Medicare Program Audit and Compliance Infrastructure Development

Parts C & D Measure Data Validation Standards and Procedures

Document Overview

Draft

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1.0 BACKGROUND AND OVERVIEW OF DATA VALIDATION PROCESS

1.1 Background and Timelines

Organizations contracted to offer Medicare Part C and Part D benefits are required to report data to the Centers for Medicare & Medicaid Services (CMS) on a variety of reporting requirements per 42 CFR §422.516 (a) and §423.514. In order for the data to be useful for monitoring and performance measurement, it must be reliable, valid, complete, and comparable among sponsoring organizations. To meet this goal, CMS has developed data validation specifications and reporting standards based on the 2010 Part C and Part D Reporting Requirements. Part C organizations and Part D sponsors (sponsoring organizations) are responsible for contracting with an independent data validation contractor (reviewer), who will conduct retrospective data validation reviews for the Part C and Part D measures identified in Table 1 and provide the findings to CMS. The reviewer will use these standards to assess an organization's information systems capabilities and overall processes for collecting, storing, compiling, and reporting the required data. The majority of the data validation reviews will take place in March-May 2011 and assess data reported per the 2010 CMS Part C and Part D Reporting Requirements. Specific timelines for organization reporting, including dates the data validation findings are due to CMS (from the reviewer), are included in Table 1.

Table 1: Part C and Part D Measures Requiring Data Validation in 2011

Measure	Reporting Period(s)	Data Submission Due Date(s) to CMS	Data Validation Findings Due to CMS[*]
Part C			
Benefit Utilization	1/1/10 - 12/31/10	8/31/11	11/30/11
Procedure Frequency	1/1/10 - 12/31/10	5/31/11	8/31/11
Serious Reportable Adverse Events	1/1/10 - 12/31/10	5/31/11	8/31/11
Provider Network Adequacy	1/1/10 - 12/31/10	2/28/11	5/31/11
Grievances	1/1/10 - 3/31/10 4/1/10 - 6/30/10 7/1/10 - 9/30/10 10/1/10 - 12/31/10	5/31/10 8/31/10 11/30/10 2/28/11	5/31/11
Organization Determinations/Reconsiderations	1/1/10 - 3/31/10 4/1/10 - 6/30/10 7/1/10 - 9/30/10 10/1/10 - 12/31/10	5/31/10 8/31/10 11/30/10 2/28/11	5/31/11
Employer Group Plan Sponsors	1/1/10 - 12/31/10	2/28/11	5/31/11
Plan Oversight of Agents	1/1/10 - 12/31/10	2/28/11	5/31/11
Special Needs Plans (SNPs) Care Management	1/1/10 - 12/31/10	5/31/11	8/31/11
Part D			
Retail, Home Infusion, and LTC Pharmacy Access	1/1/10 - 3/31/10 (Sections A&B) 1/1/10 - 12/31/10 (Sections C&D)	5/31/10 (A&B) 2/28/11 (C&D)	5/31/11
Medication Therapy Management Programs	1/1/10 - 12/31/10	2/28/11	5/31/11
Grievances	1/1/10 - 3/31/10 4/1/10 - 6/30/10 7/1/10 - 9/30/10 10/1/10 - 12/31/10	5/15/10 8/15/10 11/15/10 2/15/11	5/31/11
Coverage Determinations and	1/1/10 - 3/31/10	5/15/10	5/31/11

Measure	Reporting Period(s)	Data Submission Due Date(s) to CMS	Data Validation Findings Due to CMS*
Exceptions	4/1/10 - 6/30/10 7/1/10 - 9/30/10 10/1/10 - 12/31/10	8/15/10 11/15/10 2/15/11	
Appeals	1/1/10 - 3/31/10 4/1/10 - 6/30/10 7/1/10 - 9/30/10 10/1/10 - 12/31/10	5/15/10 8/15/10 11/15/10 2/15/11	5/31/11
Long-Term Care (LTC) Utilization	1/1/10 - 12/31/10	6/30/11	9/30/11
Employer/Union-Sponsored Group Health Plan Sponsors	1/1/10 - 12/31/10	2/28/11	5/31/11
Plan Oversight of Agents	1/1/10 - 12/31/10	2/28/11	5/31/11

Dates are tentative and based on the assumption that the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) review and clearance process will be completed according to the CMS-established schedule. Dates may be subject to change pending any changes in the OMB schedule.

The data validation program is tentatively scheduled to begin in Fall 2010 and is dependent on completion of the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) review and clearance process. Data validation reviews are scheduled to occur between March-May 2011, with data validation findings being due to CMS as soon as May 31, 2011. However, and as noted in Table 1, five measures have a data submission due date that will not allow for a retrospective data validation review during the March-May 2011 timeframe. These measures include:

- Benefit Utilization - data due to CMS by 8/31/11
- Procedure Frequency - data due to CMS by 5/31/11
- Serious Reportable Adverse Events - data due to CMS by 5/31/11
- Special Needs Plans Care Management - data due to CMS by 5/31/11
- Long-Term Care Utilization - data due to CMS by 6/30/11

Given their data submission due dates range from 5/31/11 to 8/31/11, these five measures will follow an extended data validation schedule so that a retrospective review of data can occur. Data validation reviews will begin once the organization's data is submitted to CMS, and the data validation review findings are due to CMS on the following dates:

- Benefit Utilization - findings due to CMS by 11/30/11
- Procedure Frequency - findings due to CMS by 8/31/11
- Serious Reportable Adverse Events - findings due to CMS by 8/31/11
- Special Needs Plans Care Management - findings due to CMS by 8/31/11
- Long-Term Care Utilization - findings due to CMS by 9/30/11

1.2 Data Validation Review Process

Table 2 below outlines the specific steps involved with the data validation review process, beginning with CMS' release of the *Manual of Data Validation Standards and Procedures* (tentatively scheduled for release in October 2010) and ending with CMS' determination for the organization (tentatively scheduled for Summer 2011) based on the findings from the data validation review.

The data validation review process will largely entail a collaborative effort between the organization and the reviewer in terms of information sharing up to the point of the reviewer's final submission of data validation review findings to CMS. Each of these steps, including specific

roles for the organization and reviewer, are detailed in Table 2. The documents referenced are further described in Section 2.

Table 2: Data Validation Review Process

#	Step	Responsible Party	Date*
1	Release *Manual of Data Validation Standards and Procedures*	CMS	October 2010
2	Select appropriate data validation contractor based on *Standards for Selecting a Data Validation Contractor*	Sponsoring Organization	November-December 2010
3	*Tentative:* Attend CMS-conducted training on data validation review process	CMS, Sponsoring Organization, Data Validation Contractor	January 2011 (tentative)
4	Prepare for on-site review		March-May 2011
4.1	Complete *Organizational Assessment Instrument* (OAI) and provide appropriate documentation to selected data validation contractor per OAI's documentation request	Sponsoring Organization	
4.2	a) Review completed OAI and documentation provided by sponsoring organization b) Alter *Interview Discussion Guide* as needed to obtain additional information	Data Validation Contractor	
5	Conduct on-site review		March-May 2011**
5.1	a) Participate in interviews b) Provide demonstration(s) of systems/reporting c) Work with data validation contractor to pull data samples for applicable measures per *Sampling Instructions for Data Validation Contractors*	Sponsoring Organization	
5.2	a) Using *Interview Discussion Guide,* conduct interviews with appropriate sponsoring organization staff to collect data and examine reporting processes to ensure pertinent information is captured via discussion and demonstrations of systems/reporting b) Work with organization to pull data samples for applicable measures per *Sampling Instructions for Data Validation Contractors*	Data Validation Contractor	
6	Determine compliance with *Data Validation Standards*		March-May 2011**
6.1	a) Evaluate sample data in conjunction with documentation provided by the organization b) Assess organization's compliance with the *Data Validation Standards* c) Record data validation review findings in the *Findings Data Collection Form for Data Validation Contractors*	Data Validation Contractor	
7	Review preliminary findings		May 2011**
7.1	Review the preliminary findings from the data validation contractor and provide any additional	Sponsoring Organization	

#	Step	Responsible Party	Date*
	documentation necessary		
7.2	Assess any additional documentation provided by the organization	Data Validation Contractor	
8	Submit data validation review findings to CMS via the Health Plan Management System (HPMS)	Data Validation Contractor	May 2011**
9	Make "Pass" or "Not Pass" determination based on findings from data validation review	CMS	Summer 2011

Dates are tentative and based on the assumption that the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) review and clearance process will be completed according to the CMS-established schedule. Dates may be subject to change pending any changes in the OMB schedule.

*** For measures with data submission due dates of 5/31/11, 6/30/11, and 8/31/11, the timeframe for on-site reviews, determining compliance with the standards, and submission of data validation results will be extended so that the reviews are retrospective.*

2.0 OVERVIEW OF DATA VALIDATION DOCUMENTS

CMS has developed the following documents to be used to conduct the data validation reviews:

- Organizational Assessment Instrument
- Interview Discussion Guide
- Data Validation Standards
- Sampling Instructions for Data Validation Contractors
- Findings Data Collection Form for Data Validation Contractors
- Standards for Selecting a Data Validation Contractor

These documents are based on the Medicare Part C and Part D Plan Reporting Requirements Technical Specifications Documents for CY 2010. CMS refined the validation documents based on comments received from an industry review that occurred in September 2009. Each document will undergo two public comment periods as part of the Office of Management and Budget (OMB) review process, which is expected to begin in early 2010. Based on comments submitted during the public comment periods, CMS will make additional revisions before the final version of the documents are released to the industry. Below is a brief overview of the documents; further details and instructions for use can be found in each document that follows.

Note: For purposes of these documents, and in order to streamline terms used, Part C measures and Part D sections are referred to as "measures."

2.1 Organizational Assessment Instrument

The Organizational Assessment Instrument (OAI) is a tool for reviewers to use in efforts to gain an understanding of organizations' reporting processes. The information collected in the OAI will better prepare reviewers and will reduce resources required for the on-site portion of the review. It is strongly recommended that organizations complete the OAI to add efficiencies to the review process.

2.2 Interview Discussion Guide

The Interview Discussion Guide is a supplemental tool to the OAI that reviewers may use to obtain further information about the organization and its reporting processes. It is intended to facilitate discussions during the on-site portion of the review and includes both general and selected measure-specific questions that the reviewer may choose to ask of the appropriate organization staff. The reviewer may alter these questions depending on the information needed, and may combine the measure-specific questions as appropriate to allow for efficient use of on-

site discussion time should the organization's staff be involved with reporting for more than one measure.

2.3 Data Validation Standards

The Data Validation Standards include general standards and measure-specific criteria that the reviewer will use to determine whether the organization's HPMS-reported data are accurate, valid, and reliable. Each measure's data validation standards include identical instructions relating to the types of information that will be reviewed, a set of validation standards (also identical for each measure), and measure-specific criteria that are based on the applicable Part C/Part D reporting requirements.

The reviewer must use these standards in conjunction with the Sampling Instructions and the Findings Data Collection Form to evaluate the organization's processes for producing and reporting the measures. Upon review of the information and documentation provided by the organization and completion of the on-site review, the reviewer will determine compliance with each of the standards and record their findings in the Findings Data Collection Form.

2.4 Sampling Instructions for Data Validation Contractors

The Sampling Instructions for Data Validation Contractors document provides guidance to reviewers regarding the drawing and evaluation of data samples that will support validation of the reported measures. Examples of characteristics evaluated using sample data include appropriate date ranges, appropriate data inclusions and exclusions, correctness of data values and handling of missing values. Sampling will be conducted for the majority of measures, and reviewers will use the selected samples as a key source as they validate the quality of the data used to calculate the measures.

2.5 Findings Data Collection Form for Data Validation Contractors

The Findings Data Collection Form is a tool for reviewers to record their validation findings for each organization contract. The Findings Data Collection Form mirrors the content of the data validation standards document, but allows the reviewer to record notes, data sources referenced, and findings for the different criteria specified within a given standard.

The reviewers will generate and record criterion-level findings for each measure's standards. Findings from the data validation review will address two aspects of the organization's processes and outcomes, including:

1. Whether the organization has "adequate processes" in place to assure accurate and valid data results; and
2. Whether the organization has reported "adequate results" (i.e., whether there are any data issues that might impact accurate reporting).

The reviewer will share these findings with the organization and then submit the completed Findings Data Collection Form to CMS, who will process the criterion-level findings for each measure and standard to derive an overall "Pass" or "Not Pass" determination.

2.6 Standards for Selecting a Data Validation Contractor

The Standards for Selecting a Data Validation Contractor document includes guidance for organizations to use in their selection of a data validation contractor. These standards include minimum qualifications, credentials, and resources that the selected data validation contractor must possess to ensure the data validation reviews are conducted in an effective, consistent manner. The standards also include guidance regarding the organization's use of external contractors and the ability for contractors to subcontract data validation components as needed.

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