AMERICAN ACADEMY OF FAMILY PHYSICIANS

January 25, 2019

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

Dear Administrator Verma:

On behalf of the American Academy of Family Physicians (AAFP), which represents 131,400 family physicians and medical students across the country, I write in response to the proposed rule titled, "Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses" as published by the Centers for Medicare & Medicaid Services (CMS) in the November 30, 2018, *Federal Register*.

This proposed rule amends the Medicare Advantage (MA) program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations in an effort to lower drug prices and thus reduce the out-of-pocket costs for Part C and D enrollees.

Negotiated Price
CMS proposes to define "negotiated price" in the regulation to eliminate post-point of sale price concessions. The negotiated price will be the lowest possible payment the pharmacy can receive, and CMS anticipates the effect on beneficiaries will be lower cost sharing in co-pays.

The AAFP supports steps to reduce costs to beneficiaries in the Part C and D programs. Managing prescription drug prices for their patients is an important concern for family physicians. Family physicians have a meaningful interest in the drug pricing debate, in part because of the complexity of care provided and the fact that the number and complexity of conditions, complaints, and diseases seen in family medicine is far greater than those seen by any other physician specialty. Ensuring access to affordable medications is an integral part of a family physician's role as an advocate for their patients.

Part D Explanation of Benefits
CMS proposes to require the inclusion of drug pricing information and lower cost therapeutic alternatives in the Explanation of Benefits (EOB) that Part D plans send members.

The AAFP fully supports this step within the Part C and D programs. We offered our support for this policy in a December 12, 2018, letter in response to the proposed rule titled, "Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency." As stated in that letter, **the AAFP wholeheartedly supports the policy objective of ensuring beneficiaries are**

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provided with relevant information about the costs of prescription drugs and biological products. The inclusion of drug pricing information in the Part D EOB will allow patients to make more informed decisions in the future that minimize their out-of-pocket costs and total expenditures borne by the Part C and D programs.

Protected Class Drugs

The proposed rule maintains all six protected drug classes (anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection) but offers three exceptions that would allow Part D sponsors more ability to negotiate with manufacturers. First, it would permit Part D plans to implement broader use of prior authorization, step therapy, and indication-based formulary design for protected class indications. This would also allow Part D sponsors to exclude the protected class drug from the formulary for non-protected class indications. Second, Part D plans would be permitted to exclude from their formularies a protected class drug or biologic that is a new formulation that does not provide a unique route of administration, regardless of whether the older formulation remains on the market. Finally, Part D plans could exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold relative to the price in a baseline month and year, beyond the rate of inflation.

Beneficiary protections would be in place and include CMS' review of Part D plan formularies, an expedited appeals process, and a requirement for plans to cover two drugs in every therapeutic class.

The AAFP opposes any actions that limit a patient' access to medications prescribed by their physician(s). For this reason, the AAFP opposes the proposed changes to the current status of the protected drug classes. We recognize there may be noteworthy proposals under consideration that may result in lower costs but urge the Administration to prioritize patient access to these essential drugs.

Medicare Advantage

The rule reaffirms MA plans' existing authority to implement utilization management and prior authorization programs for managing Part B drugs.

While the AAFP recognizes the agency's desire to lower the overall cost of prescription drugs to the Medicare programs and to beneficiaries, the AAFP reminds CMS that physicians already face recurrent and burdensome administrative requirements like prior authorizations that create treatment barriers. According to a 2017 American Medical Association survey, 92 percent of respondents reported care delays due to prior authorizations, and 78 percent reported that prior authorizations can lead to treatment abandonment. **The AAFP urges the Administration to address drug prices, but not by imposing further prior authorizations onto physicians.**

We appreciate the opportunity to comment. Please contact Robert Bennett, Federal Regulatory Manager, at 202-655-4908 rbennett@aafp.org with any questions or concerns.

Sincerely,

Michael L. Munger, MD, FAAFP
Board Chair