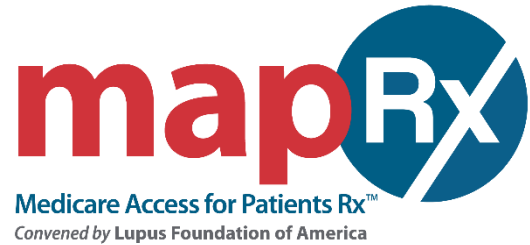


February 15, 2021

The Honorable Xavier Becerra  
Secretary Designee  
U.S. Department of Health and Human Services  
200 Independence Ave. SW  
Washington, D.C. 20201



Dear Secretary Designee Becerra,

The Medicare Access for Patients Rx (MAPRx) Coalition is writing in opposition to recent changes, announced on January 19, 2021 under the prior administration, allowing plans to severely limit Part D formularies in the CMS Center for Medicare and Medicaid Innovation (CMMI) Part D Payment Modernization (PDM) Model for plan year 2022. We urge you to rescind these formulary changes, which circumvent current law and allow plans flexibility with the six protected classes and enable plans to significantly restrict drug coverage to one drug per class for all drugs covered under Part D. These changes undermine long-standing beneficiary protections and could not only limit the ability of beneficiaries to access needed medications, but also jeopardize the health – and in some instances, life - of those with serious and chronic conditions.

Our group, MAPRx, is a national coalition of beneficiary, caregiver, and healthcare professional organizations committed to improving access to prescription medications and safeguarding the well-being of Medicare beneficiaries with chronic diseases and disabilities. We strongly support current Medicare policy that requires plan sponsors to include on their formularies at least two drugs per class and to cover all or substantially all drugs within the six protected classes. These policies have enabled millions of Medicare beneficiaries timely access to the medications they need to treat complex conditions such as cancer, epilepsy, mental health, HIV/AIDs, and many others. Indeed, these policies are important factors in the success of the Part D program. However, the changes announced on January 19 would roll back these vital beneficiary safeguards and weaken the Part D program. In short, they are a move in the wrong direction for particularly vulnerable Medicare beneficiaries, bad policy, and in direct opposition to what Congress intended when it established the statutory two drugs per class requirement and the protected classes. We again urge you to rescind these policy changes to the PDM model.

**Two Drug Per Class Requirement.** When Congress created Part D, it required plan formularies to include at least two drugs per class in order to ensure that Medicare beneficiaries have access to the treatment options that meet their specific medical needs. Many Medicare beneficiaries have complex medical needs that necessitate access to a full range of treatment. While current Part D policy affords beneficiaries a minimum number of treatment options, plans continue to have the flexibility to encourage the use of lower cost drugs through a variety of utilization management tools. This balance of beneficiary protections and plan flexibility has been in place since the inception of Part D and, again, has been a key component of its success.

We see no reason to erode this beneficiary protection, including as part of a demonstration. This policy is especially important in an age of personalized medicine and when many beneficiaries have multiple chronic conditions. These beneficiaries need access to a variety of medications to effectively treat their conditions and to avoid interactions between drugs. In addition, limiting access to the most clinically appropriate medications could have a significant ripple effect on out-of-pocket costs for beneficiaries and on Medicare and Medicaid program costs. These higher costs would result from the destabilization of patients' conditions, and

increased physician visits and hospitalizations that occur when patient do not have access to prescribed medications. Waiving the two drug per class requirement in the PMD Model would effectively eliminate a key component of the Part D benefit.

**Six Protected Classes.** The six protected class policy is also a critical protection for some of the most vulnerable Medicare beneficiaries because it requires plans to cover all drugs (subject to certain exceptions) for six classes containing lifesaving drugs - anticonvulsants, immunosuppressants, antidepressants, antipsychotics, antineoplastics, and antiretrovirals. The protected class policy has successfully allowed beneficiaries with cancer, HIV, transplant recipients, epilepsy, and mental illness, among others, to receive and continue to access the full range of treatment options. People with serious mental illness and substance use disorders need access to antipsychotics and antidepressants and also have high rates of co-occurring HIV-AIDS infections for which the protected class antiretrovirals are lifesaving. Anticonvulsants are often used as mood stabilizers in bipolar illness.

Eliminating the six protected class protections would undermine the health care and treatment of people who are already stable on a medication and could destabilize their health if required to switch medications when enrolling in a Part D plan for the first time. For example, for people living with epilepsy and seizures, it can take a long time for a person with epilepsy and seizures to identify the anticonvulsant that helps them maintain seizure control and if forced to switch, the likelihood of breakthrough seizures and related complications including injury, disability and even death increases.

The six protected classes policy safeguards those with serious and life-threatening disease, ensures continuity of care, and limits barriers to access the most clinically appropriate medications. This policy protects beneficiaries from discriminatory plan designs that would discourage the enrollment of those most in need of the benefits Part D was established to provide. In these ways, the six protected class policy has been an important success of Part D. The change announced on January 19 would eliminate protections for five of the six protected classes of the demonstration in plan year 2022 and eliminate all six protected classes in plan year 2023. Congress has specifically sought to maintain these protections in a bipartisan manner on multiple occasions. Similar changes proposed by the Obama and Trump Administrations were reversed after Congress, patient groups and other stakeholders voiced opposition.

**Smoothing Mechanism.** While MAPRx strongly opposes changes to the two drug per class and the six protected class policies, we strongly support the PMD model's prior inclusion of a smoothing mechanism that would enable beneficiaries to manage costs by allowing them the option of spreading those costs across the plan year. A smoothing mechanism (ideally, coupled with an out-of-pocket cap) is an innovative and much needed option for Part D beneficiaries. Unlike the changes proposed on January 19, which would limit access and weaken Part D, a smoothing mechanism has been included in the PMD model for CY2021 and beyond since it was proposed and would strengthen Part D and improve beneficiary access and adherence to medication. We encourage CMMI to continue to promote this option as part of the PMD model.

Thank you for your consideration of our concerns and strong opposition to the changes to the PDM model for CY 2022 announced January 19. The undersigned members of MAPRx Coalition urge you to rescind those policy changes proposed by the prior administration, and we welcome the opportunity to work with you to preserve and strengthen Medicare Part D. Please do not hesitate to contact Bonnie Hogue Duffy, Convener, MAPRx Coalition, at [bduffy@nvglc.com](mailto:bduffy@nvglc.com), if you have any questions or if we can be of any assistance.

Sincerely,

Allergy & Asthma Network  
Alliance for Aging Research  
Alliance for Patient Access  
ALS Association  
American Association on Health and Disability  
American Autoimmune Related Diseases Association  
American Cancer Society Cancer Action Network  
American Kidney Fund  
American Society of Consultant Pharmacists  
Arthritis Foundation  
Caregiver Action Network  
Epilepsy Foundation  
GO2 Foundation for Lung Cancer  
HealthyWomen  
HIV + Hepatitis Policy Institute  
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)  
Lupus Foundation of America  
Medicare Rights Center  
Men's Health Network  
Mental Health America  
Movement Disorders Policy Coalition  
National Alliance on Mental Illness  
National Council for Behavioral Health  
National Council on Aging  
National Health Council  
National Kidney Foundation  
National Multiple Sclerosis Society  
National Organization for Tardive Dyskinesia  
National Patient Advocate Foundation  
National Psoriasis Foundation  
National Community Pharmacists Association  
Patient Access Network (PAN) Foundation  
Retire Safe  
The AIDS Institute  
The Assistance Fund  
The Leukemia & Lymphoma Society  
The Michael J. Fox Foundation for Parkinson's Research  
Tourette Association of America