January 25, 2019

Centers for Medicare & 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 Medicare Rights Center (Medicare Rights) appreciates the opportunity to comment on the proposed rule, Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P). Medicare Rights is a national, nonprofit organization that works to ensure access to health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Medicare Rights provides services and resources to three million people with Medicare, family caregivers, and professionals each year and we are committed to advancing policies that make prescription medications affordable and accessible for people with Medicare.

The following comments are informed by our experience assisting beneficiaries and their family members as they struggle to afford the medications they need to maintain their health and well-being.

Today, high prescription drug prices can force people with Medicare to choose whether to take the medicines they need or to ration or go without needed treatments. It is in this context that the Centers for Medicare & Medicaid Services (CMS) has proposed several changes to Medicare Advantage (MA) and standalone Part D prescription drug plans with a goal of supporting negotiation for lower drug prices and reducing out of pocket costs for enrollees.

Unfortunately, while we are in alignment with CMS about the need to address rising drug prices, we strongly disagree with the agency's proposals to weaken the "protected classes" protections and permit step therapy for Part B drug coverage. Such changes have the dangerous potential to disrupt or even end access to some medications for people with Medicare.

Providing Plan Flexibility to Manage Protected Classes (§ 423.120(b)(2)(vi))

Current Part D policy requires Medicare Advantage Part D (MA-PD) and standalone Part D (PDP) plan sponsors to include on their formularies all drugs in each of six categories or classes of clinical concern ("protected classes"): (1) antidepressants; (2) antipsychotics; (3) anticonvulsants; (4) immunosuppressants for treatment of transplant rejection; (5) antiretrovirals; and (6) antineoplastics; except in limited circumstances. While some utilization management is currently permissible for the protected classes, CMS proposes to allow plans greater flexibility to use such tools more broadly for these drugs, for example by requiring step therapy and prior authorization even for patients who are stable on existing treatments.

We believe this proposal creates significant risk for people with Medicare who rely on these classes of medications to improve or maintain their health. These categories of drugs are not easily substituted and interruptions in drug therapies could have significant individual and public health consequences. For example, choosing the appropriate regimen for HIV treatment is necessarily individualized to patient- and virus-specific factors.[1] Requiring these individuals to undergo step therapy—to first demonstrate poor adherence or experience a serious adverse event on a regimen that is not recommended by the clinician—before they can obtain the medication that works best for them, or delaying access to treatment by imposing unnecessary prior authorization hurdles, could result in negative health outcomes and additional costs to the healthcare system. While we appreciate the need to control drug costs, CMS must avoid impeding access to needed medications. The concerns and reasoning that led to the establishment of the protected classes remain relevant.[2]

Some restriction and oversight of the use of medications in the protected classes may be appropriate, for example, with regard to antipsychotic drugs improperly used to restrain residents of facilities. However, the onus for ensuring these strategies are implemented without jeopardizing beneficiary health or access must be placed on clinicians and on plan sponsors who can root out abuses through utilization review, rather than penalizing beneficiaries.

CMS points to changes since Part D was implemented to imply the protected classes are less urgent, including its reliance on "our partners that assist enrollees with making enrollment choices."[3] But our experience in helping people with Medicare choose between their coverage options reveals that there is still widespread confusion, a lack of high-quality resources, and choice overload. Beneficiaries are not in a good position to distinguish between plans that use or do not use utilization management widely, but face potential steep penalties if they err and choose a plan that does not fit their needs.

CMS asks if utilization management flexibilities should be limited to newly-started prescriptions only. While we oppose the imposition of these additional controls, if CMS moves forward with this approach, we strongly urge the agency to limit any changes to new starts only. The successful therapies of stable

[1] Centers for Medicare & Medicaid Services. (2005). "Why is CMS Requiring "All or Substantially All" of the Drugs in the Antidepressant, Antipsychotic, Anticonvulsant, Anticancer, Immunosuppressant, and HIV/AIDS Categories?" https://www.cms.gov/Medicare/PrescriptionDrugCoverage/PrescriptionDrugCovContra/downloads/FormularyGuidanceAllorSubAll.pdf
[2] *Id.*
[3] FR at 62155.

patients must not be disrupted. CMS notes that best practices in utilization management "would not require an enrollee who has been stabilized on an existing therapy of a protected class drug for a protected class indication to change to a different drug in order to progress through step therapy requirements, and we would not expect Part D sponsors to require, nor would CMS be likely to approve, this if our proposed exceptions to the protected class policy were finalized."[4] And: "While we are proposing to permit prior authorization for protected class drugs for both new starts and existing therapy, we would not approve onerous prior authorization criteria that are not clinically supported."[5] But the agency also says the sponsors would be permitted to use utilization management "without distinguishing between new starts or existing therapies."[6] This is puzzling, as it appears to give the sponsors permission to take actions which will not be ultimately approved. We urge CMS to clearly state that utilization management in the protected classes should be, if utilized at all, restricted to new starts.

CMS also suggests that consumers affected by sponsor use of new utilization management tools would be protected by the current appeals and exceptions process in Part D, but the Part D appeals process is deeply flawed. Few consumers understand their rights and this is exacerbated by plan and systemic errors and lack of oversight. As MedPAC commented in 2018, "Beneficiary advocates, prescribers, plan sponsors, and CMS have all noted frustrations with Part D coverage determinations, exceptions, and appeals processes."[7] We cannot support weakening other beneficiary access protections in reliance on a frayed safety net.

It is especially troubling to increase the risk for people with Medicare while research conducted by Avalere Health[8] and Pew[9] suggest that there may be few savings to be had through this proposal, and that it may increase other Medicare costs, including costs associated with hospitalizations. For these reasons, we urge CMS to withdraw this proposal and work toward solutions that provide general relief from high list prices and out-of-pocket costs for needed medications, rather than piecemeal approaches that put people with Medicare at risk of losing access to health-protecting therapies.

In addition to utilization management tools, CMS proposes to allow plan sponsors to exclude a protected-class drug from the formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market. We recognize the flexibility to exclude new formulations of existing drugs that do not provide a unique route of administration is an attempt to disincentivize significant price increases and the commercial withdrawal of older products from the market as a strategy to preserve and extend innovator drug products' monopolies in the protected classes. While Medicare Rights supports methods of curtailing gaming, it is important to base decisions about new formulations on more complete data than simply

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[4] FR 62163.
[5] FR 62158.
[6] Id.
[7] Medicare Payment Advisory Commission, "Report to Congress: Medicare Payment Policy. Chapter 14: The Medicare Prescription Drug Program (Part D): Status Report" (March 2018), http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf.
[8] Partnership for Part D Access, "Medicare Part D's Six Protected Classes Policy: A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs" (2018), http://www.partdpartnership.org/uploads/8/4/2/1/8421729/partnership_for_part_d_report_2018.pdf.
[9] Pew Charitable Trusts, "Policy Proposal: Revising Medicare's Protected Classes Policy" (March 7, 2018), https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicares-protected-classes-policy.

administration route or even moiety. For example, new formulations could have superior adherence, safety and/or efficacy, as determined in clinical trials or other scientifically sound prospective studies. Whether a drug is truly "new" or merely the same drug in a new package must be ascertained through individual, evidence-based assessments. To the extent that CMS wishes to work together with other agencies to address abuses of patent and drug marketing laws, we support those efforts. CMS must ensure, however, that efforts to penalize bad actors do not actually harm beneficiaries instead of outlier manufacturers.

Finally, CMS proposes to allow plans to exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period. CMS's reassurance that plans would not be required to exclude such drugs from their formularies is not sufficient to address our concerns with the details of this proposal. Certain options CMS is considering within this proposal are especially dangerous, including: 1. Potentially allowing plans to exclude all national drug codes for a drug if the Wholesale Acquisition Cost (WAC) of that drug increases faster than inflation; 2. Potentially allowing plans to exclude the drug for any future contract year; and 3. Potentially allowing a price threshold exception for all drugs made by the manufacturer if any protected-class drug's WAC increases faster than inflation. Each of these creates an unsupportable risk for beneficiary access. While we agree that the current climate of constant price hikes is unsustainable and also a threat to beneficiary access, this piecemeal and arbitrary approach makes the access threat more imminent rather than less. Instead, CMS and Congress must focus on a comprehensive plan to meaningfully address increasing drug prices and skyrocketing out-of-pocket costs in a way that does not undermine beneficiary access and protections.

E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards

CMS proposes to require plan sponsors to implement electronic real-time benefit tools (RTBTs) that would reveal potential beneficiary-specific coverage and cost information to providers who could then use that information to better inform their prescribing choices. Medicare Rights applauds efforts to increase provider understanding of prescription drug costs that enable providers to better help consumers afford their therapies.

We encourage CMS to work with diverse stakeholders to ensure that this update is conducted in a way that is usable accurate for plans and prescribers, and to engage in adequate training and provide supportive resources so that prescribers understand how to utilize these tools. For example, providers might need to access more detailed information about a patient's PDP or MA-PD than they do now. Knowing just the name of the insurance company will be insufficient, as formularies can vary wildly between different plan offerings from the same plan sponsor. Prescriber education and support will be necessary to avoid creating additional burdens for beneficiaries.

Part D Explanation of Benefits

CMS proposes to require Part D plan sponsors to add more information about negotiated price changes and lower-cost therapeutic alternatives in the Part D Explanation of Benefits. We support Medicare beneficiaries having access to additional information, especially when it is personalized to their needs.

Medicare Rights does not have any objection to including specific information about price changes, and supports including information about lower-cost alternatives in the EOB. However, we encourage CMS to carefully test model language reflecting these changes to ensure that the information is provided in a way that is understandable, actionable, and does not interfere with or detract from the primary message of the EOB, which is to provide specific information about the coverage or non-coverage of items or services, the appeals process, and where to get help.

In addition, this proposal does not address significant problems that arise when beneficiaries choose appropriate plans or medications during the Annual Enrollment Period and then find on January 1, or any other time during the year, that the chosen plan is no longer the most economical for the same drugs. Despite these changes over which they have no control, beneficiaries have no way to change plans. They may be able to change medications, but this is not a simple matter for many beneficiaries even if providers are given new tools. Moreover, since CMS is prohibited by statute from regulating or even inquiring into pricing relationships between plans and drug manufacturers, there is no regulator looking at how or why these variations occur and providing oversight of this system.

Medicare Advantage and Step Therapy for Part B Drugs

This proposed rule also codifies changes CMS has already proposed regarding MA plans utilizing step therapy on Part B drugs (first in 2018 sub-regulatory guidance; and now to be codified in this proposed rule)[10]. While Medicare Rights appreciates CMS's effort to establish more detailed guidelines and safeguards in this proposed rule, this policy will nevertheless limit beneficiary access to Part B drugs, including in the treatment of life-threatening conditions like cancer.

In addition to jeopardizing access, these new changes—including combined step therapy requirements where a preferred Part B-covered medication must be tried before a non-preferred Part D-covered treatment—will further complicate enrollment decisions. While CMS requires plans to announce to enrollees that they intend to use this flexibility in the Annual Notice of Change, they do not require plans to send personalized or targeted notices to people currently taking, or who have a diagnosis that might require, the affected medications.

Medicare Rights is concerned that it will be especially challenging to compare plans where Part B step therapy is used unless there are updates and improvements to the Medicare Plan Finder tool. Currently, Plan Finder does not accommodate searches for costs or coverage restrictions for services covered by MA plans and does not include personalized MA cost projections for different plans. Instead, general information about MA cost-sharing is provided in chart form. CMS has not indicated where on the Medicare Plan Finder tool this, or other information about new plan flexibilities, will be located, if anywhere.

In addition to these challenges, we are concerned that in this context, the proposed alignment of the appeals processes for Part B drugs and Part D will be insufficient to resolve resulting issues in a timely manner. We are particularly concerned that appeals will be mis-directed or mishandled as related to Part

[10] Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage (August 2018), https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf.

B or Part D, and that integration between these two processes is currently insufficient, even within MA-PDs. If CMS continues to allow these restrictions, they must create additional oversight mechanisms to ensure that the updated appeals standards are being met.

Pharmacy Price Concessions to Drug Prices at the Point of Sale

We support the inclusion of Direct and Indirect Renumeration (DIR) in the price at point of sale, because doing so will produce greater transparency. Currently there is inconsistent reporting of DIR to CMS. Some plan sponsors may include certain pharmacy price concessions in the negotiated price, while others continue to report them as DIR. This makes it difficult for patients to accurately compare plans as to the true costs of their medications. Requiring all fees to be accounted for in the negotiated price would enhance the quality of information available to beneficiaries and provide them with a better understanding of how they will progress through the Medicare program and of their costs based on their current medications.

Thank you again for this opportunity to comment on these proposals. For additional information, please contact Lindsey Copeland, Federal Policy Director at LCopeland@medicarerights.org or 202-637-0961 and Casey Schwarz, Senior Counsel, Education & Federal Policy at CSchwarz@medicarerights.org or 212-204-6271.

Sincerely,

Joe Baker
President
Medicare Rights Center