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October 5, 2020

Ms. Amy Larrick Chavez-Valdez
Director, Medicare Drug Benefit and C & D Data Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Part D Medication Therapy Management Program; Comprehensive Medication Review

Dear Director Larrick Chavez-Valdez:

The Academy of Managed Care Pharmacy (AMCP) thanks you for the opportunity to submit this letter detailing our feedback on the Part D Medication Therapy Management (MTM) program, in particular on the ability of plan sponsors and MTM vendors to provide the annual comprehensive medication review (CMR) to an individual other than the beneficiary in certain circumstances in which the beneficiary is unable to participate. We appreciate the opportunity to leverage our members' expertise in offering feedback on this program and hope to work together with the Centers for Medicare and Medicaid Services (CMS) to ensure a robust Part D MTM program that is responsive to beneficiary needs.

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 economics 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 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. The collective expertise of the MTMAG and the broader AMCP membership informs these comments.

Background

The Part D program requires that all Part D plan sponsors establish a MTM program to ensure that drugs prescribed to beneficiaries are "appropriately used to optimize therapeutic outcomes through improved medication use" and that the programs are "designed to reduce the risk of adverse events, including adverse drug interactions" for targeted beneficiaries.[1] As implemented by the Medicare Modernization Act of 2003 and strengthened by the Affordable Care Act, the Part D MTM program requires plan sponsors to adopt certain MTM strategies, including the provision of an annual CMR to all targeted beneficiaries. CMRs have been shown to be valuable to beneficiaries and to the Medicare program. A CMS commissioned study of the MTM program found that "MTM enrollees who received CMRs were more likely to experience increases in medication adherence and improvements in quality of prescribing, suggesting that the annual CMR may be one of the more important components of the MTM Program."[2] Additionally, CMS recognizes the importance of the CMR in its Part D Star Ratings program with the inclusion of a measure of a plan sponsor's CMR completion rate.

Given the recognized importance of the CMR, CMS has issued several regulations and guidance documents related to the offering of the CMR to targeted beneficiaries. Part D regulations require that a CMR "must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider" and that standardized action plans and summaries are to be provided to enrollees who accept a CMR.[3] Further, the regulation states that "[if] a beneficiary is offered the annual comprehensive medication review and is unable to accept the offer to participate, the pharmacist or other qualified provider may perform the comprehensive medication review with the beneficiary's prescriber, caregiver, or other authorized individual."[4]

In subsequent guidance, CMS has repeatedly stated that it recommends that the qualified MTM provider reach out to the beneficiary's prescriber, caregiver, or other authorized individual to take part in the beneficiary's CMR "in the event the beneficiary is cognitively impaired or *otherwise unable to participate*."[5] This broad language suggests that plan sponsors have the flexibility to design their MTM programs to have MTM providers perform the CMR with an individual other than the beneficiary in situations beyond when a beneficiary is determined to be cognitively impaired, and a plain reading of this language suggests that there are additional situations in which providing the CMR to a beneficiary's prescriber or caregiver is appropriate. However, CMS has interpreted this guidance, and the Part D regulation, to mean that the CMR can be provided to a prescriber or caregiver only when the beneficiary is determined to be cognitively impaired.

This imposed policy removes all flexibility from plan sponsors to implement more robust and responsive MTM programs and ultimately leads to fewer CMR completions. Plan sponsors should be expected to utilize more than one approach to connect with targeted beneficiaries directly and we

[1] See: 42 CFR § 423.153(d)
[2] Medication Therapy Management in Chronically Ill Populations: Final Report
[3] See: 42 CFR § 423.153(d)
[4] Ibid.
[5] See: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Memo-Contract-Year-2017-Medication-Therapy-Management-MTM-Program-Submission-v-040816.pdf, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Memo-Contract-Year-2020-Medication-Therapy-Management-MTM-Program-Submission-v-041019-.pdf, and https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Memo-Contract-Year-2018-Medication-Therapy-Management-MTM-Program-Submission-v-041817.pdf

agree with CMS that plan sponsors should be proactive in their attempts to provide MTM services to targeted beneficiaries. Nevertheless, there are additional circumstances under which a beneficiary may be unable to accept the offer to participate in the annual CMR or in which the MTM provider may be unable to reach a targeted beneficiary, making providing the CMR to a prescriber or caregiver appropriate. These situations are not captured by CMS's narrow interpretation of the regulatory language, as detailed below. We encourage CMS to reconsider its limited interpretation to ensure that more CMRs are completed and that MTM programs are responsive to their beneficiaries. We believe that it is in the best interest of beneficiaries, plan sponsors, and the Medicare program for more CMRs to be completed, whether directly with the beneficiary or with a prescriber or caregiver in the appropriate situation, to improve medication use and decrease the risk of adverse events.

Social Determinants of Health (SDOH)

The Department of Health and Human Services' (HHS) Healthy People 2020 initiative defines SDOH as the "conditions in the environments in which people live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality of life outcomes and risks."[6] Federal, state, and local governments are increasingly recognizing the impact of SDOH on physical and mental health and have included a focus on understanding and mitigating the impact of SDOH in various policies, programs, and initiatives. CMS itself has incorporated SDOH it its programs, signaling the agency's understanding of the importance of the effect of SDOH on Medicare beneficiaries. CMS granted Medicare Advantage plans greater flexibility to provide additional supplemental benefits, known as Special Supplemental Benefits for the Chronically Ill (SSBCI), to certain beneficiaries, including benefits that are non-primarily health related, such as meal delivery, food and produce, and non-medical transportation.[7] The CMS Innovation Center (CMMI) has established multiple models designed to help address SDOH including in the Medicare Advantage Value-Based Insurance Design Model, in which participants have the flexibility to offer certain benefits based on an enrollee's socioeconomic status, and through the Accountable Health Communities Model, which was designed to systematically identify and address the health-related social needs of Medicare and Medicaid beneficiaries through screenings and referrals.[8]

Medicare beneficiaries can be impacted by SDOH including lack of stable housing, lack of transportation, and lack of access to technology and/or the internet, among others. These issues make beneficiaries particularly vulnerable and can affect a beneficiary's ability to participate in a CMR. Despite the progress CMS has made in accounting for SDOH in other Medicare programs, CMS's guidance on the Part D MTM program appears to prevent plan sponsors from identifying targeted beneficiaries who they cannot reach and who may be experiencing negative SDOH, in order to provide the CMR to the beneficiary's prescriber or caregiver. The guidance language on the ability to offer the annual CMR to a prescriber or caregiver states that it "does not apply to situations where the sponsor is simply unable to reach the beneficiary or there is no evidence of cognitive impairment," leaving some of the most vulnerable Medicare beneficiaries without access to a CMR.

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[6] See: https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health
[7] See: https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/Supplemental_Benefits_Chronically_Ill_HPMS_042419.pdf
[8] See: https://innovation.cms.gov/innovation-models/vbid and https://innovation.cms.gov/innovation-models/ahcm

While we agree that all due diligence should be done and multiple efforts should be made to reach the beneficiary directly, it is our belief that performing the CMR with the beneficiary's caregiver or prescriber is preferable to not completing the CMR at all. Doing so allows the beneficiary to still benefit from the identification of potential concerns with their medications and promoting optimal medication use.

Health Literacy

HHS defines health literacy as "the degree to which individuals have the capacity to obtain, process, and understand basic health information needed to make appropriate health decisions."[9] Health literacy affects many aspects of health care, including a patient's ability to understand their health insurance coverage or their ability to read and understand a prescription drug label. Studies have shown that lower rates of health literacy can lead to increased costs for Medicare beneficiaries and to comorbidities and poor access to health care in older Americans.[10,11] A Medicare beneficiary with limited health literacy may not be able to actively participate in a CMR or may have difficulty understanding and acting on the information provided. Plan sponsors should be able to design their MTM programs to address the needs of these beneficiaries, including offering the CMR to an individual other than the beneficiary if the beneficiary, through previous outreach, demonstrates an ongoing inability to understand drug adherence and safety concerns generally or the CMR process itself.

Language Barriers

Studies have shown that language barriers can have a significant negative impact on health care and health care access, such as research showing that patients with limited English proficiency have lower rates of health care screenings and increased and more severe hospital adverse events.[12,13] Importantly for the Part D MTM program, research has shown that patients with limited English proficiency report issues understanding medication labels and are at increased risk of adverse medication reactions.[14] Given that one of the goals of the Part D MTM program is to reduce the risk of adverse events, including drug interactions, plan sponsors should have the flexibility, utilizing the tools and information available such as a patient's medical record or repeated previous outreach, to provide the annual CMR to an individual other than the beneficiary in circumstances where there is a significant language barrier.

Behavioral and Mental Health

[9] See: https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/health-literacy#1
[10] https://www.amjmed.com/article/S0002-9343(05)00011-2/fulltext
[11] https://pubmed.ncbi.nlm.nih.gov/16696742/#:~:text=CONCLUSION%3A%20Limited%20health%20literacy%20was,health%20disparities%20in%20older%20people.
[12] https://ajph.aphapublications.org/doi/10.2105/AJPH.2004.041418
[13] https://academic.oup.com/intqhc/article/19/2/60/1803865
[14] https://link.springer.com/article/10.1111%2Fj.1525-1497.2005.0174.x

Research has shown that behavioral and mental health diagnoses lead to higher health care costs for Medicare beneficiaries.[15] Studies have also demonstrated that patients with mental health conditions may have issues coping with medical conditions, navigating the health care system, and engaging in appropriate self-care.[16] For beneficiaries who fail to respond to outreach for MTM services, Part D plan sponsors should have the ability to review medical records for information such as prescribed medications to treat mental health conditions or other possible evidence of behavioral health conditions and, if found, offer the annual CMR to another individual such as the beneficiary's prescriber or caregiver.

Additionally, some patients may have a behavioral or mental health diagnosis that leads them to be unable to participate in the annual CMR even though they are cognitively intact. Other specialized clinical situations as identified and documented by the MTM provider's clinical judgement, for example a patient diagnosed with schizophrenia, should be acceptable reasons for a CMR to be completed with an alternative recipient even if there is no evidence of cognitive impairment.

Beneficiary Choice

In some circumstances, a beneficiary who is cognitively intact may state his preference that the annual CMR be performed with another individual. A targeted beneficiary who is blind, deaf or hard of hearing, who does not manage their own medications, or who is experiencing any one of the abovementioned issues such as lack of stable housing, lack of access to a telephone, mental health concerns, or language discordance may not be cognitively impaired and may respond to plan sponsor outreach but prefer to have their CMR performed with their caregiver or prescriber. Further, in some situations, a prescriber may indicate that they would like to receive a CMR on behalf of a beneficiary who is unable to participate or who is not responsive to plan sponsor outreach. Given that the Part D MTM program is designed to be a beneficiary-focused program, CMS should recognize beneficiary choice as an acceptable circumstance under which a CMR can be provided to an individual other than the beneficiary.

Conclusion

The Part D MTM program, in particular the performance of a CMR, has been proven to improve medication adherence and quality prescribing. AMCP believes that increasing the number of CMRs completed should be a priority for the Medicare Part D program generally, and for plan sponsors in particular, and that allowing flexibility in the determination of whether a beneficiary is unable to participate will lead to more CMRs completed and to the subsequent increases in positive outcomes. We do not believe that any of the abovementioned situations should be used to justify offering the CMR to a prescriber or caregiver prior to, or in lieu of, diligent efforts to reach the beneficiary directly, but do believe that additional flexibility is warranted to make the MTM program more responsive to beneficiary needs, particularly for those most vulnerable. AMCP urges CMS to issue guidance providing additional flexibility in the Part D MTM Program for annual CMRs to be performed with an individual other than the beneficiary in appropriate circumstances as described above.

[15] https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1532-5415.2008.02134.x
[16] https://www.sciencedirect.com/science/article/pii/S221133551830113X

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