

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 that the data reported are accurate, valid, and reliable. To maintain the independence of the 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 2015, the DVCs will review data submitted by sponsoring organizations for CY2014.

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

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

The review is conducted over a three-month period (April – June) 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. The completed "OAI" may reduce required DVC resources and make the data validation review more efficient and effective. Sponsoring organizations should provide the completed "OAI" to their selected DVC electronically.

Appendix 3: "Data Extraction and Sampling Instructions for Data Validation Contractors" –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" –This document provides guidance about how to use the FDCF.

Appendix 5: "Findings Data Collection Form (FDCF)" –DVCs use this tool to record the validation findings for each contract included in the scope of the review. The FDCF mirrors the data validation standards and reporting-section-specific criteria described in Appendix 1, "Data Validation Standards." The FDCF allows contractors 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 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. If the 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 process does not result in a duplication of similar information.

5. Small Businesses

The data validation process 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. In addition, CMS is now making available data from some reporting sections in the form of public use files (PUFs) in support of its transparency goals. It, therefore, is especially important that the data be valid and reliable.

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 13, 2014 (79 FR 33927). As a result of 508 file issues, CMS extended the comment period on August 12 (79 FR 47144). Comments were received. The comments have been attached to this package along with our response.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents associated with the data validation request.

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)

New burden estimates for the CMS Medicare Part C and Part D data validation program are described below. This new 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;
- Increases/decreases in the average number of data elements per reporting section; New (updated) wage statistics fringe benefits and overhead costs for both sponsoring organizations and DVCs;
- BLS job categories most appropriate for developing estimates of wages;
- 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 2013 wage statistics supplied by the Department of Labor's Bureau of Labor Statistics when developing the estimates of direct wages. This publication is available at:

<http://www.bls.gov/oes>.

Two labor categories, General and Operations Managers and Management Analysts were used.. Fringe benefits and overhead were estimated to be 35% of wages. The formula was “Hourly Wage” = Wage found in Bureau of Labor statistics for May 2013 x 1.35. Thus, the “Hourly wage” listed in the tables below actually included fringe benefits and overhead estimates. For the sponsoring organizations, the estimated cost per hour is \$68.18 for a Management Analyst and \$94.66 for a General or Operations Manager (includes wage, fringe benefits and overhead which we estimated). For the DVCs, the estimated cost per hour is \$72.26 for an Analyst and \$97.55 for a Manager (wage fringe benefits, and overhead). 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 (Management Analyst and Manager) travel.

Table 1 summarizes the 2015-2017 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 2015-2017 Data Validation Cycle Statistics

Medicare Part C and Part D 2015-2017 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	4	16	16	1
Part D Only	5	56	77	1.375
Part C and Part D	9	142	613	4.317

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. Travel time for DVCs has been factored into the estimated cost burden. 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-			
Assumption / Estimate	Part C Only	Part D Only	Part C and Part D

Hourly Wage: SO Analyst (a)	\$68.18	\$68.18	\$68.18
Hourly Wage: SO Manager (b)	\$94.66	\$94.66	\$94.66
Hourly Wage: DVC Analyst (c)	\$72.26	\$72.26	\$72.26
Hourly Wage: DVC Manager (d)	\$97.55	\$97.55	\$97.55
LOE in Hours: SO Analyst (e)	98.25	115.5	201.75
LOE in Hours: SO Manager (f)	134	141	176
Total SO Hours	232.25	256.5	377.75
LOE in Hours: DVC Analyst (h)	178	212	382
LOE in Hours: DVC Manager (i)	72.75	80.5	119.25
Total DVC Hours	250.75	292.5	501.25
Total SO + DVC Hours	483.0	549.0	1032.0
SO Analyst Cost (k)	\$6,698.69	\$7,874.79	\$13,755.32
SO Manager Cost (l)	\$12,684.44	\$13,347.06	\$16,660.16
Total SO Cost (m)	\$19,383.13	\$21,221.85	\$30,415.48
DVC Analyst Cost (n)	\$12,862.28	\$15,319.12	\$27,603.32
DVC Manager Cost (o)	\$7,096.76	\$7,852.78	\$11,632.84
DVC Travel Expense (p)	\$2,686	\$2,686	\$5,372
Total DVC Cost (q)	\$22,645.04	\$25,857.90	\$44,608.16
Total Cost Burden (r)	\$42,028.17	\$47,079.75	\$75,023.63
Additional LOE (Hours) per Additional Contract	17.06	26.78	49.09
Additional Cost per Additional Contract	\$1,484.47	\$2,296.53	\$3,781.00

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-			
Assumption / Estimate	Part C Only	Part D Only	Part C and Part D
Hourly Wage: SO Analyst (a)	\$68.18	\$68.18	\$68.18
Hourly Wage: SO Manager (b)	\$94.66	\$94.66	\$94.66
Hourly Wage: DVC Analyst (c)	\$72.26	\$72.26	\$72.26
Hourly Wage: DVC Manager (d)	\$97.55	\$97.55	\$97.55
Average LOE in Hours: SO Analyst (e)	98.25	115.5	201.75
Average LOE in Hours: SO Manager (f)	134	141	176

Average LOE in Hours: DVC Analyst (h)	178	222.0425	544.83
Average LOE in Hours: DVC Manager (i)	72.8	80.5	119.5
Avg. DVC Hours per SO (j)	250.8	302.5	664.3
Avg. SO Hours Per SO	232.3	256.5	377.8
Total Hours Per SO	483.0	559.0	1042.1
SO Analyst Cost (k)	\$6,698.69	\$7,874.79	\$13,755.32
SO Manager Cost (l)	\$12,684.44	\$13,347.06	\$16,660.16
Average SO Cost (m)	\$19,383.13	\$21,221.85	\$30,415.48
DVC Analyst Cost (n)	\$12,862.28	\$16,044.79	\$39,369.18
DVC Manager Cost (o)	\$7,096.76	\$7,852.78	\$11,657.23
DVC Travel Expense (p)	\$2,686	\$2,686	\$2,686
Average DVC Cost per SO (q)	\$22,645.04	\$26,583.57	\$53,712.40
Total Average Cost Burden per SO (r)	\$42,028.17	\$47,805.42	\$84,127.88

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 – 2015-2017 Data Validation Cycle

Total Burden: All Sponsoring Organizations, All Data Validation Contractors, All Reviews			
Estimate	Part C Only	Part D Only	Part C and Part D
Total Hours: All SO Analysts	1,572	6,468	28,649
Total Hours: All SO Managers	2,144	7,896	24,992
Total Hours: All DVC Analysts	4,012	16,942	94,334
Total Hours: All DVC Managers	1,164	4,074	10,331
Total Data Validation Hours: All Reviews	8,892	35,380	158,305

Grand Total - Hours: All Reviews for Part C, Part D, and Part C&D	202,578		
Total SO Cost: All Reviews	\$310,130.00	\$1,188,423.60	\$4,318,997.45
Total DVC Cost: All Reviews	\$362,320.68	\$1,488,679.70	\$7,627,161.03
Total Data Validation Cost: All Reviews	\$672,450.68	\$2,677,103.30	\$11,946,158.48
Grand Total - Cost: All Reviews for Part C, Part D, and Part C&D	\$15,295,712.46		

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 the Health Plan Management System (HPMS).

15. Changes to Burden

The changes in the data validation program for the annual 2015-2017 data validation cycles will result in an estimated increase in the level of effort by 23,277 hours (13 percent) and an estimated increase in the cost to industry of \$358,713 (2.4 percent). This increase in burden is attributed to an increased number of sponsoring organizations and the average number of contracts per sponsor.. The number of reporting sections undergoing data validation decreased from 11 to 9, but the level of effort per reporting section increased because of increases in the number of data elements. It was assumed that these two factors offset each other, and, therefore, did not affect burden. Table 5 lists the four Part C and five Part D reporting sections that will undergo validation.

Table 5 Part C and Part D Reporting Sections in the 2015-2017 Data Validation Cycle

Part C Reporting sections	Part D Reporting Sections
<ul style="list-style-type: none"> • Part C Grievances • Organization Determinations and Reconsiderations • Part C Plan Oversight of Agents • Special Needs Plan Care Management 	<ul style="list-style-type: none"> • Medication Therapy Management (MTM) Programs • Part D Grievances • Coverage Determinations and Redeterminations • Long-term Care (LTC) Utilization • Part D Plan Oversight of Agents

Additional changes to the inputs are described in Table 6 below.

Table 6 2013-2015 vs. 2015-2017 Changes in Calculation Factors

Factor	Annual Estimate (2013-2015)	Current Annual Estimate (2015-2017)
Hourly Wage*: Sponsoring Organization	\$71.34 (Analyst) \$87.88 (Manager)	\$68.18 (Management Analyst) \$94.66 (General and Operations Manager)
Hourly Wage**: DV Contractor	\$76.69 (Analyst) \$94.48 (Manager)	\$72.26 (Management Analyst) \$97.55 (General and Operations Manager)
Fringe Benefits and Overhead	Used published data	1.35 times wage
Profit Margin	Used published data	Not included
Total Number of CMS Contracts (Part C and Part D)	657	706
Total Number of Sponsoring Organizations	208	214
Average Number of Contracts per Sponsoring Organization	1.13 (Part C Only) 1.30 (Part D Only) 4.19 (Part C & Part D)	1.00 (Part C Only) 1.38 (Part D Only) 4.32 (Part C & Part D)
Total Number of Reporting Sections Undergoing Data Validation	5 (Part C Only) 6 (Part D Only) 11 (Part C & Part D)	4 (Part C Only) 5 (Part D Only) 9 (Part C & Part D)
Total Industry LOE	179,301 hours	202,578
Total Industry Cost	\$14,936,999	\$15,295,712

*Includes fringe benefits and overhead costs

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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.