively impacted by the failure to implement its data archive/restoration plan during the reporting period.

7.2.2.6 Standard 6

This validation standard is assessed at the measure-level and is used to assess whether the validity of the organization's data was adversely impacted by any changes to data systems during the reporting period. The data sources and criteria for evaluating Standard 6 are described in Exhibit 28.

Standard 6 applies if an organization's data systems underwent any changes during the reporting period. The reviewer should mark "Not Applicable" in the PDVRM (and *FDCF*, if used) if Standard 6 is not applicable to the contract under review.

Exhibit 28. Criteria for Evaluating Standard 6: Data System Changes

SOURCE	CRITERIA
OAI Sections 4.1, 4.3, and 5 *IDG* Sections 2.2, 2.3, and 2.4	Determine if there were any changes to data sources used for data collection and storage, data processing, analysis, and reporting for the measure under review. Determine if data system changes were the root cause of any outlier notices received from CMS for the measure under review. Determine if the organization implemented any process or quality improvement activities during the reporting period specifically related to the data system change for the measure under review. Determine if the validity of the organization's data was adversely impacted by any changes to data systems during the reporting period.

7.2.2.7 Standard 7

This validation standard is assessed at the measure-level and is used to assess whether the organization routinely monitors the quality of a delegated entity's work and processes related to the reporting requirements. The data sources and criteria for evaluating Standard 7 are described in Exhibit 29.

Standard 7 applies if any of the data collection or validation processes are outsourced to another entity. The reviewer should mark "Not Applicable" in the PDVRM (and *FDCF*, if used) if Standard 7 is not applicable to the measure or contract under review.

Exhibit 29. Criteria for Evaluating Standard 7: Oversight of Delegated Entity Reporting

SOURCE	CRITERIA
OAI Sections 4.1 and 5 *IDG* Sections 2.2, 2.3, 2.4, 3 and 4	Determine if and how the organization monitors the data production process for the measure for which the delegated entity is responsible, including ensuring quality and timeliness of the data. Determine if the organization has a policy or procedure for overseeing the delegated entity's reporting process or outcomes for the measure under review.

7.3 REVIEW DRAFT FINDINGS WITH SPONSORING ORGANIZATION

Once the findings have been documented in the PRDVM (and *FDCF*, if used), the reviewer must share the draft findings with the organization. The sponsoring organization and data validation contractor should build time into the April-June data validation schedule to allow sufficient review of the findings. Any issues identified during this review must be resolved prior to the data validation reviewer's June 30 deadline for submitting findings to CMS.

7.4 FINALIZE FINDINGS

Following any review of the draft findings with the sponsoring organization, the data validation reviewer must update the PRDVM (and *FDCF*, if used) with any necessary revisions. This final version will be used to report the results of the data validation review to CMS.

7.5 ARCHIVE WORK PAPERS / RECORD RETENTION

The data validation reviewer must prepare a complete archive of work papers associated with the annual data validation and provide it to the sponsoring organization. At a minimum, this archive must contain the documentation described in Exhibit 30. The data validation reviewer should also retain a complete copy of this archive in accordance with its contract with the sponsoring organization .

When the sponsoring organization receives the archive from the data validation reviewer, the sponsoring organization must add the documentation of its data validation contractor selection process to the archive, including how its chosen data validation contractor meets the minimum qualifications, credentials, and resources set forth in the *Standards for Selecting a Data Validation Contractor*. The sponsoring organization must retain this complete archive for the 10-year retention period required per federal regulations[6] and be prepared to provide the archive to CMS upon request.

Exhibit 30. Minimum Documentation Required For Data Validation Archive

DATA VALIDATION ARCHIVE	
• Documentation of Data Validation Contractor Selection Process • Documentation of completion of CMS Data Validation Training for all staff assigned to the data validation team • Completed *OAI*, including all documentation provided in response to *OAI* Section 5 • Final Site Visit Agenda • Completed Sign-in Sheets from site visit (if used) • Final *Interview Discussion Guide* used during site visit	• Copies of any formal presentations during site visit • Notes on staff interviews and demonstrations during site visit • Census/sample data • Additional documentation provided by sponsoring organization during/after site visit • Draft findings in *FDCF* (if findings not entered directly into PRDVM) • Notes on issues resulting in changes to draft findings • Final *FDCF* (if findings not entered directly into PRDVM)

[6] See 42 CFR §422.504(d) and § 423.505(d)

8 SUBMIT FINDINGS TO CMS

8.1 SUBMIT FINDINGS IN HPMS PLAN REPORTING DATA VALIDATION MODULE

Following the conclusion of the data validation review and the finalization of findings, the data validation contractor must report the findings directly to CMS via the PRDVM in HPMS by June 30. Instructions for using this module are contained in the PRDVM Quick Reference Guide, which is available in the PRDVM. The data validation contractor will report to CMS information that mirrors the *FDCF*. This includes review results and/or data sources that were reviewed for each Standard or Sub-Standard, as well as the Yes, No, or Not Applicable finding associated with each Standard or Sub-Standard.

8.2 SPONSORING ORGANIZATION DISAGREEMENT WITH FINDINGS

If the sponsoring organization disagrees with any of the findings submitted by the data validation contractor, it may submit information indicating this disagreement to CMS. Submissions should be sent to CMS via the PartCandD_Data_Validation@cms.hhs.gov email box and should contain all of the following information in order to be considered for review.

- Email subject line must state: "Data Validation: Reported Findings Discrepancy"
- Content of email must include the information below, in list format and in the following order:
  - Name of Sponsoring Organization
  - CMS Contract Number(s)
  - Organization's Contact Name, Title, Phone Number and Email Address
  - Name of Data Validation Contractor Organization
- For each area of discrepancy, list the following information:
  - Part C or Part D, Name of Measure
  - Standard/ Sub-Standard ID, Measure Specific Criteria ID
  - Description of data validation reviewer's finding
  - Reason for disagreement with finding
  - Steps that were taken to resolve the disagreement with the data validation reviewer prior to the submission of the finding
  - Outcome of discussions, areas of impasse, and any additional information

CMS will review any findings disagreements on a case by case basis.

9 CMS DETERMINATION OF PASS/NOT PASS

9.1 PASS/NOT PASS DETERMINATION

For each data measure, CMS has assigned a score to each of the Standards or Sub-Standards. CMS will determine, for each measure, a Pass or Not Pass determination according to the findings entered into the PDVRM by the data validation reviewer. A Standard or Sub-Standard receiving a "Yes" finding will receive the points assigned to that Standard or Sub-Standard, while a "No" finding will result in zero points being assigned to the Standard or Sub-Standard. The *Data Validation Pass/Not Pass Determination Methodology* document (Appendix K) identifies the individual score CMS has assigned to each Standard and Sub-Standard for all data measures.

After all findings are submitted to CMS, CMS will calculate a percentage score for each data measure by summing the scores for all Standards or Sub-Standards in a measure and dividing this sum by the

maximum total score possible for the measure. If this percentage is at or above the threshold percentage established by CMS, the measure will receive a Pass determination. Otherwise, the measure will receive a Not Pass determination.

In addition to individual data measure Pass/Not Pass determinations, CMS will determine the score thresholds and issue a Pass/Not Pass determination for all Part C data measures as a group, all Part D data measures as a group, and a combined Part C and Part D determination for those contracts reporting both Part C and Part D data.

9.2 CMS NOTIFICATION TO SPONSORING ORGANIZATION OF PASS/NOT PASS DETERMINATIONS

CMS may notify each sponsoring organization of the Pass or Not Pass determinations via a report issued through the HPMS PRDVM.

9.3 SPONSORING ORGANIZATION APPEAL OF NOT PASS DETERMINATION

A sponsoring organization has the right to appeal any Not Pass determination(s) it receives for an individual data measure as well as any Not Pass determination(s) it receives for the Part C and/or Part D data measures or for the overall combined Part C and Part D determination.

If the sponsoring organization wishes to appeal a Not Pass determination, it must submit an appeal to CMS within 5 business days of receiving notice of the determination via the HPMS PRDVM report. Submissions must be sent to CMS via the PartCandD_Data_Validation@cms.hhs.gov email box and must contain all of the following information in order to be considered.

- Email subject line must state: "Data Validation: Appeal of Not Pass Determination"
- Content of email must include the information below, in list format and in the following order:
  - Name of Sponsoring Organization
  - CMS Contract Number(s)
  - Organization's Contact Name, Title, Phone Number and Email address
  - Name of Data Validation Contractor Organization
- For each Not Pass determination included in the appeal, list the following information:
  - Indicate the name of the individual data measure that received a Not Pass determination , or indicate that the appeal pertains to the overall Not Pass for Part C or Part D measures
  - CMS Contract Number(s) that received the subject Not Pass determination
  - Justification for appeal
  - Include as attachment any documentation supporting the justification for appeal. The documentation must have been in existence at the time of the data validation. For example, if after the data validation, the sponsoring organization resubmits corrected data, revises a policy and procedure, or corrects a programming code that caused it to improperly calculate reported data, the organization cannot submit documentation of these corrections to appeal a Not Pass determination.

Once the appeal is received, CMS will carefully consider the justification and any supporting documentation to determine if the Not Pass determination should be changed to a Pass determination. CMS has not established a timeframe for the consideration of sponsoring organization appeals.