DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR MEDICARE

TO: All Medicare Advantage Organizations, Part D Sponsors, and 1876 Cost Plans

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SUBJECT: Lessons Learned from the Medicare Part C and Part D Reporting Requirements Data Validation Program Pilot Test

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For the Part C and Part D Reporting Requirements Data Validation program, the Centers for Medicare & Medicaid Services (CMS) has established data validation standards and procedures to ensure that Part C and Part D sponsoring organizations' reported data are reliable, valid, complete, and comparable. CMS contracted with Booz Allen Hamilton (Booz Allen) to assist in establishing these data validation standards and to develop a program to validate the data reported by sponsoring organizations. On behalf of CMS, Booz Allen conducted a multi-phase pilot test of the data validation review process and tools with two organizations (one large Medicare Advantage-Prescription Drug (MA-PD) Organization and one standalone Prescription Drug Plan (PDP)), which included on-site reviews at the organization's facilities. The purpose of the pilot test was not to evaluate the validity of the pilot organizations' data samples, systems, or processes; rather, it was to assess and improve the tools and processes developed for the data validation program. The following is a summary of the pilot test purpose and scope, and a description of the lessons learned and recommendations that have been implemented to make the tools, processes, and data validation reviews more efficient and effective. The complete Data Validation Pilot Test report is available on CMs' website at www.cms.gov/PrescriptionDrugCovContra/9_PartCDDataValidation.asp.

Pilot Test Purpose and Scope

The first phase of the data validation pilot test occurred in the fall of 2009 and was focused on assessing the effectiveness of the *Organizational Assessment Instrument* (OAI) and the *Interview Discussion Guide*. CMS identified the following subset of Part C and Part D data measures for inclusion in the Phase I pilot:

Part C Data Measures	Part D Data Measures
Benefit Utilization Grievances Organization Determinations/Reconsiderations Agent Compensation Structure	Grievances Coverage Determinations and Exceptions Appeals

Following the Phase I site visit and completion of post on-site activities, Booz Allen refined the data collection tools based on lessons learned from Phase I and comments received from an industry review held in September 2009.

The primary purpose of the Phase II pilot, conducted in the spring of 2010, was to assess the data extraction and sampling process per the methodology included in the *Data Extraction and Sampling Instructions for Data Validation Contractors*, which reviewers will use to determine if the data each sponsoring organization reported to CMS are reliable, valid, complete, and comparable. Additionally, Booz Allen assessed use of the OAI (revised since Phase I pilot), including its documentation request component, as part of the Phase II pilot review.

Given the interdependencies between the data validation tools, the secondary purpose of the Phase II pilot was to re-assess the remaining data validation tools and identify recommendations for improvement. Ultimately, Booz Allen performed a comprehensive evaluation of the following data validation tools:

- Data Extraction and Sampling Instructions for Data Validation Contractors
- Organizational Assessment Instrument
- Interview Discussion Guide
- Data Validation Standards
- Findings Data Collection Form

CMS and Booz Allen selected a subset of Part C and D data measures for inclusion in the Phase II pilot, based on the data available at the time. The MA-PD pilot specifically focused on Part C measures and the PDP pilot focused on Part D measures. The measures assessed (per the 2009 CMS Reporting Requirements) included the following:

Part C Data Measures (MA-PD	Part D Data Measures (PDP)
Provider Network Adequacy Grievances Organization Determinations/Reconsiderations Plan Oversight of Agents	Grievances Exceptions Appeals Medication Therapy Management Programs

Lessons Learned for Data Extraction Approach and Sampling Methodology

Based on discussions held with each pilot organization's measure report owners and leadership, observation of the processes used to obtain and review sample data, and further review of the methodology included in the *Data Extraction and Sampling Instructions* document, Booz Allen generated lessons learned and corresponding recommendations for improvement to the sampling approach and methodology (see Table 1). Where applicable, these recommendations have been incorporated into the *Data Extraction and Sampling Instructions* document that sponsoring organizations and data validation contractors are required to use to conduct the data validation review.

Table 1: Summary of Lessons Learned/Recommendations Regarding the Data Extraction Approach and Sampling Methodology

Category	Lesson Learned	Recommendation for Improvement
Data Validation and Review	Visual demonstrations of the organization's databases and data systems at the on-site visit were very effective.	The data validation reviewer should provide clear instructions and expectations for the on-site review in advance so the organization can prepare a structured and focused presentation. Sponsoring organizations should facilitate the data validation reviewer's activities by providing an overview during the on-site visit of each of the relevant data systems used in gathering data and producing reports.
Data Volume	After extracting sample data sets for some measures and extracting the entire data set or "census" for other measures, it was determined that extraction of the entire data set did not add an undue burden to the organization undergoing review.	When possible, the data validation reviewer should obtain the census, or universe, of data records used to report a measure. This will ensure that the source data through final stage data sets support the data reported to CMS per the reporting requirements. The reviewer can determine compliance with validation standards using the census, instead of relying on an estimate generated by sampling. The use of random sampling should be left to the discretion of the data validation reviewer and should be limited to situations where pulling all records for a measure would create too heavy a burden on the organization.
Data Volume	Using sample data to check manual processes or to check for errors that occur relatively infrequently may require larger sample sizes than those outlined in the *Sampling Instructions*.	If the data validation reviewer chooses to use samples rather than census data, it should have the flexibility to request sample data sets larger than the minimum sizes prescribed in the *Data Extraction and Sampling Instructions* (i.e., more than 150 or 205 records) if additional data are required to complete the review.
Data Volume	It was no more difficult to pull data for the entire year vs. pulling sample data for only one reporting period (e.g., one quarter).	The data validation reviewer should select and review the entire year's data for a measure, despite the measure's reporting frequency requirements (e.g., quarterly, bi-annual). This will simplify the process for the data validation reviewer and allow thorough examination of all reported data, thus eliminating issues related to data seasonality.

Category	Lesson Learned	Recommendation for Improvement
Data Volume	While two to four gigabyte flash drives were sufficient for collecting data for the pilot tests, larger external drives may be needed for data covering multiple contracts and data measures.	The data validation reviewer should work with the sponsoring organization prior to the site visit to determine file sizes and ensure that data storage requirements are sufficient for data transport.
Currency of Data	If the source data rely on a transactional database where records are often updated, the source files may not be archived. Similarly, many of the intermediate files created using query programs may not be archived.	The sponsoring organization should ensure that copies of source, intermediate, and final stage files are saved so that reporting requirements can be re-generated at any given time for validation purposes (e.g., so that the reviewer can confirm counts in the files match counts in the data reported to CMS).
Data Content	Sample data sets provided by the organization should include all data required for the measure per the standards and measure-specific criteria included in the *Data Validation Standards* document in order to assess the accuracy of the reported data.	An organization's measure report owners/data providers should familiarize themselves with the standards and measure-specific criteria included in the *Data Validation Standards* document. This will ensure that the report owners/data providers are prepared to pull the appropriate data fields necessary during the sampling process. The data validation reviewer should also reference this document as needed when conducting the on-site review to confirm that the required data fields are provided.
Data Content	Without intermediate data sets, it may be difficult for the review team to determine whether data sets were extracted properly (e.g., tables may have been joined incorrectly, or records may have been improperly included or excluded).	For more complex measures that draw data from multiple databases or intermediate data source files, the data validation reviewer should require a sample or census from each of the intermediate data sets; this will aid the data validation reviewer in determining if tables are being joined properly.
Data Security	An organization's security software may interfere with transferring data to an encrypted flash or hard drive (e.g., use of software that automatically encrypts files copied to an external device).	The reviewer and organization should confirm that the type of device used to transfer data will be compliant with the organization's systems.

Category	Lesson Learned	Recommendation for Improvement
Data Security	Data fields that involve protected health information (PHI) are generally not necessary for the data validation review.	If a sponsoring organization is concerned about allowing PHI to be transferred to a reviewer, it may want to consider masking member ID numbers and stripping the census or sample file of all other protected information (e.g., member names, HICN, home addresses, phone numbers). Data are not typically combined across measures, so masked IDs would not affect data review across different measures.

Lessons Learned for OAI and Documentation Request

Based on Booz Allen's review of the completed OAI and documentation request, and data provided by the pilot organizations, Booz Allen generated lessons learned and corresponding recommendations for improvements to enhance the OAI. These enhancements will ensure provision of complete and organized documentation from organizations for a more efficient data validation review (see Table 2). Where applicable, these recommendations have been incorporated into the OAI document that sponsoring organizations and data validation contractors are required to use to conduct the data validation review.

Table 2: Summary of Lessons Learned/Recommendations Regarding the Revised OAI and Documentation Request

Category	Lesson Learned	Recommendation for Improvement
OAI: Documentation Request	The level of detail in the documentation provided by the pilot organizations varied.	The OAI should include a data dictionary template as a reference to help organizations more effectively prepare their documentation for reviewers. For example, the dictionary template could illustrate pertinent content such as data field name, data field description, and code definitions.
OAI: Documentation Request	There were gaps in the documentation provided, and it was not always possible to replicate a data report that was submitted to CMS.	The OAI should include instructions for the organization to reference the CMS Reporting Requirements Technical Specifications to ensure documentation is provided for all data elements.
OAI: Documentation Request	Organizations that provide well-written and documented queries/programming code with comments facilitate more efficient review of the data.	The OAI should include examples of what to include in programming code and the type of documentation requested in order to encourage organizations to submit organized and detailed programming code.

Lessons Learned for Other Data Validation Tools

Booz Allen reviewed the *Data Validation Standards* document and compared its validation standards and measure-specific criteria to the documentation and data received from the pilot organizations. The standards and measure-specific criteria were clearly specified, and the data seemed to reflect the requirements of the standards and reporting requirements. Based on this assessment, Booz Allen did not have any recommendations for substantial changes to the data validation standards and measure-specific criteria.[1]

Given the comprehensive nature of the pilot, Booz Allen had the opportunity to use the *Interview Discussion Guide* to facilitate discussion with each pilot organization's report owners and subject matter experts, and to review the *Findings Data Collection Form* (FDCF) and identified several lessons learned regarding this tool. Table 3 presents a summary of the issues and recommendations for improvement. Where applicable, these recommendations have been incorporated into the instructions to reviewers and the *FDCF* that data validation contractors may use to record findings from the data validation review.

Table 3: Summary of Lessons Learned/Recommendations Regarding the Interview Discussion Guide and Findings Data Collection Form

Category	Lesson Learned	Recommendation for Improvement
Interview Discussion Guide: Content	The IDG should be a dynamic document, designed to be adapted and altered as needed to obtain the information required for data validation.	The reviewer should modify the Guide as necessary to add new questions that may identify any vulnerabilities or opportunities for repeated errors with data collection or reporting, especially if, during review of the documentation provided in response to the OAI, the data validation reviewer discovers error trends with an organization's data or reporting processes. Additionally, the reviewer should use his/her discretion to go into more detail during site visit interviews as needed and to ensure that additional detail is documented appropriately.

[1] The Data Validation Standards document continues to be updated to reflect clarifications to the Part C or Part D Reporting Requirements Technical Specifications.

Category	Lesson Learned	Recommendation for Improvement
FDCF: Visual Display and Navigation of the Tool	Measures vary considerably in the number of data elements, and some findings are recorded for each data element, while others are recorded at the measure level. The Form is a single document with all standards laid out in a linear fashion. Color, graphics, and layout are employed to delineate different sections, but it is still difficult to view and navigate.	The FDCF should allow the reviewer to view the section currently in process without the distraction of other sections. Separating the form by measure, standard and sub-standard would alleviate this confusion. The reviewer will complete a version of the FDCF in a new HPMS Plan Reporting Data Validation Module to report findings to CMS. This version of the FDCF includes the review results and/or data sources that were reviewed for each standard or sub-standard, as well as the Yes, No, or Not Applicable finding associated with each standard or sub-standard. The reviewer will be able to enter the findings and other information for one data measure at a time.
FDCF: Data Accuracy	Given the length and complexity of the form, there is a risk for mistakes and confusion for the reviewer.	The reviewer will complete a version of the FDCF in a new HPMS Plan Reporting Data Validation Module to report findings to CMS. This version of the FDCF includes visual displays and logic to facilitate accurate and efficient data entry (e.g., instructional text, column headers always visible, ability to duplicate identical findings for multiple contracts, data entry allowed only for data measures applicable to a specific contract). The reviewer will also be able to view which contracts and data measures have had complete findings entered, which have the entry of findings partially entered, and which still require entry of findings.

We hope this information is helpful to you as you prepare to implement the data validation requirement. If you have additional questions regarding the data validation program, please direct them to: PartCandD_Data_Validation@cms.hhs.gov. Questions regarding the Part C and Part D Reporting Requirements Technical Specifications should be directed to Partcplanreporting@cms.hhs.gov and PartD-PlanReporting@cms.hhs.gov, respectively.

Thank you.