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March 2, 2020

Ms. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Baltimore, MD 21244-8016  
Attention: CMS-9916-P

***Re: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans***

Dear 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the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to its new Draft Guidance, *"Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans"* published in the Federal Register on February 6, 2020. We appreciate the opportunity to leverage our members' expertise in offering feedback on this guidance. AMCP offers comments on the following sections of the notice:

- A. Cost Sharing Requirements (§ 156.130)
- B. Reimbursement for Clinical Services Provided to Enrollees (§ 158.140)

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.

**A. Cost Sharing Requirements (§ 156.130)**

*CMS Proposal*

CMS proposes to revise existing regulations to permit, but not require, amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by a drug manufacturer to enrollees for a specific prescription drug to be counted toward

the enrollee's annual cost sharing. Under the revised proposal, plans will have the flexibility to determine whether to include or exclude coupon amounts, regardless of whether a generic equivalent is available.

#### *AMCP Response*

AMCP encourages CMS to finalize this proposal, as it will help plans continue to effectively utilize proven cost management tools. Nearly all employer-sponsored group health plans require employees and their dependents to pay a portion of the costs for most prescriptions out-of-pocket and these expenses generally come in the form of deductibles, copays, and coinsurance. The intent of these costs is to influence a number of outcomes including: lowering monthly premiums in exchange for the enrollee covering additional costs throughout the plan year if needed; helping direct patients to more cost-effective therapies, including the use of low-cost generic medications; and ensuring that patients understand the financial impact of high cost prescription medications by engaging enrollees as consumers involved in financial decisions around their treatment options. The amount of out-of-pocket costs an individual or family may be subject to pay in a given plan year is also often limited by a defined maximum out-of-pocket (MOOP) amount.

Drug manufacturers regularly offer financial assistance to patients (generally referred to as "copay cards" or "coupons") to offset out-of-pocket expenses for certain high-cost drugs. Although these programs can help offset costs for plan enrollees, they have the overall effect of increasing prescription drug costs for plans, as patients will no longer be incentivized to use lower cost alternatives, including generic drugs, when they reach their MOOP limit.

Manufacturer coupons and other forms of financial assistance programs sponsored by manufacturers distort the economic incentives used by health plans and pharmacy benefit managers (PBMs) to encourage patients to use prescription drugs with lower overall costs and can undermine the formulary development process and utilization management techniques. Perhaps counterintuitively, they also raise the risk of increased overall costs for patients. While the patient has a lower cost-sharing responsibility at the initial point of sale for a high cost drug, the health plans, pharmacy benefit managers, or plan sponsors are responsible for the reimbursement cost to the pharmacy. This raises the costs of administering the prescription drug benefit as a whole, which in turn leads to higher premiums for patients. Additionally, some programs can needlessly encourage the use of more expensive brand-name products over their generic counterparts and can undermine the formulary development process by encouraging the use of products that have lower cost therapeutic alternatives.

AMCP is supportive of programs that help patients afford their prescription drugs. However, counting financial assistance programs toward deductibles and MOOP limits can have a substantial negative impact on the use of managed care tools implemented to drive members to use evidence-based, cost-effective therapies. By not requiring ACA-compliant plans to count coupon discount amounts towards members' cost-sharing limits, patients will still be able to continue to benefit from the available assistance programs while preserving

plan's ability to implement the managed care tools that have proven to lower costs for patients and for the health care system overall. AMCP urges CMS to finalize this proposal.

## **B. Reimbursement for Clinical Services Provided to Enrollees (§ 158.140)**

### *CMS Proposal*

CMS proposes to require plans to deduct any price concessions received by the plan, as well as any price concessions received and retained by an entity providing pharmacy benefit management services to the plan, including drug price negotiations, from incurred claims toward the calculation of the plan's medical loss ratio (MLR). CMS proposes to define the phrase "price concessions" to "capture any time an issuer or an entity that provides pharmacy benefit management services to the issuer receives something of value related to the provision of a covered prescription drug (for example, manufacturer rebate, incentive payment, direct or indirect remuneration, etc.) regardless from whom the item of value is received (for example, pharmaceutical manufacturer, wholesaler, retail pharmacy, vendor, etc.)."

### *AMCP Response*

AMCP is concerned that CMS's included definition of "price concessions" is without reference to any existing regulatory definitions and is not consistent with other uses of "price concessions" existing elsewhere in CMS regulations. If finalized, this proposal and definition would require issuers to deduct from the numerator of the MLR ratio (incurred claims) payments such as bona fide service fees which manufacturers pay to PBMs for a variety of critical services under a well-developed four-part test that ensures these payments are fair-market-value for services actually performed. While AMCP urges CMS not to finalize this proposal, given that these are fees that are, by definition, *not* price concessions, if the proposal is finalized, CMS should adopt a definition of price concession that is consistent with its use in section 1150A of the Social Security Act (regarding PBM transparency requirements).

AMCP is further concerned at what amounts to interference in contractual arrangements between issuers and their contracted vendors, including PBMs. Under the current regulatory regime, issuers are given a choice to adopt a pass-through model, or else permit their contracted PBM to retain at least a portion of rebates as compensation. The proposed rule very clearly disadvantages one type of contract over another, forcing plans to choose a model that might not otherwise be in the best interests of their enrollees, particularly in keeping premiums affordable. It is possible that premiums may actually increase with this change in contracting incentives and the cost to enrollees for their prescriptions at the pharmacy counter will remain unchanged by this proposal. AMCP supports the goals of improving access to prescription drugs at lower prices and reducing overall health care costs but this proposal falls short in making medications more affordable for consumers.

## Conclusion

AMCP appreciates the opportunity to comment on CMS-9916-P: *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans*. We are committed to 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](mailto:scantrell@amcp.org).

Sincerely,

A handwritten signature in black ink, appearing to read "SCantrell", is positioned above the typed name.

Susan A. Cantrell, RPh, CAE  
Chief Executive Officer