

**Supporting Statement A**  
**Medicare Part C and Part D Data Validation (42 CFR 422.516(g) and 423.514(g))**  
**CMS-10305, OMB 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, the data 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, reliable, and valid. 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. For the retrospective review, in 2017, the DVCs will review data submitted by sponsoring organizations for CY2016.

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. The standards are listed in Appendix 1. 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 (RSC) 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.

The review is conducted over a three-month period (April – June) following the final submission of data by the sponsoring organizations. The DVCs employ a set of information guides and collection tools when performing their reviews. The Organizational Assessment Instrument (Appendix 2) is completed by the SO prior to the review and is shared with the DVCs. The tool used to record the results of the data validation is the “Findings Data Collection Form” (FDCF). The FDCF, displayed in Appendix 3, 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.

The FDCF is revised for the 2017 and 2018 DV collection periods by changing the scoring of six standards from a binary scale to a five-point Likert-type scale. This change is expected to improve the precision of the data validation scores by increasing overall variation in total scores among the MAOs and PDPs. The applicable standards are: 1c, 1d, 1e, 1g, 1h and 2e. Please refer to Appendix 3. This revision is not expected to alter resource requirements, since the assessment by DV contractors in scoring standards will continue to be based on the percentage of records that meet the standards. The new scoring scale is as follows for assessing the sponsoring organization (SO):

1. A score of 1 if the SO has more than 20 percent error in records
2. A score of 2 if the SO has between 15.1 percent and 20 percent error in records.
3. A score of 3 if the SO has between 10.1 percent and 15 percent error in records.
4. A score of 4 if the SO has between 5.1 percent and 10 percent error in records.
5. A score of 5 if the SO has fewer than 5 percent error in records.

The next step is identifying how to accord the weights for each standard (or sub-standard) based on the scores received as described above. In the binary system, all fails get zero times the weight of the data element (equaling to a score of 0), and all passes get one times the weight of the data element (equaling to a 100% of the weight of the corresponding standard/sub-standard). In the proportionate scale, we have to accommodate for scores other than zero and one.

We will be using the following weights:

1. If SO receives a score of 5, the standard receives 100% of the assigned weight.
2. If SO receives a score of 4, the standard receives 75% of the assigned weight.
3. If SO receives a score of 3, the standard receives 50% of the assigned weight.
4. If SO receives a score of 2, the standard receives 25% of the assigned weight.
5. If SO receives a score of 1, the standard receives 0% of the assigned weight.

## **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](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 are 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 FDCE; specifically DVCs use the Plan Reporting Data Validation Module (PRDVM), which mirrors the FDCE. 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

Respondents are required to retain records (excluding health, medical, government contract, grant-in-aid, or tax records) for more than three years. §§42 CFR 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.

Otherwise, there are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

## 8. Federal Register/Outside Consultation

The 60-day notice published in the Federal Register on June 30, 2016 (81 FR 42710). Comments were received and our response has been added to this PRA package.

Changes subsequent to the publication of the 60 day notice include:

For Part C and Part D grievances we do not exclude expedited grievances. This makes the standards consistent with the technical specifications.

The standards in Organizations/Determinations and Reconsiderations erroneously excluded Dismissals and Withdrawals. To be consistent with the technical specifications, we included dismissals and withdrawals.

CMS excluded high cost edits for compounds to be consistent with the 2017 technical specifications.

CMS included fraud and similar fault in the DV standard to be consistent with Chapter 13 of the Medicare Managed Care Manual.

CMS included members who dis-enrolled from and re-enrolled into the same plan if an initial Health Risk Assessment (HRA) was performed within 90 days of re-enrollment and the member has remained continuously enrolled in the same plan **for up to 365 days** since the initial HRA.

All changes were made in the Find Data Collection Form (FDCF) to be consistent with changes in the Data Validation Standards.

#### 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

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

#### 12. Burden Estimates (Hours & Wages)

Burden for this iteration of the CMS Medicare Part C and Part D data validation program are described below. A discussion of the revisions to our currently approved estimates are set out in section 15 of this Supporting Statement.

## Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates for all salary estimates ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage. Applying BLS' data to the sponsoring organizations (SOs) and data validation contractors (DVCs), we expect respondents would be a Management Analyst and a General or Operations Manager.

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
General and Operations Managers	11-1021	57.44	57.44	114.88
Management Analysts	13-1111	44.12	44.12	88.24

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

## Burden Estimates

Table 1 summarizes the 2017-2018 data validation cycle statistics. These statistics include the number of reporting sections validated, the number of sponsoring organizations, and the 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 developing overall burden estimates.

Sponsoring Organization (SO) Type	Number of Reporting Sections Validated	Number of Sponsoring Organizations (SOs)	Number of Contracts	Avg. Number of Contracts per SO
Part C Only	4	15	15	1.00
Part D Only	4	59	67	1.14
Part C and Part D	8	195	557	2.86
Overall	N/A	Total=269	Total=639	Avg. per SO=2.38

Table 2 contains the estimated annual cost for the CY 2017-2018 data validation cycles. The table contains both the “level of effort” (LOE) and costs for the data validation reviews for one contract and for each additional contract reviewed per sponsoring organization.

Average (mean) total hours *per contract* for Part C only sponsors are 493.68, for Part D only sponsors, 456.16, and for Part C/Part D sponsors, 808.50. The average hourly burden for each additional contract undergoing the DV review for a single SO is estimated at 18.08 hours for Part C only sponsors, for Part D only sponsors, 29.46 hours, and for Part C/ part D sponsors, 47.13 hours.

The Total Cost for Part C sponsors only, Part D sponsors only, and for sponsors offering both Part C and Part D benefits is calculated as follows for each of these types of sponsors:

Total Cost = (Total Cost for One Contract x No. SOs) + (Additional Cost per Additional Contract x No. Additional Contracts). The Total Hour and Cost for Part C only SOs were 7,405.20 and \$736,052, respectively. The Total Hour and Cost for Part D only SOs are 27,149.10 and \$2,674,153 respectively. The Total Hour and Cost for Part C/Part D SOs are 174,716.82 and \$16,780,359, respectively. The Grand Total Cost is the sum of the Total Cost for each of the types of sponsoring organizations—Part C Only, Part D Only (PDPs), and Part C and Part D (MAPDs). The Grand Total Hours burden across all SOs is 209,271 and the Grand Total Cost is \$20,190,564.

**Table 2: Estimated Cost Burden: Data Validation Review CY2017-2018 DV Cycle**

Assumption / Estimate	Part C Only Organizations	Part D Only Organizations	Part C and Part D Organizations	Totals
Hourly Wage: SO Analyst	\$88.24	\$88.24	\$88.24	
Hourly Wage: SO Manager	\$114.88	\$114.88	\$114.88	
Hourly Wage: DVC Analyst	\$88.24	\$88.24	\$88.24	
Hourly Wage: DVC Manager	\$114.88	\$114.88	\$114.88	
LOE in Hours: SO Analyst	98.25	92.40	179.33	
LOE in Hours: SO Manager	134	112.8	156.44	
Total SO Hours	232.25	205.20	335.78	
LOE in Hours: DVC Analyst	188.7	186.56	366.72	
LOE in Hours: DVC Manager	72.75	64.4	106.00	
Total DVC Hours	261.4	250.96	472.72	
Total SO + DVC Hours	493.68	456.16	808.50	
SO Analyst Cost	\$8,670	\$8,153	\$15,824	
SO Manager Cost	\$15,394	\$12,958	\$17,972	
Total SO Cost	\$24,064	\$21,112	\$33,797	
DVC Analyst Cost	\$ 16,649	\$ 16,462	\$ 32,359	
DVC Manager Cost	\$ 8,358	\$ 7,398	\$ 12,177	
Total DVC Cost	\$ 25,007	\$ 23,860	\$ 44,537	
Total Cost Burden (one Contract)	\$ 49,070	\$ 44,972	\$ 78,333	
LOE (Hours ) per Additional Contract	18.08	29.46	47.13	
Avg. Hourly Cost Additional Contracts	\$ 88.24	\$ 88.24	\$ 88.24	
Additional Cost per Additional Contract	\$ 1,596	\$ 2,599	\$ 4,158	
No. SOs	15	59	195	
No. Additional Contracts	-	8	362	370
Total Additional Cost	\$ -	\$ 20,795	\$ 1,505,353	\$ 1,526,148
Total Hours (All Contracts)	7,405.20*	27,149.12**	174,718.56***	209,272.88
Total Cost Burden (All Contracts)	\$ 736,052	\$ 2,674,153	\$ 16,780,359	\$ 20,190,564

\*7,405.20 hours = 493.68 hours x 15 SOs (no additional contracts)

\*\*27,149.12 hours = (456.16 hours x 59 SOs) + (8 additional contracts x 29.46 hours/contract)

\*\*\*174,718.56 hours = (808.50 hours x 195 SOs) + (362 additional contracts x 47.13 hours/contract)

*Information Collection Instruments/Instruction/Guidance Documents*

Appendix 1: Data Validation Standards (Version 7)

Appendix 2: Organizational Assessment Instrument (Version 7.0)

Appendix 3: Findings Data Collection Form



Appendix 4: Data Validation Procedure Manual (Version 7.0)

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. Program and Burden Changes

Table 3 lists the four Part C and Part D reporting sections that will undergo validation. The Long Term Care Pharmacy Utilization reporting section was suspended from reporting in 2016, accounting for the decrease from 5 to 4 in reporting sections undergoing the data validation for PDPS and from 9 to 8 in reporting sections undergoing the data validation for MAPDs.

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

Table 4 summarizes changes in calculation factors between the 2015-2017 ICR and this 2017-2018 ICR for the data validation of Part C and Part D reporting requirements. The changes in the data validation program for the annual 2017-2018 data validation cycles will result in an estimated increase in the level of effort (LOE) by 6,695 hours (3.3 percent) and an estimated increase in the cost to industry of \$3,241,863 (17.5 percent). This increase in cost is attributed to an increase in the hourly wage estimates because of the update in the BLS data used, a change in methodology for determining fringe benefits, and the increased LOE.

The LOE estimates for Part C only DV contractor analysts are increased by 6 percent because of the addition of 38 new items to be scored in the FDCF so they exceed those contained in the

currently approved information collection request.

For DV contractor analysts reviewing Part D only contracts (i.e., PDPs), we used the currently approved LOE estimates multiplied by 4/5 to account for the decrease from 5 to 4 in the reporting sections undergoing the data validation review. We then increased that intermediate estimate by 10 percent (1/10) to account for the addition of 73 new items to be scored in the FDCF.

For DV analysts reviewing Part C/Part D sponsors (MAPDs), we multiplied the previous LOE estimates by 8/9 to account for the reduction in reporting sections undergoing the data validation review from 9 to 8. We then increased that intermediate estimate by 8 percent to account for the increase of 111 hours per contract due to the addition of 111 items to be scored (38 for Part C and 73 for Part D).

<b>Table 4: 2016-2017 vs. 2017-2018 Changes in Calculation Factors</b>		
<b>Factor</b>	<b>ICR 2016-2017 Annual Estimate</b>	<b>ICR 2017-2018 Annual Estimate</b>
Total Number of CMS Contracts (Part C and Part D)	706	639
Total Number of Sponsoring Organizations	214	269
Total Number of Reporting Sections Undergoing Data Validation	4 (Part C Only)	4 (Part C Only)
	5 (Part D Only)	4 (Part D Only)
	9 (Part C & Part D)	8 (Part C & Part D)
Total Industry LOE	202,578	209,273
Total Industry Cost	\$15,295,712	\$20,190,564

For Part C and Part D grievances we do not exclude expedited grievances. This makes the standards consistent with the technical specifications.

The standards in Organizations/Determinations and Reconsiderations erroneously excluded Dismissals and Withdrawals. To be consistent with the technical specifications, we included dismissals and withdrawals.

CMS excluded high cost edits for compounds to be consistent with the 2017 technical specifications.

CMS included fraud and similar fault in the DV standard to be consistent with Chapter 13 of the Medicare Managed Care Manual.

CMS included members who dis-enrolled from and re-enrolled into the same plan if an initial Health Risk Assessment (HRA) was performed within 90 days of re-enrollment and the member has remained continuously enrolled in the same plan **for up to 365 days** since the initial HRA.

All changes were made in the Find Data Collection Form (FDCF) to be consistent with changes in the Data Validation Standards.

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 expiration date will be displayed.

18. Certification Statement

There are no exceptions to the certification statement.