

**Medicare Part C and Part D Reporting Requirements
Data Validation Procedure Manual**

**Appendix A: Standards for
Selecting a Data Validation Contractor**

Prepared by:
Centers for Medicare & Medicaid Services
Center for Medicare
Medicare Drug Benefit and C & D Data Group

Last Updated: December 2021

Table of Contents

1.	BACKGROUND	1
2.	STANDARDS FOR ORGANIZATIONAL INDEPENDENCE	1
3.	STANDARDS FOR RELEVANT DATA VALIDATION EXPERIENCE	2
3.1	Previous Experience Conducting Similar Types of Work	2
3.2	Successful Completion of Similar Data Validation Projects	3
3.3	Completion of CMS Data Validation Training	3
4.	STANDARDS FOR ORGANIZATIONAL BACKGROUND	3
4.1	Staff Credentials.....	3
4.2	Management Personnel Credentials.....	3
4.3	Overall Management Framework	4
4.4	Facility Requirements	4
4.5	Overall Resource Availability	4
5.	STANDARDS FOR CONDUCT	4
6.	DOCUMENTATION OF DATA VALIDATION CONTRACTOR SELECTION.....	5

1. BACKGROUND

Part C and Part D sponsoring organizations (SOs) are responsible for contracting with an independent data validation (DV) contractor to conduct the CMS-required annual validation of Part C and D Reporting Requirements data.

CMS is providing this set of *Standards for Selecting a Data Validation Contractor* as guidance for SOs to use in acquiring a DV contractor. These standards describe the minimum qualifications, credentials, and resources that the selected contractor must possess.

SOs must acquire one DV contractor to conduct the DV review on reported data. The DV contractor may subcontract in order to ensure it has the expertise required for each DV area and to meet the minimum standards described in this document.

2. STANDARDS FOR ORGANIZATIONAL INDEPENDENCE

In order to ensure the independence of the DV contractor, SOs may not use their own staff to conduct the DV review. CMS requires that the data validation review be conducted by an independent entity and believes that an independent external DV review is the only way to ensure that the Part C and Part D reporting results will be seen as credible by CMS and other stakeholders. Therefore, the SO is responsible for ensuring that the DV contractor staff (and subcontractor(s), if applicable) meet the following standards:

- Is not employed, contracted, sub-contracted, represented or considered to be a first-tier, downstream or related entity by the SO (the definitions of these terms are in the federal regulations at 42 CFR § 422.500 and § 423.501);
- Is free of conflict of interest (conflict of interest occurs when a person or person's objectivity in performing the data validation review is compromised by their proximity or relationship to the immediate task, and can possibly give cause for influencing a decision) ; and
- Companies who provide management consulting or assist the SO with its reporting procedures, reporting processes, or information systems used in storing, compiling, or reporting the Part C and/or Part D Reporting Requirements data to CMS may not serve as the DV contractor for that SO.

Exhibit 1 provides additional guidance on whether an entity's relationship with an SO meets CMS' standards for organizational independence in conducting the DV review. The SO should direct any specific questions regarding whether or not a particular entity meets these standards to PartCandD_Data_Validation@cms.hhs.gov resource mailbox.

Exhibit 1. Examples of Relationships that Meet/Do Not Meet Standards for Organizational Independence

Examples of Entity Relationships	Meets Standards for Organizational Independence? Y/N
Internal corporate audit team	No
Internal organization staff	No
Contractor who assists in preparing the SO's Part C/Part D reporting requirements data*	No
Contractor who monitors/maintains/creates data used by the SO for reporting*	No
Contractor not affiliated with the SO, who is hired to perform a "pre-review", "mock audit", or "pre- assessment" before or during the formal review period of April 1 through June 30	No
Contractor who assists in populating the <i>Organizational Assessment Instrument (OAI)</i> *	No
Contractor who assists in creating Part C/Part D reporting requirements policies and procedures for the SO*	No
External Quality Review Organizations (EQROs) and quality improvement organizations (QIO) contracted with a State Medicaid agency or the sponsoring organization to perform quality and other non-audit related activities	Yes

*For any given reporting period, DV contractors are prohibited from performing a DV review on any Part C and/or Part D reporting section for which the DV contractor also provided management consultation or assistance to the SO. Management consultation activities include performing mock audits, pre-assessments, and any other types of reviews on reported data. Contractors that provide management consultation activities to the SO to improve reported data cannot perform the DV review of those reported data. For example, if the DV contractor provided these consultation activities for CY2021 reported data, it cannot conduct a DV review of these data during the 2022 DV cycle.

SOs may use their own staff to assist the DV contractor in obtaining the information, data, and documents needed to complete the DV review. SOs can also hire separate contractors to perform mock audits prior to the formal DV period, but that organization must be different from the organization performing the formal DV review.

3. STANDARDS FOR RELEVANT DATA VALIDATION EXPERIENCE

3.1 Previous Experience Conducting Similar Types of Work

The DV contractor must have at least two years of previous experience conducting similar types of data review and validation or auditing with projects of similar size and scope. The DV contractor must possess, at a minimum, the following specialized expertise:

- Knowledge of the Part C and Part D Reporting Requirements and Technical Specifications;
- Knowledge of managed care and pharmacy benefits operations and management and how they relate to Medicare Parts C and Part D;
- Ability to evaluate an SO's performance of Medicare Part C and Part D data collection, storage, compilation, and reporting using CMS' data validation standards;
- Ability to conduct source/programming code review;
- Ability to interface with a variety of data systems in a secure environment;
- Experience in conducting DV (e.g., HEDIS Compliance Audits™) for commercial entities or governmental agencies;
- Thorough understanding of HIPAA and Privacy requirements; and
- Thorough understanding of the Medicare Advantage and Prescription Drug Benefit Programs.

3.2 Successful Completion of Similar Data Validation Projects

The DV contractor must demonstrate successful performance of current and previous DV or auditing projects of similar size and scope. This may be demonstrated by submitting descriptions of previous projects that required DV, information on any problems encountered during the execution of the project and how they were resolved, and whether budgets and deadlines established for the project were met. If available, third-party performance evaluations should also be submitted to the SO.

3.3 Completion of CMS Data Validation Training

Prior to working on the DV project, each individual staff member of the selected DV contractor must take the web-based CMS DV Training. All staff performing the DV, including the team project manager(s), are required to complete this training. The training will provide each participant with documentation that the training was completed, and the DV contractor must provide this documentation to any hiring SO before commencing work on the DV project.

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

4. STANDARDS FOR ORGANIZATIONAL BACKGROUND

4.1 Staff Credentials

The DV contractor must provide a cross-functional team to conduct the DV review. The size and composition of this team will depend on the scope and complexity of the *Part C and/or Part D Reporting Requirements* and the expertise required for each DV area. Available staff must include individuals with the following qualifications:

- IT staff with knowledge of different coding languages and methodologies (e.g., SAS, SQL, Crystal Reports, Cognos, MS Access);
- Statisticians;
- Individuals with experience in the review of claims and medical records data;
- Staff with demonstrated understanding of and subject matter expertise in managed care and pharmacy benefits operations and management and how they relate to Medicare Part C and Part D; and
- Analysts with demonstrated understanding of and subject matter expertise in *Title I and II of the Medicare Modernization Act (MMA)*, *Medicare Part C and Part D regulations* (42 CFR § 422 and § 423), the *Medicare Managed Care Manual* and the *Prescription Drug Benefit Manual*.

The DV contractor must ensure that it has the right mix of expertise and qualified staff that can efficiently and successfully carry out all tasks prescribed in the least disruptive manner to the SO and/or its delegated entities.

4.2 Management Personnel Credentials

The DV contractor must provide management personnel with demonstrated project management experience leading to the successful completion of projects of similar size and scope, including maintaining project schedules and budgets.

The DV contractor's management personnel should also have

- Technical knowledge of CMS Part C and Part D Reporting Requirements; and

- Knowledge of different coding languages and methodologies (e.g., SAS, SQL, Crystal Reports, Cognos, MS Access) and statistical methodologies.

4.3 Overall Management Framework

The DV contractor must provide an organization chart to the SO showing the management framework and placement of all personnel who will be affiliated with the DV review. The organization chart must be sufficient to provide an understanding of the roles and responsibilities or placement of proposed personnel.

4.4 Facility Requirements

The DV review can be conducted through on-site (at the Part C/Part D sponsoring organization location) or virtual and off-site activities. Therefore, the DV contractor must provide the facilities any equipment necessary to perform the off-site portion of the DV review. Given that the reviewer will be handling Personally Identifiable Information (PII) and proprietary/sensitive information regarding Part C/Part D SO internal operations, it must provide a facility and equipment that complies with applicable industry security standards, as well as maintain appropriate administrative, procedural, technical, and physical procedures to safeguard this information. The SO is responsible for ensuring that it has established mutually agreeable methods for sharing propriety and/or secure (PHI/PII) data with the DV contractor and that the DV contractor complies with all HIPAA privacy and security requirements. This includes, but is not limited to the following essential physical and operational security requirements:

- Ability to store secure data (hard copies and soft copies);
- Ability to provide a secure workspace to ensure employees not directly involved with the DV project do not have routine access to sensitive information;
- Systems capable of storing data and retrieving it securely; Computer files with sensitive information shall not be filed or backed up on the hard drive of computers, unless one of the two following exceptions are met: 1) the hard drive is a removable one that can be secured at night (the presumption is that a computer with a fixed hard drive is not secure); or 2) the computer can be protected (secured with a “boot” password, a password that is entered after the computer is turned on or powered on). This password prevents unauthorized users from accessing any information stored on the computer's local hard drive(s); and
- Ability to securely shred and dispose of documents.

4.5 Overall Resource Availability

The DV contractor must have the resources required to successfully perform the DV review on time and within budget while handling competing obligations. It must clearly demonstrate to the SO an approach to executing this project that provides a clear chain of responsibility, quality assurance monitoring, cost control, contract administration, and adequate, qualified staff resources.

5. STANDARDS FOR CONDUCT

CMS maintains that certain standards or best practices should be followed to ensure efficient and reliable DV reviews are performed. The list below outlines fundamental standards that all DV contractor staff should adhere to as they conduct each DV review.

- The DV contractor should remain an objective, independent third party and avoid acting in a consulting capacity.
- The DV contractor's focus should be to determine, after a thorough evaluation, if the SO's systems, programs, data, etc. are accurate, reliable, valid, and complete based on instructions and standards outlined in the DV Procedure Manual and its appendices and CMS' policies. The DV contractor

should remain impartial. For example, it should not pass judgment on the perceived value of SOs' systems, programs, data, etc. or develop findings based on personal preferences or any other method not addressed in the outlined standards or CMS' policies.

- The DV contractor should provide general feedback and specific information on deficiencies to help SOs improve during the formal DV period. However, SOs' submissions of corrective action plans to CMS (either written or verbal) are not required to be provided to the DV contractor.
- The DV contractor should maintain confidentiality of SOs' privileged information. The DV contractor should avoid sharing general or specific information about how SOs' data look and/or compare to one another. DV contractor staff are encouraged to promote effective communication, and open discussions of any issues and findings with the specific SOs. The DV contractor staff should refrain from discussing a specific SO's issues and findings with other SOs.
- The DV contractor may act as a conduit to obtain clarification about data validation procedures from CMS (i.e., by submitting questions to CMS at the following email address: PartCandD_Data_Validation@cms.hhs.gov). The DV contractor should not submit questions on behalf of the SO regarding correct reporting procedures of data in order to maintain its independence, and to not appear to assist the SO with its reporting processes.
- The DV contractor should provide regular status updates to the SO and prompt responses to SO requests.
- The DV contractor should request that the SO provides source documentation and reports as early as possible in the review cycle.
- The DV contractor should maintain a central data and documentation repository with adequate storage capacity and consistent file naming conventions.
- The DV contractor should ensure its staff are cross trained on applicable reporting sections.

6. DOCUMENTATION OF DATA VALIDATION CONTRACTOR SELECTION

SOs must document their DV contractor selection process and be able to show, upon request by CMS, how their chosen contractor meets the minimum qualifications, credentials, and resources set forth in this document. This includes maintaining a copy of the documentation that all staff completed the web-based CMS DV Training (see Section 3.3). CMS requires that the SO retain this documentation for the 10-year retention period per federal regulations.

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