Supporting Statement for Paperwork Reduction Act Submissions
Medication Therapy Management Program – Standardized Format
CMS-10396, OMB 0938-1154

Note: The currently approved title of this collection of information request is, "Medication Therapy Management Program Improvements." In this iteration we are revising the title to read, "Medication Therapy Management Program - Standardized Format."

Background

Section 1860D–4(c) of the Social Security Act ("the Act") requires all Part D plan sponsors to have a Medication Therapy Management (MTM) program that is designed to assure, with respect to targeted beneficiaries, that covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events. This requirement was codified at § 423.153(d)(1) in the January 2005 Part D final rule (70 FR 4279). CMS subsequently finalized a requirement at § 423.153(d)(1)(vii)(B) specifying that, beginning in 2011, MTM programs must offer each MTM enrollee an annual comprehensive medication review (CMR) unless the beneficiary is in a long-term care (LTC) setting (75 FR 19772 through 19774). For 2013 and subsequent plan years, the Affordable Care Act (ACA) amended the Act by adding section 1860D– 4(c)(2)(C)(i), which requires all Part D sponsors to offer all MTM enrollees an annual CMR. Consistent with the statutory change, CMS revised the regulation at § 423.153(d)(1)(vii)(B) in the April 2012 final rule (77 FR 22072) to remove the exemption for residents of LTC settings beginning in 2013.

Sponsors must summarize the CMR and provide an individualized written or printed summary to the beneficiary. The ACA further required that the Secretary, in consultation with relevant stakeholders, develop a Standardized Format for the CMR action plan and summary. In the April 2011 final rule (76 FR 21431), we described our plan to work with stakeholders to develop a Standardized Format for the action plan and summary that may result from the CMR. The final rule also revised §423.153(d)(1)(vii) to require standardized action plans and summaries to comply with requirements specified by CMS for the Standardized Format.

Through extensive engagement with stakeholders, CMS prepared the Standardized Format for the written summary and action plan, which includes three components:

- Beneficiary Cover Letter,
- Medication Action Plan, and
- Personal Medication List.

The Office of Management and Budget (OMB) approved the Standardized Format on January 20, 2012. Part D sponsors have been required to use the Standardized Format for CMR summaries sent to Part D beneficiaries since January 1, 2013. A collection of information revision detailed the additional burden associated with the provision of CMRs with written summaries in Standardized Format to beneficiaries in LTC settings.

In our January 2020 final rule (86 FR 5864), we finalized changes to the Part D MTM program requirements for Part D sponsors to target at-risk beneficiaries (ARBs) under a drug management program (DMP) for enrollment in MTM programs and to furnish MTM enrollees with information on safe disposal requirements. Corresponding changes to the Standardized Format took effect on January 1, 2022. The requirement/burden associated with the preparation of the safe disposal documentation is addressed under OMB control number 0938-0964 (CMS-10141).

This collection of information request solicits OMB approval to: (1) extend the current expiration date for another three years, (2) extend (without change) the currently approved Standardized Format, and (3) update our currently approved burden estimates based on more current data.

A. Justification

1. Need and Legal Basis

Section 1860D-4(c)(2)(C)(i) of the Act requires plan sponsors to offer MTM services that include an annual CMR with a written summary and action plan provided in a standardized format developed in consultation with stakeholders. This requirement is codified at § 423.153(d)(1)(vii)(D), which requires that the standardized action plan and summary comply with requirements specified by CMS for the standardized format. Components of the CMR summary in Standardized Format should include a cover letter, personalized medication list, and action plan if applicable.

2. Information Users

Users include members in a Part D sponsors' plan who are eligible are enrolled in the sponsors' MTM program and offered a CMR. The CMR is a consultation between the MTM provider (such as a pharmacist) with the beneficiary to review their medications.

The MTM provider is either an employee/contractor of the plan itself or of a downstream entity contracted by the plan to provide MTM services.

After a CMR is performed, the sponsor creates and sends a summary of the CMR to the beneficiary that includes a medication action plan and personal medication list using the Standardized Format.

Information collected by Part D MTM programs as required by the Standardized Format for the CMR summary is used by beneficiaries or their authorized representatives, caregivers, and their healthcare providers to improve medication use and achieve better healthcare outcomes.

3. Use of Information Technology

The Standardized Format must comply with applicable industry standards for MTM and electronic data interchange, and should enable CMR data elements to be captured for clinical, reporting or measurement purposes.

The National Council for Prescription Drug Programs (NCPDP) WG10 MTM and Pharmacist Clinical Services Task Group prepared a Health Level Seven (HL7®) Clinical Document Architecture (CDA) template using standard code sets and nomenclature to support the rendering of the CMR summary in Standardized Format from digital data stored in electronic health records. The use of standardized coding systems and industry-supported templates for the Standardized Format will encourage Part D sponsors and MTM vendors to incorporate CMR data in electronic health records, bi-directional digital communications with providers, and other aspects of national health information technology.

The CMS Interoperability Rule (CMS-9115-F) established a framework for sharing the data across the industry, which may be suitable to use when conveying data from the MTM provider to the prescriber. The rule includes encouraging use of HL7® Fast Healthcare Interoperability Resources (FHIR®)-based APIs to make other health information more widely accessible. CMS encourages Part D MTM providers to use FHIR-enabled MTM platforms when providing MTM to Part D enrollees to facilitate integration of the MTM service elements into prescribers' EHRs.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

The Standardized Format, which has been used since January 2013, does not impose a significant impact on small businesses and other small organizational entities. Part D applicants must possess an insurance license and be able to accept risk. Generally, state statutory licensure requirements effectively prevent small organizations from accepting the level of risk needed to provide the pharmacy benefits required in the Medicare Prescription Drug Benefit Program. Medicare Advantage and Part D prescription benefit plans are not small businesses.

6. Less Frequent Collection

The Standardized Format does not affect the timing of the information collection. Use of the format depends on when the CMR is scheduled with the beneficiary. Once enrolled in the sponsors' MTM program, the beneficiaries are offered an annual CMR, and the CMR is scheduled with the beneficiary based on their availability. Then, after the CMR is done, the Standardized Format is used by the sponsor to create the CMR summary to be delivered to the beneficiary.

If a beneficiary does not receive the CMR summary in the Standardized Format, they would not be provided information, including a medication action plan, to reinforce what was discussed in the CMR or could be provided information in an inconsistent manner.

Failure of the Part D sponsor to provide a CMR and summary to MTM program enrollees may result in a lower CMR completion rate and negative impact on the plan's Star Ratings. In addition, Part D sponsors could be subject to compliance actions if they fail to provide CMR summaries in the Standardized Format to MTM enrollees who receive a CMR.

7. Special Circumstances

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;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- 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

Federal Register

The 60-day notice published in the Federal Register (88 FR 88622) on December 22, 2023. We received 7 comments regarding the "My notes and questions" section, the timeline of the Standardized Format implementation, electronic delivery of the CMR summary, and the intended audience of the Recommended To-Do List. We also received a few comments in general support of extending the approval of the current Standardized Format without changes. Comments are attached to this package along with our responses.

The 30-day notice published in the Federal Register (89 FR) on TBD.

Outside Consultation

From June 2018 through September 2018, we tested stakeholders' satisfaction with the now expired Standardized Format and attempted to identify potential revisions. The stakeholders included Medicare beneficiaries and caregivers, and pharmacists and other representatives from Part D plan sponsors, Pharmacy Benefit Managers, and MTM vendors. In general, these stakeholders supported the development of a more streamlined written summary in a chart format with visual cues. The results of these interviews produced a number of potential revisions to the Standardized Format (approved by OMB on October 15, 2021).

Those proposed changes to the Standardized Format did not affect the frequency of instructions, frequency of collection, or the use to which the information is put.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents associated with the Standardized Format. However, there is a Part D Star Rating measure associated with the CMR completion rate, which provides Part D sponsors with an incentive to respond.

10. Confidentiality

CMS will adhere to all statutes, regulations, and agency policies. MTM program materials, including the Standardized Format, that address issues unique to individual members are not subject to review by CMS. Healthcare providers, including those providing MTM services to beneficiaries, are subject to HIPAA privacy and security requirements.

11. Sensitive Questions

The discussion of sensitive issues is inherent in the delivery of healthcare and interactions between patients and their healthcare providers. Accordingly, sensitive issues are likely to be discussed during CMRs and recorded on the Standardized Format. For example, the medication action plan may include a discussion of a beneficiary's failure to comply with their medication therapy, and the personal medication list may include certain medications and conditions that are considered "sensitive" such as mental health disease or HIV/AIDs. These interactions and the use of the Standardized Format are subject to HIPAA privacy and security requirements.

12. Burden Estimates

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS's) May 2022 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following Table presents BLS' mean hourly wage, our estimated cost of fringe benefits and overhead (calculated at 100 percent of salary), and our adjusted hourly wage. The adjusted wages are used to derive our cost estimates.

National Occupational Employment and Wage Estimates

Occupation Title	Occupation Code	Median Hourly Wage ($/hr)	Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Pharmacist	29-1051	63.82	63.82	127.66

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, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Requirements and Associated Burden Estimates

To estimate the cost of preparing the CMR, we note that the CMR is a clinical consultation service and therefore must be administered by a pharmacist, physician, nurse practitioner, or other clinician. Currently, 100 percent of MTM programs employ pharmacists to conduct CMRs, which is the basis of the hourly wage estimate.

The regulatory requirement to provide MTM services, including the Standardized Format, is the responsibility of the plan.

The burden upon Part D Plans to conduct annual, interactive comprehensive medication reviews (CMRs) with written summaries and action plans using the Standardized Format includes:

A. Time and effort to conduct CMRs using the Standardized Format (as discussed in this section 12), and,

B. Printing and postage costs to mail the written summaries to beneficiaries (as discussed in section 13 of this Supporting Statement).

The number of Part D contracts (849) with an approved MTM program is based on the number of MTM program submissions for CY 2024.

Conducting CMRs with the Standardized Format

Using 2022 Part D enrollment data, we estimate that the program size is 3,599,356 out of a total of 49,863,487 Part D enrollees, or 7.22%. The average rate of beneficiaries that accept the CMR offer is 66.2%.

Number of MTM Enrollees Who Will Receive a CMR

Item	Number	Source
Number of enrollees in Part D contracts with MTM in 2022	3,599,356	Internal CMS data
Estimated % of Part D enrollees targeted for MTM	7.22%	Internal CMS Data
Estimated CMR acceptance rate (% of MTM targeted who will receive a CMR)	66.2%	Internal CMS data
Number of Part D enrollees under proposed criteria who will receive a CMR	2,382,774	3,599,356*0.662

This figure is based on our estimate that conducting CMRs and preparing the Standardized Format will require 40 minutes with an average cost of $85.10/CMR (or $127.66/hour).

Regulation under Title 42 of the CFR	Annual Frequency	No. Responses (per respondent)	Total Responses	Time per Response	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
423.153(d)	Annual	1	2,382,774 (Total CMRs)	40 min	1,588,595	127.66	202,800,038

Information Collection Instruments and Instruction/Guidance Documents

Medication Therapy Management Program Standardized Format (No changes)

13. Capital Costs

There are no capital costs associated with the Standardized Format. However, there are fulfillment costs related to the provision of the CMR summary.

Sponsors either use their own pharmacists or hire vendors (who also use pharmacists) to conduct the CMR (see section 12 of this Supporting Statement), then the sponsor or vendor mails or delivers the CMR to the beneficiary. On average we estimate:

Cost per item/page	Cost per CMR (6 pages)
Postage (metered mailing)	$0.64
Paper: $0.007 per page	$0.042

Toner: $0.007 per page	$0.042
Envelope: $0.044 each	$ 0.044
Total Fulfillment Cost	$0.768

TOTAL: $1,829,970 ($0.768/CMR x 2,382,774 CMRs/year)

14. Cost to Federal Government

The cost to develop the currently approved Standardized Format was approximately $270,000. Other than development costs, there are no additional costs to the Federal Government associated with use of the Standardized Format. CMS will not collect the written summaries prepared by MTM programs using the Standardized Format.

15. Changes to Burden

There are no proposed changes to the Standardized Format document. This submission adjusts our burden estimates based upon updated wage information and an increase in the number of CMRs due to updated cost estimates for labor, mailing, and supplies.

Total Change to Burden

The burden to conduct annual interactive CMRs with written summaries in CMS Standardized Format in all care settings beginning in 2021 was 807,774 hours (40 minutes per CMR) with a total cost of $177,074,087 ($80.46 per CMR, for 2,379,512 CMRs).

We estimate that the number of CMRs increased from 807,774 (2021 estimate) to 2,382,774 for the 2024 estimate, an increase of 1,575,000. The annual hours required for these CMRs increased from 1,448,908 (2021 estimate) to 1,588,595 hours for the 2024 estimate (increase of 139,687). The greater number of CMRs results in an estimated higher total cost burden of $204,534,697 in 2024, which is $27,460,610 higher than the 2021 estimate ($177,074,087).

The total annual burden associated with conducting CMRs with the Standardized Format is estimated to be 1,588,595 hours with a cost of $204,630,008 ($202,800,038 for labor + $1,829,970 for fulfillment) across 868 Part D contracts, or 1,830 hours and $235,749 per contract.

16. Publication/Tabulation Dates

The current Standardized Format document (OCN 0938-1154) is posted on the CMS Part D MTM webpage at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM and expires on February 29, 2024.

17. Expiration Date

The expiration date is displayed in the footnotes on each page of the MTM Standardized Format.

18. Certification Statement

There are no certification statements.

B. Collections of Information Employing Statistical Methods

Sponsors are required to submit certain data to CMS regarding their MTM programs pursuant to the Part D Reporting Requirements (see OMB control number 0938-0992). Sponsors already report the number of beneficiaries eligible for MTM and the number of beneficiaries who opted out of the MTM program, the receipt of the CMR, the number of targeted medication reviews, number of prescriber interventions, and the change(s) in therapy directly resulting from the MTM interventions. These data will enable CMS to perform more robust analysis of the MTM programs and interventions, evaluate the revised MTM requirements, and identify additional best practices.