

December 30, 2016

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier CMS-10396
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-10396 Medication Therapy Management Program Improvements

Dear Sir or Madam:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to provide comments on the notice titled "CMS-10396 Medication Therapy Management Program Improvements" published in the Federal Register on October 31, 2016. Under the notice, the Medicare Part D Medication Therapy Management (MTM) Program Standardized Format ("standardized format") would be reauthorized in its current format for an additional three years through 2020. While AMCP understands the need to reauthorize the standardized format in its current format at this juncture, AMCP strongly urges CMS to work with the pharmacy profession to modernize, test, and validate alternate formats to maximize its intended benefit for Medicare beneficiaries and to work towards implementing a new standardized format in advance of 2020.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy's 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

AMCP has established a MTM Advisory Group (MTMAG) to advise AMCP staff on critical issues in the delivery of MTM related services and provide practical recommendations for MTM practice and administration. The MTMAG is comprised of 40+ MTM stakeholders, including AMCP members and non-members who represent Medicare Part D sponsors, MTM vendors, technology vendors, community MTM providers, pharmacy professional organizations, EHR vendors, integrated delivery networks, and academia. One of the goals of the MTMAG is to evaluate how the current Medicare Part D MTM Program Standardized Format can be

modernized to maximize its intended benefit for Medicare beneficiaries. This document outlines the initial recommendations from the MTMAG on how the current standardized format can be amended to allow for innovation and flexibility in its delivery.

The Medicare Part D MTM Program Standardized Format is a written summary of a comprehensive medication review (CMR). Part D sponsors must at least annually offer a CMR for targeted beneficiaries and provide written summaries. Currently, the summaries must comply with requirements as specified by CMS and include a CMR Cover Letter (CL), Medication Action Plan (MAP), and a Personal Medication List (PML). Existing flexibility in the presentation of CMR summaries is limited to the inclusion of supplemental information only. The format with the standardized information currently may not be modified which creates barriers to innovative approaches Part D plans may utilize to more efficiently and clearly communicate content to beneficiaries. These innovative approaches reflect effective delivery mechanisms for today's Medicare beneficiaries such as streamlined paper documents, emails, patient portals, text messaging, and mobile app technology Furthermore, the lack of flexibility in the approach does not allow beneficiaries to designate their preferred format for the summary which may decrease its usability and may not result in the intended benefit to patients and caregivers. Therefore, the development and testing of alternate formats is warranted to improve beneficiary outcomes.

Plans are at the forefront of developing innovative solutions to more meaningfully engage targeted beneficiaries in managing care plans developed through CMRs. Plans have invested in qualitative research, including indepth in-person interviews with beneficiaries, retrospective surveys, and app usability testing, to better understand how to improve the beneficiary CMR experience. The research demonstrates that beneficiary CMR expectations are grouped around two major themes:

- First, the information provided in the CMR experience should focus on having utility when it is needed most, during transitions of care such as a hospital or emergency room admission or during a doctor's appointment.
- Secondly, the information should come from a clinician they value as a trusted source.

In order to bridge this gap between the limited utility of the standardized CMR format and beneficiary expectations based on research, AMCP believes CMS should permit plans to develop alternative CMR formats that deliver the summary in a more interactive and relevant manner to beneficiaries based upon their preferred delivery method.

The following are initial suggestions from AMCP with input from the MTMAG on how the Medicare Part D MTM Program Standardized Format may be improved to align with updates in technology and the need for beneficiaries to have choice in how they receive this information. These recommendations are intended to serve as an opportunity to begin dialogue with CMS in this area to see how the pharmacy profession and CMS can work together to improve the standardized format to maximize the beneficiary experience.

Streamlined Paper Format:

AMCP recognizes that some beneficiaries will choose paper as their preferred format and therefore the paper format should not be eliminated. However, AMCP is concerned that the current paper format does not meet the intent of the Paper Reduction Act as it averages 10+ pages and costs an average of \$1.39 to mail to the beneficiary. Therefore, AMCP believes that the current paper format is unwieldy and can be streamlined to maximize its intended benefit to beneficiaries.

AMCP recommends that the paper format be modified in the following manner to improve portability and usability for beneficiaries:

- Remove repetitive narrative from the PML and MAP to the CL and streamline the messaging presented in the CL.
- Remove the following sections:
 - o MAP "My follow-up plan (add notes about next steps)"
 - o MAP "Questions I want to ask (include topics about medications or therapy)"
 - o PML "Other Information"
- Change format of the MAP and PML
 - o Minimize white space
 - o Change to landscape orientation
 - o Eliminate repetitive headers
 - o Present in tabular (Excel-type) format

Initial schematics of how the MAP and PML can be streamlined are included in Appendix A.

Mobile App Technology:

Mobile app technology lends itself to addressing these gaps for those beneficiaries who desire an interactive experience where and when they need it. The existing standardized CMR only captures a point in time and does not evolve with the beneficiary treatment experience over time. Medication changes initiated after one CMR are not memorialized in the standardized format for up to one year later, assuming that the beneficiary continues to meet MTM targeting criteria. Interactive applications that are accessible to beneficiaries duplicating the MAP and MPL functionality are currently available but are not recognized by CMS as CMRs because they do not meet current format specifications.

Innovative mobile app functionality could transform static CMR summaries into an interactive continuum of MTM interventions by leveraging industry accepted standardized formats to drive interoperability. For example, with a beneficiary's ability to update their PML through mobile app technology, plans could detect the need for an additional intervention well before the next TMR or annual CMR. This additional beneficiary MTM interaction created by the app's interactive functionality has the potential to reduce adverse events or detect gaps in care. Additionally, this incremental TMR interaction would document any new MAPs created which are included in the CMR history within the app. More importantly, it actively engages beneficiaries in managing

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¹ Data provided by MTMAG members

their health. Beneficiaries would have a real time organized list of their MAP and PML to use in the event they are hospitalized, at a physician appointment, or admitted to an emergency room. They would be able to show these to the clinicians involved in their care and be confident that it is up to date and accurate.

Utilizing mobile app technology could provide an engaging, always-on communication channel with clinicians about medications in a context that's integrated and shared across the care team to achieve the best health for beneficiaries. The most valuable asset of this alternative CMR format is the creation of two way communication channel between an MTM beneficiary and a MTM provider, a trusted clinical resource. The app technology could provide beneficiaries on-demand availability to a clinician when needed as well as allowing aggressive monitoring, communication, and documentation for beneficiaries to engage in a continuum of MTM interventions.

AMCP recommends that CMS permit plans to utilize alternatives to the standardized CMR format that duplicate the CL, MAP, and MPL content requirements and provide additional choices to beneficiaries including electronic, mobile application technologies, or other innovative communication mediums.

In summary, AMCP and its MTMAG strongly urge CMS to work with the pharmacy profession to modernize, test, and validate alternate standardized formats to maximize its intended benefit for Medicare beneficiaries and to work towards implementing a new standardized format in advance of 2020. AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-683-8416 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE

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Chief Executive Officer

Appendix A: Draft Streamlined PML and MAP Paper Formats

PERSONAL MEDICATION LIST FOR NAME, DOB: XX/XX/XXXX						
		ATE PREPARED: XX/XX/XXX				
		FECTS: NO KNOWN ALLER				
MEDICATION	HOW I USE IT	WHY I USE IT	PRESCRIBER	START DATE-STOP DATE	WHY I STOPPED	
Metformin 500mg tablet(s)	1 tablet orally twice a day	diabetes	Jones	xx/xx/xxx -		
Tylenol PM tablet(s) 325mg/12.5mg	2 tablets orally at bedtime	foot pain	Self	xx/xx/xxx -		
Personalized message with pharmacist	name/contact information	if member wishes to follo	ow up:			
According to the Paperwork Reduction	Act of 1995					

DATE PREPARED: XX/XX/XXXX					
What we talked about:	What I need to do:	What I did and when I did it:			
The pins and needles pain in your feet may	Stop taking the Tylenol PM, and call your				
be diabetic nerve pain. Tylenol PM does not	doctor to discuss. Our pharmacist will				
help this, and may cause the confusion in	also call your doctor to discuss as well.				
the morning we discussed.					