Supporting Statement Part A
Medicare Part C and Part D Data Validation (42 CFR §422.516(g) and §423.514(g))
CMS-10305, OCN 0938-1115

Background

The Centers for Medicare and Medicaid Services (CMS) established reporting requirements for Medicare Part C and Part D sponsoring organizations (Medicare Advantage Organizations [MAOs], Cost Plans, and Medicare Part D sponsors) under the authority described in 42 CFR §422.516(a) and §423.514(a), respectively. Under these reporting requirements, each sponsoring organization must submit Medicare Part C, Medicare Part D, or Medicare Part C and Part D data (depending on the type of contracts they have in place with CMS). Sponsoring organizations must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires. At the same time, the sponsoring organization must safeguard the confidentiality of the doctor-patient relationship, statistics, and other information with respect to the cost of its operations, patterns of service utilization, availability, accessibility, and acceptability of its services, developments in the health status of its enrollees, and other matters that CMS may require.

In order for the reported data to be useful for monitoring and performance measurement, it must be reliable, valid, complete, and comparable among sponsoring organizations. In 2009, CMS developed the Data Validation Program as a mechanism to verify the data reported are accurate, valid, and reliable. To maintain the independence of the data validation process, sponsoring organizations do not use their own staff to conduct the data validation. Instead, sponsoring organizations are responsible for hiring external, independent data validation contractors (DVCs) who meet a minimum set of qualifications and credentials, which CMS outlines in the "Standards for Selecting Data Validation Contractors" document. The DVCs work closely with the sponsoring organizations to perform a retrospective data review, which includes an in-person review at the sponsoring organizations' facilities. As an example of this retrospective review, in 2013, the DVCs will review data submitted by sponsoring organizations for CY2011 and CY2012 reporting requirements, depending on the Part C or Part D reporting section being validated.

CMS developed standards and data validation criteria for specific Medicare Part C and Part D reporting requirements that the DVCs use in validating the sponsoring organizations data.[1] These standards and criteria are described in Appendix 1 "Data Validation Standards." The data validation standards for each reporting section include standard instructions relating to the types of information that should be reviewed, and reporting section criteria (MSC) that are aligned with the "Medicare Part C and Part D Reporting Requirement Technical Specifications." Furthermore, the standards and criteria describe how the DVCs should validate the sponsoring organizations' compilations of reported data, taking into account appropriate data exclusions, and verifying calculations, source code, and algorithms. The data validation reviews are conducted at the contract level given that the Medicare Part C and Part D data are generally available at the contract

1 *CMS determines annually which Medicare Part C and Part D reporting sections are included in the data validation program.*

level and the contract is the basis of any legal and accountability issues concerning the rendering of services.

The review is conducted over a three-month period following the final submission of data by the sponsoring organizations. In addition to the "Data Validation Standards" described in Appendix 1, the DVCs employ a set of information collection tools when performing their reviews, which are included in the appendices described below:
Appendix 2: Organizational Assessment Instrument
Appendix 3: Data Extraction and Sampling Instructions
Appendix 4: Instructions for the Findings Data Collection Form
Appendix 5: Findings Data Collection Form (FDCF)

Appendix 2: Organizational Assessment Instrument (OAI) −The DVC uses the "OAI" to collect information and documentation from the sponsoring organization about how the sponsoring organization collects, stores, and reports information to CMS. CMS requires that sponsoring organizations complete this document in advance of the data validation, as the data validation review relies significantly on the information captured in this tool. The completed "OAI" may reduce required DVC resources and make the data validation review more efficient and effective. Sponsoring organizations must provide the completed "OAI" to their selected DVC electronically.

Appendix 3: "Data Extraction and Sampling Instructions"−This document provides guidance to the DVC regarding extracting and evaluating census and/or sample files from each reporting section's final data set as well as reviewing a sample of source data or the underlying data from which the final data set was derived. DVCs must follow the "Data Extraction and Sampling Instructions" document.

Appendix 4: "Instructions for the Findings Data Collection Form (FDCF)"−This document provides guidance about how to use the FDCF.

Appendix 5: "Findings Data Collection Form"−DVCs use this tool to record the data validation findings for each contract included in the scope of the review. The FDCF mirrors the data validation standards and reporting section criteria described in Appendix 1, "Data Validation Standards." The FDCF allows DVCs to record notes, reference data sources, and capture findings for the different standards and criteria specified for a given reporting section.

Using the FDCF, the DVC conducts the review and records findings for each reporting section's standards at the reporting section-level, and in some cases at the data element-level. The DVC submits the completed FDCF to CMS via the Health Plan Management System (HPMS). The DVC may print the findings entered into HPMS and share them with the sponsoring organization at any point during the review by accessing the HPMS report entitled "Review Data Validation Findings Report." Once the data validation period ends, CMS evaluates the findings for each reporting section's standards to derive an overall "Pass" or "Not Pass" determination.

A. Justification

1. *Need and Legal Basis*

Sections 1857(e) and 1860D-12 of the Social Security Act ("the Act") authorize CMS to establish information collection requirements with respect to MAOs and Part D sponsors. Section 1857(e)(1) of the Act requires MAOs to provide the Secretary of the Department of Health and Human Services (DHHS) with such information as the Secretary may find necessary and appropriate. Section 1857(e)(1) of the Act applies to Prescription Drug Plans (PDPs) as indicated in section 1860D-12. Pursuant to statutory authority, CMS codified these information collection requirements in regulation at §422.516(g) and §423.514(g), respectively.

Consistent with the regulatory authority to collect information, CMS developed specific Medicare Part C and Part D reporting requirements to assist in monitoring the Medicare Part C and D programs, to respond to questions from Congress, oversight agencies, and the public. These inquiries cover a variety of topics, including costs, availability of services, beneficiary use of available services, patient safety, grievance rates, and other factors pertaining to MAOs and Part D Plans. The current Medicare Part C reporting requirements (OMB 0938-1054) may be accessed at: http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/ReportingRequirements.html. The current Medicare Part D reporting requirements (OMB 0938-0992) may be accessed at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.html.

2. *Information Users*

Data collected via "Medicare Part C and Part D Reporting Requirements Technical Specifications" is an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare benefits to beneficiaries. CMS uses the data collected through the Medicare Data Validation Program to substantiate the data collected via Medicare Part C and Part D Reporting Requirements Technical Specifications. If CMS detects data anomalies, the CMS division with primary responsibility for the applicable reporting requirement assists with determining a resolution.

3. *Use of Information Technology*

Sponsoring organizations use HPMS when submitting data to CMS. DVCs also use HPMS for submitting or entering findings from the FDCF; specifically DVCs use the Plan Reporting Data Validation Module (PRDVM), which mirrors the FDCF. CMS grants access to HPMS for each user. System access requires an individual login and password but does not require an electronic signature.

4. *Duplication of Efforts*

The Data Validation Program does not result in a duplication of similar information.

5. *Small Businesses*

The Data Validation Program does not impose a significant impact on small businesses and other entities.

6. Less Frequent Collection

The data are collected and validated annually. If the collection is not conducted or is conducted less frequently, the reliability, validity, completeness, and comparability of the Medicare Part C and Part D reporting requirements data cannot be ensured. CMS could not confidently use the data for public reporting and the value of the data for monitoring would be questionable.

7. Special Circumstances

As mandated by 42CFR §422.504 (d) and § 423.505(d), MAOs and Part D sponsors must agree to maintain books, records, documents, and other evidence of accounting procedures and practices for 10 years. If CMS requires any clarification regarding submitted data, the agency will contact MAOs and Part D sponsors within 60 days of data submission.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on June 28, 2013 (78 FR 38986). A 60-day notice was also published on July 24, 2012 (77 FR 43289). In error, that package was not submitted to OMB. This 2103 package includes a summary of the comments pertaining to the 2012 60-day notice and our response. No comments were received on the 2013 60-day FR notice.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents associated with the Data Validation Program.

10. Confidentiality

CMS adheres to all confidentiality-related statutes, regulations, and agency policies.

11. Sensitive Questions

CMS adheres to all relevant statutes, regulations, and agency policies pertaining to sensitive questions.

12. Burden Estimates (Hours & Wages)

Revised burden estimates for the CMS Medicare Part C and Part D Data Validation Program are described below. This estimate takes into account the following factors:

- Total number of Medicare Part C and Part D reporting sections that are required to be validated each year;
- New wage statistics, fringe benefits, and overhead costs for both sponsoring organizations and DVCs;
- Travel costs;

- Total number of sponsoring organizations;
- Total number of contracts;
- Average number of contracts per sponsoring organization; and
- Level of effort associated with the different tasks for the Data Validation Program.

CMS used May 2011 wage statistics supplied by the Department of Labor's Bureau of Labor Statistics (BLS) when developing the estimates of direct wages, fringe benefits, and overhead costs. In addition, information published by Deltek, Inc.[2], was used to identify a reasonable profit margin for the DVC. Two labor categories, Analyst and Manager, were used. For the sponsoring organizations, the estimated cost per hour is $71.34 for an Analyst and $87.88 for a Manager (wage, fringe benefits, and overhead). For the DVCs, the estimated cost per hour is $76.69 for an Analyst and $94.48 for a Manager (wage, fringe benefits, overhead, and profit). Travel costs for the in-person site visit, including airfare, lodging, car rental, and meals were estimated to be $2,686 per review, assuming both DVC staff (Analyst and Manager) travel.

Table 1 summarizes the 2013-2015 data validation cycle statistics, which are key inputs required to calculate the cost burden. These include the number of reporting sections validated, the number of sponsoring organizations, and the average number of contracts per sponsoring organization. These are used in conjunction with the hourly wage estimates described above and level of effort (LOE) estimates for performing reviews at the contract level.

Table 1 2013-2015 Data Validation Cycle Statistics

Medicare Part C and Part D 2013-2015 Data Validation Cycle - Statistics				
Sponsoring Organization Type	**Number of Reporting Sections Validated**	**Number of Sponsoring Organizations (SOs)**	**Number of Contracts**	**Avg. Number of Contracts per SO**
Part C Only	5	16	18	1.13
Part D Only	6	57	74	1.30
Part C and Part D	11	135	565	4.19

Table 2 summarizes the estimated cost burden of conducting a data validation review for one contract across three scenarios, where a sponsoring organization reports data for: (1) Medicare Part C data only; (2) Medicare Part D data only; and (3) both Medicare Part C and Part D data. This table also summarizes the estimated cost burden to perform data validation for each additional contract, should one sponsoring organization have multiple contracts.

Table 2 Burden Estimate for a Data Validation Review of One Contract

Cost Burden: Data Validation Review -for one contract- Totals may not be exact due to rounding of level of effort			
Assumption / Estimate	**Part C Only**	**Part D Only**	**Part C and Part D**
Hourly Wage: SO Analyst (a)	$71.34	$71.34	$71.34

2 *http://www.federaltimes.com/article/20120314/ACQUISITION03/203140304*

Cost Burden: Data Validation Review **-<u>for one contract</u>-** Totals may not be exact due to rounding of level of effort			
Assumption / Estimate	**Part C Only**	**Part D Only**	**Part C and Part D**
Hourly Wage: SO Manager (b)	$87.88	$87.88	$87.88
Hourly Wage: DVC Analyst (c)	$76.69	$76.69	$76.69
Hourly Wage: DVC Manager (d)	$94.48	$94.48	$94.48
LOE in Hours: SO Analyst (e)	99	116	202
LOE in Hours: SO Manager (f)	134	141	176
Total SO Hours (g) (e) + (f)	**232**	**257**	**378**
LOE in Hours: DVC Analyst (h)	178.00	212.00	382.00
LOE in Hours: DVC Manager (i)	73	81	119
Total DVC Hours (j) (h) + (i)	**251**	**293**	**501**
SO Analyst Cost (k) (a) x (e)	$7,009.15	$8,239.76	$14,392.83
SO Manager Cost (l) (b) x (f)	$11,776.50	$12,391.69	$15,467.64
Total SO Cost (m) (k) + (l)	**$18,785.65**	**$20,631.45**	**$29,860.47**
DVC Analyst Cost (n) (c) x (h)	$13,650.89	$16,258.37	$29,295.74
DVC Manager Cost (o) (d) x (i)	$6,873.10	$7,605.29	$11,266.22
DVC Travel Expense (p)	$2,686	$2,686	$2,686
Total DVC Cost (q) (n) + (o) + (p)	**$23,209.99**	**$26,549.65**	**$43,247.95**
Total Cost Burden (r) (m) + (q)	**$41,995.64**	**$47,181.10**	**$73,108.42**
Additional LOE (Hours) per Additional Contract	**17**	**27**	**49.**
Additional Cost per Additional Contract	**$1,265.18**	**$2,113.41**	**$3,874.59**

Table 3 uses the inputs included in Table 1 and the cost burden outlined in Table 2 and factors in the average number of contracts per sponsoring organization, which increases the level of effort (hours) for the DVC.

Table 3 Burden Estimate for a Data Validation Review of Multiple Contracts

Cost Burden: Data Validation Review per Sponsoring Organization -using the average number of contracts per SO- Totals may not be exact due to rounding of level of effort			
Assumption / Estimate	**Part C Only**	**Part D Only**	**Part C and Part D**
Hourly Wage: SO Analyst (a)	$71.34	$71.34	$71.34
Hourly Wage: SO Manager (b)	$87.88	$87.88	$87.88
Hourly Wage: DVC Analyst (c)	$76.69	$76.69	$76.69
Hourly Wage: DVC Manager (d)	$94.48	$94.48	$94.48
Average LOE in Hours: SO Analyst (e)	98	116	202
Average LOE in Hours: SO Manager (f)	134	141	176
Average SO Hours (g) (e) + (f)	**232.25**	**256.50**	**377.75**
Average LOE in Hours: DVC Analyst (h)	180	219	519
Average LOE in Hours: DVC Manager (i)	73	82	139
Average DVC Hours per SO (j) (h) + (i)	**254**	**301**	**658**
SO Analyst Cost (k) (a) x (e)	$7,009.15	$8,239.76	$14,392.83
SO Manager Cost (l) (b) x (f)	$11,776.50	$12,391.69	$15,467.64
Average SO Cost (m) (k) + (l)	**$18,785.65**	**$20,631.45**	**$29,860.47**
DVC Analyst Cost (n) (c) x (h)	$13,837.83	$16,803.88	$39,775.05
DVC Manager Cost (o) (d) x (i)	$6,906.32	$7,700.39	$13,128.18
DVC Travel Expense (p)	$2,686	$2,686	$2,686
Average DVC Cost per SO (q) (n) + (o) + (p)	**$23,430.13**	**$27,190.26**	**$55,589.23**
Total Average Cost Burden per SO (r) (m) + (q)	**$42,215.78**	**$47,821.71**	**$85,449.70**

Using the information from Table 3 the total estimated cost burden by labor category, organization (i.e., sponsoring organization and DVC) and type of reporting (i.e., Part C, Part D, and Part C and Part D) is outlined in Table 4.

Table 4 Total Cost Burden – 2013-2015 Data Validation Cycle

Total Burden: All Sponsoring Organizations, All Data Validation Contractors, All Reviews Totals may not be exact due to rounding of level of effort			
Estimate	**Part C Only**	**Part D Only**	**Part C and Part D**
Total Hours: All SO Analysts	1,572	6,584	27,236
Total Hours: All SO Managers	2,144	8,037	23,760
Total Hours: All DVC Analysts	2,887	12,489	70,017
Total Hours: All DVC Managers	1,167	4,646	18,759
Total Data Validation Hours: All Reviews	**7,773**	**31,756**	**139,773**
Grand Total - Hours: All Reviews for Part C, Part D, and Part C&D	**179,301**		
Total SO Cost: All Reviews	$300,570.38	$1,175,992.81	$4,031,163.79
Total DVC Cost: All Reviews	$374,882.16	$1,549,844.61	$7,504,545.54
Total Data Validation Cost: All Reviews	**$675,452.54**	**$2,725,837.42**	**$11,535,709.33**
Grand Total - Cost: All Reviews for Part C, Part D, and Part C&D	**$14,936,999.28**		

13. Capital Costs

There is no capital cost associated with the data validation activities.

14. Cost to Federal Government

It will cost an estimated $300,000 to maintain HPMS.

15. Changes to Burden

The changes in the Data Validation Program for the annual 2013-2015 data validation cycles will result in an estimated decrease in the level of effort by 24 percent (57,826 hours) and an estimated decrease in the cost to industry by 12 percent ($2,081,861). This decrease in burden is attributed to a reduced number of sponsoring organizations, a reduction by CMS in the number of reporting sections eligible for validation, and a reduction in travel expenses per review. Table 5 includes the Part C and Part D reporting sections removed from validation.

Table 5 Part C and Part D Reporting Sections Removed from the 2013 – 2015 Data Validation Cycle

Part C Reporting Sections	Part D Reporting Sections
• Benefit Utilization • Procedure Frequency • Provider Network Adequacy • Employer Group Plan Sponsors	• Retail, Home Infusion, and LTC Pharmacy Access • Employer/Union-Sponsored Group Health Plan Sponsors

The BLS labor categories did not change. However, CMS previously estimated the profit margin for the DVC within the overhead rate when determining the hourly cost for each labor category. Profit is calculated as an addition to overhead for this Paperwork Reduction Act submission. Additional changes to the inputs are described in Table 6 below.

Table 6 2012-2014 vs. 2013-2015 Burden Estimate Assumptions

Assumption	Previous Annual Estimate (2012-2014)	Current Annual Estimate (2013-2015)
Hourly Wage*: Sponsoring Organization	$62.84 (Analyst) $76.33 (Manager)	$71.34 (Analyst) $87.88 (Manager)
Hourly Wage**: DVC	$62.84 (Analyst) $76.33 (Manager)	$76.69 (Analyst) $94.48 (Manager)
Travel Expenses per Review	$4,150	$2,686
Total Number of CMS Contracts (Part C and Part D)	634	657
Total Number of Sponsoring Organizations	259	208
Average Number of Contracts per Sponsoring Organization	1.20 (Part C Only) 1.29 (Part D Only) 2.89 (Part C & Part D)	1.13 (Part C Only) 1.30 (Part D Only) 4.19 (Part C & Part D)
Total Number of Reporting Sections Undergoing Data Validation	9 (Part C Only) 8 (Part D Only) 17 (Part C & Part D)	5 (Part C Only) 6 (Part D Only) 11 (Part C & Part D)
Total Industry LOE	237,127 hours	179,301 hours
Total Industry Cost	$17,018,860	$14,936,999

*Includes fringe benefits and overhead costs
**Includes fringe benefits, overhead costs, and profit

16. Publication/Tabulation Dates

Collection of the relevant Medicare Part C and Part D data occurs during a three-month period each year from April 1 through June 30.

17. Expiration Date

The data validation activities do not possess an expiration date.

18. Certification Statement

MAOs and Part D sponsors that have terminated their contracts prior to the start of the data collection year are exempt from this collection process.