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 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.

After analyzing common practices, requirements for 2010 were revised for greater consistency among the Part D MTM programs and to raise the level of the MTM interventions offered to positively impact the medication use of Medicare Part D beneficiaries. For complete details of MTM program changes for 2010, see pages 68-73 of the 2010 Call Letter (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads//2010CallLetter.pdf).

One of the changes to Part D MTM programs for 2010 included the following requirement:

> Sponsors must offer an interactive, person-to-person comprehensive medication review (CMR) by a pharmacist or other qualified provider at least annually, and provide an individualized written or printed summary to the beneficiary. A CMR is a review of a beneficiary's medications, including prescription and over-the-counter (OTC) medications, herbal therapies, and dietary supplements, which is intended to aid in assessing medication therapy and optimizing patient 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. 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, "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, CMS-4157-FC, "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 July 2014, OMB extended the approval of OCN 0938-1154, including nonmaterial changes to the components of the written summary and action plan, until July 30, 2017.

The purpose of this submission is to request an extension with adjustments to our burden estimates to account for increased number of Part D enrollees, cost of printing, postage, and length of the CMR summary. For details, please see section 15 of this Supporting Statement.

A. Justification

1. Need and Legal Basis

   Under title 42 CFR Part 423, Subpart D, each Part D sponsor must offer standardized action plans and summaries that comply with requirements as specified by CMS for the standardized format. The OMB approval of this collection instrument expires on July 31, 2017. With this submission, we are requesting an extension of the current approval (OCN 0938-1154) for an additional three (3) years.

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 medication therapy management 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 an 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.

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 information collection. The scheduling of CMRs and subsequent use of the standardized format are determined by Part D plans and their beneficiaries.

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, they 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.

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 on October 31, 2016 (81 FR 75406). Over 30 public comments were received from 11 organizations, and are attached to this package along with our responses.

This package has been revised subsequent to the publication of the 60-day notice. There have been changes/updates made to the burden estimates to incorporate increased postage cost and

other costs related to mailing.

The 30-day notice published in the Federal Register on February 21, 2017 (82 FR 11222). No comments were received.

Outside Consultation

From October 2014 through March 2015, we tested stakeholders' satisfaction with the standardized format and attempted to identify potential revisions to the standardized format. The stakeholders included a diverse technical expert panel of MTM stakeholders, MTM providers and Medicare beneficiaries. These activities demonstrated that beneficiaries are satisfied with the standardized format without a consensus for specific revisions to the standardized format.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents associated with the standardized format.

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)

The burden to conduct annual interactive CMRs with written summaries in CMS standardized format in all care settings beginning in 2015 was 186,901 hours (40 minutes per CMR) with a total cost of $22,683,280 ($80.91 per CMR, for 280,352 CMRs).

With this request for extension, we have re-estimated and adjusted the burden to conduct CMRs to 807,774 hours (40 minutes per CMR) with a total cost of $98,629,205 ($81.40 per CMR, for 1,211,661 CMRs). This change accounts for an increase in the number of Part D

enrollees eligible for MTM, as well as an increase in the cost of printing and postage for CMR summaries which are longer than original estimates. 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.

Hourly labor costs used in the following estimates include direct wages plus fringe benefits, overhead, general and administrative expenses and fee. The number of active **Part D contracts (591)** with an approved MTM program is based on the number of MTM program submissions for CY 2017.

A. 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 $81.40/CMR (or $122.10/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	1,211,661 (Total CMRs)	40 min	807,774	122.10	98,629,205

B. Fulfillment Burden: This figure is based on our estimate that the standardized format will require 10 pages for each CMR summary and be mailed to beneficiaries, costing $1.40 per CMR:

Cost per item/page	Cost per CMR (10 pages)
Postage (1st class mail) $0.70	$0.70
Paper: $0.02 per page	$0.20
Toner: $0.04 per page	$0.40
Envelopes: $0.02 each	$0.02
Folding & stuffing: $0.08 each	$0.08
Total Fulfillment Cost	**$1.40**
TOTAL: $1.40/CMR x 1,211,661 CMR/year = $1,696,325	

C. TOTAL BURDEN

The total annual burden associated with conducting CMRs with the standardized format is estimated to be **807,774 hours** with a cost of **$100,325,530** ($98,629,205 + $1,696,325) across 591 Part D contracts, or 1,367 hours and $169,756 per contract.

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 Standardized Format document. As discussed, this submission adjusts our burden estimates based upon increased postage rates and other mailing costs that were not included in previous submissions, in addition to an increase in number of CMRs since 2014.

Since 2015, 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. The higher CMR rates may be influenced by a new 2016 Star Ratings measure, MTM Program Completion Rate for CMR. First class postage rates also increased since 2015. See the calculations below for additional information.

A. Conducting CMRs in all settings with the standardized format: The new labor cost calculation is based on our estimate that 2.559% of enrollees in Part D contracts with MTM programs will receive CMRs with the standardized format, and the number of beneficiaries in Part D contracts with MTM Programs has increased 8.11% each year from 2015 to 2017. The number of MTM enrollees in 2017 is reduced by nearly 1.6 million due to the Part D plans participating in the CMMI Enhanced MTM model.

Enrollees in Part D contracts with MTM in 2015	41,863,180
Number of CMRs in 2015	1,071,386
Percent who received a CMR in 2015	2.559%
Estimated # of enrollees in Part contracts with MTM in 2017	48,928,731
Estimated # of enrollees in CMMI Enhanced MTM model	1,579,726
Net enrollment in Part D contracts with MTM in 2017	47,349,005
Estimated # 2017 CMR summaries (# net enrollees x CMR rate)	1,211,661

B. Fulfillment Burden in all settings: The higher fulfillment cost, $1.40, as compared to $0.91 in 2015 is due to an increase in first class postage from $0.61 to $0.70; in addition, we factored in the cost of envelopes at $0.02 each and finishing (stuffing and folding) at $0.08. This figure is based on a revised estimate that the standardized format will require an average of 10 pages for each CMR summary and will be mailed to beneficiaries.

Cost per item/page	**Cost per CMR (10 pages)**
Postage (1st class mail) $0.70	$0.70
Paper: $0.02 per page	$0.20
Toner: $0.04 per page	$0.40
Envelopes: $0.02 each	$0.02
Folding & stuffing: $0.08 each	$0.08
Total Fulfillment Cost	**$1.40**

C. <u>Total Change to Burden</u>: We estimate that the number of CMRs increased from 280,352 (2015 estimate) to 1,211,661 for the 2017 estimate, an increase of 931,309. The annual hours required for these CMRs increased from 186,901 (2015 estimate) to 807,774 hours for the 2017 estimate (increase of 620,873). The greater number of CMRs and higher fulfillment cost results in an estimated higher total cost burden of $100,325,530 in 2017, which is $77,642,250 higher than the 2015 estimate ($22,683,280).

16. <u>Publication/Tabulation Dates</u>

    The final standardized format, as discussed in the Final 2013 Call Letter, is posted on www.cms.gov. Part D Plan sponsors were required to comply with the requirements of the standardized format as of January 1, 2013.

17. <u>Expiration Date</u>

    The expiration date is displayed.

18. <u>Certification Statement</u>

    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.