

Part C & D Reporting Requirements and Data Validation

Agenda

- Welcome and Introductions
- Background and Overview of Data Validation Program
- Data Validation Process and Documents
- Outstanding Issues to be Addressed
- Questions

Background for Developing Data Validation Standards

- CMS is establishing data validation standards and procedures for reporting requirements, as cited per 42 CFR §422.516 (a) and §423.514
 - Applicable to Part C and Part D sponsors
 - 2010 Call Letter informed sponsors of new reporting requirements and plans for data validation review
- The standards will ensure that data reported by sponsoring organizations are reliable, valid, complete, and comparable

Data Validation Program Requirements

- The data validation standards will assess the validity of the sponsoring organization's data reported per the Part C and Part D Reporting Requirements
- The data validation reviews will involve a retrospective review of processes for collecting, storing, analyzing, and reporting measure data

Data Validation Program Requirements

- Sponsoring organizations are expected to undergo data validation reviews beginning in Spring 2011 (for CY 2010 data), and adhere to the following:
 - Contract with independent, third-party reviewers
 - Use CMS-issued processes and tools for the data validation
- Data validation reviews will be performed at the organization's contract level

Part C Measures to Undergo Data Validation

- Benefit Utilization
- Procedure Frequency
- Serious Reportable Adverse Events
- Provider Network Adequacy
- Grievances
- Organization Determinations/Reconsiderations
- Employer Group Plan Sponsors
- Plan Oversight of Agents
- Special Needs Plan Care Management

Part D Sections to Undergo Data Validation

- Retail, Home Infusion, and Long-Term Care Pharmacy Access
- Medication Management Therapy Programs
- Grievances
- Coverage Determinations and Exceptions
- Appeals
- Long-Term Care Utilization
- Employee/Union-Sponsored Group Health Plan Sponsors
- Plan Oversight of Agents

Data Validation Program: Timeline to Date

Task	Date	Summer 2009	Fall 2009	Winter 2010
Stakeholder Interviews	June–July 2009			
Data Validation Document Development	July–August 2009			
Industry Comment Period	September 2009			
Pilot Testing (Phase I)	September–October 2009			
Document Revisions & Development of Addit' l Data Validation Tools/ Documents	November 2009–February 2010			

Data Validation Program: Timeline for Upcoming Milestones

Task	Date	Spring 2010	Summer 2010	Fall 2010	
Pilot Testing (Phase II)	March–April 2010				
OMB Paperwork Reduction Act public comment period, review, and clearance	April– Fall 2010				
CMS Training	Fall 2010*				
Release <i>Manual of Data Validation Standards and Procedures</i>	Late Fall 2010*				

* Dates are tentative.

Data Validation Program: Timeline for Upcoming Milestones

Task	Date	Spring 2011	Summer 2011	Fall 2011
Data Validation Reviews	March–May 2011*			
Data Validation Review Findings Due to CMS	Summer 2011*			
CMS Assigns “Pass”/“Not Pass” Determinations	Fall 2011			

* For measures with submission dates of 5/31, 6/30, and 8/31, an extension for data validation reviews and submission of findings to CMS is being considered

Data Validation Process for Sponsoring Organizations

1. Attend CMS training on data validation process
2. Select appropriate data validation contractor based on *Standards for Selecting a Data Validation Contractor*
3. Review *Manual of Data Validation Standards and Procedures*
4. Complete *Organizational Assessment Instrument (OAI)* in order to facilitate data validation review

Data Validation Process for Sponsoring Organizations

5. Host and participate in on-site data validation review
6. Provide sample data and any additional documentation requested by the data validation contractor
7. Review preliminary review findings with the data validation contractor

Data Validation Process for Data Validation Contractors

1. Attend CMS training on data validation process
2. Review *Manual of Data Validation Standards and Procedures*
3. Review completed OAI and documentation provided by the sponsoring organization
4. Conduct on-site data validation review, including review of sample data provided by the sponsoring organization

Data Validation Process for Data Validation Contractors

5. Determine organization's compliance with *Data Validation Standards* and record findings in *Findings Data Collection Form*
6. Review preliminary review findings with the sponsoring organization
7. Submit findings to CMS via HPMS

Data Validation Documents

Organizational Assessment Instrument (OAI)

- A tool for data validation contractors to understand the sponsoring organization's procedures and processes related to compiling, validating, storing, and reporting data measures
- OAI responses will allow contractors to review the material and prepare questions so that the on-site review is most efficient

Data Validation Documents

Data Validation Standards

- A tool for data validation contractors to use in determining whether the sponsoring organization's HPMS-reported data are accurate, valid, and reliable
- The document includes general standards and measure specific criteria:
 - Validation standards are identical for each measure
 - Measure-specific criteria are based on Parts C & D Reporting Requirements Technical Specifications

Data Validation Documents

Sampling Instructions

- A tool to guide data validation contractors in drawing and evaluating data samples for reported measures
- Sampled data will evaluate items such as:
 - Date ranges
 - Data inclusions and exclusions
 - Data values
 - Missing values

Data Validation Documents

Findings Data Collection Form

- A tool that mirrors the content of the data validation standards and allows for contractors to record notes, data sources, and findings for each measure
- Findings will address two aspects of the sponsoring
 - “Adequate Processes” in place for accurate and valid results
 - “Accurate Results” reported

Additional Data Validation Tools/Documents

- **Interview Discussion Guide**
 - A supplement to the OAI to facilitate discussion during on-site reviews, including general process and measure-specific questions for the organization
- **Standards for Selecting a Data Validation Contractor**
 - A document that outlines minimum qualifications, credentials, and resources that contractors must possess to ensure reviews are effective and consistently performed

Additional Data Validation Tools/Documents (Continued)

Manual of Data Validation Standards and Procedures

- A tool that includes standards and procedures that CMS requires be followed for data validation reviews

Outstanding Issues to be Addressed

- Data validation reviews of data provided by PBMs and delegated entities
- On-site vs. remote data validation reviews
- Scoring and thresholds for “Pass”/“Not Pass” determinations
- Consequences of receiving a “Not Pass” determination

Questions?

- For questions related to the data validation program:
 - Terry.Lied@cms.hhs.gov
- For questions related to the Part C and Part D Reporting Requirements:
 - Partcplanreporting@cms.hhs.gov
 - PartD-PlanReporting@cms.hhs.gov