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

Note: This collection of information request is associated with our final rule that published in the Federal Register on January 19, 2021 (86 FR 5864) as CMS-4190-F2 (RIN 0938-AT97). As explained below in section 8, it is also associated with a non-rule 30-day notice that published on May 14, 2021 (86 FR 26521). We are submitting this request to OMB under the non-rule 30-day notice to accommodate the public comment process and sync regulations.gov with ROCIS.

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.

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 approved by OMB in July 2014 detailed the additional burden associated with the provision of CMRs with written summaries in Standardized Format to beneficiaries in LTC settings. In August 2017, nonmaterial changes to the components of the written summary and action plan were approved by OMB.

CMS issued a final rule (86 FR 5864)[1] on January 19, 2021, that implements changes to the MTM program beginning January 1, 2022. The final rule expands the definition of beneficiaries targeted for MTM to include at-risk beneficiaries (ARBs) under a Drug Management Program (DMP), regardless of whether those individuals meet other MTM targeting criteria. It also requires plans to provide all MTM enrollees with information about the safe disposal of prescription drugs that are controlled substances, including opioids. In February 2020, CMS proposed changes to the Standardized Format consistent with these regulatory changes (see 85 FR 10444),with a 60-day comment period. We also proposed 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[2].

The purpose of this submission is to request approval of changes to the burden estimate, and to the order and components of the cover letter, written summary and action plan in response to comments received during the proposed rule's 60-day comment period as well as to request a three year extension of the current expiration date. The finalized changes to the Standardized Format would take effect on January 1, 2022 pending OMB approval of this collection of information request.

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

1 "Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Program, and Programs of All-inclusive Care for the Elderly" (CMS 4190-F2)

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

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.

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. In addition to proposed revisions to improve and stream line the Standardized Format, the changes finalized in regulation regarding safe disposal information also require changes to the Standardized Format.

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 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 May 2020 CMS Interoperability Rule (85 FR 25510) 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 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 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. 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

Federal Register

Serving as the 60-day notice, the proposed rule published in the Federal Register on February 18, 2020 (85 FR 9002) (CMS-4190-P, RIN 0938-AT97). Comments were received and are summarized and responded to as an attachment to this collection of information request. Based on these comments, the information on safe disposal was removed from the To-Do List and instead given its own page. Additionally, the order of the documents in the CMR summary was reverted to Cover Letter, then To-Do List, then Personal Medication List. For more information, please see the attached comment response document as well as the attached Crosswalk.

The final rule published in the Federal Register on January 19, 2021 (86 FR 5864) as CMS-4190-F2 (RIN 0938-AT97).

As specified on page 5898 of the final rule, we have published a 30-day Federal Register notice that: (1) will allow the public to view and comment on the additional revisions to the Standardized Format, (2) updates the burden estimate and reflects changes made as a result of comments from the 60-day comment periods, and (3) implements changes made to the CMR summary as a result of the January 2021 final rule. The 30-day notice published on May 14, 2021 (86 FR 26521). Comments must be received by June 14, 2021.

Outside Consultation

From June 2018 through September 2018, we tested stakeholder satisfaction with the 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 the proposed revisions to the Standardized Format, which are included in the crosswalk documents for this package.

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

Wage Estimates

A CMR is a clinical consultation service that may be administered by clinician types such as a pharmacist, physician, or nurse practitioner. Currently, 100% of MTM programs employ pharmacists to conduct CMRs. We therefore estimated the labor cost for Part D plans to conduct annual, interactive CMRs with written summaries and action plans using the Standardized format using pharmacists as the clinician type.

To derive average costs for the private sector, we used data from the U.S. Bureau of Labor Statistics' (BLS's) May 2020 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.

Table 1. National Occupational Employment And Wage Estimates

Occupation Title	**Occupation Code**	**Mean Hourly Wage ($/hr)**	**Fringe Benefits and Overhead ($/hr)**	**Adjusted Hourly Wage ($/hr)**
Pharmacist	29-1051	60.32	60.32	120.64

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

The burden upon Part D Plans to conduct annual, interactive comprehensive medication reviews (CMRs) with written summaries and action plans using the revised Standardized Format beginning January 1, 2022 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 (807) with an approved MTM program is based on the number of MTM program submissions for CY 2021. We expect this number to be similar in 2022.

A. Conducting CMRs with the Standardized Format:

Estimates of total enrollees in a Part D program in 2022 are 50,684,424. We estimate that the SUPPORT Act will add 10,366 beneficiaries to be targeted for MTM in 2022; therefore, 50,674,058 (50,684,424 enrollees – 10,366 beneficiaries) Part D enrollees will not meet the ARB criteria.

Based on our experience with the MTM program, we estimate that 6.54 percent of Part D enrollees meet the current criteria for being targeted for MTM and of these, 71.8 percent accept the offer of a CMR. Therefore, we expect 2,379,512 enrollees (0.654 * 0.718 * 50,674,058 Part D enrollees) to accept the offer of a CMR. We add to this 7,443 beneficiaries (0.718 * 10,366) who are expected to accept a CMR based on the proposed provision from the SUPPORT Act. Thus we expect 2,386,955 enrollees (2,379,512 + 7,443) to receive CMRs in 2022. These calculations are summarized in Table 2 below.

Table 2. Estimating Number of MTM Enrollees Who Will Receive A CMR

Item	Number	Source
Estimated # of enrollees in Part D contracts with MTM in 2022	50,684,424	Internal CMS data
Enrollees estimated to meet ARB criteria	10,366	Internal CMS data
Part D enrollees who do not meet ARB criteria	50,674,058	50,684,424 - 50,674,058
Estimated % of Part D enrollees targeted for MTM	6.54%	Internal CMS Data
Estimated CMR acceptance rate in 2022 (% of MTM targeted who will receive a CMR)	71.8%	Internal CMS data
Number of Part D enrollees under current criteria who will receive a CMR	2,379,512	50,674,058 * 6.54% * 71.8%
Estimated number of ARBs who will receive a CMR	7,443	10,366 * 71.8%
Total number of Part D enrollees who will receive a CMR	2,386,955	2,379,512 + 7,443

We estimate it will take 40 minutes (0.6667 hr) at $120.64/hr for a pharmacist to conduct CMRs with the Standardized Format, or 1,586,421 hours for enrollees targeted under existing criteria and 4,962 hours for enrollees targeted as ARBs for a total of 1,591,389 hours. At $120.64 per hour, this amounts to $191,984,433 for labor ($191,385,787 for the enrollees targeted under existing criteria and $598,646 for ARBs).

Table 3. Estimating Time and Labor Costs to Conduct all CMRs

Requirements in Title 42 of the CFR	Annual Frequency	No. Respondents	Total Responses	Burden per Response (hr)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
423.153(d)	On occasion	807	2,386,955	0.6667	1,591,389	120.64	191,984,433

B. Fulfillment Burden: This figure is based on our estimate that the Standardized Format will require 7 pages for each CMR summary (including the additional page for information regarding safe disposal of prescription drugs if the MTM provider discusses this with the enrollee) and be mailed to beneficiaries, costing $0.93 per CMR:

Table 4. Estimating Fulfillment Cost for All CMRs

Cost per item/page	Cost per CMR (7 pages)
Postage (1st class mail) $0.70	$0.70
Paper: $0.005 per page	$0.035
Toner: $0.005 per page	$0.035
Envelopes: $0.08 each	$0.08
Folding & stuffing: $0.08 each	$0.08
Total Fulfillment Cost	**$0.93**

TOTAL FULFILLMENT FOR BENEFICIARIES ENROLLED UNDER EXISTING CRITERIA: $0.93/CMR x 2,379,512 CMR/year = $2,212,946
TOTAL FULFILLMENT FOR ARBs: $0.93/CMR x 7,443 = $6,922

C. TOTAL BURDEN

The total annual burden associated with conducting CMRs with the Standardized Format is estimated to be **1,591,383 hours** with a cost of **$194,204,313** ($2,219,868 + $191,984,445) across 807 Part D contracts, or 1,971 hours and $240,650 per contract. For additional information and calculations regarding the changes in burden related to CMS-4190-F2, please see Section 15.

Information Collection Instruments and Instruction/Guidance Documents

Medication Therapy Management Program Standardized Format (Revised, see Crosswalk for changes)

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

The final rule published in the Federal Register on January 19, 2021 (86 FR 5864) as CMS-4190-F2 (RIN 0938-AT97). As specified on page 5898 of the final rule, we have also published a 30-day Federal Register notice (May 14, 2021; 86 FR 26521) that: (1) will allow the public to view and comment on the additional revisions to the Standardized Format, (2) updates the burden estimate and reflects changes made as a result of comments from the 60-day comment periods, and (3) implements changes made to the CMR summary as a result of the January 2021 final rule.

The implementation date of new requirements also changed between the February 2020 proposed rule and the January 2021 Final Rule from January 1, 2021 to January 1, 2022. This altered the burden estimates for the number of Part D beneficiaries who were expected to be targeted for CMRs since the Centers for Medicare & Medicaid Innovation (CMMI) Enhanced MTM model will end in 2021 and excluded over 1.5 million Part D beneficiaries from previous burden calculations. In addition, comments received in the 60-day notice indicated that the previous estimate for CMR acceptance rate was too high, and that a separate page for information regarding the safe disposal of prescription drugs was preferred.

This submission contains updated burden estimates that take into account the end of the Enhanced MTM program and updated CMR acceptance rates and BLS wages, and the addition of a separate page for information regarding the safe disposal of prescription drugs.

We estimate that in 2022 there will be 50,684,424 beneficiaries enrolled in Part D plans with MTM programs (line 1 of Table 5). According to internal data, we estimate that section 6064 of the SUPPORT Act requires targeting 10,366 ARBs for MTM in 2022 (line 2). Based on our experience with the MTM program, we estimate that 71.8 percent of beneficiaries targeted for MTM under the existing requirements will accept the offer of a CMR (line 3). This number has been updated based on more recent data which became available after the proposed rule was published. We assume this percentage will also apply to beneficiaries who will be enrolled in MTM programs under the new criteria; therefore, 7,443 ARBs (line 4) (10,366 targeted ARBs x 0.718) are expected to accept a CMR under the new provision.

To estimate the burden on Part D plans of furnishing CMRs to the 7,443 ARBs who would be expected to accept the offer of a CMR under the final policy, we separately calculate the labor cost of preparing the CMR and packaging it, and the non-labor cost of mailing.

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 qualified provider. Currently, 100 percent of MTM programs employ pharmacists to conduct CMRs, which is the basis of the hourly rate estimate. Stakeholder comments that were received outside of this rulemaking effort and responded to in a previous collection of information request indicate that an average CMR requires 40 minutes or 0.6667 hours (line 5) at $120.64/hr (line 7) for a pharmacist to complete. This results in an annual labor burden of 4,962 hours (line 6) (7,443 ARBs x 0.6667 hr) at a cost of $598,616 (line 8) (4,962 hr x $120.64/hr).

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 per cartridge and lasts for 10,000 sheets (at $0.005 per sheet). We estimate that the average CMR summary will be 6 pages in length based on revisions which would streamline the Standardized Format; therefore, the paper and printing costs for each CMR summary will be $0.06. 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 each, while 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 (line 9). This results in a cost of $6,848 (line 10) ($0.92 cost per mailing x 7,443 ARBs).

Therefore, we estimate that the total annual cost of providing CMRs to 7,443 ARBs is $605,464 (line 11) ($598,616 labor costs + $6,848 non-labor mailing costs). These figures and calculations are summarized in Table 5. The Line ID column contains identifiers for each row following the flow of logic and calculations. Where applicable, the calculations are described in the "Source" column.

Table 5: Estimated Burden of Targeting ARBs for MTM

Line ID	Item	Number	Source
(1)	Part D enrollees in 2022	50,684,424	Internal CMS Data
(2)	Part D enrollees expected to meet the ARB criteria	10,366	Internal CMS data
(3)	Percent of enrollees under the existing program targeted for a CMR who accept the offer	71.8%	Internal CMS data
(4)	ARBs targeted for MTM expected to accept CMR offer	7,443	(2)*(3)
(5)	40 minutes is the industry standard for conducting a CMR	0.6667	Industry data
(6)	Number of hours needed to fulfill the preparation of CMRs under the new provision including stuffing and mailing	4,962	(4)*(5)
(7)	Wage for a pharmacist to prepare a CMR	$120.64	BLS Wage data
(8)	Cost to send CMRs to ARBs under the new provision	$598,616	(6)*(7)
(9)	Non-labor cost of mailing one CMR: 6	$0.92	See narrative

Line ID	Item	Number	Source
	pages * ($2.50*500 cost per page + $50/10000 cost of toner)+ $0.08 stuffing + $0.08 envelope + $0.70 for postage		
(10)	Non-labor cost of mailing	$6,848	(8)*(9)
(11)	Total cost for preparing and mailing the CMR to ARBs	$605,464	(8)+(10)

Mailing Safe-Disposal Information as Part of the CMR Summary

Under the revisions to § 423.153(d)(1) adopted in the final rule, Part D plans are required to provide all MTM enrollees with information about safe disposal of prescription medications that are controlled substances. The provision allows plans to mail the required safe disposal information either as part of the CMR summary, a TMR, or other MTM correspondence or service. We estimate the safe disposal information will take one page, may include personal information, and can be mailed out as a standalone correspondence if not included in the annual CMR.

For those enrollees receiving a CMR, we believe it will be most economical to include the one page with the existing CMR summary. We solicited comments regarding this assumption, but did not receive any feedback. Therefore, we are estimating that the cost of mailing one extra page per enrollee is $0.01 (line 21 ([1 page x $2.50 / ream of 500 sheets] + [1 page x $50 toner/10,000 sheets]). Although folding and stuffing envelopes with 7 pages versus 6 pages might require some extra effort, we do not believe this will raise the $0.08 current cost estimate and we did not receive any comments on this assumption. Additionally, the $0.70 first class postage for 2 ounces is sufficient for 7 pages so there is no increase in postage.

To estimate total mailing cost, we add the estimates of i) total number of Part D enrollees who are not ARBs who will receive a CMR under the existing criteria and ii) total number of ARBs who will receive a CMR under the new criteria we adopted in the final rule.

As shown in Table 5, lines (1) and (2), we estimate that in 2022 there will be 50,684,424 Part D enrollees and, as previously determined, 10,366 of those will meet the new MTM targeting criteria, leaving 50,674,058 Part D enrollees (Table 6, line 14) (50,684,424 Part D enrollees minus 10,366 enrollees meeting the ARB criteria) that must be targeted for MTM if they meet the existing criteria. Our internal data shows that 6.54 percent (line 15) of Part D enrollees will be targeted for MTM programs under the existing criteria. Hence, this leaves 3,314,083 Part D enrollees (0.0654 * 50,674,058) who will be targeted for MTM under the existing criteria (line 16). Of the 3,314,083 targeted enrollees, as stated previously, based on internal CMS data, we estimate 71.8 percent will accept the annual CMR offer (line 17). Therefore 2,379,512 beneficiaries (3,314,083 * 0.718) will receive a CMR under the existing criteria (line 18).

Hence, in 2022 a total of 2,386,955 enrollees will receive a CMR under the existing and new criteria (7,443 ARBs under the new criteria + 2,379,512 under the existing criteria) (line 20), at a total non-labor mailing cost of $23,870 (2,386,955 enrollees x $0.01 mailing cost per enrollee) to

add an additional page containing safe disposal information to all CMRs (line 22).

The figures and calculations are summarized in Table 6.

Table 6: Estimated Burden for Mailing Safe Disposal Information as Part of the CMR

Line ID	Item	Number	Source
(12)	Part D enrollees in 2022	50,684,424	(1)
(13)	Enrollees estimated to meet ARB criteria under the new provision	10,366	(2)
(14)	Part D enrollees who do not meet ARB criteria	50,674,058	(12)-(13)
(15)	Percentage of Part D enrollees who meet the existing criteria for MTM	6.54%	Internal CMS data
(16)	Estimated number of Part D enrollees not meeting ARB criteria who are targeted for MTM under the existing criteria	3,314,083	(14)*(15)
(17)	Percent of enrollees under the current program targeted for an MTM who accept the offer	71.8%	Internal CMS data
(18)	Estimated number of Part D enrollees under the existing criteria who will receive a CMR	2,379,512	(16)*(17)
(19)	Estimated number of Part D enrollees under the new provision meeting ARB criteria who will elect to receive a CMR	7,443	(4)
(20)	Total number of Part D enrollees (under the existing and new criteria) who will receive a CMR	2,386,955	(18)+(19)
(21)	Non-labor costs of one extra page (2.50/500) and toner for one page ($50/10000)	$0.01	See narrative
(22)	Estimated cost of mailing safe disposal information with a CMR	$23,870	(20)*(21)

We estimated the burden to conduct annual interactive CMRs with written summaries in CMS Standardized Format in all care settings in 2021 to be 1,448,908 hours (40 minutes per CMR) with a total cost of $174,854,217 for 2,173,254 CMRs.

We estimate that the number of CMRs will increase from 2,173,254 (2021 estimate) to 2,386,955 for the 2022 estimate, an increase of 213,701. The annual hours required for these CMRs increased from 1,448,908 (2021 estimate) to 1,591,383 hours for the 2022 estimate (increase of 142,475 hours). The greater number of CMRs results in an estimated higher total cost burden of $194,204,313 in 2022, which is $19,350,096 higher than the 2021 estimate ($174,854,217).

The total annual burden associated with conducting CMRs with the Standardized Format is estimated to be 1,591,383 hours with a cost of $194,204,313 ($2,219,868 for fulfillment + $191,984,445 for labor) across 807 Part D contracts, or 1,972 hours and $240,650 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.

We request that the proposed revisions take effect January 1, 2022.

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.