Supporting Statement for Paperwork Reduction Act Submission: Part C Medicare Advantage Reporting Requirements and Supporting Regulations in 42 CFR 422.516(a)

CMS-10261 (OMB 0938-1054)

Background

The Centers for Medicare and Medicaid Services (CMS) established reporting requirements for Medicare Advantage Organizations (MAOs) under the authority described in 42 CFR 422.516(a). It is noted that each MAO must have an effective procedure to develop, compile, evaluate, and report to CMS, its enrollees, and the general public at the times and in the manner that CMS requires. At the same time, each MAO must, in accordance with 42 CFR 422.516(a), safeguard the confidentiality of the doctor-patient relationship, statistics and other information with respect to the following:

(1) The cost of its operations.
(2) The patterns of service utilization.
(3) The availability, accessibility, and acceptability of its services.
(4) To the extent practical, developments in the health status of its enrollees.
(5) Information demonstrating that the MAO has a fiscally sound operation
(6) Other matters that CMS may require.

CMS also has oversight authority over cost plans which includes establishment of reporting requirements. If CMS initiates any new Part C reporting requirements, the Office of Management and Budget (OMB) must approve the "Information Collection Request" (ICR) under the Paperwork Reduction Act of 1995 (PRA). National PACE plans and 1833 cost plans are excluded from reporting all the new Part C Reporting Requirements sections.

The changes for the 2020 Reporting Requirements will require plans to report Telehealth benefits. This is a revision to the currently approved reporting requirements. The data collected in this measure will provide CMS with a better understanding of the number of organizations utilizing Telehealth per contract and to also capture those specialties used for both in-person and Telehealth. This data will allow CMS to improve its policy and process surrounding Telehealth. In addition, the specialist and facility data we are collecting aligns with some of the provider and facility specialty types that organizations are required to include in their networks and to submit on their HSD tables in the Network Management Module in Health Plan Management System.

In response to the 60 day comments, CMS has provided clarifying language for some the data elements. In lieu of providing guidance regarding the list telehealth specialties during the 30 day comment period, CMS will require plans to report telehealth specialties provided using additional Telehealth benefits. The NPRM # for the Telehealth rule is CMS-4185-F and published to the Federal Register April 16, 2019. The federal register citation is 84 FR 15680 and link to locate FR Notice is provided below:

https://www.govinfo.gov/content/pkg/FR-2019-04-16/pdf/2019-06822.pdf

Justification

1. Need and Legal Basis

In accordance with 42 CFR 422.516(a), each MA organization under Part C Medicare is required to have an effective procedure to provide statistics indicating:

- The cost of its operations.
- The patterns of utilization of its services.
- The availability, accessibility, and acceptability of its services.
- To the extent practical, developments in the health status of its enrollees.
- Other matters that CMS may require.

These Part C Reporting Requirements fill the need for the data that had not been available prior to the inception of the requirements in 2008. Further information about the need for such changes is included in the Background section.

In addition, Section 1852(m) of the Social Security Act (the Act) and CMS regulations at 42 CFR § 422.135 allow Medicare Advantage (MA) plans the ability to provide "additional telehealth benefits" to enrollees starting in plan year 2020 and treat them as basic benefits. MA additional telehealth benefits are limited to services for which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act. In addition, MA additional telehealth benefits are services that been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic information and telecommunications technology (or "electronic exchange") when the physician (as defined in section 1861(r) of the Act) or practitioner (as defined in section 1842(b) (18) (C) of the Act) providing the service is not in the same location as the enrollee. Per § 422.135(d), MA plans may only furnish MA additional telehealth benefits using contracted providers.

2. Information Users

There are a number of information users of Part C reporting. They include CMS central and regional office staff that use this information to monitor health plans and to hold them accountable for their performance. Among CMS users are group managers, division managers, branch managers, account managers, and researchers. Other government agencies such as GAO and OIG have inquired about this information.

Health plans can use this information to measure and benchmark their performance. CMS receives inquiries from the industry about the beneficiary use of available services, patient safety, grievance rates, and other factors pertaining to the performance of MA plans.

3. Use of Information Technology

MA organizations and other health plan organizations (e.g., cost plans) utilize the Health Plan Management System (HPMS) to submit or enter data for 100% of the data elements listed within these reporting requirements. MA organizations also use HPMS to submit applications to CMS, and CMS uses the system for announcements. HPMS,

therefore, is a familiar tool to MA organizations. Access to HPMS must be granted to each user and is protected by individual login and password; electronic signatures are unnecessary.

4. Duplication of Efforts

This collection does not contain duplication of similar information.

5. Small Businesses

The collection of information will have a minimal impact on small businesses since applicants must possess an insurance license and be able to accept substantial financial risk. Generally, state statutory licensure requirements effectively preclude small business from being licensed to bear risk needed to serve Medicare enrollees.

6. Less Frequent Collection

The Part C reporting requirements data with the exception of enrollment and disenrollment for reporting year 2020 are reported on an annual basis. Less frequent collection of these data from MA organizations would severely limit CMS' ability to perform accurate and timely oversight, monitoring, compliance and auditing activities around the Part C MA benefits.

7. Special Circumstances

As mandated by 42 CFR 422.504(d), MA organizations must agree to maintain for 10 years books, records, documents and other evidence of accounting procedures and practices. CMS could potentially require clarification around submitted data, and therefore CMS may need to contact organizations within 60 days of data submission. Otherwise, there are no special circumstances since this information collection request does not do any of the following:

- Require respondents to report information to the agency more often than quarterly;
- Require respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Require respondents to submit more than an original and two copies of any document;
- Require respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Is connected with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Require the use of 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 statue 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

- Require respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect die information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

The 60-day notice was published in t he Federal Register on 04/24/2019 (84 FR 17166) and CMS received a total of fourteen comments. Most of the comments requested clarification of the reporting elements and in response CMS made some clarifications to the reporting elements and outlined changes in the attached document.

The 30 day Federal Notice was published in the Federal Register (84 FR 47958) on 09/11/2019, and we received only one comment with no changes made to the reporting requirements. The commenter from Blue Cross and Blue Shield Association (BCBSA) expressed the concern that CMS's approach to collecting additional telehealth benefits data by county creates an increased burden for MA plans. Their example was based on a misinterpretation of CMS' approach. Specifically, their interpretation would require an MA plan to report a 500 row listing for five individual telehealth providers offering dermatology that covered 100 counties (five individual dermatologist times 100 counties served). Instead, we are asking plans to list counties and states for each telehealth specialty type listed by the plan. Therefore, the MA plans would be required to list the 100 counties served by the specialty type dermatology.

9. Payments/Gifts to Respondents

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

10. Confidentiality

CMS will adhere to all statutes, regulations, and agency policies regarding confidentiality.

11. Sensitive Questions

Consistent with federal government and CMS policies, CMS will protect the confidentiality of the requested proprietary information. Specifically, only information within a submitted application (or attachments thereto) that constitutes a trade secret, privileged or confidential information, (as such terms are interpreted under the Freedom of Information Act and applicable case law), and is clearly labeled as such by the Applicant, and which includes an explanation of how it meets one of the expectations specified n 45 CFR Part 5, will be protected from release by CMS under 5 U.S.C. §552(b) (4). Information not labeled as trade secret, privileged, or confidential or not including an explanation of why it meets one or more of the FOIA exceptions in 45 CFR Part 5 will not be withheld from release under 5 U.S. C.
552(b) (4).

12. Burden Estimates (Hours & Wages)

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates for all salary estimates http://www.bls.gov/oes/current/oes_nat.htm. In this regard, Table 1 below presents the mean hourly wage, the cost of fringe benefits, and the adjusted hourly wage.

Anticipated staff performing the activities required of this data collection and reporting vary, but we believe computer systems analysts would be the primary staff person responsible for this work. We believe that other staff that are involved have a similar wage therefore we use an average hourly rate of $90.02/hour (including the fringe benefits adjustment) was used to calculate estimated costs.

We adjusted 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.

Table 1: National Occupational Mean Hourly Wage and Adjusted Hourly Wage

Occupation Title	Occupation Code	Mean Hourly Wage	Fringe Benefit ($/hr.)	Adjusted Hourly Wage ($/hr.)
Computer Systems Analyst	15-1121	$45.01	$45.01	$90.02

Burden Estimates

The burden associated with this ICR is the time and resources it takes to develop computer code, to "de-bug" computer code, gather the "raw" data, "clean" the data in order to eliminate errors, enter data, to compile the data, review technical specifications, and perform tests on the data. Also included is burden that is not strictly "technical." "Non-technical" aspects of the burden include time to read instructions, answer questions, research solutions to any impediments, to develop estimates of any additional human resources needed, and to use other administrative resources involved in improving the reporting sections.

We used the average hour estimates per contract and reporting section that were applied in the 2019 ICR and updated those estimates using May 2018 wage data and the number of approved contracts for the 2019 reporting year. To estimate the burden for telehealth we used the burden hours estimated for Rewards and Incentives reporting section. We believe this is the best estimate due to the similarities of the file layout, specifically the number of data elements and the use of free text for entering data. See section 15 of this Supporting Statement for a more detailed discussion of this package's program changes and burden adjustments.

Burden Summary

Table 2: Annual Record Keeping and Reporting Requirements

Potential no. of respondents (based on the number of approved contracts for 2019)	No. of responses per contract based on number of Part C reporting sections	No. of Responses (No. of Respondents*Reporting Frequency) - based on no of 2019 approved contracts	Burden per Response (total annual burden hours/no. of respondents)	Total annual burden hours for all Part C reporting sections	Hourly labor cost of Part C Reporting ($/hour)	Total Cost for all Part C Reporting
594	**8**	**4,752**	**39.55**	**187,926**	**$90.02**	**$16,917,113**

Please note that respondents usually have more than one response per respondent because each reporting section is counted as one response and respondents (plans) generally report on multiple reporting sections. If a plan reports on eight sections annually, that would be eight responses for that particular plan. The number of approved contracts for CY 2019 reporting is 594, more than the 566 approved 2018 contracts used in the previous burden estimates.

This discrepancy may have been have due to the lack of updated information available for the previous ICR.

Information Collection Instruments/Instructions

Medicare Part C Plan Reporting Requirements Technical Specifications Document Contract Year 2020. This document provides a description of the reporting sections, reporting timeframes and deadlines, and specific data elements for each reporting section.

13. Capital Costs

There is no capital cost associated with this collection because as indicated above, MAOs are familiar with the electronic system used to fill out this data, HPMS.

14. Cost to Federal Government

The estimated annual cost is $300,000 to support reporting through the Health Plan Management System (HPMS). This is the same as previously reported. This is a "standard" estimate that we have used in our ICRs when the Health Plan Management System resources support the CMS information processing and reporting role.

15. Program and Burden Changes

In response to the 60 day comments, a new data element C was added for Telehealth Reporting for clarification purposes. Despite the additional element there were no changes to the burden estimate because the number of elements for Telehealth are now equivalent to the number of data elements for the Part C Rewards and Incentives

reporting section. A crosswalk of changes between the 60 day and 30 day documents is attached.

The table below has the estimated burden changes in hours and costs for the 2020 ICR. We estimated the number of contracts reporting in 2019 based on the number of contracts that will be reporting in CY 2019 (n=594). The average number of annual responses for the Part C reporting section was then 594 x 1=594 for sections reporting annually. Total hour change in burden is estimated at an increase cost of $1,196,379.84 hours for Telehealth which is inclusive of the cumulative total of $2,039,746.56 cost increase for Part C Reporting.

Table 3: Estimated Cost of Information Collection Requirements (ICR)

Reporting Section	2019	2019 Cost	2020	2020 Cost	Increase/Decrease
Telehealth	0	0	13,290	$1,196,379.8 4	
Total Burden	**166,824**	**$14,877,3**	**187,926**	**$16,917,112.**	**$2,039,747**

16. Publication/Tabulation Dates

The data are collected and validated annually. CMS makes data available to the public by posting the Part C and the Part D annual reports on the CMS.gov website. The 2017 annual report for Part C is currently available at the CMS.gov website listed below:
https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2017-Parts-C-and-D-Annual-Report-July-2019.zip

In addition, CMS makes data from some reporting sections available on an annual basis in the form of public use files (PUFs) in support of its transparency goals. The data is released late in the calendar year once CMS has verified that it is accurate. The 2017 public use files for Part C reporting is also available on the CMS.gov website at:
https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2017-Parts-C-and-D-Reporting-Requirements-PUF-not-incl-Part-D-MTM-data.zip

17. Expiration Date

The expiration date will be displayed.

18. Certification Statement

There are no exceptions to the certification statement.

19. Collections of Information Employing Statistical Methods

This information collection does not require statistical analyses to be conducted by the reporting organizations.