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June 14, 2021

Mr. William N. Parham, III
Director, Paperwork Reduction Staff
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-8016

Attention: CMS-10396 (OMB control number: 0938-1154)

Re: Medication Therapy Management Improvements – Standardized Format (CMS-10396/OMB control number 0938-1154)

Dear Mr. Parham:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to its Information Collection Request titled "*Medication Therapy Management Improvements – Standardized Format (CMS-10396)*" published on May 14, 2021. We appreciate the opportunity to leverage our members' expertise in offering feedback on this information request.

AMCP is the professional association leading the way to help patients get the medications they need at a cost they can afford. AMCP's diverse membership of pharmacists, physicians, nurses, biopharmaceutical professionals, and other stakeholders leverage their specialized expertise in clinical evidence and pharmacoeconomics to optimize medication benefit design and population health management and help patients access cost-effective and safe medications and other drug therapies. AMCP members improve the lives of nearly 300 million Americans served by private and public health plans, pharmacy benefit management firms, and emerging care models.

AMCP established a Medication Therapy Management Advisory Group (MTMAG) several years ago to advise AMCP staff on critical issues in the delivery of medication therapy management (MTM) related services and provide practical recommendations for MTM practice and administration. The MTMAG is comprised of over 70 MTM stakeholders, including AMCP members and non-members representing Medicare Part D sponsors, MTM vendor companies, technology vendors, community MTM providers, pharmacy professional organizations, EHR vendors, integrated delivery networks, academia, and standards development organizations. Evaluating the Standardized Format and how it can be modernized to maximize its intended benefit for Medicare beneficiaries has been a focus of the MTMAG and we are pleased to provide the following more detailed comments on the proposed changes.

AMCP funded a survey of Medicare beneficiaries who received a Comprehensive Medication Review (CMR) to better understand beneficiary perceptions of the Standardized Format in order to evaluate its utility and to inform potential modifications that could be made to make the Standardized Format more useful. The results of this survey and various recommendations were published in 2019 in the Journal of Managed Care & Specialty Pharmacy. Overall, only 40-45% of respondents found the Standardized Format excellent or very good. Survey respondents found the Medication List more useful than the Medication Action Plan (MAP)[1]and expressed interest in including additional information in the Personal Medication List (PML) such as information on common drug interactions and special instructions, as well as information about alternative medications in the same class that might be less expensive. More than half of respondents (55.3%) were in favor of integration of their medication summary into their medical record and an additional[2] We encourage CMS to review the results of this beneficiary survey as the agency considers modifications to the Standardized Format as well as broader changes to the Part D MTM Program.

The results from this beneficiary survey and the collective expertise of the MTMAG informed the following comments, as well as the comments AMCP submitted in April 2020, on the proposed changes to the Standardized Format.

Changes to the Standardized Format

In the May 2021 version of the Standardized Format, CMS reorders the document by placing the Medication List after the To-Do List, the opposite of the proposed change in the February 2020 version. While AMCP supported the previous reordering to put the Medication List upfront, we are persuaded by CMS's reasoning that the Medication List should be at the end of the document so that it can be more easily detached from the rest of the document. In AMCP's beneficiary survey, respondents found the Medication List to be more useful than the To-Do List, so we support making this change for ease of use.[3] AMCP also supported the change in February 2020 version that changed the Medication List format to landscape orientation and changed the presentation to a tabular chart format and we are pleased that CMS proposes to keep this change.

In this updated version, CMS proposes to change "side effect history" with "side effects I have had." AMCP supports this change as it addresses a concern we raised in our April 2020 comments about what information needs to be included in this section. We agree that this change will help to prevent confusion about potential side effects that a patient could experience, while instead providing information on the patient's actual experience. It will also allow pharmacists and other MTM providers to choose the information most relevant to the patient.

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[2] *Findings from a National Survey of Medicare Beneficiary Perspectives on the Medicare Part D Medication Therapy Management Standardized Format*. J Manag Care Spec Pharm. 2019;25(3):366-91

[3] Ibid.

CMS proposes to add the "Other Information" section back into the Medication List and AMCP supports this addition. We raised concerns in our previous comments about the elimination of the open text field that provided pharmacists and other MTM providers with the opportunity to provide additional patient-centric information, such as information about nutritional resources that may be relevant to the medications they are taking or to provide supplementary information the patient might need. We are pleased to see this open field section in the Standardized Format.

CMS proposes to add a full page to the Standardized Format for MTM providers to include information on the safe disposal of prescription medicines. AMCP believes that this should be an optional section for use by MTM providers if the information about safe medication disposal is not included in other forms of MTM enrollee communication. In the final rule implementing this provision of the SUPPORT Act, CMS states that plans can "meet the safe-disposal educational requirement through use of a CMR, targeted medication review (TMR), or other MTM correspondence or service, such as an MTM welcome letter."[4] As such, we do not believe that plans are required to provide this information as part of the CMR and so it should be optional whether to include the additional page from the Standardized Format.

While supportive of the above proposed changes to the Standardized Format, AMCP urges CMS to delay implementation of the revised document until at least January 1, 2023. On February 1, 2021, the Office of Management and Budget (OMB) extended the approval of the current version of the Standardized Format, without changes, through February 29, 2024.[5] However, CMS published these new proposed changes on May 14, 2021, with a 30-day comment period and a proposed implementation date of January 1, 2022.[6] Part D plans rely on the guidance issued by OMB and CMS to appropriately manage and allocate resources to ensure compliance and provide the best possible service to their enrollees. The changes proposed by CMS were unexpected, given the previous OMB announcement and the proposed January 1, 2022, implementation deadline will not give Part D plans adequate time to develop and test needed changes which could result in inconsistencies across plans. CMS should provide at least 12 months for Part D plans to implement and test this process and as such, must delay the effective date for use of this Standardized Format until January 1, 2023.

[4] CMS, Final Rule, 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 Plan Program, and Programs of All-Inclusive Care for the Elderly, 86 Fed. Reg. 5864, 5899 (Jan. 19, 2021).
[5] https://www.cms.gov/files/document/memo-contract-year-2022-medication-therapy-management-mtm-program-submission-v-043021.pdf
[6] Supporting Statement for Paperwork Reduction Act Submissions, Medication Therapy Management Program Improvements, CMS-10396, OMB 0938-1154

Additional Recommendations

Digital technologies, such as mobile apps, provide a mode of addressing gaps for beneficiaries who desire an interactive experience where and when they need it. The existing standardized CMR only captures a static point in time and does not evolve with the beneficiary treatment experience which can change over time. Medication changes initiated after one CMR may not be updated in the standardized format for up to one year later, and only then if the beneficiary continues to meet MTM targeting criteria. Interactive technologies that are accessible to beneficiaries duplicating the functionality of the Standardized Format are available today but are not recognized by CMS as an official CMR format because they do not meet current format specifications.

Innovative technical functionality could transform static CMR summaries into an interactive continuum of MTM interventions. For example, with the ability to update a beneficiary's Medication List through technology such as a mobile app, 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 interactive functionality has the potential to reduce adverse events or detect gaps in care. Additionally, this incremental TMR interaction would document any new To-Do Lists created which can be included in the CMR history within the app. More importantly, it actively engages beneficiaries in managing their health. Beneficiaries would have a real-time, organized list of their medications and recommendations to use in the event they are hospitalized, at a physician appointment, or admitted to an emergency room. This information could be shared with the beneficiary's clinician and everyone could be confident that it is up to date and accurate.

Utilizing more personalized interactive technology could provide an engaging, continuous communication channel with clinicians about medications in a context that is integrated and shared across the health care team to achieve best health outcomes for beneficiaries. The most valuable asset of an electronic CMR format is the creation of two-way communication channel between an MTM beneficiary and an MTM provider, a trusted clinical resource. This provides beneficiaries with on-demand availability to a clinician when needed as well as allowing more proactive monitoring, communication, and documentation for beneficiaries to engage in an enhanced continuum of MTM interventions.

AMCP recommends that CMS permit plans to utilize alternatives to the standardized CMR paper format that meet the minimum content requirements and provide additional choices to beneficiaries including electronic, mobile application technologies, or other innovative communication mediums. CMS recognizes the importance of innovation in the MTM program, as evidenced by its testing of the Part D Enhanced MTM Model through the Innovation Center. This model allowed participants to "identify and implement innovative strategies to optimize medication use, improve care coordination, and strengthen health care system linkages."[7] CMS should continue to pursue innovation in the MTM program by allowing plans to implement alternatives to the Standardized Format.

[7] https://innovation.cms.gov/innovation-models/enhancedmtm

Conclusion

AMCP appreciates the opportunity to comment on the Information Collection Request "*Medication Therapy Management Improvements – Standardized Format (CMS 10396).*" We are committed to serve as a valuable resource to CMS on improving access to prescription drugs at lower costs, reducing costs in the health care system, and improving the Part D MTM Program. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer