

January 25, 2019

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**VIA ELECTRONIC SUBMISSION**

Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-4180-P  
P.O. Box 8013  
Baltimore, Maryland 21244-8013

Dear Administrator Verma:

On behalf of the American College of Osteopathic Family Physicians (ACOFP), we appreciate the opportunity to respond to the *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses* proposed rule.

ACOFP is the professional organization representing more than 20,000 practicing osteopathic family physicians, residents, and students throughout the United States who are deeply committed to advancing our nation's health care system by improving health care delivery and outcomes, and ensuring that patients receive high-quality care. Generally, we support efforts to rein in the growing cost of prescription drugs to ensure patients have access to the medications as prescribed by their physicians.

Overall, as an organization our osteopathic family physicians practice in variety of settings, including in solo, small, group, rural, Native American Indian healthcare, and alternative payment models (APM). Generally, we are supportive of efforts to transition the health care system toward value-based care, which emphasizes holistic care, wellness, prevention, and avoiding unnecessary resource use. We also support proposals designed to leverage primary care to improve outcomes and reduce costs and to ensure vulnerable populations have sustained access to family physicians. We are concerned with proposals that may create unnecessary and additional barriers to patient access to needed care.

Our full comments are detailed on the following pages. Thank you for the opportunity to share these with you. Should you need any additional information or if you have any questions, please feel free to contact ACOFP at [advocacy@acofp.org](mailto:advocacy@acofp.org) or (847) 952-5100.

Sincerely,



Duane G. Koehler, DO, FACOFP *dist.*  
ACOFP President

ACOFP appreciates CMS' continued focus and effort to lower drug prices and reduce patient out-of-pocket costs. We understand and support the goal of alleviating financial pressures for Medicare beneficiaries when purchasing prescription drugs. Too often, patients will forego needed medication or will not adhere to their medication regimen due to the rising cost of prescription drugs. This is especially problematic for patients with long-term, chronic conditions who rely on these medications. Included among this patient population are those who rely on medications in the six protected classes. Medication adherence is critical not just in terms of clinical effectiveness of the drug but also in terms of reducing or avoiding unnecessary, downstream medical costs. We therefore reiterate our appreciation for the agency's efforts to ensure patients have access to these and other critically important medications.

We also support the agency's efforts to prevent pharmaceutical manufacturers from "gaming" the system through unjustified price increases and introducing "new" formulations of the same drug and removing the cheaper older version from the market. We also support the agency's proposed implementation of the legislation banning gag clauses, which we believe will improve patient access to medications, and CMS' proposal to require plan sponsors to implement a real-time benefit tool (RTBT). ACOFP believes that the RTBT will improve transparency and assist physicians in terms of drug counseling activities and assisting patients to best identify clinically appropriate and affordable medications.

While we support the overarching goals of these proposals, ACOFP also has concerns that some of the proposed changes may create new barriers and challenges for patients with timely access to needed medications. Specifically, we are concerned with the burden of step therapy on physicians and significant potential harm this may have on beneficiaries. While CMS previously announced that Medicare Advantage (MA) plans may use utilization management tools for Part B drugs (i.e., step therapy), we are extremely concerned with the impact this will have on patient care. ACOFP is also concerned with the CMS' proposal to allow prior authorization or step therapy requirements for protected class drugs. CMS states that these efforts will help to manage costs. As the agency is well-aware, actions driven by financial incentives can and often do result in patient harm. This is especially true when newer medications have shown a significant benefit that can positively impact the patient's overall condition, but are avoided due to costs. For example, Jardiance demonstrated significant reduction in cardiac events in diabetic patients and Trintellix demonstrated significantly fewer side effects and greater efficacy among patients with depression. If the physician sees a distinct advantage in individualized therapy, step therapy is a delay in needed treatment.

Therefore, we urge the agency to, at a minimum, ensure that this policy only apply to new prescriptions and not existing courses of successful treatment. Further, we ask that CMS consider explicitly requiring Part D and MA plan sponsors to coordinate with and involve practicing physicians in the development of utilization management tools.

ACOFP reiterates its appreciation and support for CMS' efforts to ensure patients can continue to access needed Part D and B drugs. While we support efforts to reduce financial burdens and barriers, we urge the agency to ensure new barriers are not created. Based on our first-hand experience, prior authorization and step therapy is especially challenging for patients. Any utilization management tools should not be applied to patients already on the medication in question and should only be applied to new starts. Further, stringent monitoring and protections must be in place to ensure there is no patient harm resulting from such policies.