Medicare Part C and Part D Reporting Requirements Data Validation

Procedure Manual

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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. .[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 allows CMS to more effectively monitor and compare the performance of SOs over time. These data may be used for Star Ratings, and other performance measures. 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) 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.

1.2. Data Validation Scope

CMS requires that the annual, DV be conducted once per year. For the 2022 DV cycle, the DV will take place during the April 1, 2022 – June 30, 2022 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, 2022.

The DV reviews will continue to 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.

1.3. 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 Reporting Requirements, 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.
- Organizations/sponsors that non-renew or terminate during the measurement year or reporting/data validation year and are not included in the HPMS plan table.
- Organizations/sponsors with contracts or Plan Benefit Packages (PBPs) that non-renewed or terminated in 2021 or prior to July 1, 2022, are not required to report 2021 Part C/D reporting requirements data (due in 1Q of 2022), or undergo Part C/D data validation of 2021 data (due June 2022).

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 DVC 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 DVC for validation if they submit data to an SO that is used for any reporting section.

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

1.4. Required Data Validation Manual and Tools

This manual and its appendices must be used to conduct the annual data validation. The following documents are included:

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 Contractor (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 for On-site or Virtual Visits (Appendix G)
8. Data Extraction and Sampling Instructions (Appendix H)
9. Example Data File Inventory Log (Appendix I)
10. Findings Data Collection Form (FDCF) (Appendix J)
11. Pass/ Not Pass Determination Methodology (Appendix K)

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. In order to ensure that the DV documentation can incorporate periodic clarifications to the Part C and Part D Reporting Requirements and Technical Specifications, CMS updates this Manual and the DV tools contained in its appendices as needed; the most current version is posted publicly at: Medicare Part C and D Data Validation and 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 DVCs 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 Reporting Requirements and the Data Validation Standards reporting section criteria, the Data Validation Standards supersede the Reporting Requirements DVCs must use the Data Validation Standards reporting section criteria to determine DV findings. CMS will take a conflict between the Reporting Requirements and the Data Validation Standards into consideration when evaluating the results of the DV review.

1.5. Organization of the Procedure Manual

Exhibit 1 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 1. DATA VALIDATION PROGRAM PHASES

Planning for DV Activities => Performing DV Activities=> Analyzing Results and Submission of Findings => Completing Post-DV Activities

Each phase of the DV review process contains several activities. Exhibit 2 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 DVC and ending with the appeal of DV determinations. The DV review process largely entails a collaborative effort between the SO and its independent, external DVC in terms of information sharing up to the point of the DVC's final submission of DV review findings to CMS. Each of these steps is described in more detail throughout the Manual.

EXHIBIT 2. 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	January-March
Performing DV Activities	5	SO	Complete Organizational Assessment Instrument (OAI) and provide appropriate documentation to selected DVC per the OAI's documentation request	March 2 - April 1
	6	DVC, SO	Analyze OAI Responses	March 2 or later
	7	DVC, SO	Prepare for on-site or virtual visit (site visit agenda, resource needs, and logistics)	Early April
	8	DVC, SO	Conduct on-site or virtual review (convene entrance conference, conduct interviews with SO staff, observe SO's reporting processes, and obtain census and/or sample files)	Early April (allow for up to 1 week)
	9	DVC	Request additional documents following on-site or virtual visit (if applicable)	Mid/Late April
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)	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- Activities	14	DVC, SO	Compile archive of DV work papers	July 31
	15	SO	Receive Pass or Not Pass threshold level and assess Pass or Not Pass determination based on final DV scores	Summer/Fall
	16	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 IN 2022

This section provides an overview of the Part C and Part D reporting sections that will undergo validation. 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 2022

Seven Part C and Part D reporting sections are included in Exhibit 3.

EXHIBIT 3. PART C AND PART D REPORTING SECTIONS REQUIRING DATA VALIDATION IN 2022

2022 Reporting Section	Reporting Period(s)	Data Submission Due Date(s) to CMS	DV Findings Due to CMS
Part C			
Grievances	1/1 -3/31 4/1 -6/30 7/1 -9/30 10/1 -12/31	First Monday of February in 2022	6/30
Organization Determinations/ Reconsiderations	1/1 -3/31 4/1 -6/30 7/1 -9/30 10/1 -12/31	Last Monday of February in 2022	6/30
Special Needs Plans (SNPs) Care Management	1/1 -12/31	Last Monday of February in 2022	6/30
Part D			
Medication Therapy Management Programs	1/1 -12/31	Last Monday of February in 2022	6/30
Grievances	1/1 -3/31 4/1 -6/30 7/1 -9/30 10/1 -12/31	First Monday of February in 2022	6/30
Coverage Determinations and Redeterminations	1/1 –3/31 4/1 -6/30 7/1 -9/30 10/1 -12/31	Last Monday of February in 2022	6/30
Improving Drug Utilization Controls	1/1 -3/31 1/1 -6/30 1/1 -9/30 1/1 -12/31	Last Monday of February in 2022	6/30

2.2. Reporting Requirements Excluded from the Validation Requirement

Exhibit 5 lists the reporting sections required for reporting but excluded from the DV review at this time.

EXHIBIT 5. 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 - Rewards and Incentives Programs - Payments to Providers	- Enrollment/ Disenrollment - Employer/ Union- Sponsored Group Health Plan Sponsors

3. PLANNING FOR DATA VALIDATION ACTIVITIES

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

The DV must be conducted by an independent, external entity to 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 Data Validation Contractor (DVC) 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 DVC (Appendix A) for SOs to use in acquiring a contractor. These standards describe the minimum qualifications, credentials, and resources that the selected DVC must possess, as well as the conduct that the DVC must exhibit. SOs must acquire one DVC to conduct the validation on reported data and if necessary, the DVC 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 DVC in obtaining the information, data, and documents needed to complete the DV review.

SOs may also permit a different DVC 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, an SO may not use the same DVC 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. While the DVC conducting the formal DV review may not participate in mock audits, pre-assessments, or other types of reviews, the DVC 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 contains best practices that DVCs are expected to adhere to throughout the course of the review. The DVC should remain an objective, independent third party and avoid acting in a consulting capacity. The DVC 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 DVC 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 DVC 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 DVC 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 DVC 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 DVC. If a change in contractor is required, the new DVC 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 DVC 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 resource mailbox.

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 DVC selection process and be able to show, upon request by CMS, how their chosen DVC 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 DVC 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.[2]

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

*Submission of this information to CMS is not required but should be available upon request by CMS.

3.2.2   Request Access to HPMS Plan Reporting Data Validation Module

Once the SO has selected a DVC, the next step is for the DVC to request staff access to the PRDVM in HPMS. This module allows users to upload 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 DVC staff will use these credentials to access the appropriate screen(s) to upload DV findings within the PRDVM starting no earlier than April 1 of the calendar year.

3.2.2.1   Access to HPMS requires a CMS user ID. Questions regarding the user ID process should be directed to HPMS_access@cms.hhs.gov. Additional information on obtaining HPMS access can be found at the following link: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/UserIDProcess.

3.2.2.2 Process for Sponsoring Organization

In order to gain access to the PRDVM, the SO provides their DVC with an official letter in either hardcopy or an emailed pdf format attachment containing the following information:

- The SO's acknowledgment that it has contracted with the selected DVC to complete the review,
- The name of each individual who 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 DVC will need access to, and
- The SO's Chief Executive Officer's (CEO) signature.

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 DVC it used for a previous year's DV review, it must still provide the DVC with this signed letter for the current year's DV activities.

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

3.2.2.3 Process for Data Validation Contractor

DVC staff must obtain individual access to the HPMS PRDVM. If the designated user(s) from the DVC does not have active access to HPMS, each user should download the Application for Access to CMS Computer Systems at : Access to CMS Data & Application 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 allows up to 5 individuals from each DVC to have access to this Module on behalf of each SO. The DVC must create their user ID using EFI, then email the letter from each SO for which they are under contract to complete the DV review. Since we will process the request for a new user ID first the user will only get the HPMS main home page until a DV letter is received. The letters may be sent as email attachments to HPMSConsultantAccess@cms.hhs.gov:

Users may follow the instructions for getting their user ID by clicking the Instructions for Requesting Plan Access via EFI link under the Download section on the CMS HPMS website: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/UserIDProcess.

When the user gets to the "I am a" question, the user must select Data Validation Consultant from the drop down. The system will automatically fill out the company name and Plan number. The HPMS team has also created a video to walk a user through getting a new CMS user ID: https://youtu.be/KAXwdnq1hKs

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 DVC to the SO 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. If a user had PRDVM access as a DVC previously, they do not need letters resent on their behalf. Letters are only required for changes to a DVC user's account.

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 early April. 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 DVC 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 DVC 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 developed a web-based DV Training for SOs and DVCs to learn more about the DV program and its specific requirements. The training is on cms.gov on the MLN page and found at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/WebBasedTraining

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

Additionally, all DV staff are required to take the CMS web-based DV Training prior to working on the DV project. Once the training is completed, a certificate of completion is generated. DVC staff should provide training certificates to the SO before commencing work on the DV.

The certificate of completion will automatically generate upon successful completion of the course. Any DVC staff that participated in a previous year's DV must still take the current year's CMS web-based DV Training.

3.4   Review all Data Validation Documents

As noted in Section 1.4, there are 11 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 staff must use to determine whether the data each SO reported to CMS per the Part C/Part D Reporting Requirements and 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 Reporting Requirements and 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 DVC 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 and reporting section criteria that are based on the applicable Reporting Requirements and Technical Specifications.

The DVC uses these standards in conjunction with the Data Extraction and Sampling Instructions (Appendix H) and the Excel version FDCF (Appendix J) to evaluate the SO's processes for producing and reporting the reporting sections. CMS strongly recommends that the DVC 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 details the documents and reports that the DVC uses 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 6.

EXHIBIT 6. 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 • Outlier/data integrity notification(s)- See OAI 4.3.3 for instructions on how to retrieve notices • Results of interviews with organization staff • Census and/or sample data	• Data file created for submission to CMS and copy of HPMS screen shots of data entered • Other relevant information provided by organization

Also contained within this section, if applicable, are notes to the DVC regarding a specific reporting section and any nuances or differences that may be encountered during the review of that reporting section. 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 Standard 1

Standard 1 (see Exhibit 7) contains the general and specific criteria for validating source documentation that the SO provides to the DVC.

EXHIBIT 7. 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 are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via CMS systems.
	    b. Source documents create all required data fields for reporting requirements.
	    c. Source documents are error-free (e.g., programming code and spreadsheet formulas have no messages or warnings indicating errors, use correct fields, have appropriate data selection, etc.).
	    d. All data fields have meaningful, consistent labels (e.g., label field for patient ID as Patient ID, rather than Field1 and maintain the same field name across data sets).
	    e. Data file locations are referenced correctly.
	    f. If used, macros are properly documented.
	    g. Source documents are clearly and adequately documented.
	    h. Titles and footnotes on reports and tables are accurate.
	    i. Version control of source documents is appropriately applied.

3.4.2.2.2 Standard 2

Standard 2 (see Exhibit 8) instructs the DVC 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 sections 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 terms "Coverage Determinations and Redeterminations" in accordance with CMS regulations, guidance, and the Reporting Requirements and 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.

	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, 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):
	j. The appropriate date range(s) for the reporting period(s) is captured.
	k. Data are assigned at the applicable level (e.g., plan benefit package or contract level).
	l. Appropriate deadlines are met for reporting data.
	m. Terms used are properly defined per CMS regulations, guidance, Reporting Requirements, and Technical Specifications.
	n. 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 9) is used to determine whether an SO implements policies and procedures for each reporting section's data submission. Not only should the DVC 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 CMS systems. If a reporting section requires both a file upload and data entry, both have to occur in order for an SO to meet Sub-Standard 3a.

EXHIBIT 9. STANDARD 3: DATA SUBMISSION

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

3.4.2.2.4 Standards 4 and 5

For Standards 4 and 5 (see Exhibit 10), the DVC 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 10. STANDARDS 4 AND 5: DATA SYSTEM UPDATES AND ARCHIVE/RESTORATION

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

3.4.2.2.5 Standards 6 and 7

Standards 6 and 7 (see Exhibit 11) 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 DVC 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 DVC should mark "Not Applicable" in the Excel-version FDCF if Standard 6 or 7 is not applicable to the reporting section or contract under review.

EXHIBIT 11. 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., because 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 12) are used to validate whether the SO is utilizing the appropriate reporting period, reporting level, and reporting deadline(s) per CMS requirements.

EXHIBIT 12. 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.
3	Organization meets deadline for reporting annual data to CMS by 2/28/2022. *Note to reviewer: If the organization has, for any reason, re-submitted its data to CMS for this reporting section, the reviewer should verify that the organization's original data submission met the CMS deadline in order to have a finding of "yes" for this reporting section criterion. However, if the organization re-submits data for any reason and if the re-submission was completed by 3/31 of the data validation year, the reviewer should use the organization's corrected data submission for the review of 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, Reporting Requirements and Technical Specifications. Exhibit 13 shows an example of this criterion for the Part D Coverage Determinations and Redeterminations reporting section.

EXHIBIT 13. REPORTING SECTION CRITERION FOR DEFINING KEY TERMS IN PART D COVERAGE DETERMINATIONS AND REDETERMINATIONS SECTION

	REPORTING SECTION CRITERIA
4	Organization properly defines the term "Coverage Determinations" in accordance with 42 C.F.R. Part 423, Subpart M, and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance. This includes applying all relevant guidance properly when performing its calculations and categorizations. Organization properly defines the term "Redetermination" in accordance with 42 C.F.R. Part 423, Subpart M, and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance. 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 Reporting Requirements when possible and differ considerably depending on the reporting section and data element. Exhibit 14 shows an example of selected reporting section criteria applicable to the Part C Grievances reporting section. The exact criteria for each Part C and D reporting section are based on the Reporting Requirements and Technical Specifications.

EXHIBIT 14. REPORTING SECTION CRITERIA FOR SELECTED PART C GRIEVANCES DATA ELEMENTS

	REPORTING SECTION CRITERIA
6	Organization accurately calculates the total number of grievances, including the following criteria: a. Includes all grievances that were completed (i.e., organization has notified member of its decision) during the reporting period, regardless of when the grievance was received. b. Includes all grievances reported by or on behalf of members who were previously eligible, regardless of whether the member was eligible on the date that the grievance was reported to the organization. c. If a grievance contains multiple issues filed under a single complainant, each issue is calculated as a separate grievance. d. If a member files a grievance and then files a subsequent grievance on the same issue prior to the organization's decision or the deadline for decision notification (whichever is earlier), then the issue is counted as one grievance. e. If a member files a grievance and then files a subsequent grievance on the same issue after the organization's decision or deadline for decision notification (whichever is earlier), then the issue is counted as a separate grievance. f. Includes all methods of grievance receipt (e.g., telephone, letter, fax, and in-person). g. Includes all grievances regardless of who filed the grievance (e.g., member or appointed representative) h. Includes only grievances that are filed directly with the organization (e.g., excludes all complaints that are only forwarded to the organization from the CMS Complaint Tracking Module (CTM) and not filed directly with the organization). If a member files the same complaint both directly with the organization and via the CTM, the organization includes only the grievance that was filed directly with the organization and excludes the identical CTM complaint. i. For MA-PD contracts: Includes only grievances that apply to the Part C benefit (If a clear distinction cannot be made for an MA-PD, cases are reported as Part C grievances). j. Excludes withdrawn grievances. [Data Elements A-E]

7	Organization accurately calculates the number of grievances for which it provided timely notification of the decision, including the following criteria:
	 a. Includes only grievances for which the member is notified of decision according to the following timelines:
	     i. For standard grievances: no later than 30 days after receipt of grievance.
	     ii. For standard grievances with an extension taken: no later than 44 days after receipt of grievance.
	     iii. For expedited grievances: no later than 24 hours after receipt of grievance.
	
	 [Data Elements B]

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, of two weeks to complete and should 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. SOs should provide the completed OAI to their selected DVC electronically. CMS estimates that the OAI should take a minimum be submitted to the DVC no later than early April. SOs may not send their completed OAI or source code, SOPs, etc. to their DVCs prior to the start of the DV cycle on April 1.

Each SO must provide to its DVC 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 DVC 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 2021 reporting period, the SO should include only diagrams of the information systems in place in 2021 or the programming code used in 2021 to calculate the reporting sections.

It is up to the SO and its DVC 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 DVC's facility, equipment, and processes must comply. The SO is responsible for ensuring that the DVC 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 DVC is required to select "No" or 0 in the FDCF for that standard or sub-standard.

4.2   Analyze OAI Responses

CMS recommends DVCs perform a preliminary review of the documentation submitted in the OAI in advance of each site visit (on-site or virtual) so that any follow-up regarding the documentation can be done during the site visit (on-site or virtual). 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 DVC 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 Reporting Requirements and/or 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 DVC should review the document for completeness and accuracy. Sections of the OAI that are missing or incomplete should be noted, and the DVC should follow-up with the SO to complete. It is up to the DVC to determine whether any identified gaps in the OAI responses require addressing prior to the site visit (on-site or virtual) or can be addressed during the site visit (on-site or virtual) portion of the review.

4.2.2. Review Source Code and Other Documentation

Data dictionaries and source code are critical for allowing the DVCs 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 DVC in gaining a more thorough understanding of the SO. The DVC should be familiar with data systems and processes detailed by the SO in the OAI to ensure thorough preparation for the site visit (on-site or virtual).

4.2.3. Prepare Interview Discussion Guide

The Interview Discussion Guide (IDG) (Appendix F) is intended to facilitate the discussion between the DVC 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 DVC discovers evidence that may indicate errors in the SO's data or reporting processes, the DVC 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 DVC; it is up to the DVC's discretion to include additional questions and/or detail to the document to discuss during on-site or virtual interviews and to ensure the additional detail is documented accordingly.

4.3   Prepare for On-Site or Virtual Visit

4.3.1   Select Dates and Appropriate Location(s) of On-Site or Virtual Visit

During the site visit (on-site or virtual), the following DV review activities occur: (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 DVCs are responsible for determining mutually agreeable dates for performing the site visit or holding a virtual site meeting. It is estimated that the site visit (on-site or virtual) 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 DVC to determine the most appropriate location(s) of the site visit (e.g., virtual, SO's facility, PBM's facility, other delegated entity's facility). SOs and DVCs may elect to conduct a physical site visit or use virtual meeting tool(s) or teleconference(s), if appropriate.

4.3.2   Develop Agenda for On-Site or Virtual Visit

The DVC and SO should work together to prepare a site visit (on-site or virtual) agenda. A sample agenda in Appendix G can be used either for a virtual or on-site visit. The sample 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 DVC have a method to collect contact information for each SO's report owners and subject matter experts in case any follow-up is required.

The time required to complete an on-site or virtual 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. A DVC session with the SO's report owner(s) for each reporting section must be scheduled to 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). To ensure optimal time and resource management during the on-site or virtual visit, a DVC may either conduct multiple sessions concurrently, or structure the agenda to allow scheduling of interviews and demonstrations of reporting processes by each report owner 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).

4.3.3   Prepare for Data Extraction and Sampling

In preparation for the data extraction and sampling during the site visit (on-site or virtual), the DVC 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 DVC 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 DVC 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, DVCs should attempt to extract the full census. Extracting the census will enable the DVC 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 DVC and/or SO, then the second method, extraction of a random sample, which is a subset of the full census, can be used. DVCs should 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, DVCs should 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 DVC is unable to supervise the data extraction process.

4.4 Conduct On-Site or Virtual Visit

4.4.1 Conduct Entrance Conference

The entrance conference provides an opportunity for the DVC and the SO's management and individual report owners to introduce themselves and discuss expectations for the on-site or virtual visit. At the entrance conference, the DVC 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 visit to go over administrative needs and review the day's agenda.

4.4.2 Conduct Interviews with Organization Staff

During the on-site or virtual visit, the DVC 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 DVC to gain a thorough understanding of each SO's data collection and reporting processes involved with meeting CMS reporting requirements. The DVC should reference the IDG as needed to ensure that all key topics are addressed during the interviews. In addition, 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 on-site or virtual visit allows the opportunity for the SO to provide a significant amount of useful information to the DVC. 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 CMS systems. If SOs and DVCs elect to conduct a virtual visit, designated SO staff can use virtual meeting tool(s) or teleconference(s) to provide visual demonstrations. The following is a sample list of the parts of the process that should be demonstrated:

- Contact information and location of report owner and data providers
- Function and location 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 (e.g., building or server), security, and access constraints

The visual demonstrations provide a clear illustration of the reporting processes, provide the DVC 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 DVC 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 DVCs. 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, DVCs should attempt to extract the full census. Extracting the census enables the DVC 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. 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 uploading the DV findings to CMS in the PRDVM, the DVC must report which data extraction method was used (full census or random sample) to validate data for each standard. For both methods, DVCs 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. Source data examples for each reporting section are provided in the Data Extraction and Sampling Instructions.

DVCs 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 FDCF, 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 FDCF and include the sample size selected for the source data.

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

CMS recommends that the DVC 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 DVC 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 DVC will be able to easily reference the data files during its post-site visit assessment of data.

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 DVC's secure storage device for each reporting section's data. The SO must also provide the DVC 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 DVC must ensure that they have established mutually agreeable methods for sharing protected health information and that the DVC 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 on-site or virtual visit to go over any action items or outstanding documentation needs. The on-site or virtual visit should conclude with an exit conference, where the DVC 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 on-site or virtual visit and follow-up conversations and requests may be required. The DVC should make every attempt to gather all required data and documentation during the on-site or virtual visit. In the event that not all information is available, or follow-up is required after the conclusion of the scheduled on-site or virtual visit, the DVC should have additional conversations with the SO and/or make requests for documentation. DVCs 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 on-site or virtual 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) to Upload into the HPMSPRDVM

Following the on-site or virtual visit, the DVC assesses 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.

The DVC completes the Excel version of the FDCF as it determines the findings for each contract included in the scope of the review. DVCs uses the Excel version of the FDCF to record findings and then translates the findings into the PRDVM in a data file upload. The FDCF mirrors the content of the DV Standards document, but allows the DVC to record notes, data sources referenced, and findings for the different standards and criteria specified for a given reporting section. The DVC 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. Once the DVC uploads the FDCF into PRDVM, the DVC may print the findings he/she uploaded into 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."

When using the FDCF, DVCs 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 DVC should enter the data sources used and review results for each standard or sub-standard. Next to this column, in the "Findings" column, the DVC selects the appropriate choice based on whether or not the plan met the requirement for the standard or sub-standard.

5.1.1.   Reporting Findings for Standards Using Binary Scale

For all standards except 1.c, 1.d, 1.e, 1.g, 1.h, and 2.e, the findings are reported using binary scale. The DVC selects "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 DVC must select "N." In instances where a standard or sub-standard is not applicable, the DVC must select "N/A" and must enter the reason for the "N/A" in the "Review Results" field.

CMS expects that there will be situations when the DVC finds that an SO is only in partial compliance with specific DV standards. CMS 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 (see Exhibit 16). Exhibit 17 provides examples of how to calculate this minimum threshold specifically for Standard 3.a, for which the DV involves samples or the complete census of records and/or data values.

EXHIBIT 16. 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 standard to be recorded as "Yes".
205	0.90 x 205 = 184.5	At least 185 of the records are correct for the standard to be recorded as "Yes" (round 184.5 to 185).

EXHIBIT 17. EXAMPLE OF HOW TO DETERMINE MINIMUM THRESHOLD OF IMPLEMENTED POLICIES OR
PROCEDURES FOR "YES" FINDING

Standard	Standard Description	Minimum Threshold for a "Yes" Finding
3	Organization implements policies and procedures for periodic data system updates (e.g., changes in enrollment, provider/pharmacy status, and 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. Reporting Findings for Standards Using Likert Scale

For standards 1.c, 1.d, 1.e, 1.g, 1.h, and 2.e, the scoring uses a five-point Likert-type scale. DVCs review the percentage of records that meet the standards, and enter a score based on the Likert- type scale. The scale corresponds to the percentage of errors that are found in plan data as shown below:

1. Contract data has more than 20 percent error in records – Contract will receive a score of 1 for the given standard/ sub-standard.
2. Contract data has between 15.1 percent and 20 percent error in records – Contract will receive a score of 2 for the given standard/ sub-standard.
3. Contract data has between 10.1 percent and 15 percent error in records – Contract will receive a score of 3 for the given standard/ sub-standard.
4. Contract data has between 5.1 percent and 10 percent error in records – Contract will receive a score of 4 for the given standard/ sub-standard.
5. Contract data has less than or equal to a 5% error in records – Contract will receive a score of 5 for the given standard/ sub-standard.

Exhibit 18 provides examples of different scenarios a DVC might face and corresponding scores assigned to the contract for the standards that may use either Likert or binary scoring.

EXHIBIT 18. EXAMPLE OF HOW TO DETERMINE MINIMUM THRESHOLD OF IMPLEMENTED POLICIES OR
PROCEDURES FOR FINDINGS USING BINARY AND LIKERT SCORE.

Standard	Percentage of Errors That are Found by the DVC in Plan Data	DV Response (DV Findings Reported on Column 'H' on FDCF)
1a, 1.b, 1.i, 2.a, 2.b, 2.c, 2.d, 3.a, 3.b, 4, 5, 6, 7	Fewer than 10 percent error in contract data for the given reporting section/ data element(s)	Yes
1a, 1.b, 1.i, 2.a, 2.b, 2.c, 2.d, 3.a, 3.b, 4, 5, 6, 8	More than 10 percent error in contract data for the given reporting section/ data element(s)	No
1a, 1.b, 1.i, 2.a, 2.b, 2.c, 2.d, 3.a, 3.b, 4, 5, 6, 9	Standard not applicable	Leave blank
1.c, 1.d, 1.e, 1.g, 1.h, 2.e	If any of the listed standards is not applicable	Leave blank

Standard	Percentage of Errors That are Found by the DVC in Plan Data	DV Response (DV Findings Reported on Column 'H' on FDCF)
1.c, 1.d, 1.e, 1.g, 1.h, 2.e	More than 20 percent error in contract data for the given reporting section/ data element(s)	1
1.c, 1.d, 1.e, 1.g, 1.h, 2.e	Between 15.1 percent and 20 percent error in contract data for the given reporting section/ data element(s)	2
1.c, 1.d, 1.e, 1.g, 1.h, 2.e	Between 10.1 percent and 15 percent error in contract data for the given reporting section/ data element(s)	3
1.c, 1.d, 1.e, 1.g, 1.h, 2.e	Between 5.1 percent and 10 percent error in contract data for the given reporting section/ data element(s)	4
1.c, 1.d, 1.e, 1.g, 1.h, 2.e	5 percent error or less in contract data for the given reporting section/ data element(s)	5

5.1.3. Review of the Findings Data Collection Form

Exhibit 19 illustrates an example of the FDCF for Standard 1. The DVC will assess this standard at the reporting section-level and determines a finding for each of the nine sub-standards contained in Standard 1.

EXHIBIT 19. 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	Enter 'Findings' using the applicable choice in the appropriate cells. Cells marked with an '*' should not be edited.
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 are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via 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:**	

Standard/ Sub-standard ID	Reporting Section Criteria ID	Standard/Sub-standard Description	Data Sources and Review Results: Enter review results and/or data sources	Enter 'Findings' using the applicable choice in the appropriate cells. Cells marked with an '*' should not be edited.
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 DVC 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 20 illustrates an example of the FDCF for Standard 2, Sub-Standards 2.a through 2.d. for the Part D Grievances reporting section.

EXHIBIT 20. EXAMPLE OF THE FDCF FOR STANDARD 2, SUB-STANDARDS 2.A - 2.D. FOR THE 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	Enter 'Findings' using the applicable choice in the appropriate cells. Cells marked with an '*' should not be edited.
2		A review of source documents (e.g., programming code, spreadsheet formulas, analysis plans, saved data queries, file layouts, process flows) and census or sample data, whichever is applicable, indicates that data elements for each reporting section are accurately identified, processed, and calculated.	**Data Sources:**	*
2.a	RSC-1	The appropriate date range(s) for the reporting period(s) is captured. Organization reports data based on the periods of 1/1 through 3/31, 4/1 through 6/30, 7/1 through 9/30, and 10/1 through 12/31.	**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.	**Review Results:**	

Standard/ Sub-standard ID	Reporting Section Criteria ID	Standard/Sub-standard Description	Data Sources and Review Results: Enter review results and/or data sources	Enter 'Findings' using the applicable choice in the appropriate cells. Cells marked with an '*' should not be edited.
2.c	RSC-3	Appropriate deadlines are met for reporting data (e.g., quarterly). Organization meets deadlines for reporting data to CMS by 2/7/2022. [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 the CMS deadline in order to have a finding of "yes" for this reporting section criterion. However, if the organization re-submits data for any reason and if the re-submission was completed by 3/31 of the data validation year, the reviewer should use the organization's corrected data submission for the review of this reporting section.]	**Review Results:**	
2.d	RSC-4	Terms used are properly defined per CMS regulations, guidance, Reporting Requirements and Technical Specifications. Organization properly defines the term "Grievance" in accordance with 42 CFR §422.564 and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Manual. This includes applying all relevant guidance properly when performing its calculations.	**Review Results:**	

The DVC also determines 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. For example, in Part D Grievances, RSC-5, RSC-6, and RSC-7 provide the calculations to determine the data element findings. Exhibit 21 illustrates an example of the FDCF for Standard 2, Sub-Standard 2.e, RSC-5 for the Part D Grievance reporting section.

EXHIBIT 21. EXAMPLE ROWS FROM FDCF FOR STANDARD 2, SUB-STANDARD 2.E RSC-5 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	Enter 'Findings' using the applicable choice in the appropriate cells. Cells marked with an '*' should not be edited	Standard /Sub-Standard ID
2.e	RSC-5	The number of expected counts (e.g., number of members, claims, grievances, procedures) are verified; ranges of data fields are verified; all calculations (e.g., derived data fields) are verified; missing data has been properly addressed; reporting output matches corresponding source documents (e.g., programming code, saved queries, analysis plans); version control of reported data elements is appropriately applied; QA checks/thresholds are applied to detect outlier or erroneous data prior to data submission. RSC-5: Organization accurately reports data by applying data integrity checks listed below and uploads it into HPMS. a: Number of total grievances in which timely notification was given (Data Element B) does not exceed number of total grievances (Data Element A).		**Data Sources:**	*
2.e	RSC-5.a		Data Element B	**Review Results:**	
2.e	RSC-5.b	RSC-5: Organization accurately reports data by applying data integrity checks listed below and uploads it into HPMS. b: Number of expedited grievances in which timely notification was given (Data Element D) does not exceed number of total grievances in which timely notification was given (Data Element B).		**Data Sources:**	*
2.e	RSC-5.b		Data Element D	**Review Results:**	
2.e	RSC-5.c	RSC-5: Organization accurately reports data by applying data integrity checks listed below and uploads it into HPMS. c: Number of expedited grievances (Data Element C) does not exceed total grievances (Data		**Data Sources:**	*

Standard/ Sub-Standard ID	Reporting Section Criteria ID	Standard/Sub-standard Description	Data Sources and Review Results: Enter review results and/or data sources	Enter 'Findings' using the applicable choice in the appropriate cells. Cells marked with an '*' should not be edited	Standard /Sub-Standard ID
		Element A).			
2.e	RSC-5.c		Data Element C	**Review Results:**	
2.e	RSC-5.d	RSC-5: Organization accurately reports data by applying data integrity checks listed below and uploads it into HPMS.

d: Number of expedited grievances in which timely notification was given (Data Element D) does not exceed total expedited grievances (Data Element C). | | **Data Sources:** | * |
| 2.e | RSC-5.d | | Data Element D | **Review Results:** | |
| 2.e | RSC-5.e | RSC-5: Organization accurately reports data by applying data integrity checks listed below and uploads it into HPMS.

e: Number of dismissed grievances (Data Element E) are excluded from the total. | | **Data Sources:** | * |
| 2.e | RSC-5.e | | Data Element E | **Review Results:** | |
| 2.e | RSC-5.f | RSC-5: Organization accurately reports data by applying data integrity checks listed below and uploads it into HPMS.

f: If the organization received a CMS outlier/data integrity notice, validate whether or not an internal procedure change was warranted or resubmission through HPMS. | | **Data Sources:** | * |
| 2.e | RSC-5.f | | Data Elements A-E | **Review Results:** | |

Standard 3 contains two Sub-Standards. Sub-Standard 3.a requires the DVC 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 are 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 22 illustrates an example of the FDCF for Standard 3 for the Part D Grievances reporting section.

EXHIBIT 22. 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	Enter 'Findings' using the applicable choice in the appropriate cells. Cells marked with an '*' should not be edited.
3.		Organization implements policies and procedures for data submission, including the following:		**Data Sources:**	*
3.a		Data elements are accurately uploaded into CMS systems and entries match corresponding source documents.	Data Element A	**Review Results:**	
3.a			Data Element B	**Review Results:**	
3.a			Data Element C	**Review Results:**	
3.a			Data Element D	**Review Results:**	
3.a			Data Element E	**Review Results:**	
3.b		All source, intermediate, and final stage data sets and other outputs relied upon to enter data into CMS systems are archived.		**Review Results:**	

Standards 4 through 7 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 23 displays example rows from the FDCF for Standards 4 through 7.

EXHIBIT 23. 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	Enter 'Findings' using the applicable choice in the appropriate cells. Cells marked with an '*' should not be edited.
4		Organization implements policies and procedures for periodic data system updates (e.g., changes in enrollment, provider/pharmacy status, and claims adjustments).	**Review Results:**	
5		Organization implements policies and procedures for archiving and restoring data in each data system (e.g., disaster recovery plan).	**Review Results:**	
6		If organization's data systems underwent any changes during the reporting period (e.g., because 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 Results:**	
7		If data collection and/or reporting for this reporting section is delegated to another entity: Organization regularly monitors the quality and timeliness of the data collected and/or reported by the delegated entity or first tier/downstream contractor.	**Review Results:**	

5.1.4. 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 DVCs use to determine findings for each of the DV standards.

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 in Exhibit 24.

EXHIBIT 24. 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*	
Criteria	**Guidance**
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 datasets). 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.	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. Ensure that all source documentation is legible, descriptive, and understandable, including each of the following: • Standard Operating Procedures (SOPs) 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 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 DVC 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.

Standard 2

This validation standard assesses whether the data elements for each reporting section are accurately identified, processed, and calculated. Each DVC 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 in Exhibit 25.

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 incorrectly identified, processed, or calculated the data reported for any of the PBPs included under a contract, then the DVC must assign a "No" finding in the FDCF 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 DVC. 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 25. 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.*	
Criteria	Guidance

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, Reporting Requirements, and 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.
	    o 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.
	    o If full census data is not extracted, verify that the sample size is sufficient and representative of the population of interest.
	    o 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 sizes that any estimates generated are statistically significant.
	 • All data elements are accurate: Verify that each data element is consistent with the reporting section criteria.

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.

Criteria	Guidance

	(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:
	
	• 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 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 31st 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 FDCF.

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.	
Criteria	Guidance
	(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:
	o 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.
	o Calculating frequency of occurrence for certain data fields might also alert the reviewer to obvious mistakes in the data extraction.
	o Verify that data has been selected at the proper level (e.g., either the contract or the plan benefit package level).
	o Check date ranges, demographic information, and eligibility information to examine proper data filtering.
	• Individual data sets are joined or merged correctly:
	o 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.
	o 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:
	o Recalculate the data fields that the SO used to calculate the data elements and refer to the reporting section criteria for each reporting section.
	o Calculate sums of the individual records within each reporting section to ensure that they equal those reported to CMS.
	Verify that the calculation of each of the data elements is consistent with the reporting section criteria*.

*CMS has added a reporting section criterion (RSC #5) which will be used by the DVCs to confirm that the data does not have any logical errors. RSC #5 includes data integrity checks that the DVC must verify at the data element level. These data integrity checks include confirming that a data element does not include outlier records.

Exhibit 25 provides several examples of how to review source code and evaluate the integrity of the data. However, the DVC may use other methods of DV to ensure a comprehensive and complete review of the source code and census/sample data. The DVC 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 FDCF. 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 FDCF.

Standard 3

This validation standard assesses whether the SO implements policies and procedures for entering and/or uploading each data submission to CMS systems. The guidance for evaluating Standard 3 is described in Exhibit 26.

EXHIBIT 26. GUIDANCE FOR STANDARD 3

Data Validation Standard 3: *Assesses whether the SO implements policies and procedures for entering or uploading each data submission to CMS systems.*	
Criteria	Guidance
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 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 screenshots 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 FDCF 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 an 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.

Standard 4

This validation standard is assessed at the reporting section-level and is used to assess whether the SO has and implements policies and procedures for regular database updates. The data sources and criteria for evaluating Standard 4 are described in Exhibit 27.

EXHIBIT 27. 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 policies and procedures for regular database updates.*	
Criteria	Guidance
Organization implements policies and procedures for periodic data system updates (e.g., changes in enrollment, provider/pharmacy status, and 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?).

Standard 5

This validation standard is assessed at the reporting section-level and is used to assess whether the SO has and implements policies and procedures for data archiving and restoration. The data sources and criteria for evaluating Standard 5 are described in Exhibit 28.

EXHIBIT 28. 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 policies and procedures for data archiving and restoration*	
Criteria	Guidance
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?).

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 29.

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

EXHIBIT 29. 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.*	
Criteria	Guidance
If organization's data systems underwent any changes during the reporting period (e.g., because 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.

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 30.

Standard 7 applies if any of the data collection or validation processes are outsourced to another entity. The DVC should mark "Not Applicable" in the FDCF if Standard 7 is not applicable to the reporting section or contract under review.

EXHIBIT 30. 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.*	
Criteria	Guidance
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.

5.2 Provide Draft Findings to Sponsoring Organization

Once the findings have been documented in the FDCF, the DVC must share the draft findings with the SO.

When the DVC uploads the Microsoft Excel version of the FDCF into the PRDVM during its review, they may print the findings uploaded 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 DVC 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 contractor's June 30 deadline for submitting findings to CMS.

Following any review of the draft findings with the SO, the DVC must update the FDCF 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 DVC must report the findings by uploading the FDCF 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 FDCF 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, or a 1-5 Likert scale. Associated with each standard or substandard.

DVCs should also indicate which extraction method (full census or sample) was used for each standard.

5.4.2. Sponsoring Organization Disagreement with Findings

If the SO disagrees with any of the findings submitted by the DVC, it may submit information indicating this disagreement to CMS by the June 30th data validation deadline. Submissions should be sent to CMS via the PartCandD_Data_Validation@cms.hhs.gov resource mailbox 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 DVC 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 DVC's finding
  - Reason for disagreement with finding
  - Steps that were taken to resolve the disagreement with the DVC prior to the submission of the findings
  - 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 DVC 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 31. The DVC 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 DVC, the SO must add the documentation of its DVC selection process to the archive, including how its chosen DVC 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 31. 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 Section5 - 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 Notes on issues resulting in changes to draft findings - Final FDCF

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 of the standards, sub-standards, and data elements, the reviewer must assess a "Yes/No" finding or a score using a 1-5 Likert scale. Each finding is associated with CMS-assigned percentage points and can vary depending on the sub-standard or data element being scored. A "No" or 1 finding, however, will always result in a score of zero percentage points. 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.

Contracts can view their data validation results in HPMS (https://hpms.cms.gov/). To access this page, from the top menu select "Monitoring," then "Plan Reporting Data Validation." Select the appropriate contract year. Select the PRDVM Reports. Select "Score Detail Report." Select the applicable reporting section. If you cannot see the Plan Reporting Data Validation module, contact CMSHPMS_Access@cms.hhs.gov.

6.2.2   Passing Data Validation – Minimum threshold

CMS has established 95% as the passing DV threshold for each reporting section, as well as for the Part C, Part D, and combined scores. SOs may view their individual contracts' validation results in HPMS. CMS will send follow-up communication to active contracts scoring below 95% on the overall Part C, Part D, or combined score.

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

An SO has the right to appeal:

- Reporting section score of less than 95%
- Non-compliant data validation standards/sub-standards i.e., a "No" or a 1, 2, or 3 on the 5-point Likert scale in the specific data element's data validation
- Contracts that score < than 95% on either Part C and/or Part D overall
- Contracts that score < than 95% in their combined Part C and Part D score

If the SO wishes to appeal, it must submit an appeal to CMS by June 30th deadline. Submissions must be sent to CMS via the PartCandD_Data_Validation@cms.hhs.gov resource mailbox and must contain all of the following information in order to be considered.

- Email subject line must state: "Data Validation: Appeal of <one of the appeal reasons from the list above>"
- 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 DVC organization
- For each appeal, list the following information:
    - 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.

Once the appeal is received, CMS will carefully consider the justification and any supporting documentation to determine if any changes should be made. CMS has not established a timeframe for the consideration of SO appeals.