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April 24, 2020

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 February 18, 2020. We appreciate the opportunity to leverage our members' expertise in offering feedback on this information request.

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 healthcare 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 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 50 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.

The Medicare Part D MTM Standardized Format is a written summary of a comprehensive medication review (CMR). Part D sponsors must at least annually offer a CMR to targeted beneficiaries and provide those receiving the CMR with a written summary. The summaries must comply with the requirements specified by CMS and include the CMR Cover Letter, Medication Action Plan (MAP), and Personal Medication List (PML). Flexibility in the presentation or delivery format of this material is limited only to supplemental information to the required paper version, stifling innovative approaches that Part D plans may wish to implement in order to more clearly and efficiently communicate this information to their enrollees. Such innovative approaches that could be used by plans include more streamlined paper forms, emails, patient portals, text messaging, mobile applications (apps) and other digital, electronic technologies. Additionally, the lack of flexibility prevents enrollees from being able to specify their preferred communication method, which may limit the usefulness of this information and result in the CMR service not providing the desired results.

AMCP funded a survey of Medicare beneficiaries who received a 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 PML more useful than the MAP and expressed interest in including additional information in the 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 42.9% felt that and electronic version would be helpful.[1] 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 on the proposed changes to the Standardized Format.

Proposed Changes to the Standardized Format

AMCP supports the proposed changes to the Cover Letter to improve its readability. AMCP also supports removing the instructions to update the list and to take the medication list everywhere from the Cover Letter since this information is included in the other CMR components. We agree with CMS that this improves the clarity of the document and more concisely presents the purpose of the complete CMR service.

AMCP supports the renaming of the PML and MAP to Medication List and Recommended To-Do list, respectively. These titles are more concise and more clearly state the purpose of each document.

[1] *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

We also support switching the order, to include the Medication List before the Recommended To-Do List. In the beneficiary survey, respondents found the PML/Medication List to be more useful than the MAP/Recommended To-Do List and so it is logical to include this document upfront.[2] AMCP supports the removal of the plan logo from the header as a requirement, but recognize it may be helpful to include to increase an enrollee's attention and confidence in the information provided. AMCP also supports removing repetitive information and the inclusion of the member's name to each page to prevent errors. Additionally, while AMCP is supportive of drawing attention to certain important information, such as noting changes in how listed medications are taken and the importance of sharing the list with providers and caregivers, we note that if CMS is going to require plans to use the specific icons included in the proposed format, plans will need these icons available in the format specifications. AMCP encourages CMS to allow plans the flexibility to determine the specific graphic icons they use to reduce implementation burden.

For the PML/Medication List, AMCP supports switching the format to landscape orientation and changing the presentation to a tabular chart format. The tabular format greatly improves readability and accessibility for beneficiaries and will make the Medication List significantly more usable. We are also supportive of the reduction of the Medication List introduction text as this removes repetitive information and decreases the amount of text included in the document, again improving readability and usability.

CMS proposes to move the "allergies" and "side effects" section to the end of the Medication List. While AMCP does not have concerns with this change, we urge CMS to be clear on what information needs to be included in the "side effects" category. Detailed information about potential medication side effects can come from a variety of sources, including the drug label and package inserts. While it is important for patients to know and understand potential side effects, providing all this information in the CMR paperwork will make the process more burdensome for pharmacists and plans and will lead to a much less usable document for patients by providing too much information. We urge CMS to allow flexibility to pharmacists in this section to use their clinical expertise and discretion to include the most relevant side effect information necessary for patient-centered communication and safe medication use. If not, CMS must specify what source should be used to provide side effect information.

CMS proposes to revise the "Other Information" section into the "My Notes and Questions" section with the goal of increasing member engagement. While AMCP strongly supports efforts to increase member engagement, we ask CMS to clarify whether this section is intended solely for the use of the patient, or if the pharmacist may provide additional information in this section. The removal of an open text field for pharmacists will eliminate opportunities for pharmacists 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 notes on information a patient may need. The previously cited Medicare beneficiary survey found that nearly half of responding patients did not fill

[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

out the sections of the CMR document that were meant for completion by the beneficiary, so we are concerned that this change is unlikely to lead to increased beneficiary engagement.[3]

With respect to the MAP/Recommended To-Do List, AMCP supports the changes and reductions to the instructions at the top of the document to improve readability and reduce burden. We also support the change to combine three sections from the previous version into one "What Should I Do?" column to support accessibility and to make the document more understandable. Placing the "What We Talked About" and "What Should I Do?" sections next to each other horizontally and adding a checkbox to the "What Should I Do?" column also improve the readability and practicality of this document and we support finalizing this change.

AMCP requests that CMS clarify which "federal government safe disposal website information" is supposed to be included in the Recommended To-Do List. Understanding that this is a statutory requirement and given the number of federal government websites related to the safe disposal of prescription drugs,[4] it is imperative for CMS to provide specifications about what information plans must provide.

Implementation of these proposed changes to the Standardized Format will require the allocation of considerable time and cost resources by plan sponsors and vendors. It is important that CMS recognize this and provide plan sponsors with details on the exact specifications and requirements of the new Standardized Format and ensure that the final specifications provide plans and vendors with sufficient time to implement them.

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 PML/Medication List through technology such as a mobile app, plans could detect the need for an additional intervention well before the next targeted medication review (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 MAPs/Recommended To-Dos created which can be included in the CMR history

[3] *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
[4] FDA, HHS, DEA, EPA

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 from 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, always-on communication channel with clinicians about medications in a context that's 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. Providing 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."[5] CMS should continue to pursue innovation in the MTM program by allowing plans to implement alternative to the Standardized Format.

Conclusion

AMCP appreciates the opportunity to comment on the Information Collection Request "*Medication Therapy Management Improvements – Standardized Format (CMS 10396).*" We are committed to be being 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

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