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

***Re: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses,* (CMS-4180-P)**

Dear Administrator Verma:

The Association of American Medical Colleges (AAMC) welcomes the opportunity to submit comments on the proposed rule entitled "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses" 83 *Fed. Reg.* 62152 (November 30, 2018) issued by the Centers for Medicare and Medicaid Services (CMS).

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 152 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The AAMC appreciates CMS's efforts to address drug prices. As drug prices take a larger share of the health care dollar, AAMC members struggle firsthand to ensure patient access to needed medications. Our members are frequently the sole source of care for low-income and otherwise underserved populations of Medicare beneficiaries. Many of these beneficiaries' struggle with higher disease burden and require complex, coordinated medical care. Balancing access to medications to treat their conditions, however, can be made harder when there are additional steps – *e.g.*, prior authorization, tiering, step therapy – providers must take to secure drugs for their patients.

While the AAMC is supportive of ways to improve competition and decrease drug prices, we are concerned that allowing for drug exclusions on MA and Part D formularies could result in some beneficiaries being unable to access needed medications. As CMS considers ways to tackle high drug costs, it must ensure that: (1) beneficiaries' access to medications is not compromised and (2) burden on providers is not expanded through the use of prior authorization and step therapy. Even if prior authorization and exception requests are required, the most important factor must be the treating provider's clinical judgment about what is best for the patient rather than limitations based solely on cost.

Ensure Changes to the "Protected Classes" Do Not Limit Access to Needed Medication

In the proposed rule, CMS proposes to relax the requirements to cover "all or substantially all" drugs in six therapeutic classes of drugs for MA and Part D plans. Currently, MA and Part D plans are required to include on their formularies "all or substantially all" drugs in six categories or classes – antidepressants, antipsychotics, anticonvulsants, immunosuppressants for treatment of transplant rejection, antiretrovirals, and antineoplastics. The requirement for these "protected classes" was put in place to ensure beneficiary access to these drugs. However, CMS states in the proposed rule that the protected classes: policy "significantly reduces any leverage the sponsor has in price negotiations" and that the proposals outlined in the proposed rule will provide plan sponsors greater leverage to negotiate lower drug prices. (83 FR 62156) The AAMC is concerned that changes to the protected classes requirement does not reflect Congressional intent to ensure beneficiaries have access to needed medications in these drug classes.

While the cost of prescription drugs within the protected classes may decrease as a result of these proposals, medical costs, particularly acute care, and total costs of care could actually increase for patients that do not receive or are delayed in receiving their drugs. Interruptions or noncompliance with medication regimens can result in exacerbation of illnesses that require emergent care, with many patients seeking emergency care at AAMC-member hospitals. According to the Agency for Healthcare Research and Quality (AHRQ) there has also been a rise in emergency department (ED) visits for treatment of mental health conditions. The rate of mental health-related ED visits increased 44.1 percent from 2006 to 2014.[1] Limiting access to medications, such as those to treat mental health conditions that are included in the protected classes, could increase the rate of these ED visits. CMS should monitor increases in ED visits for mental health conditions that could be the result of decreased access to needed medications.

Utilization Management Tools Should Not Be Overly Restrictive on Beneficiaries

CMS is proposing to allow utilization management (UM) tools – specifically, step therapy and prior authorization – for drugs in the protected classes and these tools would apply to beneficiaries who are initiating therapy (new starts) or are currently taking a drug (existing therapy). (p. 62157) Compelling beneficiaries to complete step therapy requirements before the new plan will cover their current medications would not only limit beneficiaries' options to change plans to one that better suits their needs but also may harm beneficiaries' health. The AAMC urges CMS to make clear that the clinical judgement of the treating provider should be paramount when considering whether step therapy should be required for a patient initiating therapy with a drug in one of the protected classes. In addition, those beneficiaries who are stable on current medication should not be made to undergo step therapy to "try and fail" different drug regimens, many of which they may have already tried. For example, it often is an arduous process to stabilize patients on medication to treat mental illness; once sable these patients should not be faced with the possibility that they can be forced to try a different medication regime.

Maintain Access to Single-Source Drugs Included Within the Protected Classes

Part of the CMS proposed rule is that if a manufacturer removes a single-source drug in a protected class from the market and replaces it was a new drug that is not that dissimilar from the drug or biologic currently on the market – same active ingredient or moiety and does not have a unique route of administration – formulary exclusions for the new drug formulation would be allowed. This would mean that neither drug would be on the formulary and beneficiaries would be left without any coverage for

[1] Agency for Healthcare Research and Quality. Trends in Emergency Department Visits, 2006 – 2014. September 2017. https://www.hcup-us.ahrq.gov/reports/statbriefs/sb227-Emergency-Department-Visit-Trends.pdf

either of these drugs. The AAMC believes that beneficiaries would be harmed by this proposal. Plans should be required to inform beneficiaries of any changes immediately. If plan sponsors cannot negotiate coverage for the existing drug, plans should be required to cover the new drug through the remainder of the plan year to ensure that beneficiaries have access to it. Beneficiary cost sharing for the new drug should not be different from the cost sharing of the drug removed from the market to continue beneficiaries' access to the drug. Further, if plan sponsors choose not to cover the drug in the next plan year, they should be required to inform beneficiaries as soon as possible to ensure that beneficiaries can exercise their options during open season to select an MA or Part D plan that better meets their prescription drug needs.

Minimize Provider Burden When Expanding Formulary Utilization Management Tools

Drug utilization management tools often impose unnecessary administrative burdens on prescribers and access delays on patients. These tools frequently are used to reduce utilization and spending on high-cost prescription drugs by requiring providers to submit additional documentation to MA and Part D plans to secure coverage for a needed medication. Providers treating patients enrolled in a variety of Part D plans, each with their own formularies and UM requirements, are often required to sift through a myriad of information from different plans to ensure patients receive the drugs that best treat their conditions. Like quality measurement requirements, physicians receive no compensation for the administrative time required to address burdens plans often have in place to access these medications. CMS must ensure that MA and Part D plans do not create UM requirements so onerous that they impose undue burden on providers and does not delay coverage for needed medication.

Require Part D Plans to List All Drugs that Require Step Therapy and Prior Authorization

CMS proposes requiring all Part D plans to implement real-time benefit tools (RTBT) by January 1, 2020. The RTBTs would have to integrate with prescribers' e-Prescribing (eRx) and electronic medical records (EMR) systems to "provide complete, accurate, timely, clinically appropriate and patient-specific real-time formulary and benefit information to the prescriber." (p. 62154) Increased transparency and the ability to access real-time patient data would benefit patients seeking information about the cost of medications associated with their care, in addition to reducing burden on the practitioners who treat them. AAMC believes that the administrative burden placed on physicians could be lessened if there were greater transparency about which medications require UM tools such as prior authorization and step therapy and drug price.

CMS notes in the proposed rule, there currently is no industry-established standard for RTBT and that without a standard, the RTBT tool used by a Part D plan "may not be integrated with a prescribers' EMR, thus limiting its utility." (p. 62165) In order to comply with the proposal, Part D plans would be required to select or develop an RTBT system capable of integration with at least one prescriber's EMR and eRx. According to Kaiser Family Foundation, the number of Part D plans per region has increased in 2019, with the average beneficiary having a choice of 27 Part D plans.[2] This means that providers and hospitals that care for a large Medicare population could potentially be required to interact with many RTBTs causing increased provider burden. If CMS finalizes this proposal, providers should be held harmless if their eRx and EMR systems are not compatible with Part D plans RTBT tools. In the case where systems are not compatible, Part D plan sponsors should have an alternative way for providers to seek information on what drugs require prior authorization or exceptions and drug pricing. The AAMC recommends that

[2] Kaiser Family Foundation. Medicare Part D: A First Look at Prescription Drug Plans. October 16, 2018. https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2019/

CMS not finalize this proposal since there are no nationally recognized RTBT standards. Instead, CMS should work with stakeholders to ensure interoperability of any new RTBT to encourage utilization of the tool.

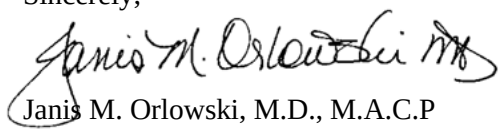
AAMC Supports Lifting Restrictions on Pharmacists to Inform Patients of Cheaper Drugs

The AAMC strongly supports the "Know the Lowest Price Act" (Pub. L. 115-262) which lifts restrictions on pharmacists to inform consumers about cheaper drug alternatives. Currently, some insurer contracts with pharmacies include a provision that prohibits the pharmacists from advising patients of cheaper alternatives to their prescribed drugs. This includes telling the patient that the prescription could be less costly if they elected not to use their insurance. Removing this restriction will benefit patients that struggle to afford their medications.

Conclusion

Thank you for the opportunity to comment on this proposed rule that would expand the use of utilization management tools to drugs in the protected classes. We share CMS's desire to find ways to reduce drug prices but feel that any changes should ensure beneficiaries' access to essential medications. We look forward to future opportunities to engage with CMS to achieve the goals of reducing cost, improving care, and preserving the essential role of teaching hospitals and health systems in our nation's health care system. If you have questions regarding our comments, please feel free to contact Mary Mullaney at 202.909.2084 or mmullaney@aamc.org.

Sincerely,



Janis M. Orlowski, M.D., M.A.C.P
Chief Health Care Officer

cc: Ivy Baer, AAMC