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April 6, 2020

Mr. Alex M. Azar, II
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
P.O. Box 8013
Baltimore, MD 21244-8013

Attention: CMS–4190–P

Re: Medicare and Medicaid Programs; Contract Year 2021 and 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

Dear Secretary Azar and Administrator Verma:

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 proposed rule, *"Medicare and Medicaid Programs; Contract Year 2021 and 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"* published on February 18, 2020. We appreciate the opportunity to leverage our members' expertise in providing feedback on this proposed rule.

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 offers comments on the following sections of the notice:

A. Permitting a Second, "Preferred", Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)
B. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)
C. Establishing Pharmacy Performance Measure Reporting Requirements (§ 423.514)
D. Beneficiaries With History of Opioid-Related Overdose Included in Drug Management Programs (DMP) (§ 423.100)

In addition, AMCP urges CMS to consider postponing implementation of many of the changes proposed to take effect in 2021 due to the ongoing public health emergency related to the COVID-19 outbreak. AMCP members and their organizations are working tirelessly with patients and with CMS to ensure continued access to necessary medications during this emergency. Given the need for continued focus on these efforts, we encourage CMS to consider whether the resources and effort required to implement many of the changes proposed in this rule, both by plans and by CMS, will take away from the effort to address the public health emergency.

A. Permitting a Second, "Preferred", Specialty Tier in Part D

CMS Proposal
CMS proposes to allow Part D plan sponsors to establish up to two specialty tiers, with sponsors having the flexibility to determine which drugs are placed on each specialty tier.

AMCP Response
AMCP supports this proposal to allow Part D plan sponsors to establish two specialty tiers and the proposed ability for plan sponsors to determine which drugs are included on each specialty tier. AMCP supports the use of well designed, evidence-based formularies to enhance the quality of pharmaceutical care while lowering costs by encouraging the use of those prescription medications that are demonstrated to be the safest, the most effective, and that produce positive patient outcomes. Permitting Part D plan sponsors to establish a second specialty tier will allow plan sponsors to design formularies that are even more effective at recommending the most appropriate drug choice for patients while limiting patient out-of-pocket costs.

CMS states that the introduction of more biosimilar biological products to the pharmaceutical market is a factor in its decision to propose the option of a second specialty tier in Part D. Biologics and biosimilars are playing an increasingly important role in the country's health care system – both in terms of scientific improvements in the treatment of disease and influencing overall drug costs. AMCP believes that providing this additional formulary flexibility will both allow for increased uptake in the use of biosimilars and allow for lower costs for patients, as the addition of a preferred and non-preferred specialty tier will lead to increased negotiation from manufacturers for formulary placement, encouraging greater competition and lower costs. AMCP agrees with the Medicare Payment Advisory Commission's (MedPAC) recommendation that a second specialty tier, if well-designed and implemented, could reduce the need for nonformulary exceptions which would reduce plan

administrative burden and encourage beneficiaries to switch to lower cost biosimilar products.[1]

As CMS considers additional policy changes to increase the use of biosimilar products, the agency should consider expanding the scope of the permitted midyear formulary changes in Part D to include biosimilars. In its CY 2019 Medicare Advantage and Part D Policy and Technical Changes Rule [CMS-4182-F], CMS finalized a policy allowing Part D plan sponsors more flexibility to implement midyear generic substitutions by permitting sponsors to immediately remove or change the preferred or tiered cost-sharing of brand name drugs to substitute or add therapeutically equivalent generic drugs to their formularies.[2] However, CMS explicitly did not include biological products in this policy change. AMCP supports the ability for plan sponsors, using a well-designed and implemented formulary development and maintenance process led by a Pharmacy & Therapeutics Committee, to make midyear formulary changes to encourage greater use of safe, effective, and lower cost therapies and recommends that CMS allow plan sponsors to make midyear formulary changes for biological products as well. Food and Drug Administration (FDA)-approved biosimilars must be found to be highly similar to and have no clinically meaningful difference from the FDA-approved reference biological product.[3] Given the rigorous biosimilar evaluation and approval process, "prescribers and patients should have no concerns about using these medications instead of reference products" and CMS should allow Part D plan sponsors to make midyear formulary changes, in a manner similar to current process for therapeutically-equivalent generic drugs, to encourage greater use of biosimilars.[4]

B. Beneficiary Real Time Benefit Tool (RTBT)

CMS Proposal
CMS proposes to add a requirement that Part D plan sponsors implement a beneficiary RTBT that would allow enrollees to view accurate, timely, and clinically appropriate, patient-specific, real-time formulary and benefit information, effective January 1, 2022.

AMCP Response
AMCP supports the use of RTBTs in the Part D program that would allow beneficiaries to view specific out-of-pocket cost information and we agree that increasing prescription drug price transparency is critical to lowering both overall drug costs and patients' out-of-pocket costs. The National Council for Prescription Drug Programs' (NCPDP) task group, "Real Time Prescription Benefit Standard Task Group," focused on developing an industry wide standard for real time benefit checking and has approved a beta version of the NCPDP Real-Time Prescription Benefit (RTPB) Standard, which is available for pilot use.[5] Given that a recognized and balloted standard for real time benefit checking is likely to be available for plan use by the January 1, 2022 effective date, AMCP encourages CMS to finalize this provision.

[1] June 2016 Report to Congress: Medicare and the Health Care Delivery System; Chapter 6
[2] https://www.regulations.gov/document?D=CMS-2017-0156-1670
[3] https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products
[4] https://www.fda.gov/media/108905/download
[5] https://www.ncpdp.org/NCPDP/media/pdf/pressrelease/NCPDP-Announces-BETA-Version-of-RTPB-Standard-081319.pdf

Additionally, AMCP recommends that CMS coordinate with the Office of the National Coordinator for Health IT (ONC) to include certification requirements and testing for a RTBT in the federal health IT certification programs. Any burden for meeting certification requirements for a RTBT should lie with the technology vendors and not with the PDP sponsors who rely on vendors to provide usable functionality.

C. Establishing Pharmacy Performance Measure Reporting Requirements

CMS Proposal
CMS proposes to establish new reporting requirements to require Part D plan sponsors to disclose the pharmacy performance measures they use to evaluate pharmacy performance in their network pharmacy agreements. CMS also seeks comments on Part D pharmacy performance measures more broadly, including recommendations for potential Part D Star Ratings measures to incentivize utilization of a standard set of pharmacy performance measures.

AMCP Response
AMCP supports the continued development of performance measures, and partners with complementary organizations, such as the Pharmacy Quality Alliance (PQA), to ensure alignment of all health care stakeholders in the pursuit of improvements in the quality of patient care management. AMCP is an active member of PQA and supports their efforts to bring the industry together in a transparent and collaborative process to develop a set of pharmacy performance measures.

As to the proposed requirement that Part D plan sponsors disclose to CMS the pharmacy performance measures they use to evaluate network pharmacy performance, AMCP encourages CMS to ensure that any public reporting of the measures is effective for communicating this information to beneficiaries and with pharmacies and that the format does not cause confusion for these stakeholders. CMS should make sure that the information reported is relevant to pharmacies and beneficiaries and does not disclose any plan proprietary information that could jeopardize financial agreements between plans and pharmacies. CMS should engage relevant stakeholders in a collaborative and transparent process to determine the most appropriate format and reporting medium for this information. Additionally, AMCP urges CMS to allocate adequate funding to support the development of a standard set of pharmacy measures and to establish a timeline for the use of these measures in Part D that is developed with industry and other stakeholder input.

D. Beneficiaries With History of Opioid-Related Overdose Included in Drug Management Programs (DMP)

CMS Proposal
Per the SUPPORT Act statute, CMS proposes to require Part D plan sponsors to implement Drug Management Programs (DMPs) designed to engage in targeted care management for beneficiaries at-risk for abuse or misuse of frequently abused drugs, beginning on January 1, 2022. Specifically, Part D plan sponsors will be required to expand the population of

beneficiaries who are eligible and targeted for medication therapy management (MTM) programs to include these at-risk beneficiaries.

AMCP Response
AMCP believes that a holistic, comprehensive, and multi-stakeholder approach among health care providers and patients is necessary to truly address the substance abuse epidemic and that pharmacists play a vital role in this effort. AMCP is also strongly supportive of effective MTM programs designed based on the needs of identified populations, that utilize appropriate patient selection criteria and interventions to meet the needs of individual members and optimize medication use. We were supportive of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act and commend CMS for its actions to implement these important provisions.

As CMS implements the requirements for Part D plan sponsors to include beneficiaries at-risk for abuse or misuse of frequently abused drugs in their MTM programs, the agency must ensure that plans do not face additional Part D MTM data reporting burdens for the Part D Reporting Requirements and that plans are not disproportionately impacted by reporting requirements for a program that CMS estimates will include approximately 10,000 beneficiaries. CMS should consider reducing the number of required reporting elements for the MTM program and ensure that plans are given an adequate amount of time to operationalize the changes to their MTM programs required by this proposal.

Conclusion

AMCP appreciates the opportunity to comment on CMS–4190–P: *Medicare and Medicaid Programs; Contract Year 2021 and 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*. We are committed to be being a valuable resource to CMS on improving access to prescription drugs at lower costs and reducing costs in the health care system. 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