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

Appendix A: Standards for Selecting a Data Validation Contractor

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1 BACKGROUND

Part C and Part D sponsoring organizations (SOs) are responsible for contracting with an independent data validation (DV) contractor (reviewer) 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 reviewer. These standards describe the minimum qualifications, credentials, and resources that the selected reviewer must possess.

SOs must acquire one reviewer to conduct the DV review on reported data. The reviewer 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, 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 reviewer (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); and
- 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). Consultants 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 reviewer for that SO.

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

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 *Organizational Assessment Instrument (OAI)**	No
Contractor who assists is 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, reviewers are prohibited from performing a DV review on any Part C and/or Part D reporting section for which the DV reviewer organization 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. Reviewers 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 reviewer provided these consultation activities for CY2016 reported data, it cannot conduct a DV review of these data during the 2017 DV cycles (unless "grandfathered" via a multi-year contract signed prior to January 24, 2012).

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

3 STANDARDS FOR RELEVANT DATA VALIDATION EXPERIENCE

3.1 Previous Experience Conducting Similar Types of Work

The reviewer 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 reviewer 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 Part 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; and
- Thorough understanding of HIPAA and Privacy requirements.
- Thorough understanding of the Medicare Advantage and Prescription Drug Benefit Programs.

3.2 Successful Completion of Similar Data Validation Projects

The reviewer 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 reviewer must take the web-based CMS DV Training. All reviewer staff assigned to a DV team, 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 reviewer must provide this documentation to any hiring SO for all staff assigned to the applicable DV team before commencing work on the DV project.

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

4 STANDARDS FOR ORGANIZATIONAL BACKGROUND

4.1 Staff Credentials

The reviewer 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 reviewer 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 reviewer 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 reviewer'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 reviewer 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 will be conducted through a combination of on-site (at the Part C/Part D sponsoring organization location) and off-site activities.[1] Therefore, the reviewer must provide the facilities and 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 reviewer and that the reviewer 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 work space 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.

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

4.5 Overall Resource Availability

The reviewer 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 reviewers should adhere to as they conduct each DV Review.

- The reviewer should remain an objective, independent third party and avoid acting in a consulting capacity.
- The reviewer'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 reviewer should remain impartial. For example, he/she 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 reviewer 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 reviewer.
- The reviewer should maintain confidentiality of SOs' privileged information. The reviewer should avoid sharing general or specific information about how SOs' data look and/or compare toone another. Reviewers are encouraged to promote effective communication, and open discussions of any issues and findings with the specific SOs. The reviewer should refrain from discussing a specific SO's issues and findings with other SOs.
- The reviewer should act as a conduit to obtain clarification from CMS (i.e., by submitting questions to CMS at the following email address: PartCandD_Data_Validation@cms.hhs.gov)
- The reviewer should provide regular status updates to the SO and prompt responses to SO requests.
- The reviewer should request that SOs provide source documentation, interim, and final data as early as possible in the review cycle so that the reviewer can begin recalculations at the start of the DV review cycle.
- The reviewer should maintain a central data and documentation repository with adequate storage capacity and consistent file naming conventions.
- The reviewer should ensure its staff are cross-trained on applicable reporting sections.

6 DOCUMENTATION OF DATA VALIDATION CONTRACTOR SELECTION

SOs must document their reviewer selection process and be able to show, upon request by CMS, how their chosen reviewer meets the minimum qualifications, credentials, and resources set forth in this document. This includes maintaining a copy of the documentation that all staff assigned to the applicable DV team completed the 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 reviewer it used for a previous year's DV, it must still document the selection process as described above.