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VIA ELECTRONIC SUBMISSION — PartDPolicy@cms.hhs.gov; PartDBenefits@cms.hhs.gov

RE: CY 2025 Part D Redesign

On behalf of the undersigned organizations representing patients and clinicians across the country, we write with important recommendations to bear in mind when undertaking Part D redesign provisions from the Inflation Reduction Act (IRA). We represent the millions of Americans that rely upon their Medicare Part D drug benefit to help manage their health conditions, including mental illness, organ transplants, epilepsy, Parkinson's disease, Tourette syndrome, lupus, cancer, and HIV.

Background on the Part D Six Protected Classes

Since the inception of the Part D program, both Congress and the Centers for Medicare and Medicaid Services (CMS) have recognized that because people with certain health conditions react differently to different medications, access to the full range of approved treatments is necessary to ensure they can access the medication(s) that they and their physician identify as the most effective. Medicare's "Six Protected Class" (6PC) policy has been a foundational protection within the program and has long stood as an assurance to people with certain health conditions that their access to the most effective medication(s) would never be in doubt.

The six drug classes were identified because they treat conditions in which one size does not fit all, and medication choice and access are critical to optimal outcomes and in some cases, survival. Medications in these classes are not interchangeable and affect people in different ways, render different side effects, and manifest varying degrees of effectiveness. The policy has resulted in increased and needed access to

protected medicines[1], and contributed to meaningful clinical gains, including increased life expectancy for people living with HIV.[2] Additionally, the death rate from cancer in the U.S. declined by 29% from 1991 to 2017, including the largest drop of 2.2% from 2016 to 2017. The drop in the overall death rate is linked to advances in treatment.[3] Weakening of this protection would directly – and negatively – impact persons with mental health conditions, epilepsy, Parkinson's disease, Tourette syndrome, lupus, HIV/AIDS, cancer and those needing or recovering from organ transplants.

Current Level of Access to Drugs in the Six Protected Classes

Part D plans are required to cover "all or substantially all" drugs in each of the six classes. Despite assumptions that Part D plans are constrained in their flexibility, however, plans already have significant latitude in managing the utilization of protected-class drugs and negotiating rebates with drug manufacturers. Under CMS guidance, for drugs other than those relating to HIV, Part D plans may use prior authorization and step therapy to manage therapies for any beneficiary just starting on a protected-class drug.

In two separate studies, Avalere found that Prescription Drug Plans (PDPs) can and frequently do utilize a variety of available tools to manage costs, including within the 6PC.

> Utilization management: Across the 6PC, plan sponsors employ utilization management tools at least 40% of the time. Plans apply utilization management policies for a majority of branded drugs (57%) in the protected classes. In particular, prior authorization is already used in a majority of brand drug prescriptions (55%) in the protected classes to ensure that treatments are being used for clinically appropriate purposes.
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> Specialty tiering: According to Avalere, nearly two-thirds of all covered medications in the 6PC were placed in a nonpreferred or specialty category, with 89% of branded products categorized as non-preferred or specialty and 37% of generics also subject to placement on the higher tiers. In aggregate, Part D plans placed drugs from the protected classes on high tiers (non-preferred or specialty) 64% of the time.

In addition, Avalere found that plans covered just 54% of drugs across the protected classes — a decrease of nearly 20% since 2016 when the coverage rate was 67%.

Recommendations

As CMS is implementing provisions of the IRA related to Part D, we offer three recommendations to ensure that the agency does not lose sight of these critical access protections and that the Six Protected Classes policy is maintained:

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[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

[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/S2352-3018(23)00028-0

[3] Simon, S. (2020, January 8). Facts & figures 2020 reports largest one-year drop in cancer mortality. American Cancer Society. Retrieved January 10, 2022, from https://www.cancer.org/latest-news/facts-and-figures-2020.html

1. **Conduct rigorous formulary reviews**. In light of the changing plan designs that will result from the IRA and the increasing financial responsibility of health plans, we urge you to conduct more rigorous formulary reviews as part of the bid process, and hold plans accountable to the Congressional intent of the Six Protected Class provisions which was to ensure access to "all or substantially all" products. As we reviewed above, long before the IRA was in play, health plans are limiting access to products within the Six Protected Classes. CMS should ensure that the level of access under the current policy is not further eroded and, as warranted, restore product access to the previous higher levels.
2. **Send strong enforcement signals to PDPs**. We recommend CMS proactively communicate to plans that they will be conducting strict formulary review processes for plan designs to ensure that, as the law requires, all or substantially all drugs in the six protected classes are covered. This kind of communication can improve initial submissions and signal CMS' dedication to enforcement of this policy.
3. **Increase transparency of 6PC enforcement**. For the benefit of patients and their providers, we urge you to be more transparent about the results of these formulary reviews. We recommend an annual report on CMS' oversight and outcomes of the formulary reviews outlined in the Part D Benefits Manual to protect against discriminatory benefit designs that prevent access to new innovative medicines.

We look forward to working with you to ensure that the Six Protected Classes policy is maintained so that people with mental health conditions, epilepsy, Parkinson's disease, Tourette syndrome, lupus, HIV/AIDS, cancer and those needing or recovering from organ transplants continue to have access to the most effective and needed medication(s).

We would welcome a meeting with you to discuss these important recommendations.

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
Color of Crohn's and Chronic Illness
Epilepsy Foundation
HIV+Hepatitis Policy Institute
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Men's Health Network
Mental Health America
The Michael J. Fox Foundation for Parkinson's Research
National Alliance on Mental Illness
National Council for Mental Wellbeing
National Kidney Foundation
Tourette Association of America