Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

March 1, 2024

Re: Calendar Year (CY) 2025 Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part C and D Payment Policies and Draft Calendar Year (CY) 2025 Part D Redesign Instructions

Dear Administrator Brooks-LaSure:

On behalf of the undersigned organizations representing patients and clinicians across the country, thank you for the opportunity to respond to the Calendar Year (CY) 2025 Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part C and D Payment Policies (the Advance Notice) and Draft Calendar Year (CY) 2025 Part D Redesign Instructions. The Partnership includes patient groups, advocacy organizations, and members of the private sector who work in coalition to ensure access to the full range of medications under Medicare Part D- particularly those under Medicare's "six protected classes" (6PC) policy.

Medicare's 6PC policy requires Part D plans to cover "all or substantially all" drugs in each of the following six classes: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antineoplastics, and antiretrovirals. These six classes represent conditions where medication choice and access are critical to outcomes; drugs within these classes are not easily interchangeable. The 6PC policy protects patients, ensuring they can access the specific drug needed to treat their condition, as determined by their provider. 6PC policy has resulted in increased and needed access to protected medicines[1] and contributed to meaningful gains for

[1] Yarbrough, Courtney R. "How protected classes in Medicare Part D influence U.S. drug sales, utilization, and price." Health Economics, Feb. 2020. https://doi.org/10.1002/hec.4006

patients, including increased life expectancy for people living with HIV.[2] Now it is especially important that CMS protect 6PC when it is expected that patient access to drugs for diseases like cancer, chronic disease, neurological conditions, and mental illness is expected to be most impacted by the IRA.[3]

Weakening the 6PC protections would have devastating consequences for patients who depend on access to these drugs for a variety of conditions- mental health, epilepsy, Parkinson's disease, Tourette's syndrome, lupus, HIV/AIDS, cancer, those recovering from organ transplants and more. We urge CMS to uphold these important protections as you implement the changes to the Part D program required under the Inflation Reduction Act.

Discussion

First, we understand that CMS plans to address feedback to formulary tier models in future guidance. As you do so, we urge you to reiterate the agency's strong commitment to 6PC drugs, and signal to both Medicare Advantage Prescription Drug Plans (MA-PDPs) and stand-alone Prescription Drug Plans (PDPs) that the agency will rigorously enforce the law. The array of changes under the Part D program going into effect in 2025 will undoubtedly change the way that plans design their bids and patients experience their benefits. On behalf of the most vulnerable Medicare beneficiaries who would be most impacted by changes in access to medications, we urge the agency to be clear and forceful in their commitment to providing access to "all or substantially all" drugs in the 6PC as required under the law.

The agency's public and clear position is particularly important because although neither the Advance Notice nor the Redesign Instructions mention the 6PC outright, they do contain policies that could incentivize PDPs to restrict access to these medications- including through narrowing formularies and increase utilization management-- especially considering that plan liability is expected to increase across the board due to changes under the IRA. We appreciate that the agency deployed tools to ensure stability in plan offerings, including risk adjustment.

Without intentional policy from CMS, changes resulting from the IRA to the Part D program might cause PDPs to begin looking for ways to control for this increased liability and manage costs more aggressively, which could impact access to the 6PC. Specifically, PDPs may choose to employ more aggressive utilization management and formulary design strategies. PDPs could narrow formulary coverage, implement new and additional step therapy edits, or institute prior authorization requirements in order to incentivize patients to choose lower cost medications.[4]

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[2] Tickey, et al. "Life expectancy after 2015 of adults with HIV on long-term antiretroviral therapy in Europe and North America: a collaborative analysis of cohort studies." The Lancet, March 2023. https://doi.org/10.1016/52352-3018(23)00028-0.

[3] "IRA: Patient Access to Therapeutic Options." Hayden CG. April 2023. https://haydencg.com/ira-patient-access-to-therapeutic-options/

[4] Gergen, et al. "Medicare Part D risk and claim cost changes with the Inflation Reduction Act." Milliman White Paper. Jan. 2023. https://us.milliman.com/-/media/milliman/pdfs/2023-articles/1-18-23_part-d-risk-ira-article.ashx

They may also seek to add these harmful utilization management techniques to antiretrovirals, which has been prohibited due to the nature of treating HIV.

Because utilization management and tiering are two of the only levers PDPs currently have to manage costs within the 6PC, we are particularly concerned about the impact of these changes. Currently, plan sponsors employ utilization management about 40% of the time across the 6PC, with an even higher amount, 57%, for branded drugs. Regarding tiering, almost 2/3 of 6PC drugs were placed in a nonpreferred or specialty tier, and both brand and generic drugs were often placed on higher tiers.[5] More aggressive usage of these tools would be detrimental to patient access to the 6PC given how much utilization management already exists across these drugs.

Recommendations

1. **Formulary Review** - We urge CMS to conduct rigorous formulary reviews as part of the Part D bid process. Should CMS find due to these reviews that product access has worsened, CMS should restore access to the previous higher levels. Further, CMS should not approve formularies if they include lessened access to the 6PC.
2. **Transparency-**The results of the abovementioned formulary reviews should be public so that patients and providers can understand how plans are treating the 6PC. In addition, we recommend that CMS conduct an annual report on the outcomes of formulary reviews.
3. **Data Collection-** We encourage the agency to conduct analysis of previous bids to establish a baseline of access to 6PC drugs and continue to collect data moving forward to ensure that protections remain in place.

Thank you for your consideration of these comments. We look forward to working with you to ensure that the 6PC protections are maintained for the patients who depend on them, and we would welcome a meeting with you to discuss further. Should you have any questions, please don't hesitate to contact Michelle Seger at mseger@vennstrategies.com.

Sincerely,

Alliance for Aging Research
American Association of Psychiatric Pharmacists
American Kidney Fund
American Society of Consultant Pharmacists
American Society of Nephrology
Cancer*Care*
Cancer Support Community

[5]"Medicare Part D's Six Protected Classes Policy: Coverage Policies Create Access Challenges for Patients with Complex, Chronic Conditions."
http://www.partdpartnership.org/uploads/8/4/2/1/8421729/avalere_report_on_six_protected_classes_--_february_2021.pdf

Epilepsy Foundation
HIV+Hepatitis Policy Institute
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Men's Health Network
National Alliance on Mental Illness
National Council for Mental Wellbeing
National Kidney Foundation
Texas Kidney Foundation
The AIDS Institute
Transplant Recipients International Organization