Supporting Statement for Paperwork Reduction Act Submissions
Medication Therapy Management Program Improvements
(CMS-10396, OMB 0938-1154)

Background

The Medicare Modernization Act of 2003 (MMA) under title 42 CFR Part 423, Subpart D, establishes the requirements that Part D sponsors, an organization which has one or more contract(s) with CMS to provide Part D benefits to Medicare beneficiaries, must meet with regard to cost control and quality improvement including requirements for medication therapy management (MTM) programs. MTM is a patient-centric and comprehensive approach to improve medication use, reduce the risk of adverse events, and improve medication adherence. At minimum, a Part D sponsors' MTM program must offer to its enrollees an annual comprehensive medication review (CMR) with written summaries, quarterly targeted medication reviews, and follow-up interventions for both beneficiaries and prescribers when necessary. The initial CMS regulations for MTM established a general framework that allowed Part D sponsors flexibility to develop and implement MTM programs that best meet the needs of their specific patient populations and achieve the best therapeutic outcomes.

The Affordable Care Act (ACA) under Section 10328 specified changes to Part D MTM programs, including many that were already implemented by CMS in 2010 through sub-regulatory guidance. The ACA further required that the Secretary, in consultation with relevant stakeholders, develop a Standardized Format for the CMR action plan and summary. In CMS' final rule (76 FR 21431), "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes," which was published in the Federal Register on April 15, 2011, 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, CMS form 10396, for a 3-year period and issued OMB Control Number 0938-1154 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.

Section 10328 of the ACA also amended section 1860D-4(c)(2) of the Social Security Act (the Act) to require that all targeted beneficiaries be offered a CMR. As amended, the Act did not

provide a basis for creating an exception to the requirement to offer a CMR based on the setting of care. Part D regulations had exempted sponsors from the requirement to offer CMRs to beneficiaries in long-term care (LTC) settings. In CMS' final rule, 76 FR 21431, "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes," which was published in the Federal Register on April 12, 2012, we described the requirement that Part D sponsors offer a CMR to beneficiaries in LTC settings, effective January 1, 2013.

A revision to OCN 0938-1154 detailed the additional burden associated with the provision of CMRs with written summaries in Standardized Format to beneficiaries in LTC settings. In August 2017, OMB extended the approval of OCN 0938-1154, including nonmaterial changes to the components of the written summary and action plan, until August 31, 2020.

In the February 2020 proposed rule (85 FR 9002), CMS proposed to implement two sections of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act which amended the Part D MTM requirements. Section 6103 of the SUPPORT Act requires Part D plans to provide all MTM targeted individuals with information about the safe disposal of controlled substances, including information on drug takeback programs, in-home disposal, and cost-effective means for disposal. Section 6064 of the SUPPORT Act requires that at-risk beneficiaries for prescription drug abuse (ARBs) be targeted for enrollment in the Part D plan's MTM program. As noted in the May 2020 final rule (85 FR 33796), CMS intends to address all of the remaining proposals from the February 2020 proposed rule in subsequent rulemaking and plans to make any provisions adopted in the subsequent, second final rule, although effective on or before January 1, 2021, applicable no earlier than January 1, 2022. This includes the proposals related to SUPPORT Act Sections 6103 and 6064.

CMS proposed rule-related changes to the Standardized Format consistent with these SUPPORT Act provisions with the February 2020 proposed rule with a 60-day comment period. We also proposed non-rule related revisions to optimize the utility of the CMR summary for beneficiaries while reducing burden on Part D sponsors based on feedback from limited cognitive interviews with consumers and other stakeholders conducted in 2018[1]. The non-rule notice was published to the Federal Register for the 60-day comment period on February 24, 2020. With these submissions, we requested revision and extension of the current approval (OCN 0938-1154) for an additional three (3) years, with the proposed changes taking effect on January 1, 2021 pending OMB approval.

After review of the comments in response to the two solicitations, any subsequent rule and non-rule related proposed changes to the Standardized Format are intertwined and cannot be separated. Also, the 30-day notice for OCN 0938-1154 cannot be published for public comment until these SUPPORT Act proposals are addressed in subsequent rulemaking. Therefore, we are requesting an extension of the currently approved Standardized Format through December 31, 2021.

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1 See Federal Register/ Outside Consultation section 8 below for references.

A. Justification

1. Need and Legal Basis

Under title 42 CFR Part 423, Subpart D, each Part D sponsor must offer a minimum level of MTM services for each beneficiary enrolled in the MTM program that includes interventions for both beneficiaries and prescribers, an annual CMR with written summaries, quarterly Targeted Medication Reviews (TMRs) with follow-up when necessary, and standardized action plans and summaries that comply with requirements as 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

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.

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.

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.

The information users are beneficiaries or their authorized representatives, caregivers, and their healthcare providers as stated in this section.

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 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 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 recent CMS Interoperability Rule (85 CFR 25510) finalized 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 application programming interfaces (APIs) to make other health information more widely accessible. CMS will encourage 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 is not a duplication of effort. The Standardized Format submitted with this request for extension will replace the current Standardized Format for CMR action plans and summaries that are given to beneficiaries.

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 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 (85 FR 9002) for proposed rule related revisions to the Standardized Format (CMS-10396) was published at: https://www.govinfo.gov/content/pkg/FR-2020-02-18/pdf/2020-02085.pdf; https://www.federalregister.gov/documents/2020/02/18/2020-02085/medicare-and-medicaid-programs-contract-year-2021-and-2022-policy-and-technical-changes-to-the. Comments were due by April 6, 2020.

The 60-day notice for proposed non-rule related revisions was published (85 FR 10444) on 2/24/2020 at: https://www.govinfo.gov/content/pkg/FR-2020-02-24/pdf/2020-03533.pdf; https://www.federalregister.gov/documents/2020/02/24/2020-03533/agency-information-collection-activities-proposed-collection-comment-request. Comments were due by April 24, 2020.

Comments received related to the effective date of the current Standardized Format or proposed revisions, which support this extension request, are attached to this package along with our responses.

As discussed in the Background section of this Supporting Statement, the 30-day notice for CMS-10396 will be published for public comment when the applicable SUPPORT Act proposals are addressed in subsequent rulemaking. The 30-day notice will address the remaining comments received in response to the two solicitations, provide additional proposed revisions if applicable to address the comments, and propose a date for when the changes would become effective. CMS staff will prepare a response document summarizing all received comments and their responses. A package will be delivered for OMB review.

Outside Consultation

From June 2018 through September 2018, we tested stakeholders' satisfaction with the currently approved 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. These changes were listed in the crosswalk documents with the two 60-day submissions.

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. A description of the revisions to the CMR documents was in the Supporting Statements for the two 60-day packages.

9. Payments/Gifts to Respondents

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

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 (Hours & Wages)

Wage Estimates

To estimate the labor cost of preparing the CMS, 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 rate estimate. To derive average costs for the private sector, we used data from the U.S. Bureau of Labor Statistics' (BLS's) May 2019 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 the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage. The adjusted wages are used to derive our cost estimates.

National Occupational Employment And Wage Estimates

Occupation Title	**Occupation Code**	**Mean Hourly Wage ($/hr)**	**Benefits and Overhead ($/hr)**	**Adjusted Hourly Wage ($/hr)**
All Occupations [used for impact on enrollees filling out forms]	00-0000	25.72	0	25.72
Pharmacist	29-1051	60.34	60.34	120.68

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

Requirements and Associated Burden Estimates

With this request for revision, we have re-estimated and adjusted the burden to conduct CMRs to 1,448,908 (40 minutes or 0.6667 hours per CMR) with a total cost of $174,854,217 ($80.46 per CMR, for 2,173,703 CMRs). This change accounts for an increase in the number of Part D enrollees in contracts with MTM programs, as well as the cost of printing and postage for CMR summaries. For details, please see section 15 of this Supporting Statement.

The burden upon Part D Plans to conduct annual, interactive comprehensive medication reviews (CMRs) with written summaries and action plans using the new Standardized Format beginning January 1, 2017 includes:

A. Time and effort to conduct CMRs using the Standardized Format, and,

B. Printing and postage costs to mail the written summaries to beneficiaries.

The number of active **Part D contracts (735)** with an approved MTM program is based on the number of MTM program submissions for CY 2020. We expect this number to be similar in 2021.

Conducting CMRs with the Standardized Format: This figure is based on our estimate that

conducting CMRs with the Standardized Format will require 40 minutes with an average cost of $80.46/CMR (or $120.68/hour).

Requirements	Annual Frequency	No. Responses (per respondent)	Total Responses	Burden per Response	Total Annual Burden (hours)	Labor Cost ($/hr)	Total Cost ($)
423.153(d)	Annual	1	2,173,254 (Total CMRs)	40 min	1,448,908	120.68	174,854,217

Information Collection Instruments and Instruction/Guidance Documents

Medication Therapy Management Program Standardized Format (Current)

13. Capital Costs

There are no capital costs associated with the Standardized Format.

14. Cost to Federal Government

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 changes to the Standardized Format document submitted with this extension request. This submission adjusts our burden estimates based upon updated wage information, more accurate estimates for paper and toner costs, and an increase in number of CMRs since 2017. Although the number of MTM-eligible beneficiaries has decreased over the last few years, the number of CMRs completed has been increasing. Assuming these trends are linear, we used data from 2015 through 2018 to project the number of MTM eligible beneficiaries and CMRs for 2021.

The SUPPORT Act created provisions that require MTM programs to target at-risk beneficiaries (ARBs) for prescription drug abuse and to provide all MTM program enrollees with information regarding the safe disposal of prescription drugs that are controlled substances. Changes to the Standardized Format and burden calculations related to the SUPPORT Act and February 2020 proposed rule will be submitted in a separate 30-day PRA package at a later date.

Since 2017, the number of CMR summaries in CMS Standardized Format delivered to Part D beneficiaries has increased. This is due to increased Part D enrollment and a greater percentage of enrollees who receive a CMR. However, the number of MTM-eligible Part D enrollees has decreased from 2015 to 2018, which means the overall percentage of Part D

enrollees who receive a CMR is increasing as well. See the calculations below for additional information.

A. <u>Conducting CMRs in all settings with the Standardized Format</u>: The new burden cost calculation is based on our estimate that 5.34% of Part D enrollees will be targeted for MTM, and that 87% of these targeted beneficiaries will accept a CMR offer. These percentages are based on internal data collected by CMS in previous years. The number of MTM enrollees in 2020 is reduced by nearly 1.6 million due to the Part D plans participating in the CMMI Enhanced MTM model, which is not subject to the requirements of a traditional Part D MTM program. The estimated number of beneficiaries in an enhanced MTM program has been excluded from the burden calculations in this section as shown below. The number of Part D enrollees who are expected to receive a CMR in 2021 under the current MTM enrollment criteria is 2,173,703.

ESTIMATING NUMBER OF MTM ENROLLEES WHO WILL RECEIVE A CMR

Item	Number	Source
Estimated # of enrollees in Part D contracts with MTM in 2021	48,338,879	Internal CMS data
Estimated # of Part D enrollees in Enhanced MTM	1,550,300	Internal CMS data
Percentage of Part D enrollees not in Enhanced MTM program	96.7929%	1,550,300/48,338,879
Estimated % of Part D enrollees targeted for MTM	5.34%	Internal CMS Data
Estimated CMR acceptance rate in 2021 (% of MTM targeted who will receive a CMR)	87%	Internal CMS data
Part D enrollees who are not in Enhanced MTM program	46,788,579	48,338,879 – 1550,300
Number of Part D enrollees under current criteria who will receive a CMR	2,173,703	46,788,579 * 5.34% * 87%

B. <u>Fulfillment Burden in all settings</u>: The lower fulfillment cost, $0.96, as compared to $1.40 in 2017 is due to more accurate estimates for paper and toner costs. We assume that the cost of envelopes at $0.08 each and finishing (stuffing and folding) at $0.08 remain the same as in 2017.

Cost per item/page	Cost per CMR (10 pages)
Postage (1st class mail) $0.70	$0.70
Paper: $0.005 per page	$0.05
Toner: $0.005 per page	$0.05
Envelopes: $0.08 each	$0.08
<u>Folding & stuffing: $0.08 each</u>	<u>$0.08</u>
Total Fulfillment Cost	**$0.96**

TOTAL: $0.96/CMR x 2,173,703 CMR/year = $2,086,755

C. <u>Total Change to Burden</u>:

The burden to conduct annual interactive CMRs with written summaries in CMS Standardized Format in all care settings beginning in 2017 was 807,774 hours (40 minutes per CMR) with a total cost of $98,629,205 ($81.40 per CMR, for 1,211,661 CMRs).

We estimate that the number of CMRs increased from 1,211,661 (2017 estimate) to 2,173,254 for the 2021 estimate, an increase of 961,593.
The annual hours required for these CMRs increased from 807,774 (2017 estimate) to 1,448,908 hours for the 2021 estimate (increase of 641,134). The greater number of CMRs results in an estimated higher total cost burden of $174,854,217 in 2021, which is $74,528,687 higher than the 2017 estimate ($100,325,530).

The total annual burden associated with conducting CMRs with the Standardized Format is estimated to be **1,448,908 hours** with a cost of **$174,854,217** ($2,086,755 for fulfillment + $174,854,217 for labor) across 735 Part D contracts, or 1,971 hours and $240,736 per contract.

16. Publication/Tabulation Dates

The currently approved Standardized Format is posted on the CMS Part D MTM webpage at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.

We are requesting an extension of the currently approved Standardized Format through December 31, 2021.

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.