Medicare Part C and Part D Reporting Requirements Data Validation

Procedure Manual

Version 3.0

Table of Contents

List of Exhibits

Appendices

Appendix A: Standards for Selecting a Data Validation Contractor
Appendix B: Part C and Part D Reporting Section Data Validation Standards
Appendix C: Model Language for Letter to Confirm Selection of Data Validation Contractor
Appendix D: Example Application for Access to CMS Computer Systems
Appendix E: Organizational Assessment Instrument
Appendix F: Interview Discussion Guide
Appendix G: Example Site Visit Agenda
Appendix H: Data Extraction and Sampling Instructions
Appendix I: Example Data File Inventory Log
Appendix J: Findings Data Collection Form
Appendix K: Data Validation Pass/Not Pass Determination Methodology
Appendix L: Acronyms

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
3.0	January 2013	Updated Release for April-June 2013 data validation

1 INTRODUCTION

1.1 Data Validation Requirement

The Centers for Medicare & Medicaid Services (CMS) requires that organizations (sponsoring organizations) (SOs) contracted to offer Medicare Part C and/or Part D benefits be subject to an independent yearly review to validate data reported to CMS per the *Medicare Part C and Part D Reporting Requirement Technical Specifications (Technical Specifications)*.[1] The purpose of the independent data validation (DV) is to ensure that Part C and Part D SOs 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 SOs. CMS uses these reported data to respond to inquiries from Congress, oversight agencies, and the public about an SO's performance using indicators such as operations, costs, availability and use of services, provider network adequacy, and grievance rates. The validated data also allow CMS to more effectively monitor and compare the performance of SOs over time. Additionally, SOs can take advantage of the DV 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 SOs and the data validation contractors (DVCs) (reviewers) they select to perform the DV with information regarding the Part C and Part D Reporting Requirements Data Validation program. The *Manual* provides background information and an overview of the DV program, discusses the scope and timeframe required for the DV, and describes the tools and processes used for conducting the DV.

All revisions to the reporting section criteria since the April – June 2012 DV cycle are identified by underlined and/or strikethrough text.The terms "section" and "measure" that previously appeared in the *Technical Specifications* have been replaced with the term "reporting section." To ensure alignment with this new terminology, all references in the DV documents to the term "measure" have been replaced with the term "reporting section." In addition, the term "measure-specific criteria" has also been revised and replaced with "reporting section criteria."

1.1.1 Data Validation Scope

CMS requires that the annual, retrospective DV be conducted once per year. For the 2012 DV cycle and beyond, the DVwill 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 an SO after March 31 cannot be used for purposes of the DV. The reviewer must submit findings from the annual DV review to CMS by June 30 of each calendar year.

The DV reviews must be conducted at the contract level. CMS believes the contract is the most appropriate unit of analysis in conducting this DV, 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.

---

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

1.2   Types of Organizations Required to Undergo Data Validation

All Part C and Part D SOs that report Part C and/or Part D data to CMS per the *Technical Specifications*, regardless of enrollment size, are required to undergo an annual DV review.

The only SOs exempt from participating in the data validation program are:
- Program of All-Inclusive Care for the Elderly (PACE) SOs and Part C Health Care Prepayment Plans.
- An SO 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 DV review for the final contract year's reported data. Similarly, for reporting sections that are reported at the plan benefit package (PBP) level, PBPs that terminate are not required to undergo a DV review for the final year's reported data.

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

1.3   Requirement to Use This Manual and Tools

CMS requires that SOs and their selected DV reviewers use the processes and tools contained in this *Manual* and its appendices to conduct the annual DV. This includes each of the following documents:
1. *Standards for Selecting a Data Validation Contractor* (Appendix A)
2. *Data Validation Standards* (Appendix B)
3. *Model Language for Letter to Confirm Selection of Data Validation Reviewer* (Appendix C)
4. *Example Application for Access to CMS Computer Systems* (Appendix D)
5. *Organizational Assessment Instrument (OAI)* (Appendix E)
6. *Interview Discussion Guide (IDG)* (Appendix F)
7. *Example Site Visit Agenda* (Appendix G)
8. *Data Extraction and Sampling Instructions* (Appendix H)
9. *Example Data File Inventory Log* (Appendix I)
10. *Findings Data Collection Form (FDCF)*[2] (Appendix J)
11. *Pass/ Not Pass Determination Methodology* (Appendix K)
12. *Acronyms* (Appendix L)

The *Data Validation Standards* (*Standards*) and other documentation associated with the implementation of the DV program assess an SO's information systems capabilities and overall processes for collecting, storing, compiling, and reporting the required Part C and Part D reporting sections. CMS expects to establish consistency in the DV program by requiring that all entities use ~~the same~~appropriate tools and follow the same process.

In order to ensure that the DV documentation can incorporate periodic clarifications to the *Part C and Part D Reporting Requirements Technical Specifications*, CMS intends to update this *Manual* and the DV tools contained in its appendices annually no later than February 28 of each year. CMS will post the

---

[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.*

most current version publicly at:
http://www.cms.hhs.gov/PrescriptionDrugCovContra/9_PartCDDataValidation.aspand within the Health
Plan Management System (HPMS) Plan Reporting Data Validation Module (PRDVM). Prior to
beginning each annual DV, it is the responsibility of all SOs and DV reviewers to confirm that they are
using the most recent DV documentation available on the CMS DV website.

In the event of a conflict between the *Technical Specifications* and the *Data Validation Standards*
reporting section criteria, the *Data Validation Standards* supersede the *Technical Specifications*.
Reviewers must use the *Data Validation Standards* reporting section criteria to determine DV findings.
CMS will take this conflict between the *Technical Specifications* and the *Data Validation Standards* into
consideration when evaluating the results of the DVreview.

1.4   Organization of the Procedure Manual

Exhibit 2 below illustrates how the *Manual* is organized. The document's content is structured according
to the four phases that comprise the DV process. The graphic presents the phases in the order in which the
annual DV cycle is conducted.

Exhibit 2. Data Validation Program Phases

Each phase of the DV review process contains several activities. Exhibit 3 displays the activities in the
order in which they are found in the document and the order in which they are conducted, beginning with
the selection of an appropriate reviewer and ending with the appeal of DV determinations. The DV
review process largely entails a collaborative effort between the SO and its independent, external
reviewer in terms of information sharing up to the point of the reviewer's final submission of DV review
findings to CMS. Each of these steps is described in more detail throughout the *Manual*.

Exhibit 3. Data Validation Program Activities

DV Phase	Step	Responsible Party	DV Activities	Timeline*
Planning for DV Activities	1	SO	Select appropriate DVC based on *Standards for Selecting a Data Validation Contractor*	December*-March
	2	DVC, SO	Notify CMS of DVC Selection / Request Access to Health Plan Management System (HPMS) Plan Reporting Data Validation Module (PRDVM)	January-April
	3	DVC, SO	Complete the web-based Data Validation Training	February-March
	4	DVC, SO	Review all DV documents the *Data Validation Standards*	January-March
Performing DVActivities	5	SO	Complete *Organizational Assessment Instrument* (*OAI)* and provide appropriate documentation to selected reviewer per the *OAI*'s documentation request	Early April 1 (allow 2 weeks)
	6	DVC, SO	Analyze *OAI* Responses	Mid April April 1 or later

DV Phase	Step	Responsible Party	DV Activities	Timeline*
	7	DVC, SO	Prepare for site visit (site visit agenda, resource needs, and logistics)	Early April
	8	DVC, SO	Conduct on-site review (convene entrance conference, conduct interviews with SO staff, observe SO's reporting processes, and obtain census and/or sample files)	~~Late~~ Early April (allow for up to 1 week)
	9	DVC	Request additional documents following site visit (if applicable)	~~Late~~ Mid/Late April/~~Early May~~
Analyzing Results and Submission of Findings	10	DVC	Determine compliance with *Data Validation Standards* and record findings in Excel-version of the *Findings Data Collection Form* (*FDCF)* or directly into the HPMS PRDVM	June
	11	DVC	Provide draft findings to SO	June
	12	DVC, SO	Review draft findings and obtain additional documentation necessary to resolve issues	June
	13	DVC	Submit findings to CMS via HPMS PRDVM and receive DV scores	No Later than June 30
Completing Post-Data Validation Activities	15	DVC, SO	Compile archive of DV work papers	~~After June 30~~ July 31
	16	SO	~~Receive CMS report of~~Receive Pass or Not Pass ~~determinations~~ threshold level and assess Pass or Not Pass determination based on final DV scores ~~based on findings from data validation review~~	Fall
	17	SO	Appeal DV determination(s) (if applicable)	Within 5 days of receiving threshold level from CMS

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

2   PART C AND PART D REPORTING SECTIONS REQUIRING DATA VALIDATION 2013-2015

This section provides an overview of the Part C and Part D reporting sections that will undergo validation over the next three years. The DV reporting section criteria that are included in the *DV Standards* are mapped specifically to these reporting sections.

2.1   Part C and Part D Reporting Sections Requiring Data Validation in 2013

The 2013 DV includes the ~~16~~ 12 Part C and Part D reporting sections included in Exhibit 4. Please note that the 2013 DV includes not only the 2012 reporting sections with a reporting deadline of 2/28/13 or before, but also ~~four~~ three 2011 reporting sections that were not required to be submitted to CMS in time for the DV performed in ~~2011~~2012. Please note that the 2013 DV includes both the 2011 and 2012 Part D Long-Term Care (LTC) Utilization reporting sections. This schedule allows CMS to meet its goal of conducting a completely retrospective DV for all required data.

Exhibit 4. Part C and Part D Reporting Sections Requiring Data Validation in 2013

2011 Reporting Section	Reporting Period(s)	Data Submission Due Date(s) to CMS	DV 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 Reporting Section	Reporting Period(s)	Data Submission Due Date(s) to CMS	DV 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	8/31~~0~~/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

2.2 Part C and Part D Reporting Sections Requiring Data Validation in 2014

CMS expects to modify the reporting deadlines for the calendar year 2013 *Part C and Part D Reporting Requirements Technical Specifications* so that all affected reporting sections are reported to CMS prior to the start of the DV timeframe, and all validations of calendar year 2013 data will be completed in 2014. This will require the 2014 DV to include the 1~~1~~9 Part C and Part D reporting sections included in Exhibit 5. Please note that the 2014 DV will include ~~not only all 16 2013 reporting sections, but also three~~ two Part C 2012 reporting sections that were not required to be submitted to CMS in time for the DV done in 2013.

Exhibit 5. Part C and Part D Reporting Sections Requiring Data Validation in 2014

2012 Reporting Section	Reporting Period(s)	Data Submission Due Date(s) to CMS	DV 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 Reporting Section	Reporting Period(s)	Data Submission Due Date(s) to CMS	DV 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 Reporting Section	Reporting Period(s)	Data Submission Due Date(s) to CMS	DV Findings Due to CMS[*]
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	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   Part C and Part D Reporting Sections Requiring Data Validation in 2015

The 2015 DV includes the 9 Part C and Part D reporting sections included in Exhibit 6. Please note that all 9 reporting sections require a reporting deadline of 2/28/15 or before.

Exhibit 6. Part C and Part D Reporting Sections Requiring Data Validation in 2015

2014 Reporting Section	Reporting Period(s)	Data Submission Due Date(s) to CMS	DV Findings Due to CMS[*]
Part C			
Serious Reportable Adverse Events	1/1/14 - 12/31/14	2/28/15[1]	6/30/15
Grievances	1/1/14- 3/31/14 4/1/14 - 6/30/14 7/1/14 - 9/30/14 10/1/14 - 12/31/14	2/28/15	6/30/15
Organization Determinations/ Reconsiderations	1/1/14 - 3/31/14 4/1/14 - 6/30/14 7/1/14 - 9/30/14 10/1/14 - 12/31/14	2/28/15	6/30/15
Special Needs Plans (SNPs) Care Management	1/1/14 - 12/31/14	2/28/15	6/30/15
Part D			
Medication Therapy Management Programs	1/1/14 - 12/31/14	2/28/15	6/30/15
Grievances	1/1/14 - 3/31/14 4/1/14 - 6/30/14 7/1/14 - 9/30/14 10/1/14 - 12/31/14	2/28/15	6/30/15

2014 Reporting Section	Reporting Period(s)	Data Submission Due Date(s) to CMS	DV Findings Due to CMS
Coverage Determinations and Exceptions	1/1/14 - 3/31/14 4/1/14 - 6/30/14 7/1/14 - 9/30/14 10/1/14 - 12/31/15	2/28/15	6/30/15
Redeterminations	1/1/14 - 3/31/14 4/1/14 - 6/30/14 7/1/14 - 9/30/14 10/1/14 - 12/31/14	2/28/15	6/30/15
Long-Term Care (LTC) Utilization	1/1/14 - 6/30/14 7/1/14- 12/31/14	8/30/14 2/28/15	6/30/15

2.4 Reporting Requirements that Are Excluded from the Validation Requirement at This Time

Twelve Part C and Part D reporting included in the *Technical Specifications* will not undergo validation ~~at this time~~ in 2013, as they have either been suspended from reporting, or will be used for monitoring purposes only.

Exhibit 7 lists the reporting sections required for reporting but excluded from the DV review at this time.

Exhibit 7. Part C and Part D Reporting Sections Excluded From Data Validation

Part C Reporting Sections	Part D Reporting Sections
• Enrollment/ Disenrollment • Employer Group Plan Sponsors • ~~Benefit Utilization~~ • PFFS Plan Enrollment Verification Calls • PFFS Provider Payment Dispute Resolution Process • ~~Agent Compensation Structure~~ • ~~Agent Training and Testing~~	• Enrollment/ Disenrollment • Retail, Home Infusions, and Long-Term Care Pharmacy Access • Access to Extended Day Supplies at Retail Pharmacies • Prompt Payment by Part D Sponsors • Pharmacy Support of Electronic Prescribing • Pharmacy & Therapeutics (P&T) Committees/ Provision of Part D Functions • ~~Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions~~ • ~~Licensure and Solvency~~ • Fraud, Waste and Abuse Compliance Programs • Employer/ Union- Sponsored Group Health Plan Sponsors

3 PLANNING FOR DATA VALIDATION ACTIVITIES

3.1 Select appropriate Reviewer based on *Standards for Selecting a Data Validation Contractor*

CMS requires that the DV 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 SO is responsible for acquiring the independent reviewer and for all other costs associated with completing the independent DV and reporting the results to CMS.

3.1.1 Standards for Selecting a Data Validation Contractor

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

SOs may also contract with reviewers to perform mock audits, pre-assessments, and any other types of review throughout the year. However, in order to meet CMS' standards for organizational independence, a SO may not use the same reviewer who conducted these activities to conduct the subsequent DV review of those reported data. More detailed information pertaining to organizational independence is included in Appendix A, *Standards for Selecting a Data Validation Contractor.* 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. While the reviewer conducting the formal DV review may not participate in mock audits, pre-assessments, or other types of reviews, they can begin preparing for the DV review prior to April 1 so that the validation review can begin as soon as possible as of April 1. These types of preparation activities may include:

- Meeting with the SO to discuss the validation process, resource needs, timeline, etc.
- Providing the SO with a list of documents, data, and materials that are needed to complete the review.

Any specific questions about what types of activities are permitted prior to April 1 or regarding whether or not a particular entity meets the organizational independence standard should be directed to PartCandD_Data_Validation@cms.hhs.gov.

The *Standards for Selecting a Data Validation Contractor* also contain best practices that reviewers are expected to adhere to throughout the course of the review. The reviewer should remain an objective, independent third party and avoid acting in a consulting capacity. The reviewer should remain impartial in all of its activities and focused on determining if SOs' systems, programs, data, etc. are accurate, reliable, valid, and complete based on instructions and standards outlined in Appendix A and CMS' policies. The reviewer should provide general feedback and specific information on deficiencies to help SOs improve, and should maintain confidentiality of SOs' privileged information.

3.1.2 Timing of Data Validation Contractor Selection

An SO may select a DV reviewer at any time, up to and during the April through June DV review period. SOs should implement the contract to allow sufficient time for the reviewer 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.

3.1.3 Requesting a Contractor Change Mid-Review

An SO may not change its DV reviewer during the formal review period (April-June) unless there are conditions that are unrelated to DV findings such as negligence or malfeasance on the part of the reviewer. If a change in reviewer is required, the new reviewer is required to complete the DV review in its entirety (starting with the OAI analysis through the submission of findings to CMS) within the required April - June DV review timeline.

CMS will consider DV reviewer change requests submitted mid-review 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.

3.2 Notify CMS of DVC Selection / Request Access to Health Plan Management System (HPMS) Plan Reporting Data Validation Module (PRDVM)

3.2.1 Documentation of Data Validation Contractor Selection Process

SOs must document their DV reviewer selection process and be able to show, upon request by CMS, how their chosen reviewer 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 reviewer staff assigned to the applicable DV review team completed the CMS Data Validation Training program (see Section 3.3). CMS requires that the SO retain this documentation for the 10-year retention period per federal regulations.[3]

If an SO chooses to select the same DV reviewer it used for a previous year's DV review, it must still document the selection process as described above.

3.2.2 Request Access to HPMS Plan Reporting Data Validation Module

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

3.2.2.1   Process for Sponsoring Organization

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

- The SO's acknowledgment that it has contracted with the selected 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 DV Training,
- The contract number(s) the reviewer will need access to, and
- The SO's Chief Executive Officer's (CEO) signature.

---

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

Model language for this letter can be found in the *Model Language for Letter to Confirm Selection of Data Validation Contractor* (Appendix C).

If an SO chooses to select the same DV reviewer it used for a previous year's DV review, it must still provide the reviewer with this signed letter for the current year's DV activities.

3.2.2.2   Process for Data Validation Reviewer

DV reviewers must obtain individual access to the HPMS PRDVM. If the designated user(s) from the reviewer does **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 *Example Application for Access to CMS Computer Systems* (Appendix D) for requesting reviewer access to the HPMS PRDVM. CMS will allow up to 5 individuals from each reviewer to have access to this Module on behalf of each SO. One application must be completed for each user. The reviewer must send the completed application(s), along with the letter from each SO (signed by the CEO) for which they are under contract to complete the DVreview. 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 DV reviewer is serving multiple SOs, only one CMS user access form is required for each of that reviewer's PRDVM users, however, a letter must be provided from each SO 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 letter from the SO. The reviewer can submit new applications as they are obtained, along with a copy of the SO 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 letter from each SO linking the reviewer to the SO (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 DV 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 DV 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 four weeks for the designated individuals to obtain the credentials (CMS EUA User IDs and passwords) to access the PRDVM.

For DV reviewer staff that participated in a previous year's DV 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 SO linking the reviewer to the SO in order to obtain access to the HPMS PRDVM for the current year's DV activities.

3.3   Complete the Web-based Data Validation Training

CMS has developed a web-based DV Training that provides an opportunity for SOs and DV reviewers to learn more about the DV program and its specific requirements. The training is offered through the CMS Medicare Learning Network and can be found at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/WebBasedTraining.html.

During the DV preparation phase, all SO staff involved in the DV should complete the CMS DV Training individually to familiarize themselves with the DV process and requirements.

Additionally, all reviewer staff assigned to a DV review team are required to take the CMS DV Training prior to working on the DV project. Once the training is completed, a certificate of completion is generated. The reviewer must provide this documentation to any hiring SO for all staff assigned to the applicable DV review team before commencing work on the DV.

CMS plans to offer continuing education credits resulting from successful completion of the DV Training. The continuing education certificate will be automatically generated upon successful completion of the course along with the certificate of completion.

Any DV reviewer staff that participated in a previous year's DV must still take the current year's CMS DV Training prior to working on the DV project and provide documentation to the hiring SO the current year's training was completed before commencing work on the DV.

3.4   Review ~~the *Data Validation Standards*~~all Data Validation Documents

As noted in Section 1.3, there are 13 documents (including this *Manual*) that should be reviewed well in advance of the DV period. This *Manual* describes these materials. This section will focus specifically on the DV standards which are further described in *Data Validation Standards* (Appendix B).

3.4.1 Introduction to the Data Validation Standards

The *DV Standards* include general standards and reporting section criteria that DV reviewers must use to determine whether the data each SO reported to CMS per the *Part C/Part D Reporting Requirements Technical Specifications* are accurate, valid, timely, and reliable.

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

In preparation for the DV process, both the SO and the reviewer must review and learn the standards. Refer to Appendix B for the complete set of *Part C and Part D Reporting Section Data Validation Standards* along with guidance related to interpreting the standards.

3.4.2 Data Validation Standards and Reporting Section Criteria

3.4.2.1 Data Validation Standards Instructions

The *DV Standards* include identical instructions relating to the types of information that must be reviewed for each reporting section, a set of validation standards (also identical for each reporting section), and reporting section criteria that are based on the applicable *Technical Specifications*.

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

The top portion of each set of standards (which is identical for each reporting section) details the documents and reports that the reviewer is required to use to determine compliance with the standards for each specific reporting section. The documents and reports are listed within the gray box underneath the name of the applicable reporting section and are displayed in Exhibit 8.

Exhibit 8. General Instructions for Data Validation Standards

[NAME OF REPORTING SECTION]	
To determine compliance with the standards for [name of reporting section], the 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 reviewer regarding a specific reporting section and any nuances or differences that may be encountered during the review of that reporting section. See Exhibit 9 for an example "Note to reviewer" for the Part C Plan Oversight of Agents reporting section.

Exhibit 9. 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 reporting section, and data validation is not required.

The second section of each set of standards is identical for all Part C and Part D reporting sections.

3.4.2.2 Data Validation Standards 1 - 7

3.4.2.2.1 <u>Standard 1</u>

Standard 1 (see Exhibit 10) contains the general and specific criteria for validating source documentation that the SO provides to the reviewer.

Exhibit 10. 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~~CMS systems. b) Source documents create all required data fields for reporting requirements. c) Source documents are error-free (e.g., programming code and spreadsheet formulas have no messages or warnings indicating errors, use correct fields, have appropriate data selection, etc.). d) All data fields have meaningful, consistent labels (e.g., label field for patient ID as Patient_ID, rather than Field1 and maintain the same field name across data sets). e) Data file locations are referenced correctly. f) If used, macros are properly documented. g) Source documents are clearly and adequately documented. h) Titles and footnotes on reports and tables are accurate. i) Version control of source documents is appropriately applied.

3.4.2.2.2   Standard 2

Standard 2 (see Exhibit 11) instructs the reviewer to validate the completeness of the underlying data and the accuracy of each reported reporting section. Standard 2 provides an overview of reporting section criteria which must be met for each of the Part C and Part D reporting section being reported and is further detailed in section 4.2.3. For example, the reporting section 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. The criteria are also used to verify that the SO has properly interpreted and defined key terms used to determine which data are applicable. For example, the SO must properly define the term "~~Appeal~~Redeterminations" in accordance with CMS regulations, guidance and the *Technical Specifications* in order to ensure the quality of the reported data for that reporting section. Standard 2e is further broken down into additional criteria that map to the relevant technical specification data elements.

Exhibit 11. 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~~whichever is applicable, indicates that data elements for each reporting section are accurately identified, processed, and calculated. Criteria for Validating Reporting Section Criteria (Refer to reporting section criteria section below): a) The appropriate date range(s) for the reporting period(s) is captured. b) Data are assigned at the applicable level (e.g., plan benefit package or contract level). c) Appropriate deadlines are met for reporting data (e.g., quarterly). d) Terms used are properly defined per CMS regulations, guidance and *Reporting Requirements Technical Specifications*. e) The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.

3.4.2.2.3   Standard 3

Standard 3 (see Exhibit 12) is used to determine whether an SO implements ~~appropriate~~ policies and procedures for each reporting section'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 and/or entered into the PRDVM. If a reporting section requires both a file upload and data entry (i.e., Part D Long-Term Care (LTC) Utilization), both have to occur in order for a SO to meet Sub-Standard 3a.

Exhibit 12. 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~~CMS systems and entries match corresponding source documents. b) All source, intermediate, and final stage data sets and other outputs relied upon to enter data into ~~HPMS~~ CMS systems are archived.

3.4.2.2.4   Standards 4 and 5

For Standards 4 and 5 (see Exhibit 13), the reviewer must verify that the SO 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 13. 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).

3.4.2.2.5   Standards 6 and 7

Standards 6 and 7 (see Exhibit 14) are applicable only in certain situations. Standard 6 is applicable if an SO's data systems underwent any changes during the reporting period. If this occurred, the 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 standard assesses whether the SO has policies and procedures in place that address routine monitoring of the delegated entities work and whether those policies and procedures are implemented.

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 reporting section or contract under review.

Exhibit 14. 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 reporting section 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 reviewer.

3.4.3 Reporting Section Criteria

In addition to the general instructions and validation standards, there is a third section which contains the reporting section criteria. The reporting section criteria vary for each Part C and Part D reporting section. Reporting section criteria are used in conjunction with Standard 2 to determine if data elements are accurately identified, processed, and calculated. The first three reporting section criteria for each reporting section (see Exhibit 15) are used to validate whether the SO is utilizing the appropriate reporting period, reporting level, and reporting deadline(s) per CMS requirements.

Exhibit 15. Example Reporting Section Criteria for Appropriate Reporting Period, Reporting Level, and Reporting Deadline

	REPORTING SECTION CRITERIA
1	Organization reports data based on the required reporting period of 1/1 through 12/31.
2	Organization properly assigns data to the applicable CMS contract 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 reporting section, the reviewer should verify that the organization's original data submission met the CMS deadline in order to have a finding of "yes" for this reporting section criterion. However, if the organization re-submits data for any reason and if the re-submission was completed by 3/31 of the data validation year, the reviewer should use the organization's corrected data submission for rest of the reporting section criteria for this reporting section.*

Several of the reporting section standards contain a reporting section criterion to validate whether the SO properly defined key terms that it used to compile reported data per CMS regulations, guidance and the *Technical Specifications*. Exhibit 16 shows an example of this criterion for the Part D ~~Appeals~~ Redeterminations reporting section.

Exhibit 16. Reporting Section Criterion for Defining Key Terms

	REPORTING SECTION CRITERIA
4	Organization properly defines the term "~~Appeal~~Redetermination" in accordance with Title 42~~1~~, Part 423, Subpart ~~B~~M §423.560, §423.580, §423.582, §423.584, and §423.590 and the Prescription Drug Benefit Manual Chapter 18, Section 10~~.1~~, 70 and 130. This includes applying all relevant guidance properly when performing its calculations and categorizations.

The other reporting section criteria reference the applicable data element from the *Technical Specifications* when possible and differ considerably depending on the reporting section and data element. Exhibit 17 shows an example of selected reporting section criteria applicable to the Part C and Part D Plan Oversight of Agents reporting section. The exact criteria for each Part C and D reporting section are based on the *Technical Specifications*.

Exhibit 17. Reporting Section Criteria for Selected Plan Oversight of Agents Data Elements

REPORTING SECTION 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 and whether the member remained enrolled, disenrolled, or declined enrollment during the enrollment process. b) Includes agents with investigations based on complaints filed directly with the organization as well as those from the HPMS Complaint Tracking Module (CTM). c) Includes all agents with investigations based on complaints against the agent under the applicable plan contract. If a complaint cannot be tied to a specific contract, then the complaint is included under all contracts that the agent is licensed to sell. d) Excludes investigations in which the member or agent could not be contacted. e) The number calculated for Data Element 12.2 is a subset of the total number of agents calculated for Data Element 12.1. [Data Element 12.2 (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 PERFORMING DATA VALIDATION ACTIVITIES

4.1 Complete *Organizational Assessment Instrument* (*OAI*) and Provide Appropriate Documentation to Selected DVC per the *OAI*'s Documentation Request

The *Organizational Assessment Instrument* (*OAI*) (Appendix E) focuses on how the SO collects, stores, and reports data. Completing the OAI is mandatory and CMS highly recommends that SOs complete this document in advance of the DV, as the DV review relies significantly on the information captured in this tool. While completion of the *OAI* by the sponsoring organization is not mandatory, The completed *OAI* may reduce required reviewer resources, and make the DV review more efficient and effective. SOs should provide the completed *OAI* to their selected DV reviewer electronically. CMS estimates that the *OAI* should take a minimum of two weeks to complete and should be submitted to the reviewer no later than early April. SOs may not send their completed *OAI* or source code, SOPs, etc. to their reviewers prior to the start of the DV cycle on April 1.

Each SO must provide to its reviewer the basic information regarding its Medicare contracts and which Part C and/or Part D reporting sections each contract submits to CMS. SOs that hold more than one contract with CMS only need to complete one version of the *OAI* that covers all of 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 SO's systems and processes that were in place during the reporting period(s) undergoing the DV review. For example, if the data being reviewed are for the 2011 reporting period, the SO should include only diagrams of the information systems in place in 2011 or the programming code used in 2011 to calculate the reporting sections.

It is up to the SO and its DV reviewer 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* (Appendix A) includes minimum security requirements with which the reviewer's facility, equipment, and processes must comply. The SO is responsible for ensuring that the reviewer complies with all Health Insurance Portability and Accountability Act (HIPAA) privacy and security requirements.

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

4.2   Analyze OAI Responses

CMS recommends DV reviewers 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 SO 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 reviewer better understand the processes used by the SO to compile and submit its reporting sections. The SO'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 *Technical Specifications* into the SO's systems, and descriptions of any past issues that may have occurred during the reporting process.

4.2.1 Perform OAI Gap Analysis

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

4.2.2 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 reporting sections will assist the reviewer in gaining a more thorough understanding of the SO. Reviewers should be familiar with data systems and processes detailed by the SO in the *OAI* to ensure thorough preparation for the site visit.

4.2.3 Prepare Interview Discussion Guide

The *Interview Discussion Guide* (*IDG*) (Appendix F) is intended to facilitate the discussion between the DV reviewer and the SO's report owners and subject matter experts. The *IDG* is a dynamic tool containing both general and reporting section questions that can guide an effective discussion regarding an SO's underlying data systems and reporting processes. If, during review of the documentation provided in response to the *OAI*, the reviewer discovers evidence that may indicate errors in the SO's data or reporting processes, the reviewer should modify the *IDG* used for that SO 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.

4.3 Prepare for Site Visit

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

CMS ~~encourages~~ <u>requires</u> SO and reviewers to include a ~~physical~~ site visit as part of the DV review to conduct the following activities: (1) conduct interviews with SO staff, (2) observe the SO's reporting processes, and (3) obtain census and/or sample files to support the validation of Part C and Part D reporting sections. SOs and DV reviewers 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 reviewer to determine the most appropriate location(s) of the ~~physical~~ site visit (e.g., <u>virtual</u>, SO's facility, PBM's facility, other delegated entity's facility). <u>CMS encourages SOs and DV reviewers to conduct a physical site visit, but SOs and DV reviewers may elect to conduct a virtual site visit,</u> using a virtual meeting tool or teleconference(s), <u>if appropriate.</u>

~~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.~~

4.3.2 Develop Agenda for Site Visit

To further prepare for each SO's site visit, the DV reviewer and SO 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 DV review. This agenda is structured to include an entrance and exit conference, and interviews and demonstrations of data systems for each reporting section included in the DV. It is also recommended that the reviewer create a sign-in sheet to be completed throughout the site visit in order to collect contact information for each SO'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 SO, efficiency of the SO's operations, level of reporting automation, and scope of the DV review. The reviewer must schedule sessions with the SO's report owner(s) for each reporting section and allow sufficient time for the SO 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 4.4.4 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 reporting sections that use the same data system(s). This will ensure optimal time and resource management during the site visit.

4.3.3   Prepare for Data Extraction and Sampling

In preparation for the data extraction and sampling during the site visit, the DV reviewer should review information provided in the completed *OAI* and, if necessary, hold conference calls with the SO to discuss the SO's processes. Calls held specifically with each reporting section's report owner can also provide an opportunity for the reviewer to review the *Data Extraction and Sampling Instructions* (Appendix H) in more detail and for the report owners to seek clarification as needed. These discussions can also inform the reviewer about the SO'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 reporting section. The first is to extract the full census of data for a reporting section, meaning that every data record that is relevant to a reporting section 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 reporting sections were submitted accurately. If the size or complexity of a database presents an unusual time burden on the reviewer and/or SO, 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 DV review. Refer to Appendix H for further details regarding these two methodologies. In addition, reviewers must determine if the SO's staff requires supervision during the actual data extraction process, or if the SO's staff are able to extract data without supervision. See Section 4.4.4 for additional requirements if the reviewer is unable to supervise the data extraction process.

4.4   Conduct Site VisitOn-Site Review

4.4.1   Conduct Entrance Conference

The entrance conference provides an opportunity for the DV review team and the SO's management and individual report owners to introduce themselves and discuss expectations for the site visit. At the entrance conference, the reviewer should describe the objectives for the review and discuss any administrative needs of the team. Optionally, the SO 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 SO'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.

4.4.2   Conduct Interviews with Organization Staff

During the site visit, the reviewer must conduct interviews with the subject matter experts and report owners for each reporting section and reporting system. These interviews provide a first-hand opportunity for the reviewer to gain a thorough understanding of each SO'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.

4.4.3   Observe Reporting Processes

The site visit allows the opportunity for the SO to provide a significant amount of useful information to the reviewer. Designated SO 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 PRDVM. 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 SO'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.

4.4.4 Extract Census or Sample Data

The next step is for the reviewer to work with the report owners to draw a census or a random sample from each reporting section's final stage data set, following the *Data Extraction and Sampling Instructions* (Appendix H). The document describes guidelines and methodologies for extracting SOs' data. Two methodologies of extraction are available to reviewers. The first method is referred to as the census. Extracting all records used in the calculation of data elements for a specific reporting section would constitute extracting a census of data. When possible, reviewers should attempt to extract the full census. Extracting the census will enable the reviewer to determine with the greatest precision whether reporting sections were submitted accurately. The second method used for data extraction is a random sample. The random sample is a subset of the census data. If extraction of the census proves to be too burdensome due to the size or complexity of the data for a specific reporting section, a sample of records should be extracted instead.

The random 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 choose 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 reporting sections 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. The processes used to draw the random data samples vary considerably, depending on the report owner and reporting section. For example, some report owners may be able to easily draw the sample data for their reporting section 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 SO'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. When providing the DV 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 reporting section. For both methods, reviewers must examine source data as a means of verifying that the organization's underlying data are correct: for example, reviewing customer service call logs or member

letters to verify that grievances were properly categorized as grievances and to verify the grievance categories applied were correct. Source data examples for each reporting section are provided in the *Data Extraction and Sampling Instructions*. Reviewers are expected to include the number and percentage of errors or variance from HPMS-filed data found when examining the source data. For purposes of recording results in the PRDVM and FDCF (if used), an error is any discrepancy that either impacted the number of events reported or has the potential to impact the number of events reported in future reporting periods. These errors must be reported in the "Review Results" area of the PRDVM and FDCF and include the sample size selected for the source data.

It is mandatory that DV reviewers follow the *Data Extraction and Sampling Instructions*. If the SO'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 must should obtain documentation from the SO describing how the extraction process was performed. For example, if a random sample is extracted, the reviewershould 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 DV reviewer record details about each reporting section's data set into a *Data File Inventory Log (*Appendix I). Appendix I contains an example log that the reviewer can use. It includes details such as the reporting section 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. Appendix I is just an example, reviewers can use their own inventory log if that is preferable.

The SO 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 DV reviewer's secure storage device for each reporting section's data. The SO 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 SO and DV reviewer must ensure that they have established mutually agreeable methods for sharing protected health information and that the reviewer complies with all HIPAA privacy and security requirements.

4.4.5 Conduct Exit Conference

CMS recommends that the entire DV review team meet briefly with the SO'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 reviewer should provide the SO with a summary of next steps and note any follow-up that may need to occur.

4.5 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 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 SO and/or make requests for documentation. Reviewers and SOs should understand that the DV is an iterative and collaborative effort, and SOs should be prepared to provide additional data and documentation after the site visit has been held.

5   ANALYZING RESULTS AND SUBMISSION OF FINDINGS

5.1   Determine Compliance with Data Validation Standards and Record Findings in Excel Version of the Findings Data Collection Form (FDCF) or Directly into the HPMS PRDVMs

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

5.1.1   Using the PRDVM and Findings Data Collection Form

The DV 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 reviewers work and enter findings directly in the PRDVM, saving data periodically to avoid the system timing out. Alternatively, reviewers may <u>first</u> use the Excel version of the *FDCF* to record findings <u>and then translate the findings into the PRDVM</u>. The PRDVM data entry screens and *FDCF* mirror the content of the *DV Standards* document, but allow the reviewer to record notes, data sources referenced, and findings for the different standards and criteria specified for a given reporting section. The reviewer will record reporting section-level, and in some cases data element-level, findings for each reporting section. Most DV standards (Standards 1, 4, 5, 6, and 7) are assessed at the reporting section-level, as they assess SO processes that are not likely to vary at the data element-level. The reviewer may print the findings he/she entered in the PRDVM and share them with the SO 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 18 illustrates an example of the *FDCF* for Standard 1. The reviewer will assess this standard at the reporting section-level and must determine a finding for each of the nine sub-standards contained in Standard 1.

Exhibit 18. Example Rows from *FDCF* for Standard 1

Standard / Sub-Standard ID	Reporting Section 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~~CMS systems.	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, use correct fields, have appropriate data selection, etc.).	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 reporting section-level findings for Sub-Standards 2.a through 2.c, which are based on reporting section criteria 1 through 3 and, if applicable, Sub-Standard 2.d, which is based on reporting section criterion 4. Exhibit 19 illustrates an example of the *FDCF* for Standard 2, Sub-Standards 2.a through 2.d. for the Part D Grievances reporting section.

Exhibit 19. Example Rows from *FDCF* for Standard 2, Sub-Standards 2.a through 2.d for Part D Grievances Reporting Section

Illustrative

Standard / Sub-Standard ID	Reprting Section 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~~ whichever is applicable, indicates that data elements for each reporting section are accurately identified, processed, and calculated.	Data Sources:	
2.a	RSC-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	RSC-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	RSC-3	Appropriate deadlines are met for reporting data (e.g., quarterly). Organization meets deadlines for reporting quarterly data to CMS by 5/31, 8/31, 11/30, and 2/28. *Note to reviewer: If the organization has, for any reason, re-submitted its data to CMS for this reporting section, the reviewer should verify that the organization's original data submissions met each CMS deadline in order to have a finding of "yes" for this reporting section criterion. However, if the organization re-submits data for any reason and if the re-submission was completed by 3/31 of the data validation year, the reviewer should use the organization's corrected data submission(s) for rest of the reporting section criteria for this reporting section.*	Review Results:	
2.d	RSC-4	Terms used are properly defined per CMS regulations, guidance and *Reporting Requirements Technical Specifications*. Organization properly defines the term "Grievance" in accordance with 42 CFR §423.564 and the Prescription Drug Benefit Manual Chapter 18, Sections 10 ~~1~~ and 20 ~~2~~. This includes applying all relevant guidance properly when performing its calculations and categorizations. Requests for coverage determinations, exceptions, or redeterminations are not improperly categorized as grievances.	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 reporting section criteria that varies across the data elements reported by the SO. Exhibit 20 illustrates an example of the FDCF for Standard 2, Sub-Standard 2.e for the Part D Grievance reporting section.

Exhibit 20. Example Rows from FDCF for Standard 2, Sub-Standard 2.e for Part D Grievances Reporting Section*

Standard / Sub-Standard ID	Reporting Section 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	RSC-~~65~~	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. Applicable Reporting Section Criteria: RSC-~~65~~: Organization accurately calculates the total number of grievances, including the following criteria: RSC-~~65~~a: Includes all grievances ~~that were received~~with a date of decision that occurs during the reporting period, regardless of when the grievance was received or completed (i.e., organization notified member of its decision). [Data Elements ~~C-D~~ A-H]	**Data Element A** Review Results:	
		RSC-~~65~~b: If a grievance contains multiple issues filed by a single complainant, each issue is calculated as a separate grievance. [Data Elements ~~C-D~~ A-H] RSC-~~65~~c: If a ~~beneficiary~~ member files a grievance and then files a subsequent grievance on the same issue prior to the organization's decision or deadline for decision notification (whichever is earlier), then the issue is counted as one grievance. [Data Elements ~~C-D~~ A-H] RSC-~~65~~d: If a ~~beneficiary~~ member files a grievance and then files a subsequent grievance on the same issue after the organization's decision or deadline for decision notification (whichever is earlier), then the issue is counted as a separate grievance. [Data Elements ~~C-D~~ A-H]	**Data Element B** Review Results:	

Please see Appendix B and the FDCF for the complete set of RSC for the Part D Grievances reporting section

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 reporting section-level findings. Sub-Standard 3.a is assessed at the data element-level for reporting sections 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 reporting sections that are reported as file uploads, it confirms at the sub-standard level that the SO used the correct file layout. Exhibit 21 illustrates an example of the *FDCF* for Standard 3 for the Part D Grievances reporting section.

Exhibit 21. Example Rows from FDCF for Standard 3 for Part D Grievances Reporting Section

Standard / Sub-Standard ID	Reporting Section 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~~ CMS systems and entries match corresponding source documents.	Data Element A	Review Results:	
			Data Element B	Review Results:	
			Data Element C	Review Results:	
			Data Element D	Review Results:	
			Data Element E	Review Results:	
			Data Element F	Review Results:	
			Data Element G	Review Results:	
			Data Element H	Review Results:	
3.b		All source, intermediate, and final stage data sets and other outputs relied upon to enter data into ~~HPMS~~ CMS systems are archived.		Review Results:	

Standards 4 through 7 do not have any sub-standards and are assessed at the reporting section-level. For example, Standard 4 assesses policies and procedures for periodic data system updates; an SO will most likely have these policies and procedures in place for an entire reporting section, as opposed to having them in place for only certain data elements. Exhibit 22 displays example rows from the *FDCF* for Standards 4 through 7.

Exhibit 22. Example Rows from FDCF for Standards 4 through 7

Standard / Sub-Standard ID	Reporting Section 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 reporting section 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 reviewer.	Data Sources: Review Results:	

5.1.2 ~~Sources and Criteria for Determining Findings~~Guidance for Interpreting Standards and Making a Findings Determination

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

CMS expects that there will be situations when the reviewer finds that an SO is only in partial compliance with specific DV standards. CMS does not believe that only a 100 percent score demonstrates compliance, and has established a threshold whereby a minimum of 90% of records are accurate (e.g., sample or census records, source documents, policies and procedures, data entry records) in order to record a "Yes" finding for any standard. Applying this threshold to standards that require the review of policies and procedures should be done when it is possible to readily quantify the adherence to or implementation of said policies and procedures. Exhibit 23 provides examples of how to calculate this minimum threshold specifically for Standard 2, for which the DV involves samples or the complete census of records and/or data values. Note that the 90% accuracy threshold does not apply to the individual grievance categories in the Part C and Part D Grievances reporting sections; 100% correct records are required for each data element measured by Standards 2e and 3a in these reporting sections.

Exhibit 23. 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 reporting section criteria to be recorded as "Yes".
205	0.90 x 205=184.5	At least 185 of the records are correct for the reporting section criteria to be recorded as "Yes" (round 184.5 to 185).

Exhibit 24. Example of How to Determine Minimum Threshold of Implemented Policies or Procedures for "Yes" Finding

Standard	Standard Description	Minimum Threshold for a "Yes" Finding
4	Organization implements policies and procedures for periodic data system updates (e.g., changes in enrollment, provider/pharmacy status, claims adjustments).	SO has a policy in place for updating its enrollment system on a monthly basis to ensure accurate information and protect the data integrity. Eleven out of the twelve months in the contract year, the SO implemented the enrollment system update policy as it is written (11/12 = 91.6%)

5.1.2.1 Standard 1

This validation standard is assessed at the reporting section-level and is used to determine that all source documents accurately capture required data fields and are properly documented. The guidance for evaluating Standard 1 is described below.

Exhibit 25. Guidance for Standard 1

Data Validation Standard 1: *Assessed at the reporting section-level and is used to determine that all source documents accurately capture required data fields and are properly documented*	
~~SOURCE~~Criteria	~~CRITERIA~~Guidance
OAI ~~Sections 4.1, 4.2, and 5~~ *IDG* ~~Sections 2.2, 2.3, 2.4, 3 and 4~~ 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 (Sub-Standards): a) Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via CMS systems. b) Source documents create all required data fields for reporting requirements. c) Source documents are error-free (e.g., programming code and spreadsheet formulas have no messages or warnings indicating errors, use correct fields, have appropriate data selection, etc.). d) All data fields have meaningful, consistent labels (e.g., label field for patient ID as Patient_ID, rather than Field1 and maintain the same field name across data sets). e) Data file locations are referenced correctly f) If used, macros are properly documented. g) Source documents are clearly and adequately documented. h) Titles and footnotes on reports and tables are accurate. Version control of source documents is appropriately applied.	Determine if the SO'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 reporting section under review and are documented with the necessary detail and information to create data file sets and other outputs. ~~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~~ include detailed workflows and processes related to managing, producing, and tracking source documents. • 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~~ • Data file locations are referenced correctly within source code (i.e., these files can be located using the references that exist within the source code). • Dated HPMS entries match the source document(s) used to create the data entered into HPMS. Ensure that the data validation reviewer is using the documentation that is current and relevant to the time period of the reporting requirements.

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 reporting section are accurately identified, processed, and calculated). For example, the 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 reporting section's validation.

5.1.2.2 Standard 2

This validation standard assesses whether the data elements for each reporting section are accurately identified, processed, and calculated. Each reviewer should ensure that it has staff fluent in the programming language (SQL, SAS, Microsoft VBA) used by the SO. The guidance for evaluating Standard 2 is described below.

Since the DV reviews must be conducted at the contract level, for the reporting sections that require reporting at the plan benefit package (PBP)-level, if the reviewer finds that the SO 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 PRDVM (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 SO 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 26. Guidance for Standard 2

Data Validation Standard 2:
Assesses whether the data elements for each reporting section 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 SO.

~~SOURCE~~Criteria	~~CRITERIA~~Guidance

~~OAI~~ Sections 4.1, 4.2, and 5
~~IDG~~ Sections 2.2, 2.3, 2.4, 3 and 4
A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) and census or sample data, whichever is applicable, indicates that data elements for each reporting section are accurately identified, processed, and calculated.
 	
Criteria for Validating Reporting Section Criteria (Refer to reporting section criteria section below):
a) The appropriate date range(s) for the reporting period(s) is captured.
b) Data are assigned at the applicable level (e.g., plan benefit package or contract level).
c) Appropriate deadlines are met for reporting data (e.g., quarterly).
d) Terms used are properly defined per CMS regulations, guidance and *Reporting Requirements Technical Specifications.*
e) The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission.
	(Sub-Standard 2a – 2d)
	Assess the programming code to determine if the data was extracted from the system properly and if the calculations used in reporting data to CMS are accurate according to the reporting section criteria applicable to each reporting section under review .
	
	A thorough review of source code must examine every line of code to ensure the following for each reporting section 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 reporting section 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~~ accurate~~ly~~: Verify that each data element is ~~calculated~~ consistent~~ly~~ with the reporting section criteria.

~~Submission Activity Report from HPMS Plan Reporting Module~~	(Sub-Standard 2c) Assess the Submission Activity Report from the HPMS Plan Reporting Module to determine if appropriate deadlines were met for reporting data by performing the following:

Data Validation Standard 2: *Assesses whether the data elements for each reporting section 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 SO.*	
~~SOURCE~~Criteria	~~CRITERIA~~Guidance

	• *Request a copy of the contract's Submission Activity Report from the SO:* This report displays information about the original submission and all subsequent resubmissions for a particular contract or contracts. The report also displays Reporting Period, Contract Number, Plan ID, Submission Version, Due Date and Date Submitted for each section.
	
	 • *Determine if the SO has, for any reason, re-submitted its data to CMS for a reporting section*: The data validation reviewer should verify that the SO's original submission(s) met the CMS deadline.
	
	   – If the deadline was met, the reviewer must assess a "Yes" finding for this reporting section criterion. However, if an SO re-submits data for any reason and if the re-submission was completed by March 31[4] 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 SO'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.
	
	   – If the SO received CMS permission to submit data after the reporting deadline (i.e., its first submission), the reviewer must request that the SO 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 reporting section criterion.
	
	   – For either of the above scenarios, the reviewer must clearly document the circumstances in the "Data Sources and Review Results" section of the PRDVM (and FDCF, if used).

~~Census/Sample Data~~	(Sub-Standard 2e)
	 Assess the census/sample data provided by the SO to determine each of the following for each reporting section under review:
	
	 • *Data records are selected properly:*
	   – Perform frequency calculations to list all unique occurrences of data fields pertinent to the calculation of the reporting section 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.
	   – Verify that data has been selected at the proper level (e.g., either the contract or the plan benefit package level).
	   – Check date ranges, demographic information, and eligibility information to examine proper data filtering.
	
	 • *Individual data sets are joined or merged correctly:*
	   – Sample a few records, when individual data sets are available (most likely for intermediate data sets), from the individual data sets to confirm that they were joined properly.
	   – 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:*
	   – Recalculate the data fields that the SO used to calculate the data elements and refer to the reporting section criteria for each reporting section.
	   – Calculate sums of the individual records within each reporting

---

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

Data Validation Standard 2:
Assesses whether the data elements for each reporting section 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 SO.

~~SOURCE~~Criteria	~~CRITERIA~~Guidance
	section to ensure that they equal those reported to CMS. Verify that the calculation of each of the data elements in consistent with the reporting section criteria.

Exhibit 26 provides several examples of how to review source code and evaluate the integrity of the data. However, the reviewer may use other methods of DV 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 PRDVM (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 PRDVM (and *FDCF*, if used).

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

5.1.2.3 Standard 3

This validation standard assesses whether the SO implements ~~appropriate~~ policies and procedures for entering and/or uploading each data submission to ~~the HPMS Plan Reporting Module~~CMS systems. The guidance for evaluating Standard 3 is described in Exhibit 27.

~~Since the DV reviews must be conducted at the contract level, for the reporting sections that require reporting at the plan benefit package (PBP) level, if the DVC finds that the SO did not accurately enter or upload data reported for any of the PBPs included under a contract, then the DVC must assign a "No" finding in the PRDVM (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 27. Guidance for Standard 3

Data Validation Standard 3:	
Assesses whether the SO implements ~~appropriate~~ policies and procedures for entering or uploading each data submission to ~~CMS systems.~~the HPMS Plan Reporting Module.	
~~SOURCE~~CRITERIA	~~CRITERIA~~ Guidance
~~*OAI* Sections 4.3.1 and 5.4~~ ~~*IDG* Sections 2.3 and 2.4~~ ~~*OAI* Section 5~~ ~~Data file created for submission to CMS and HPMS screen shots of data entered~~ Organization implements policies and procedures for data submission, including the following: a) Data elements are accurately entered / uploaded into CMS systems and entries match corresponding source documents. b) All source, intermediate, final stage data sets and other outputs relied upon to enter data into CMS systems are archived.	(Sub-Standard 3a) Determine who is responsible for entering/uploading data into CMS systems for each reporting section under review and if the SO has ~~appropriate~~ written work instructions or policies and procedures for the entry or submission of the *Part C and Part D Reporting Requirements.* Evaluate Sub-Standard 3a by performing the following actions: • 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 *Technical Specifications* document. • For the reporting sections that require reporting at the plan benefit package (PBP)-level, if the reviewer finds that the SO did not accurately enter and/or upload data reported for any of the PBPs included under a contract, then the reviewer must assign a "No" finding in the PRDVM (and FDCF, if used) for the entire contract for the applicable data element(s) for Sub-Standard 3a. • If a reporting section requires both a file upload and data entry, both have to occur in order for a SO to meet Sub-Standard 3a.
	(Sub-Standard 3b) Determine if the SO has a policy or procedure for archiving all source, intermediate, and final stage data sets relied upon to enter data into CMS systems, and confirm that the SO implemented this policy for the reporting section under review.

5.1.2.4 Standard 4

This validation standard is assessed at the reporting section-level and is used to assess whether the SO has and implements ~~appropriate~~ policies and procedures for regular database updates. The data sources and criteria for evaluating Standard 4 are described in Exhibit 28.

Exhibit 28. Guidance for Standard 4

Data Validation Standard 4: *Assessed at the reporting section-level and is used to assess whether the SO has and implements ~~appropriate~~ policies and procedures for regular database updates.*	
~~SOURCE~~Criteria	~~CRITERIA~~Guidance
~~OAI Sections 4.3 and 5.4~~ ~~IDG Sections 2.2, 2.3, and 2.4~~ ~~OAI Section 4.3~~ ~~*IDG* Sections 2.2, 2.3, and 2.4~~ Organization implements policies and procedures for periodic data system updates (e.g., changes in enrollment, provider/pharmacy status, claims adjustments).	Determine if the SO has policies and procedures in place for performing periodic updates for each data system used for the reporting section under review that ensures reported data are accurate and timely. Determine if the SO implements and adheres to the policies and procedures referenced above (i.e., was any data for the reporting section under review negatively impacted by a failure to implement or follow these policies and procedures?). ~~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.~~

5.1.2.5   Standard 5

This validation standard is assessed at the reporting section-level and is used to assess whether the SO 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 29.

Exhibit 29. Guidance for Standard 5

Data Validation Standard 5: *Assessed at the reporting section-level and is used to assess whether the SO has and implements ~~appropriate~~ policies and procedures for data archiving and restoration*	
~~SOURCE~~Criteria	~~CRITERIA~~Source
~~*OAI* Section 5.4~~ ~~*IDG* Section 2.4~~ Organization implements policies and procedures for archiving and restoring data in each data system (e.g., disaster recovery plan).	Determine if the SO has policies and procedures in place for archiving and restoring data in each data system used for the reporting section under review that ensures timely data submission or re-submission in the event of data loss. Determine if the SO implements and adheres to the policies and procedures referenced above (i.e., was any data for the reporting section under review negatively impacted by a failure to implement or follow these policies and procedures?). ~~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.~~

5.1.2.6   Standard 6

This validation standard is assessed at the reporting section-level and is used to assess whether the validity of the SO'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 30.

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

Exhibit 30. Guidance for Standard 6

Data Validation Standard 6: *Assessed at the reporting section-level and is used to assess whether the validity of the SO's data was adversely impacted by any changes to data systems during the reporting period.*	
~~SOURCE~~Criteria	~~CRITERIA~~Guidance
~~*OAI* Sections 4.1, 4.3, and 5~~ ~~*IDG* Sections 2.2, 2.3, and 2.4~~ 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.	Review documentation on data system changes and determine if changes to an SO's data system adversely impacted data reported.~~by conducting the following activities:~~ • Determine if there were any changes to data sources used for data collection and storage, data processing, analysis, and reporting for the reporting section under review. • Determine if data system changes were the root cause of any outlier notices received from CMS for the reporting section under review. • Determine if the SO implemented any process or quality improvement activities during the reporting period specifically related to the data system change for the reporting section under review. Determine if the validity of the SO's data was adversely impacted by any changes to data systems during the reporting period.

5.1.2.7   Standard 7

This validation standard is assessed at the reporting section-level and is used to assess whether the SO 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 31.

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 PRDVM (and *FDCF*, if used) if Standard 7 is not applicable to the reporting section or contract under review.

Exhibit 31. Guidance for Standard 7

Data Validation Standard 7: Assessed at the reporting section-level and is used to assess whether the SO routinely monitors the quality of a delegated entity's work and processes related to the reporting requirements.	
~~SOURCE~~Criteria	~~CRITERIA~~Guidance
OAI ~~Sections 4.1 and 5~~ *IDG* ~~Sections 2.2, 2.3, 2.4, 3 and 4~~ If data collection and/or reporting for this reporting section 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 reviewer.	Assess the following if data collection and/or reporting for a reporting section is delegated to another entity: • Determine if the SO has policies and procedures in place for overseeing the delegated entity's reporting process / results for the reporting section under review. • Determine if the SO implements and adheres to the policies and procedures referenced above (i.e., was any data for the reporting section under review negatively impacted by a failure to implement or follow these policies and procedures?). Plans are not expected to replicate the delegated entities process and recalculate all of their numbers but are expected to have policies and procedures in place for routine monitoring. It is expected that these policies and procedures are implemented as frequently as needed to verify the delegated entities' reporting. SOs are responsible for a delegated entities calculations and numbers and therefore if they are incorrect, the responsibility ultimately falls on the SO. ~~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~~.

5.2   Provide Draft Findings to Sponsoring Organization

Once the findings have been documented in the PRDVM (and *FDCF*, if used), the reviewer must share the draft findings with the SO.

If the DV reviewer chooses to enter findings directly into the PRDVM during its review (as opposed to populating the Microsoft Excel version), it may print the findings entered into the PRDVM and share them with the SO at any point during the review by accessing the PRDVM report entitled "Review Data Validation Findings Report."

5.3   Review Draft Findings with Sponsoring Organization and Obtain Additional Documentation Necessary to Resolve Issues

The SO and DV reviewer should build time into the April-June DV 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.

Following any review of the draft findings with the SO, the 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.

5.4   Submit Data Validation Review Findings via HPMS PRDVM

5.4.1   Data Validation Contractor's Submission of Findings

Following the conclusion of the DV review and the finalization of findings, the reviewer 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 reviewer 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. Reviewers should also indicate which extraction method (full census or sample) was used for each reporting section.

5.4.2   Sponsoring Organization Disagreement with Findings

If the SO disagrees with any of the findings submitted by the DV reviewer, it may submit information indicating this disagreement to CMS within 30 calendar days of the date that final findings are submitted via the PRDVM. 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 SO
    - CMS contract number(s)
    - SO's contact name, title, phone number and email address
    - Name of reviewer organization
- For each area of discrepancy, list the following information:
    - Part C or Part D, name of reporting section
    - Standard/ sub-standard ID, reporting section criteria ID
    - Description of reviewer's finding
    - Reason for disagreement with finding
    - Steps that were taken to resolve the disagreement with the 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.

6   POST- DATA VALIDATION ACTIVITIES

6.1   Compile Archive of Data Validation Work Papers

The DV reviewer must prepare a complete archive of work papers associated with the annual DV and provide it to the SO. At a minimum, this archive must contain the documentation described in Exhibit 32. The reviewer should also retain a complete copy of this archive in accordance with its contract with the SO.

When the SO receives the archive from the reviewer, the SO must add the documentation of its reviewer selection process to the archive, including how its chosen reviewer meets the minimum qualifications, credentials, and resources set forth in the *Standards for Selecting a Data Validation Contractor*. The SO

must retain this complete archive for the 10-year retention period required per federal regulations and be prepared to provide the archive to CMS upon request.

Exhibit 32. 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 *IDG* 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 SO 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)

6.2 Receive Pass or Not Pass Threshold Level and Assess Pass or Not Pass Determination based on Final Scores

6.2.1 Pass/Not Pass Determination

For each reporting section, 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~~ assigns a score based on the findings entered into the PRDVM by the DV 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* (Appendix K) identifies the individual score CMS has assigned to each standard and sub-standard for all reporting sections.

After all findings are submitted to CMS, CMS will calculate a percentage score for all Part C reporting sections as a group, all Part D reporting sections as a group, and a combined Part C and Part D determination for those contracts reporting both Part C and Part D data. CMS then establishes passing thresholds for Part C, Part D, and an overall combined Part C/Part D score based on the distribution of scores. ~~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.~~

6.2.2 CMS Notification to Sponsoring Organization of Pass/Not Pass Determinations

CMS ~~may~~ will release a memo through HPMS PRDVM regarding the thresholds established. SOs then determine if they passed or did not pass by comparing their score received via HPMS against the threshold announced in the memo. If an SO does not pass, they will receive follow-up communication from CMS. ~~notify each sponsoring organization of the Pass or Not Pass determinations via a report issued through the HPMS PRDVM.~~

6.3 Sponsoring Organization Appeal of Data Validation Determination (If Applicable)

An SO 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 reporting sections or for the overall combined Part C and Part D determination. Please note that the pass/not pass thresholds are not applied to individual reporting sections.

If the SO 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~~ information from CMS about the threshold level. 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 SO
  - CMS contract number(s)
  - SO's contact name, title, phone number and email address
  - Name of reviewer 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~~ whether the ~~indicate that the~~ appeal pertains to the overall Not Pass for Part C and/or Part D reporting sections
  - 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 DV. For example, if after the DV, the SO resubmits corrected data, revises a policy and procedure, or corrects a programming code that caused it to improperly calculate reported data; the SO 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 SO appeals.