Supporting Statement A
Medicare Part C and Part D Data Validation (42 CFR 422.516(g) and 423.514(j))
(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 (SOs). To maintain the independence of the validation process, sponsoring organizations do not use their own staff to conduct the data validation process. SOs 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 2024, the DVCs will review data submitted by SOs for contract year (CY) 2023.

CMS developed standards and data validation criteria for specific Medicare Part C and Part D reporting requirements that the DVCs use in validating the SOs' data. The standards are listed in Appendix B. The data validation standards for each reporting section include standard instructions relevant to the type of information that should be reviewed that are aligned with the Medicare Part C and Part D Reporting Requirements. The standards and criteria describe how the DVCs should validate the SOs' compilations of reported data, considering 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 the DV period (April 1 – June 15) following the final submission of data by the SOs. The DVCs employ a set of information guides and collection tools when performing their reviews. The tool used to record the results of the data validation is the "Examination Engagement Standards" (EES). The EES, displayed in Appendix B, 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 EES to CMS via the Health Plan Management System (HPMS).

The main changes for the 2024 DV documents were relevant to the type of information that should be reviewed. We worked with Parts C and D RR Subject Matter Experts (SMEs) to identify the

most valuable data elements for each Part C and D Reporting Requirements (RR) section which resulted in a labor and cost burden reduction by more than 50%.

CMS uses validated, plan-reported data to calculate two Star Ratings measures (Medication Therapy Management Programs (Part D)), Special Needs Plans Care Management (Part C)), and one Display measure (Grievances (Part C and D)). For more information please see the Star Ratings and Display technical notes posted here https://www.cms.gov/Medicare/PrescriptionDrugCoverage/PrescriptionDrugCovGenIn/PerformanceData. 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(j) *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 Medicare benefits to beneficiaries. CMS uses the findings collected through the data validation process 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 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 effectively assess their own performance and make improvements to their internal operations and reporting processes.

3. Use of Information Technology

SOs use HPMS when submitting data to CMS. DVCs also use HPMS for submitting or entering findings from the EES; specifically, DVCs use the Plan Reporting Data Validation Module (PRDVM), which mirrors the EES. CMS grants access to HPMS to 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. Moreover, these data are used for Star Ratings measures calculations, which are in turn used for payment purposes in the form of Quality Bonus Payment (QBP) calculations; less frequent validation of these data could pose a risk to the accuracy of these payments to Medicare Advantage Organizations. In addition, CMS makes 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

- CM has requested the DV documents be posted in the Federal Register on April 25, 2023 (88 FR 24990) and the 60-day comment period will end on June 26, 2023.
- From June 27, 2023 to July 27, 2023 CM staff will review all received comments and questions, and revise the documents appropriately. Also, CM staff will prepare a document summarizing responses to comments and questions. Revised DV documents will be provided.
- CM has requested the DV documents be posted in the Federal Register on August 11, 2023 (88 FR 54613) and the 30-day comment period will end on September 11, 2023.
- From September 12, 2023 to October 12, 2023, CM staff will review all received comments and questions, and revise the documents appropriately. In addition, CM staff will prepare a document summarizing responses to comments and questions. Final DV documents will be delivered for OMB review by November 6, 2023.

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.

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 2021 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 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	$48.33	$48.33	$96.66

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. Change in the level of effort is quantified by the net changes in the number of lines of instruction in the EES, as it is the instrument completed by the DVC. We calculated the projected cost of the

2024 burden using the wage estimates described above, and updated the number of burden hours using the number of lines of instruction in the 2024 EES as outlined in Table 3 below. We also updated the number of contracts validated during the most recent DV cycle.

The estimates below are an individual contract's burden for data validation. The vast labor and burden decrease are due to the updated EES document that includes fewer items for the DVC to evaluate. The DVC's evaluation is simplified due to the more focused nature of the data elements in each Parts C and D reporting section.

Table 2: OMB Approved Cost Burdens, Data Validation Review CY 2023 DV Cycle

	MA only	**PDP**	**MA-PD**
2023 PRA LOE (Hours) per contract	10.82	17.41	28.01
	MA only	**PDP**	**MA-PD**
Number of Reporting items in the FDCF	420	493	913
Time per FDCF item *(Calculated by Total hours per contract / # reporting items in FDCF)*	.26	.035	.031

Table 3: Estimated Cost Burden at Individual Contract Level, Data Validation Review CY 2024 DV Cycle

Assumption/ Estimate	**MA only**	**PDP only**	**MA-PD**	**All contracts**
Hourly Wage: Analyst	$48.33	$48.33	$96.66	
Number of contracts *(# contracts completing 2023*	7	35	767	
Number of Reporting items in EES for 2024 DV cycle	155	262	395	
Total hours (per contract)	13	13	13	
Total Burden Hours (All contracts) *(Total hours per contract * #*	*91*	*454*	*9,955*	**10,500**

contracts)				
Total Burden Cost *(All contracts) *Wage)*	$8,781.98	$43,909.90	$962,254.01	$1,014,945.88

Information Collection Instruments/Instruction/Guidance Documents

Data Validation Procedure Manual

Appendix B: Examination Engagement Standards

Appendix E: Organizational Assessment Instrument

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 4 lists the three Part C and four Part D reporting sections that will undergo validation for a total of seven sections validated.

Table 4: Part C and Part D Reporting Sections in the 2023 Data Validation Cycle

Part C Reporting sections	Part D Reporting Sections
• Part C Grievances • Organization Determinations and Reconsiderations • Special Needs Plans Care Management	• Medication Therapy Management (MTM) Programs • Part D Grievances • Coverage Determinations, Redeterminations (including At–Risk Redeterminations under a Drug Management Program) and Reopenings • Improving Drug Utilization Review Controls

Burden has decreased due to the revamp of the data validation process. Using the new EES document, the number of rows (i.e., evaluation points for DVCs) decreases by almost 50%. Overall, labor and cost burden reduce by more than 50%. Table 5 summarizes changes in

calculation factors between the 2023 ICR and the 2024 ICR for the data validation of Part C and Part D reporting requirements.

Table 5: 2023 vs. 2024 Changes in Calculation Factors

Factor	ICR 2023 Annual Estimate	ICR 2024 Annual Estimate
Total Number of CMS Contracts (MA-only, PDP and MA-PDs)	793	809
Number of Reporting Sections Undergoing Data Validation	3 (Part C) 4 (Part D) 7 (Total sections)	3 (Part C) 4 (Part D) 7 (Total sections)
Total Industry Level of Effort (Across all contracts)	21,534.67	10,500
Factor	**ICR 2023 Annual Estimate**	**ICR 2024 Annual Estimate**
Total Industry Cost (Across all contracts)	$2,020,382.59	$1,014,945.88

16. Publication/Tabulation Dates

Collection of the relevant Medicare Part C and Part D data occurs during the DV period each year from April 1 through June 15.

17. Expiration Date

The expiration date will be displayed within the DV documents (Appendix E and the DV manual).

18. Certification Statement

There are no exceptions to the certification statement.