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

Appendix E: Organizational Assessment Instrument

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1. OBJECTIVES

CMS is providing this *Organizational Assessment Instrument* (*OAI*) as a tool for data validation (DV) contractors to understand Part C and Part D sponsoring organizations' (SOs') reporting processes and to request documentation that will be evaluated during the review process. The information collected in this *OAI* will help prepare DV contractors and will reduce resources required for the site (on-site or virtual) visit portion of the review.

2. INSTRUCTIONS

2.1 INSTRUCTIONS FOR DATA VALIDATION CONTRACTORS

Review the OAI prior to the on-site or virtual visit for preliminary information about the SO's processes for collecting and reporting data. If necessary, obtain follow-up information during the on-site or virtual visit. The *OAI* captures preliminary information about the SO's processes for collecting and reporting data per the CMS reporting requirements. The DV contractor must analyze the OAI prior to the site visit (on-site or virtual) and follow-up on any incomplete or ambiguous responses during the site visit portion of the review. The *OAI* must be electronically distributed to the SO undergoing a review. Following the SO's completion of this document, the DV contractor must attach a completed copy of the *OAI* in a file of all data validation review work papers that will be shared with the organization.

2.2 INSTRUCTIONS FOR SPONSORING ORGANIZATIONS

Sponsoring Organizations must complete each section of the *OAI* in advance of the DV review period, or according to the set timeline of the reviewer. The SO should complete the OAI and provide documentation to the DV contractor as early as possible at the start of the DV review period so that data validation can begin on April 1. All documentation and responses to questions should reflect the SO's systems and processes that were in place during the reporting period(s) undergoing the data validation review. SOs with multiple contracts should complete only one *OAI*. If the information provided in the *OAI* varies by contract, the SO should specify the differences within the *OAI* to allow the DV contractor to identify differences that may affect reporting section calculations or reporting for a given contract.

The SO must submit the *OAI*, documentation, and any additional information to the reviewer electronically. The organization is responsible for ensuring that it has established mutually agreeable methods for sharing proprietary and/or secure (PHI/PII) information with the reviewer and that the reviewer complies with all HIPAA privacy and security requirements.

The completed *OAI* and any additional information provided because of this request will be assessed by the reviewer. If an SO has any questions while completing the *OAI*, it should contact the DV contractor. Each stage of the data validation review should entail a collaborative effort between the SO and DV contractor. An overview of the timeline related to *OAI* activities is outlined in Table 1.

Table 1: Timeline of OAI Activities for Performing Data Validation

Step	Responsible Party	Data Validation Activities	Timeline
1	SO	Complete *Organizational Assessment Instrument (OAI)* and provide appropriate documentation to selected reviewer per the *OAI*'s documentation request	No earlier than 30 days prior to the start of the DV cycle on April 1.
2	DVC, SO	Analyze OAI	Allow two weeks after receipt.
3	DVC, SO	Prepare for on-site or virtual visit (site visit agenda, resource needs, and logistics)	Early April
4	DVC, SO	Conduct on-site or virtual review (convene entrance conference, conduct interviews with SO staff, observe SO's reporting processes, and obtain census and/or sample files)	Early April (allow for up to 1 week)
5	DVC	Request additional documents following on-site or virtual visit (if applicable)	Mid/Late April

3. GENERAL QUESTIONS

The information gathered below will provide a better understanding of the scope for the SO's data validation review, including which contract(s) will be reviewed and which Part C and/or Part D reporting sections the SO is reporting for validation.

3.1 ORGANIZATION INFORMATION

Complete Table 2, indicating each Medicare contract that the SO held during the reporting period(s) undergoing the data validation review. Also, indicate whether the contract includes the Part C and/or Part D benefit and provide the number of plan benefit packages (PBP) associated with each contract. Indicate if any of the PBPs associated with the contract are Special Needs Plans or Employer/Union "800 Series" plans. The SO may add rows to this table as necessary but should not manipulate the columns.

For the "Contract Type" field, select from the following list:

- CCPP
- FFS
- MSA
- 1876 Cost
- Employer/Union Direct Contract (800 Series)
- PDP
- Demo

Table 2: Organization Information

Parent Organization Name:						
CMS Contract Number	Contract Type	Includes Part C? (Y/N)	Includes Part D? (Y/N)	No. of Plan Benefit Packages	Includes SNP PBP(s)? (Y/N)	Includes Employer/Union "800 Series" PBP(s)? (Y/N)
Example: *Contract 123*	*PFFS*	*Y*	*Y*	*3*	*N*	*N*
Example: *Contract 123*	*CCP*	*Y*	*Y*	*1*	*Y*	*N*
[add rows as required]						

3.2 CONTACT INFORMATION

Complete Table 3 and Table 4 indicating the SO's primary and secondary points of contact responsible for the Part C and Part D reporting requirements data validation review for each contract included in this OAI.

Table 3: Part C Contact Information

Primary Part C Point of Contact	Secondary Part C Point of Contact
Name:	Name:
Title:	Title:
Company:	Company:
Address:	Address:
City, State, Zip:	City, State, Zip:
Telephone:	Telephone:
Fax:	Fax:
Email:	Email:

Table 4: Part D Contact Information

Primary Part D Point of Contact	Secondary Part D Point of Contact
Name:	Name:
Title:	Title:
Company:	Company:
Address:	Address:
City, State, Zip:	City, State, Zip:
Telephone:	Telephone:
Fax:	Fax:
Email:	Email:

3.3 PART C AND PART D REPORTING SECTIONS UNDERGOING VALIDATION

Complete Table 5 for the contract(s) included in this *OAI*. Indicate which of the Part C and/or Part D reporting sections the SO has submitted for data validation review, the applicable contract numbers (Column B), and whether the SO is able to report on all required data elements per the CMS *Part C and Part D Reporting Requirements Technical Specifications* (Column C).

Table 5: Reporting Sections Undergoing Validation

A. Reporting Section	B. Contract Number(s)	C. Are all required data elements captured by your internal data system(s)? (Yes/No)	D. If the answer to Column C. is no, please indicate which delegated entities' data systems contain the data elements
Part C:			
Grievances			
Organization Determinations/Reconsiderations			
Special Needs Plans (SNPs) Care Management			
Part D:			
Medication Therapy Management Programs			
Grievances			
Coverage Determinations and Redeterminations			
Improving Drug Utilization Review Controls			

4. UNDERLYING DATA SOURCES AND REPORTING PROCESSES

The questions below address the underlying data sources and reporting processes used to produce the Part C and Part D reporting sections.

4.1 UNDERLYING DATA SOURCES

Complete Table 6 for the contract(s) included in this *OAI*, indicating the name of the data source(s) used to generate each Part C and Part D reporting section (Column B). If additional rows are required to list the data sources for a given reporting section, insert new rows into the table.

Please indicate all underlying data sources involved in the reporting process, beginning with the originating data systems (e.g., claims adjudication system, enrollment system) and including all other data sources used for data collection and storage, data processing, analysis, and reporting.

Table 6: Underlying Data Sources

A. Reporting Section	B. Data Source Name (e.g., Claims, Enrollment, Provider Information)
Part C:	
Example Part C Reporting Section	*Claims Adjudication System ABC*
	Enrollment System DEF
	Reporting Data Warehouse GHI
	Reporting Data Warehouse JKL
	Bob's Individual Desktop Database MNO
Grievances	
Organization Determinations / Reconsiderations	
Special Needs Plans (SNPs) Care Management	

A. Reporting Section	B. Data Source Name (e.g., Claims, Enrollment, Provider Information)
Part D:	
Medication Therapy Management Programs	
Grievances	
Coverage Determinations, Redeterminations (including At–Risk Redeterminations under a Drug Management Program), and Reopenings	
Improving Drug Utilization Review Controls	

4.2 PROGRAMMING AND SOFTWARE

In Table 7, specify the programming languages and software used to generate the reporting section data for reporting (e.g., MS Access, SAS, SQL, Crystal Reports, Cognos, SPSS) for the contract(s) included in this *OAI*.

Table 7: Programming Software Specifications

A. Reporting Section	B. Programming Code/Software
Part C:	
Grievances	
Organization Determinations/Reconsiderations	
Special Needs Plans (SNPs) Care Management	
Part D:	
Medication Therapy Management Programs	
Grievances	
Coverage Determinations, Redeterminations (including At–Risk Redeterminations under a Drug Management Program), and Reopenings	
Improving Drug Utilization Review Controls	

4.3 SUPPLEMENTAL QUESTIONS REGARDING REPORTING PROCESSES

The questions below address additional information required to review the processes used to compile and report the Part C and Part D reporting sections.

4.3.1 How does your organization ensure it meets the reporting requirements deadline for the contract(s) included in this *OAI*? Who is responsible for submitting the data into the HPMS Plan Reporting Module (i.e., responsible department, delegated entity or first tier/downstream contractor)?

4.3.2 What is your organization's process for correcting or revising data results that have been returned/rejected by CMS for the contract(s) included in this *OAI*? Who is responsible (i.e., responsible department, delegated entity, or first tier/downstream contractor)?

4.3.3 If your organization received an outlier/data integrity notification for any of the reporting sections that are currently undergoing data validation review (as identified in Table 5 for the contract(s) included in this OAI), were those notifications used to accurately report the data into HPMS? For the contract(s) included in this OAI, how does your organization track CMS- issued changes to the Part C and/or Part D Reporting Requirements Technical Specifications? Who is responsible (i.e., responsible department, delegated entity or first tier/downstream contractor)? How are these changes incorporated into your organization's data collection and reporting systems?

4.3.4 Describe any process or quality improvement activities your organization has implemented since the prior reporting year/period that may affect reporting section results submitted to CMS (e.g., development of steering committees, identification of inefficiencies) for the contract(s) included in this OAI.

5. DATA VALIDATION DOCUMENTATION REQUEST

The purpose of the documentation request is to obtain documents that will assist the reviewer in determining that data elements for each reporting section are accurately identified, calculated, and documented. This request is applicable to all organizational processes used in creating the final HPMS submission for the Part C and Part D reporting requirements.

The SO is responsible for ensuring that it has established mutually agreeable methods for sharing proprietary and/or secure (PHI/PII) information with the reviewer and that the reviewer complies with all HIPAA privacy and security requirements. Instructions for logging the information provided by the SO are included in Section 6.

5.1 REQUEST FOR PROGRAMMING CODE AND EXAMPLE OUTPUT

For the contract(s) included in this *OAI*, SOs should provide programming code/source code and example output for computer programs used to calculate the data elements collected for each of the CMS reporting sections that are currently undergoing data validation review (as identified in Table 5). Such code may include the following:

- Programming language for extracting data from the source (including any exclusion criteria)
- Joins between multiple data sources (including validation checks)
- Data preparation (such as cleansing and missing data)
- Manipulation to produce the final reports

The following are examples of the types of documents and files required:

- If using SAS, SPSS, or similar software, provide the programming code, the log file that shows the results of the compiled programming code, and the list file that shows the output (e.g., tables and listings) generated by the programming code.
- If using MS Access, SQL Server, Oracle, or other database systems, provide the code used to generate the database query, results of the compiled query, and the output generated by the query (e.g., saved data queries).
- If using MS Excel or other spreadsheet programs, provide the Visual Basic code that produced the spreadsheets (if applicable), and the actual workbooks with all formulas used to calculate the values contained in each spreadsheet.

Submitted programming code should be neatly structured and documented so that a third party can easily read it and understand the programming logic. Best practice is to include comments within the code; however, if not possible, provide documentation (e.g., work instructions) that enables the reviewer to interpret the programming logic.

5.2 REQUEST FOR DATA DICTIONARY

Organizations should provide a data dictionary or any such documentation that provides file layouts, field definitions, explanation of calculations, and other information about the underlying data that are used in creating the data submission for the Part C and Part D reporting requirements for the contract(s) included in this *OAI*. Appendix B of the *OAI* includes an example data dictionary that at a minimum should include the field name, data type, field description, and additional notes regarding the data field values.

5.3 REQUEST FOR ANALYSIS PLAN, REPORTING PROCESS FLOWS, AND DIAGRAMS

Organizations should provide a copy of their analysis plan, reporting process flows, diagrams, and any other related documents. These documents should include a description or illustration of the analysis requirements, analysis methods, and processes used for generating all reporting section output reports for the Part C and Part D reporting requirements for the contract(s) included in this *OAI*.

5.4 REQUEST FOR STANDARD OPERATING DOCUMENTS: STANDARD OPERATING PROCEDURES (SOPS), POLICIES AND PROCEDURES, OR OTHER WORK INSTRUCTIONS

Organizations should provide a copy of the documentation that describes their data and reporting systems and processes for the contract(s) included in this *OAI*. Documents of interest include:

- Work instructions, policies and procedures for the compilation, administration, and/or submission of the Part C and Part D reporting requirements
- Information Systems SOPs (e.g., system maintenance, upgrade, validation procedures)
- Data Processing SOPs (e.g., data collection and storage process and frequency)
- Data Archive/Restoration SOPs (e.g., disaster recovery plans)

6. DATA VALIDATION DOCUMENT LOG

The *Data Validation Document Log* is used as inventory for all documents and files provided by the SO as per Section 5. Organizations should complete the *Document Log* (see *Document Log* Template in Appendix A of the *OAI*) in order to facilitate review of documentation and files associated with the different stages of the reporting process.

- **Reporting Section:** Provide reporting section for document or file. For example, if submitting programming code that generates the SNPs reporting section, then indicate "SNPs" in this column. Otherwise, indicate "N/A" (note that IT system SOPs may be N/A).
- **Document Name:** Electronic file name of document.
- **Document Type:** Type of document or file (e.g., work instruction, policy and procedure, programming code, programming output/report, data dictionary/file layout, reporting process diagram).
- **Reporting Stage:** Stage in the reporting process to which the document applies. This usually applies to programming code, data queries, and programming output and reports. Examples of stages include, but are not limited to, data extract from adjudication system, data input into internal database, output/report from internal database, data analysis to summarize data for reporting, or final report for HPMS entry. Otherwise, indicate "N/A" (note that IT SOPs may be N/A).
- **Document Description:** Work instructions, policies, and procedures are usually self-explanatory. However, for programming code, SOs should include a description of the input data sources, the applicable stage in the reporting process, the intended output, and name of the output file. For data dictionaries/file layouts, indicate the name of the applicable database and source tables containing the data fields. For screen shots, process flows, and diagrams provide the relevant description of the indicated charts, diagrams, and process flows.

APPENDIX A: DOCUMENT LOG TEMPLATE

To the extent possible, list the documents in a logically ordered fashion so the reviewer can identify sets of documents relative to the reporting process stage for each reporting section.

A. Reporting Section	B. Document File Name	C. Document Type	D. Reporting Stage	E. Document Description
Example: Grievances	Grievances_SOP.doc	SOP	N/A	SOP documents the methods used to gather, analyze, and report Grievances data according to CMS reporting requirements
Example: Grievances	Grievances_Data_Load.SAS	SAS Program Code	Load grievance data into Data Warehouse	SAS program extracts data from adjudication system and loads into internal data warehouse
Example: Grievances	Grievances_Summary.SAS	SAS Program Code	Summarizes data for HPMS reporting	SAS program cleans and summarizes data for entry into HPMS
Example: Grievances	Grievances Summary Report.xls	Example Report Output	Summarized data report example for HPMS entry	Example of report output from the Grievances Summary. SAS program for HPMS entry

APPENDIX B: DATA DICTIONARY EXAMPLE

Please refer to the following as an example of the information required in a Data Dictionary.

A. Field Name	B. Type	C. Description	D. Additional Notes
Example: Redetermination ID	Long Integer	Unique ID for each case	
Example: Date Created	Date	Date the case was created	
Example: Redetermination Status	Integer	Status of the case	1=Open; 2=Closed
Example: Redetermination Outcome	Integer	Outcome of the case	1=Overturned; 2=Withdrawn; 3=Dismissed; 4=Upheld