Supporting Statement for Paperwork Reduction Act Submissions
Medication Therapy Management (MTM) 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. 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 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 detailed the additional burden associated with the provision of CMRs with written summaries in Standardized Format to beneficiaries in LTC settings. In August 2017 we made nonmaterial changes to the components of the written summary and action plan.

Serving as the 60-day notice, the proposed rule (CMS-4190-P, RIN 0938-AT97) filed for public inspection on February 5, 2020 and published on February 18. Comments are due by April 6, 2020. The proposed changes would comply with provisions from the SUPPORT Act which require that part D plan sponsors provide safe disposal information to all beneficiaries enrolled in an MTM program. Sponsors would also be required to target beneficiaries determined to be at-risk for opioid abuse (at-risk beneficiaries or ARBs) to receive MTM services including an annual CMR with a summary in the Standardized Format. The burden for including an additional page in the summary and increasing the number of beneficiaries targeted has been updated (see sections 12 and 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 August 31, 2020.

   Section 6103 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act amended MTM requirements in 1860D-4(c)(2)(B) of the Act by creating subsection (ii) which 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 amended section 1860D-4(c)(2)(A)(ii) of the Act by adding a new provision requiring that at-risk beneficiaries (ARBs) for prescription drug abuse be targeted for enrollment in the Part D plan's MTM program.

   With this submission, we are requesting revision and extension of the current approval (OCN 0938-1154) for an additional three (3) years. The proposed changes would take effect on January 1, 2021 pending OMB approval.

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 sponsor's plan who are eligible are enrolled in the sponsor's 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.

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.

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

Serving as the 60-day notice, the proposed rule (CMS-4190-P, RIN 0938-AT97) filed for public inspection on February 5, 2020 and published on February 18. Comments are due by April 6, 2020.

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)

Wage Estimates

To estimate the labor 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 rate estimate.

To derive average costs for the private sector, we used data from the U.S. Bureau of Labor Statistics' (BLS's) May 2018 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)**
Pharmacist	29-1051	59.45	59.45	118.90

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.

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.

Requirements and Associated Burden Estimates

The burden upon Part D Plans to conduct annual, interactive comprehensive medication

reviews (CMRs) with written summaries and action plans using the Standardized Format beginning January 1, 2021 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 Standardized Format currently approved by OMB via a PRA package sets out a burden of **807,774 hours** at a cost of **$100,325,530.**

The SUPPORT Act expanded the population of beneficiaries that must be targeted for Part D MTM starting in 2021 and also added an additional requirement that information on the safe disposal of prescription drugs that are controlled substances be furnished to all MTM program enrollees.

These new requirements would revise the Standardized Format such that there would be an increased burden estimated to be **5,614 hours** at a cost of **$697,069** ($7,747 non-labor + $667,505 labor + $21,817 labor) across 735 Part D contracts, or 7.64 hours and $948 per contract.

The total burden would be **813,388 hours** at a cost of **$101,022,599.** See Summary of Burden Estimates below.

Summary of Burden Estimates

Burden Category	No. Respondents	Total No. Responses (annual)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting ($/hr)	Total Annual Cost ($)
Currently Approved Burden (Labor and non-Labor, Combined)	591	1,366.79	1.0	807,774	Varies	1,696,325
Proposed Changes (CMS-4190-P)	+144	+2,198,517	Varies	+5,614	Varies	+697,069
Balance	**735**	**2,199,884**	**No change**	**813,388**	**Varies**	**2,393,394**

Collection of Information Instruments and Instruction/Guidance Documents

Medication Therapy Management Program Standardized Format (Revised)

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

Serving as the 60-day notice, the proposed rule (CMS-4190-P, RIN 0938-AT97) filed for public inspection on February 5, 2020 and published on February 18. Comments are due by April 6, 2020.

The SUPPORT Act expanded the population of beneficiaries that must be targeted for Part D MTM starting in 2021 and also added an additional requirement that information on the safe disposal of prescription drugs that are controlled substances be furnished to all MTM program enrollees; we are now proposing to modify our Part D regulations to conform with the changes to the MTM requirements enacted in the SUPPORT Act. These provisions of the SUPPORT Act will affect the number of beneficiaries enrolled in MTM programs and potentially some of the content for the Standardized Format for the CMR due to safe disposal information requirements and, therefore, the burden estimates for this document.

We are proposing to include the safe disposal information as part of the Medication Action Plan as shown in the revised Standardized Format and as indicated in part b of this section. As noted in the Crosswalk of changes between 2017 and 2020, the only additional text to the Standardized Format is related to the safe disposal information to beneficiaries.

Additional revisions made to the Standardized Format which were not part of the proposed rule are reflected in the updated document, but will have a separate PRA package. Comments to non-proposed rule related changes should be submitted separately through that PRA package.

a. <u>Burden of the expanded population of beneficiaries that must be targeted for enrollment in MTM programs</u>: We estimate that in 2021 there will be 48,338,879 beneficiaries enrolled in Part D plans with MTM programs. Out of these, 1,550,300 (or 3.2071% =1,550,300/48,338,879) are estimated to be enrolled in an Enhanced MTM program under the Enhanced MTM Model, which is a model tested by the Center for Medicare and Medicaid Innovation (the Innovation Center) under section 1115A(b) of the Act and is not subject to the current or proposed MTM requirements, and therefore these beneficiaries are excluded from the total number of Part D enrollees. This leaves 46,788,579 Part D enrollees (96.7929% =46,788,579/48,338,879) who may be eligible for MTM if they meet the targeting criteria.

According to internal data, we estimate that the SUPPORT Act requires targeting 10,000 ARBs for MTM in 2021, of which 9,679 (10,000*96.7929 percent of enrollees who are not in an enhanced MTM program) will be targeted for a CMR since those ARBs in the Enhanced MTM model plans may not be targeted. Based on our previous experience with the MTM program, we estimate that 87 percent of beneficiaries targeted for MTM under the current requirements will accept the offer of a CMR. We assume this percentage will also apply to beneficiaries who will be enrolled in MTM programs under the new criteria; therefore, 8,421 ARBs (9,679 targeted ARBs not in an enhanced MTM program * 87 percent who are expected to accept a CMR) are expected to accept a CMR based on the proposed provision.

To estimate the burden on Part D plans of furnishing CMRs to the 8,421 ARBs who would be expected to accept the offer of a CMR under the proposed policy, we separately calculate the non-labor cost of mailing and the labor cost of preparing the CMR and packaging it.

To estimate the cost of mailing, we note that paper costs $2.50 per ream (500 sheets) of paper (at $0.005 per sheet) and toner costs $50.00 and lasts for 10,000 sheets. Since CMR summaries contain private health information, they must be mailed first class for which postage costs $0.70 per mailing. Based on industry standards, we assume envelopes cost $0.08, and folding and stuffing costs about $0.08 per document. We therefore estimate the non-labor cost to print and mail a CMR summary in CMS's Standardized Format will be $0.92 per mailing. This results in a cost of $7,747 ($0.92 cost per mailing * 8,421 ARBs).

This figure is based on our estimate that the Standardized Format requires 6 pages on average and would be mailed first class to ARBs, costing $0.92 per CMR:

Cost per item/page	**Cost per CMR (6 pages)**
Postage (1st class mail) $0.70	$0.70
Paper: $0.005 per page	$0.035
Toner: $0.005 per page	$0.03
Envelopes: $0.08 each	$0.08
Folding & stuffing: $0.08 each	$0.08
Total Fulfillment Cost	**$0.92**

Industry standards indicate that an average CMR requires 40 minutes or 0.6667 hours at $118.90/hr for a pharmacist to complete and would result in a CMR summary that averages 6 pages in length. This results in an annual labor burden of 5,614 hours (8,421 ARBs * 0.6667 hours) at a cost of $667,505 (5,614 hours * $118.90/hr).

Therefore, the estimated total annual cost of providing CMRs to 8,421 ARBs would be $675,252 ($667,505 labor costs + $7,747 non-labor mailing costs).

b. <u>The burden of mailing safe disposal information to all MTM program enrollees as part of the CMR summary</u>: We estimate the safe disposal information will take no more than one page and can be included in the Medication Action Plan of the CMR

summary. Therefore, the cost of mailing one extra page per enrollee is $0.01 (1 page * $2.50 / ream of 500 sheets + 1 page * $50 toner/10,000 sheets). We note that the envelope to mail the CMR is already being paid for under current regulations (although folding and stuffing of 7 pages versus 6 pages might require some extra effort, we do not believe this will raise the $0.08 current cost); the $0.70 first class postage for 2 ounces is sufficient for 7 pages (there would be no increase in postage).

To estimate total mailing cost, we must add the estimates of i) total number of Part D enrollees not in an Enhanced MTM program under the Enhanced MTM model and who are not ARBs who will receive a CMR under the current criteria and ii) total number of ARBs who will receive a CMR under the proposed criteria.

(i) We estimate that in 2021, there will be 46,788,579 Part D enrollees not in an Enhanced MTM program under the Enhanced MTM program and as previously determined, 9,679 of those will meet the new MTM targeting criteria as ARBs. This leaves 46,778,900 Part D enrollees (46,788,579 not in an Enhanced MTM program minus 9,679 enrollees meeting the ARB criteria) that must be targeted for MTM if they meet the current criteria. Our internal data shows that 5.34 percent of the Part D enrollees will be targeted for MTM programs under the current criteria. Hence, this leaves 2,497,993 Part D enrollees (5.34 percent * 46,778,900) who will be targeted for MTM under the current criteria. Of these 2,497,993 targeted enrollees, as stated previously, based on internal CMS data, we estimate 87 percent will accept the annual CMR offer. Therefore 2,173,254 beneficiaries (2,497,993 * 0.87) will receive a CMR under the current criteria.

(ii) 8,421 ARBs are estimated to receive a CMR under the proposed criteria. Hence, in 2021 a total of 2,181,675 enrollees will receive a CMR under the current and proposed criteria (8,421 ARBs under the proposed criteria + 2,497,993 under the current criteria), at a total non-labor mailing cost of $21,817 (2,181,675 enrollees * $0.01 mailing cost per enrollee) to add an additional page containing safe disposal information to all CMRs.

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
Estimated # of ARBs to be enrolled in MTM	10,000	Internal CMS data
Number of ARBs who will be targeted for MTM	9,679	10,000 * 96.7929%
Number of ARBs estimated to accept CMR offer	8,421	9,679 * 87%
Part D enrollees who are neither in Enhanced MTM nor meet ARB criteria	46,778,900	48,338,879 – 1550,300 – 9,679
Number of Part D enrollees under current criteria who will receive a CMR	2,173,254	46,778,900 * 5.34% * 87%
Estimated # of 2021 CMR summaries (current criteria + proposed criteria)	2,181,675	2,173,254 + 8,421
Cost of additional page in CMR summary	$0.01	$0.005 paper + $0.005 toner
Cost of additional page for all MTM enrollees receiving a CMR	$21,817	2,181,675 * $0.01

c. <u>Total Change to Burden:</u> The total additional burden associated with conducting CMRs with ARBs and adding an additional page to the Standardized Format for all MTM enrollees is estimated to be **5,614 hours** at a cost of **$697,069** ($7,747 non-labor + $667,505 labor + $21,817 labor) across 735 Part D contracts, or 7.64 hours and $948 per contract.

Burden Category	No. Respondents	Total No. Responses (annual)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting ($/hr)	Total Annual Cost ($)
CMS-4190-P: Expanded Population/Enrollment in MTM Programs (Labor)	+144	+8,421	0.6667 (40 min)	+5,614	118.90	+667,505
CMS-4190-P: Expanded Population/Enrollment in MTM Programs (non-Labor)	+144	+8,421	n/a	n/a	n/a	+7,747
CMS-4190-P: Mailing Safe Disposal Information (non-Labor)	+144	+2,181,675	n/a	n/a	n/a	+21,817
Total Proposed Changes: CMS-4190-P	**+144**	**+2,198,517**	**No change**	**+5,614**	**Varies**	**+697,069**

d. <u>Burden Reconciliation</u>

In summary, the total burden for the Standardized Format would be **813,388 hours** at a cost of **$101,022,599** as a result of the SUPPORT Act's provisions**.**

Burden Category	No. Respondents	Total No. Responses (annual)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting ($/hr)	Total Annual Cost ($)
Currently Approved Burden (Labor and non-Labor, Combined)	591	1,366.79	1.0	807,774	Varies	100,325,530
Proposed Changes (CMS-4190-P)	+144	+2,198,517	Varies	+5,614	Varies	+ 697,069
Balance	**735**	**2,199,884**	**No change**	**813,388**	**Varies**	**101,022,599**

16. Publication/Tabulation Dates

The currently approved Standardized Format, as discussed in the Final 2013 Call Letter, is posted on www.cms.gov. Part D Plan sponsors will be required to comply with the requirements of the revised Standardized Format as of January 1, 2021.

17. Expiration Date

    The expiration date is displayed.

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.