



September 1, 2020

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

***Re: Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen***

Dear Secretary Azar:

The Academy of Managed Care Pharmacy (AMCP) writes to express our concerns about the “Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen,” issued on July 24, 2020. Leveraging the expertise of our members, we offer the below comments on the potential negative impact of this Executive Order on patients and the health care system.

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 supports the Administration’s goals to reduce prescription drug spending for consumers and to encourage drug pricing transparency within the health care system. As the Administration continues to work to encourage system transformation to promote affordable health care, AMCP recognizes that the need to address the rising cost of prescription medications remains critical, and we support competitive marketplace solutions to lower costs for Americans. AMCP continues its efforts and work with the Administration and Congress to find solutions and to support proposals that achieve the goals of optimizing medication use at affordable costs. To this end, AMCP registered its concerns in comments on the withdrawn proposed rule to eliminate the safe harbor protections for rebates that currently exists in the federal Anti-Kickback Statute (AKS) and to replace these protections with proposed new safe harbors allowing for point-of-sale discounts to beneficiaries and for manufacturer-paid service fees to PBMs. AMCP has similar concerns about the directive in this Executive Order that would have the Department of Health and Human Services (HHS) take the same regulatory actions related to the AKS and manufacturer rebates.

AMCP is concerned that the Executive Order and any rulemaking to implement it that removes the safe harbor protection for rebates may result in unintended consequences for patients, payers, and providers. We caution HHS that focusing only on rebates is a diversion from the issues facing Medicare beneficiaries on the list price of medications. The rebate system is currently an important lever to ensuring affordability of prescription medications and health care premiums for Americans,



and it is unclear what would replace this important mechanism that payers now use to manage overall beneficiary costs.

Based on the Centers for Medicare and Medicaid Services Office of the Actuary (CMS OACT) analysis, while estimating that Medicare beneficiaries could pay less for their prescriptions, Part D premiums would increase by \$49.9 billion, “an increase that would be borne by Medicare Part D enrollees,” and federal Medicare program spending would increase by \$196.1 billion over the next decade.<sup>1</sup> As cited in the withdrawn proposed rule, OACT estimated that beneficiary premiums would increase 19% per month.<sup>2</sup> Additionally, according to the US Government Accountability Office (GAO) and contrary to the assertions in the Executive Order text, pharmacy benefit managers (the referred-to “middlemen”) pass back 99.6% of all negotiated rebates to prescription drug plan sponsors, who in turn use the rebates to help offset the growth in drug prices to control premiums for enrollees.<sup>3</sup>

The Administration has suggested that drug list prices would likely fall in the absence of rebates, but there is uncertainty regarding how manufacturers will alter drug pricing should the rebate safe harbor be eliminated. Additionally, while beneficiaries with high copays for prescription medications where rebates are offered could stand to experience some relief in out-of-pocket costs, patients with no prescriptions or those utilizing cost-saving generics or prescription medications that are not tied to rebates are likely to see higher premiums. AMCP is also concerned that the elimination of the rebate safe harbor could disincentivize use of generics and more affordable alternative drugs if a patient would receive a steep discount on a higher-cost medication. This could lead to plan sponsors and pharmacies paying higher overall net costs as compared to patient use of a generic or lower cost alternative. Prior to making any changes to the AKS, the full implications of this proposal must be carefully examined and tested, including the effects on beneficiary premium payments and medication costs for those who do not receive the benefit of rebates.

Furthermore, given that the country is in the midst of the unprecedented COVID-19 public health emergency, now is not the time to undertake a policy change that is likely to have a negative impact on out-of-pocket costs for Medicare beneficiaries and that will significantly increase federal spending. AMCP appreciates the work HHS has done to address and manage the current public health crisis and asks that the agency take no immediate actions that would increase costs for vulnerable populations.

## Conclusion

AMCP appreciates the opportunity to voice our concerns about the “Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen.” We are committed to being a valuable resource to HHS on improving access to prescription drugs at lower costs and reducing costs in the health care system but reviving the proposed rule eliminating the AKS safe harbor for rebates is not

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<sup>1</sup> See: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf>

<sup>2</sup> See: <https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals>

<sup>3</sup> See: <https://www.gao.gov/assets/710/700259.pdf>



the solution. We stand ready to work with HHS to seek alternative policy changes that will directly address high drug prices and result in actual decreased costs for patients. 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'.

Susan A. Cantrell, RPh, CAE  
Chief Executive Officer