Supporting Statement for Paperwork Reduction Act Submissions: Medication Therapy Management Program Improvements

A. 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 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. For a description of the program requirements through 2009, see the Medicare Part D Medication Therapy Management Programs 2009 Fact Sheet (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MTMFactSheet2009.pdf).

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. Changes to Part D MTM program requirements for 2010 included:

1. Sponsors must enroll targeted beneficiaries using an opt-out method of enrollment only.
2. The annual drug cost threshold for eligibility was lowered from $4,000 to $3,000.
3. CMS established both a ceiling (3) and a floor (2) in the minimum number of chronic diseases that may be required for eligibility.
4. CMS established both a ceiling (8) and a floor (2) in the minimum number of drugs that may be required for eligibility.
5. Sponsors must target at least four of seven core chronic diseases.
6. 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. Annual CMRs are not required to be offered to targeted MTM program beneficiaries in long term care settings.
7. Sponsors must perform targeted medication reviews at least quarterly with follow-up interventions when necessary.

For complete details of MTM program changes for 2010, see the 2010 Call Letter (http://www.cms.gov/PrescriptionDrugCovContra/Downloads/2010CallLetter.pdf).

The Affordable Care Act (ACA) under Section 10328 specified other changes to Part D MTM programs, including many that were already implemented by CMS in 2010. In addition, the ACA further requires that the Secretary, in consultation with relevant stakeholders, develop a standardized format for the CMR action plan and summary, which is the subject of this Paperwork Reduction Act (PRA) submission.

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 revises §423.153(d)(1)(vii) to require standardized action plans and summaries to comply with requirements specified by CMS for the standardized format. Although the final rule indicated that there is no additional burden associated with the requirement to use the standardized format, subsequent development of the format and comments from stakeholders identified an additional burden as described in this PRA submission.

The draft format submitted for the 60-day comment period was developed from an environmental scan and literature review for formats currently in use within the industry for medication review summaries or action plans. The draft format also took into consideration a substantial number of comments and suggestions from stakeholders after the draft format was distributed broadly as described in #8 below. Further revisions were made based upon an expert panel review, practitioner and beneficiary testing, and pilot testing that were completed by a contractor between June 10 and July 26, 2011, and comments received during the 60-day comment period pursuant to this PRA submission. A guidance document will also be developed to describe requirements for implementing the format and provide answers to frequently asked questions.

The format provides a template for the written summary and action plan, and includes three components: Beneficiary Cover Letter, Medication Action Plan, and Personal Medication List. Specific content must be tailored to the beneficiary and customized for the Part D sponsor or MTM program. Limited variability is available in the format for Part D sponsors to provide additional information such as supplemental instructions and goals of therapy to meet the unique needs of each beneficiary beyond the requirements of the basic standardized format and to promote innovation. Sponsors are encouraged to augment the standardized format by providing additional materials as needed to help beneficiaries manage their healthcare needs.

Part D sponsors must begin using the standardized format in January 2013 and continue thereafter. We are requesting OMB to approve this collection for a 3-year period.

B. Justification

1. Need and Legal Basis

The Affordable Care Act (ACA) under Section 10328 specifies that the Secretary, in consultation with relevant stakeholders, shall develop a standardized format for the action plan and written or printed summary that are given to Medicare Part D beneficiaries as a result of their CMRs. This change will provide greater consistency of materials and content given to beneficiaries as a result of their CMRs and positively impact the medication use of beneficiaries.

2. Information Users

Information collected by Part D MTM programs as required by the standardized format will be used by beneficiaries and their healthcare providers to improve medication use and achieve better healthcare outcomes. MTM program practitioners will identify medication-related problems and provide recommendations for changes in the medication treatment plan to both the beneficiary and their physicians. The Medication Action Plan will include specific activities for the beneficiary to improve their medication usage and track their progress. The Personal Medication List, which is an updated list of medications currently being used by the beneficiary, will help beneficiaries manage their medications, and serve as a resource when visiting their healthcare practitioners and if admitted to a hospital.

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 data elements to be captured for clinical, reporting or measurement purposes.

The National Council for Prescription Drug Programs (NCPDP) WG10 MTM Task Group discussed the required data elements of the standardized format and verified that the data elements do not conflict with NCPDP standards. As a result of the discussion, the adverse reaction field on the Personal Medication List was combined with the allergy field because those elements are reported in the same NCPDP data field, and because beneficiaries often have difficulty differentiating allergies from side effects.

The use of a 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.

CMS hired a contractor to assist with the development of the final standardized format, and consider the development of an electronic format which can be printed,

or written, if needed. CMS will also encourage a flexible method of delivery of the standardized format documents, including but not limited to mail, email or access through a secure webpage, to allow integration with electronic systems and innovation.

4. Duplication of Efforts

This is not a duplication of effort. The standardized format will replace current 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 drug 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

Significant outside consultation with stakeholders occurred in the development of the initial draft standardized format beginning in January 2011. CMS staff performed an environmental scan and literature review for formats currently in use within the industry for medication review summaries or action plans, analyzed the findings, and developed a draft standardized format for the CMR written summary and action plan. On March 11, 2011, the draft standardized format was distributed through HPMS to stakeholders for review and comment. The draft format was also distributed through the pharmacy list serv. CMS received more than 570 comments and suggestions from 77 organizations and 5 individuals. CMS staff reviewed the comments and suggestions received and formed consensus on revisions to be made to the draft standardized format as follows:

Beneficiary Cover Letter

1. Plans can customize the inside address, salutation, and closing, and other optional fields to allow the letter to be sent from an individual reviewer/practitioner or a corporate official, and be personalized with various salutation and closing styles. Text was also revised in recognition of different practice settings.
2. The eligibility statement was removed from the first paragraph, and both the first and second paragraphs were simplified and shortened.
3. The review summary section was deleted.

Medication Action Plan

1. The introduction was revised with expanded beneficiary instructions in bullet format, and in recognition of different practice settings.
2. The titles of the text boxes were simplified.
3. The description in the additional information field was shortened.

Personal Medication List

1. The introduction was revised with expanded beneficiary instructions in bullet format, including how to use the start date and stop date fields.
2. The adverse reaction field was combined with the allergy field.
3. The titles of the text boxes were simplified, including the start date and stop date fields.
4. Fields were moved; “Why I Use It” follows “How I Use It.”
5. The prescriber’s telephone number was deleted from the prescriber field.
6. The goals of therapy field was removed. MTM programs may include goals of therapy in the optional other title field.
7. The description in the additional information field was shortened.
8. An additional information field was added to page 2.

Limited variability is available in the format for Part D sponsors to provide additional information such as supplemental instructions and goals of therapy. Sponsors are encouraged to augment the standardized format by providing additional materials as needed to help beneficiaries manage their healthcare needs.

Further revisions have been made to the format based upon an expert panel review, practitioner and beneficiary testing, and pilot testing that were completed by a contractor between June 10 and July 26, 2011, and public comments received pursuant to this PRA submission during the 60-day comment period. CMS received 234 public comments from 26 organizations; 2 of the organizations represented consumers. Revisions made to the standardized format based upon input from the expert panel, testing, and public comments are as follows:

Global Revisions

1. Prepared in 14-point font for easier reading by the beneficiaries.
2. Plan/Provider headers must appear on the first page of each document type (BCL, MAP, and PML). Recommend top left side of header for MTM Provider; top right side for Part D Plan Logo.
3. Recommend that contact information refer to MTM provider rather than the Part D Plan.
4. Added statements about sharing with family or caregivers.
5. Analyzed and simplified text based upon of health literacy and readability principles.
6. Page numbers were added so that each component may stand alone.
7. Required CMS footers were added, including the CMS form number and OMB approval number on each document, and the Paperwork Reduction Act statement on the last page.
8. Plan-specific privacy statements are not required, but may be included on the last page of the BCL, MAP, and PML, above the CMS-required footers and PRA statement.

Beneficiary Cover Letter

1. Instructions were expanded for the open space to the right of the inside address section.
2. Important information is presented in bold text.
3. Action steps are listed in bullet form.
4. Reworded the opening sentence from "Thank you for participating in <*insert name of Part D Plan*>… to "Thank you for talking with me on <date> about your health and medications." This change was made to immediately remind the beneficiary about their comprehensive medication review.

Medication Action Plan

1. Pharmacists are referenced in the instructions with doctors and other healthcare providers.
2. The font size is increased for the "date prepared" field.
3. The beneficiary's date of birth has been added.
4. Created more separation between each action plan.
5. Another set of action item fields was added.
6. The "Additional Information" box was replaced with two boxes: "My follow-up plan" and "Questions I need to ask" for beneficiaries' notes. Instructions for these two boxes were added to the bullets at the top of the form and in each box.
7. Who the beneficiary should call with questions was moved to the end of the action plan.

Personal Medication List

1. The beneficiary's date of birth has been added.
2. The list of medications to keep updated was moved to a separate text box. "Herbal remedies" and "minerals" were added to this list, and devices was removed from this list and added to the "How I use it" field.
3. The font size is increased for the "date prepared" field.
4. Additional space was added to make a clear distinction between the "Allergies or side effects" box and the "Medication" box.
5. Only active or current medications will be listed.
6. The listed medication will include both brand and generic names.
7. The "Prescriber" and "Insert other titles" fields were moved to consolidate the plan-populated fields.
8. Instructions were revised for the "Insert other titles" field.
9. Space was added for the beneficiary to record the reason why a medication was stopped.
10. The start date, stop date, and reason for stopping the medication fields, which are completed by beneficiaries, were consolidated and moved below the plan-populated fields for each medication.
11. Several blank medication sections are included for beneficiaries to fill in as needed.
12. The name of the "Additional Information" field was changed to "Other information," and only appears on the last page.
13. Who the beneficiary should call with questions was moved to the end of the action plan.

A guidance document will also be developed to describe requirements for implementing the format and provide answers to frequently asked questions.

CMS' proposed timeframe for Federal Register publication is as follows:

- The proposed standardized format was posted in the Federal Register on May 31, 2011, and the 60-day comment period ended on August 1, 2011.
- Beginning August 2, 2011, CMS staff reviewed all comments received and revised the document appropriately. CMS staff prepared a document summarizing all received comments and their responses. The standardized format was revised as necessary. CMS requests the revised standardized format be posted in the Federal Register no later than September 30, 2011, followed by a 30-day comment period.
- After the 30-day comment period, CMS staff will review all received comments, and revise the document appropriately. CMS staff will prepare a response document summarizing all received comments and their responses. A final standardized format package will be delivered for OMB review by December 29, 2011.

- The final standardized format will be posted in the Final 2013 Call Letter and on www.cms.gov after February 28, 2012.

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. CMS will not collect the confidential beneficiary data required by the standardized format. 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.

As stated in #10, CMS will not collect the confidential beneficiary data required by the standardized format.

12. Burden Estimates (Hours & Wages)

The estimate of the burden to conduct annual interactive CMRs with written summaries beginning in 2010 was 937,500 hours (30 minutes per CMR) with a total cost of $112,500,000 ($60 per CMR). This submission revises that 2010 estimate by the inclusion of mailing costs and the requirement to use the standardized format beginning in 2013, which adds 5 minutes and approximately $15.65 to the cost of each CMR. The new estimate of the burden to conduct annual interactive CMRs with summaries using the standardized format in 2013 is 1,179,894 hours (35 minutes per CMR) with a total cost of $141,839,850 ($75.65 per CMR); see #15 for a detailed description of the changes to the estimated annual burden.

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 includes:

A. Programming systems to support the standardized format,
B. Training MTM providers to use the standardized format,
C. Time and effort to conduct CMRs using the standardized format, and,
D. 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 with an approved MTM program in CY 2013 is based on the number of MTM program submissions for CY 2012.

A. Programming the standardized format: This figure is based on our estimate that programming the new standardized format will require 120 hours of software analyst's time and add $4.39 to the cost of each CMR.

120 hours x 673 contracts = 80,760 hours
80,760 hours x $102 analyst cost/hour = $8,237,520

B. Training MTM providers to use the standardized format: This figure is based on our estimate that 8 hours will be required to train the MTM providers for each contract and add $0.34 to the cost of each CMR.

8 hours x 673 contracts = 5,384 hours
5,384 hours x $120 trainer cost/hour = $646,080

C. Conducting CMRs with the standardized format: This figure is based on our estimate that conducting CMRs with the standardized format will require 35 minutes and cost $70.00 on average for each CMR.

35 minutes/CMR x 1,875,000 CMRs/year = 1,093,750 hours/ year
1,093,750 hours/year x $120 reviewer cost/hr = $131,250,000

D. 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 1,875,000 CMRs/year = $1,706,250

Therefore, the total annual burden associated with conducting CMRs with the standardized format is estimated to be 1,179,894 hours with a cost of $141,839,850, or 1,753 hours and $210,758 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 use of the standardized format changes the burden associated with providing interactive CMRs and written summaries. CMS' proposed rule to require Part D sponsors to conduct interactive CMRs with written summaries beginning in 2010 included an estimated total annual burden of 937,500 hours with a total labor cost of $112,500,000, based on 30 minutes to conduct each CMR. The estimate for 2010 did not include fulfillment costs; however, fulfillment costs have been added to this estimate because most CMR summaries are printed and mailed to beneficiaries. The total increase in burden described in this submission is 242,394 hours and $29,339,850, or 360 hours and $43,596 per contract, adding $15.65 to the cost of each CMR:

	Hours	Costs
Initial fulfillment costs beginning 2010:		$ 1,162,500
Use of standardized format in 2013:	242,394	$ 28,177,350
		$ 29,339,850

Initial fulfillment costs beginning 2010: The change in annual burden associated with including an estimate for printing and mailing costs beginning in 2010 is $1,162,500, or $1,727 per contract, or $0.62 per CMR:

Postage (1st oz., 1st class mail):	$ 0.44
Paper: 3 sheets x $.02 each	0.06
Toner: 3 x $.04 each page	0.12
Total New Material Costs/CMR	$ 0.62

$0.62/CMR x 1,875,000 CMRs/year = $1,162,500

Use of standardized format in 2013: The requirement to use the new standardized format will also increase the burden due to additional time to conduct the CMR, new programming and training costs, and higher fulfillment costs. The additional burden

upon Part D Plans for using the new standardized format for CMR action plans and summaries is estimated to be 242,394 hours with a cost of $28,177,350, or 360 hours and $41,868 per contract ($15.03 for each CMR), and includes:

A. Programming systems to support the new standardized format: 80,760 hours and $8,237,520 (see #12 above).

B. Training MTM providers to use the new standardized format: 5,384 hours and $646,080 (see #12 above).

C. Additional time required to conduct CMRs beginning in 2013: $18,750,000. This figure is based on our estimate that using the standardized format will add 5 minutes and $10 cost on average to each CMR:

5 minutes/CMR x 1,875,000 CMRs/year = 156,250 hours/ year
156,250 hours/year x $120 reviewer cost/hr = $18,750,000

D. Printing and mailing costs for the additional pages required to be included in the action plan and summaries beginning in 2013: $543,750. This figure is based on our estimate that the standardized format will add 2 additional pages to each CMR take-away, adding $0.29 cents for printing and distribution for each CMR:

Postage (2nd oz., 1st class mail):	$0.17
Paper: 2 sheets x $.02 each	0.04
Toner: 2 x $.04 each page	0.08
Total New Material Costs/CMR	$0.29

$0.29/CMR x 1,875,000 CMRs/year = $543,750

16. Publication/Tabulation Dates

The final standardized format will be posted in the Final 2013 Call Letter and on www.cms.gov after February 28, 2012. This will provide time for Part D Plans to consider the requirements of the standardized format when preparing their CY 2013 bids, and to prepare for implementation as of January 2013. Part D Plan sponsors will be required to comply with the requirements of the standardized format beginning January 1, 2013 and continue thereafter.

17. Expiration Date

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

18. Certification Statement

There are no certification statements.

C. Collections of Information Employing Statistical Methods

CMS has expanded the data elements that sponsors are required to submit to CMS regarding their MTM programs as part of the 2010 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.

Beginning in 2011 for CY 2010, at the beneficiary level, Part D sponsors must measure and report to CMS through these reporting requirements 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.

Starting in 2014, the reported data will enable CMS to evaluate the impact of the standardized format on beneficiary's health outcomes as compared to prior years' requirements, because the standardized format will be mandatory for all interactive Part D CMRs beginning in 2013.