Supporting Statement Part A
Medication Therapy Management Program Improvements
CMS-10396, OCN 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 must meet with regard to cost control and quality improvement, including requirements for medication therapy management (MTM) programs. The initial Centers for Medicare & Medicaid Services (CMS) regulations for MTM established a general framework that allowed 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 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.

The purpose of this new submission is to request an extension of OCN 0938-1154, including nonmaterial changes to the components of the written summary and action plan. This submission also includes updated burden calculations based upon the actual MTM eligibility rate of beneficiaries and delivery rate of CMRs in Part D versus projected estimates that were used in the previous submissions. Part D sponsors will begin providing CMR summaries that comply with the revised standardized format beginning January 1, 2015.

A. Justification

1. Need and Legal Basis

   The OMB approval of this collection instrument expires on January 31, 2015. With this submission, we are requesting an extension of the current approval (OCN 0938-1154) for an additional three (3) years, effective no later than January 1, 2015.

2. Information Users

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

3. Use of Information Technology

   The standardized format must comply with applicable industry standards for 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 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.

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 will 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 will 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.

7. Special Circumstances

Not applicable.

8. Federal Register/Outside Consultation

Federal Register

The 60-day Federal Register notice published on January 17, 2014 (79 FR 1154). During the 60-day comment period, 3 organizations submitted 10 applicable comments. As a result of the comments received, CMS made the following two changes to this submission:

a. The proposed statement describing the availability of translation services was deleted from revisions to the Cover Letter and mock-up of the standardized format.
b. The estimate of time required for delivery of a CMR with summary in

standardized format was increased by 5 minutes.

Part D sponsors will begin providing CMR summaries that comply with the revised standardized format beginning January 1, 2015.

Outside Consultation

From January through October 2013, we tested stakeholders' initial reactions and satisfaction with the standardized format and identified potential revisions to the standardized format. The stakeholders included Part D sponsors, MTM providers, Medicare beneficiaries, and a technical expert panel of long-term care professionals. Sample sizes for these activities were all less than 10 respondents each. We also issued a memorandum to stakeholders through the CMS Health Plan Management System (HPMS) to receive additional feedback; 23 responses were received from 19 unique entities. The result of these activities produced a number of potential revisions to the standardized format. The changes to the standardized format that we are incorporating into this extension request do not affect the instructions, frequency of collection, or the use to which the information is put.

9. Payments/Gifts to Respondents

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

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 Health Insurance Portability and Accountability Act (HIPAA) privacy and security requirements.

11. Sensitive Questions

The discussion of sensitive issues is inherent in the delivery of health care 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 his or her 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 upon Part D Plans to conduct annual, interactive CMRs with written summaries and action plans using the new standardized format beginning January 1, 2015, 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 (682) with an approved MTM program is based on the number of MTM program submissions for CY 2014.

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 and cost $80.91 on average for each CMR (these figures are inclusive of LTC and non-LTC settings).

40 minutes/CMR x 280,352 CMRs/year = 186,901 hours/year

186,901 hours/year x $120 reviewer cost/hour = $22,428,160

B. Fulfillment Burden: This figure is based on our estimate that the standardized format will require 5 pages for each CMR summary and be mailed to beneficiaries, costing $0.91 per CMR:

Postage (1st-class mail)	$0.61
Paper: $.02 each page	0.10
Toner: $.04 each page	0.20
Total Fulfillment Costs/CMR	$0.91

$0.91/CMR x 280,352 CMRs/year = $255,120

Therefore, the total annual burden associated with conducting CMRs with the standardized format is estimated to be 186,901 hours with a cost of $22,683,280, or 274.05 hours and $33,259.94 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

The previous submission included burden for programing systems and for training MTM providers. In this current package we are removing that burden since the systems programming and staff training that were needed for the initial, startup implementation of the new standardized format for 2013, is no longer required and because this package's proposed revisions are nonmaterial. If we had significantly revised the structure of the standardized format, some programming and training could've been needed again.

We have also adjusted burden estimates that are based on an estimate of the increased number of Part D enrollees through 2014 and 5 additional minutes for delivery of the CMR with summary in standardized format; and average eligibility rate for participation in Part D MTM programs, opt-out rate of eligible beneficiaries, and delivery rate of CMRs with summaries in standardized format. The net result is a lower estimate of the annual number of CMRs delivered (280,352) compared to the previous estimate (1,875,000).

The nonmaterial revisions to the standardized format will neither add nor detract from the information collection burden.

A. Conducting CMRs in all settings with the standardized format: The new labor cost calculation is based on our estimate that 10% of MTM participating beneficiaries in all settings will receive CMRs with the standardized format, requiring 0.67 hours and cost $120/hour for each CMR.

38,608,141 beneficiaries x 8.35% eligibility rate = 3,222,437 beneficiaries eligible for MTM services

3,222,437 beneficiaries - 13% opt-out rate = 2,803,520 beneficiaries in MTM programs

2,803,520 beneficiaries x 10% CMR rate = 280,352 CMRs/year

280,352 CMRs/year x 0.67 hours/CMR = 186,901 hours/year

186,901 hours/year x $120/hour = $22,428,160 annual labor cost

The estimate of the burden to conduct annual interactive CMRs with written summaries in CMS standardized format in all care settings beginning in 2013 was 1,093,750 hours (35 minutes per CMR) with a total cost of $131,250,000. With this request for extension, we have adjusted the burden to conduct CMRs to be 186,901 hours (40 minutes per CMR) with a total cost of $22,428,160 ($80.91 per CMR).

B. Fulfillment Burden in all settings: This figure is based on our estimate that the standardized format will require 5 pages for each CMR summary and be mailed to beneficiaries, costing $0.91 per CMR. The change in fulfillment burden is due to a reduced number of CMRs compared to the previous estimate:

Postage (1st-class mail)	$0.61
Paper: $.02 each page	0.10
Toner: $.04 each page	0.20
Total Fulfillment Costs/CMR	$0.91

$0.91/CMR x 280,352 CMRs/year = $255,120

16. Publication/Tabulation Dates

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. A revised standardized format will replace the final standardized format that appears on the CMS Web site after receiving OMB's approval. Part D plan sponsors will be required to implement the nonmaterial revisions to the standardized format beginning January 1, 2015.

17. Expiration Date

There is no expiration date for use of the standardized format.

18. Certification Statement

There are no certification statements.

B. Collections of Information Employing Statistical Methods

The collection instrument is neither a survey nor questionnaire for statistical analysis. Rather, the instrument is used by Part D sponsors to compile beneficiary-specific information into a standardized summary format, which is then sent or given to the beneficiary.