



January XX, 2019

The Honorable Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Administrator Verma,

The undersigned organizations represent millions of seniors, individuals with disabilities, and beneficiaries dually eligible for Medicare and Medicaid who depend on Medicare Part D to cover critical therapies within the protected categories and classes of drugs. We strongly oppose sections of the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce, which would establish broad exceptions to Part D's protected classes policy.

We want to acknowledge that CMS is working to address the affordability of prescription drugs for all patients, including Medicare beneficiaries. We support reasonable efforts to address the affordability of prescription drugs, but the changes to the protected classes policy advanced in this proposed rule threaten the well-being of Medicare beneficiaries with chronic conditions, cognitive impairments, and limitations in their activities of daily living.

Currently, Part D plans are statutorily required, with limited exceptions, to include all drugs of these six classes on their formularies: (1) anticonvulsants, (2) antidepressants, (3) antineoplastics, (4) antipsychotics, (5) antiretrovirals, and (6) immunosuppressants. Under the proposed rule, CMS seeks to advance a much more extensive set of exceptions to the protected classes policy than Congress has previously allowed or that an extensive body of literature and data analysis would support. We disagree with CMS' statement that an open coverage policy substantially limits Part D sponsors' ability to negotiate price concessions in exchange for formulary placement of drugs in the protected categories or classes of drugs.

We believe that CMS' assertion that providing plans more expansive negotiating tools in order to lower costs for Medicare and chronically ill beneficiaries is flawed and raises significant concerns. A November 2018 analysis conducted by Avalere and using CMS' own data shows plans aggressively utilize their existing authority to protect patient health and safety and promote cost effective options within the protected classes. Specifically, Part D plans already limit coverage to only 67% of all drugs in the protected classes. Plans combine these access limits with extensive use of utilization management such as prior authorization, step therapy, and formulary tiers to promote cost effective treatments. The Avalere analysis also finds that 75 percent of all protected class drugs are classified as either non-preferred or specialty, and only a small number of beneficiaries – less than one percent – filled scripts for specialty drugs in the protected classes. Additionally, the vast majority of prescriptions filled for protected class medications are for low-cost generic drugs, not for brand name drugs.

We remain concerned that broader authority for plans to use utilization management tools and prior authorization, in which doctors must obtain approval from a patient's Part D plan to prescribe a given medication, would add new barriers for patients seeking lifesaving treatments. This proposal also would, for the first time, allow plans to implement prior authorization and step therapy for antiretrovirals to treat HIV, subverting Congress's intent to establish protections specific to patients who need these lifesaving treatments.

Subjecting vulnerable Part D enrollees to more restrictive and disruptive utilization management practices heightens their chance of using medications that do not work well or have adverse side effects. Patients with complex conditions often use multiple medications, and they must work closely with their doctors to find the best treatment regimen, which may need to be changed over time or updated to assess the effectiveness of innovative therapies that are introduced into the marketplace. Medications can also become ineffective or produce complications over time, specifically in the case of enrollees using antiretrovirals to treat HIV. Patients facing medical issues that the protected classes were meant to help treat must be able to access the full range of treatment options.

Of further concern, the proposal would allow for prior authorization and step therapy for enrollees stabilized on a particular treatment in addition to enrollees initiating a treatment. As plans revise their drug designs, the significantly more expansive approach to utilization management could result in disruption in access to treatment for a patient already stabilized on a treatment within the protected classes. As a result of the rule, patients doing well with a particular treatment may be forced to newly justify their treatment regime or could be placed on a different treatment regimen that may be less effective. Taking patients off of highly effective treatment regimens in favor of other medications can undermine adherence, resulting in hospital visits and other interventions that could have been avoided.

Finally, CMS' proposal to allow Part D plans to add significant new restrictions on the protected categories and classes of drugs is short-sighted with respect to the effect on costs. CMS justifies its proposal to weaken the protected classes by stating that the protected class policy contributes to high health care costs. However, potential savings CMS

could realize from allowing plans to add new, more expansive restrictions on access to drugs in the protected classes would be reversed by increases in costs in other areas of Medicare in addition to leading to undesirable patient outcomes. CMS's analysis overlooks the importance of the costs that could be incurred from disrupting treatment for stabilized patients and restricting access for those patients starting treatment.

As discussed previously, we have significant concerns with the proposed changes to the protected classes policy, which could actually make it harder for vulnerable Medicare Part D enrollees to access and maintain the right treatment regime for their situation. We urge CMS to maintain beneficiaries' access to protected class drugs to ensure timely, quality care and to prevent the total cost of care in Medicare from rising due to avoidable complications. We ask that you continue to collaborate with patient groups and other stakeholders to ensure Medicare provides ongoing access to critical medications.

Sincerely,