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).

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. To maintain the independence of the validation process, sponsoring organizations do not use their own staff to conduct the data validation. 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. For the retrospective review in 2018, the DVCs will review data submitted by sponsoring organizations for CY2017.

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 J. 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. 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 B) is completed by the sponsoring organization 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 J, allows contractors to record notes, reference data sources, and capture findings for the different standards and criteria specified for a given reporting section. The DVC submits the completed FDCF to CMS via the Health Plan Management System (HPMS).

The main changes for the 2018 DV are to eliminate the Part C/D reporting section Sponsor Oversight of Agents, which did not prove to give valuable data for CMS' monitoring. We also added the Part D reporting section Improving Drug Utilization Review Controls to provide additional data to monitor the impact of sponsors' expanded efforts in 2019 to manage opioid overutilization.

CMS uses validated, plan-reported data to calculate two Star Ratings measures (Medication Therapy Management Comprehensive Medication Review (Part D), and Special Needs Plan Care Management (Part C)) and one Display measure (Grievance (Part C and D)). For more information please see the Star Ratings and Display technical notes posted here https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html. Star Ratings are used to calculate Quality Bonus Payments, which are discussed in more detail in the Advance Notices and Rate Announcements published at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.

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) *Validation of Part C Reporting Requirements,* and 423.514(g) *Validation of Part D Reporting Requirements* 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 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 findings collected through the Medicare data validation to substantiate the data reported via Medicare Part C and Part D Reporting Requirements. Data validation provides CMS with assurance that plan-reported data are credible and consistently collected and reported by Part C and D SOs. CMS uses validated data to respond to inquiries from Congress, oversight agencies, and the public about Part C and D SOs. The validated data also allows CMS to more effectively monitor and compare the performance of SOs over time. Validated plan-reported data may be used for Star Ratings, Display measures and other performance measures. Additionally, SOs can take advantage of the DV process to more effectively assess their own performance and make improvements to their internal operations and reporting processes.

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

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 package has been revised subsequent to the publication of the 30-day Federal Register notice. There were no changes in the burden estimates made as a result of the changes. The minor changes made to Appendix B, and the FDCF are outlined in the attached crosswalk. The changes were made in response to public comments.

9. Payments/Gifts to Respondents

There are no gifts to the respondents. However, as a matter of compliance with the requirements of this information collection request (ICR) and the Medicare program, sponsors will achieve Star Ratings and Display measure rates based on the data that undergo data validation. Sponsors are incentivized to do well in the Star ratings. Sponsors that fail to comply with the requirements contained in this ICR, that is, they fail to have their data validated, will receive compliance actions.

Confidentiality

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

10. 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.

11. 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 2016 National Occupational Employment and Wage Estimates for all salary estimates (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 data validation contractors (DVCs), we expect respondents would be a Management Analyst.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Analysts	13-1111	$44.19	$44.19	$88.38

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

We have based these burden estimates with the consideration that data validation is conducted for each Part C/D contract, and that the contract is the basis for any legal or accountability issues. We used the number of contracts (MA only, PDP and MA-PD) that completed data validation in 2017 when calculating burden. We no longer estimate burden by an average sized sponsor, as the number of contracts underlying each sponsor can vary. Additionally, prior figures may have incorrectly double-counted contracts within sponsor types. We accounted for changes in the level of effort by quantifying the net changes in the FDCF's elements for 2018, as it is the instrument completed by the DVC. We calculated the cost of burden using both the wage estimates described above and the burden hours as estimated in the approved 2017 PRA with the number of reporting items in the FDCF for 2018.

While these burden estimates appear to have significantly decreased by respondent, the estimates are more directly reflecting an individual contract's burden for data validation (versus sponsor). The decreased burden is due to the elimination of the Sponsor Oversight of Agents reporting section in HPMS which eliminated over 90 line items in the FDCF. The impact was less for Part D sponsors since validation of a new reporting section on Improving Drug Utilization Controls was added.

Table 2: OMB Approved Cost Burdens, Data Validation Review CY 2017 DV Cycle

	MA only	**PDP**	**MA-PD**
2017 PRA LOE (Hours) per contract	18.08	29.46	47.13
Number of Reporting items in the FDCF	702	834	1536
Time per FDCF item *(Calculated by Total hours per contract / # reporting items in FDCF)*	0.026	.035	0.031

Table 3: Estimated Cost Burden at Individual Contract Level, Data Validation Review CY 2018 DV Cycle

Assumption/Estimate	**MA only**	**PDP only**	**MA-PD**	**All contracts**
Hourly Wage: Analyst	$88.38	$88.38	$88.38	
Number of contracts *(# contracts completing 2017 DV)*	12	60	502	
Number of Reporting items in FDCF	605	830	1435	
Total hours (per contract) *(2017 Time per FDCF item * 2018 # reporting items in FDCF)*	16	29	44	
Total Burden Hours (All contracts) *(Total hours per contract * # contracts)*	*187*	*1759*	*22,104*	**24,050**
Total Burden Cost *(All contracts) *Wage)*	*$16,525*	*$155,471*	*$1,953,511*	**2,125,508**

Information Collection Instruments/Instruction/Guidance Documents

Data Validation Procedure Manual
Appendix B: Data Validation Standards
Appendix E: Organizational Assessment Instrument
Appendix J: Findings Data Collection Form (FDCF)

12. Capital Costs

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

13. Cost to Federal Government

It will cost an estimated $300,000 to maintain the Health Plan Management System (HPMS).

14. Program and Burden Changes

Table 4 lists the three Part C and four Part D reporting sections that will undergo validation. For 2017 Part C Reporting Requirements, the Sponsor Oversight of Agents reporting section was suspended. Although, the section was also deleted from Part D Reporting Requirements, another section for Improving Drug Utilization Review Controls was added, keeping the total number of sections for Part D Reporting Requirements to four, for a total of seven sections validated.

Table 4: Part C and Part D Reporting Sections in the 2018-2019 Data Validation Cycle

Part C Reporting sections	Part D Reporting Sections
• Part C Grievances • Organization Determinations and Reconsiderations • Special Needs Plan Care Management	• Medication Therapy Management (MTM) Programs • Part D Grievances • Coverage Determinations and Redeterminations • Improving Drug Utilization Review Controls

Table 5 summarizes changes in calculation factors between the 2015-2017 ICR and this 2018-2019 ICR for the data validation of Part C and Part D reporting requirements.

The changes in the data validation program for the annual 2018-2019 data validation cycles are most impacted by the changes in how we calculate burden estimates. As explained above, we no longer estimate based on the number of sponsoring organizations or on the average number of contracts under a sponsor. The prior annual estimates reflected the burden across sponsors, and may have double-counted respondents (contracts) by the manner sponsors were categorized. Comparing the LOE listed in table 2, the hour burden for each type of contract (MA-only, PDP, and MA-PD) are similar, and is the best unit of comparison for changes going forward.

We estimate a decrease in the level of effort (LOE) for MA contracts due to the elimination of the Sponsor Oversight of Agents reporting section. For Part D contracts, the decrease in burden due to the elimination of the Sponsor Oversight of Agents reporting section was offset by the addition of a new reporting section Improving Drug Utilization Controls.

Table 5: 2016-2017 vs. 2017-2018 Changes in Calculation Factors		
Factor	**ICR 2017-2018 Annual Estimate**	**ICR 2018-2019 Annual Estimate**
Total Number of CMS Contracts (MA-only, PDP and MA-PDs)	639	574*
Number of Reporting Sections Undergoing Data Validation	4 (Part C) 4 (Part D) 8 (Total sections)	3 (Part C) 4 (Part D) 7 (Total sections)
Total Industry Level of Effort (Across all contracts)	209,271	24,050
Total Industry Cost (Across all contracts)	$18,537,575	$2,125,508

https://hpms.cms.gov/app/NAU/NewsSearch.aspx

15. 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.

16. Expiration Date

The expiration date will be displayed.

17. Certification Statement

There are no exceptions to the certification statement.