Stephanie Carlton
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Baltimore, Maryland 21244
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February 10, 2025

Re: Draft Calendar Year (CY) 2026 Part D Redesign Instructions

Dear Acting Administrator Carlton:

The Partnership for Part D Access (the Partnership) is pleased to provide comments to the draft CY 2026 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 longstanding "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 interchangeable, and some require years of trial and error before patients find a medication that is right for them. 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 patients, including increased life expectancy for people living with HIV.[2]

Discussion

On behalf of the most vulnerable Medicare beneficiaries who would be impacted by changes to the 6PC, in the CY 2025 final Part D Redesign Instructions, we were pleased to see CMS' strong support for continued patient access to all or substantially all drugs in the protected classes in the draft redesign instructions. We especially appreciated CMS' commitment to "ensure that these drugs [the 6PC] remain accessible to all enrollees who need them."

We look forward to working in collaboration with you to further guarantee that patient access to vital medications will never be in doubt in 2026 and beyond and urge you to continue the commitment made in 2025 to protect access to the six protected classes. Here are some specific areas of alignment and opportunities for action:

In 2025, we are also encouraged by CMS' proactive focus on how altering the Part D benefit design may impact Part D plan benefit offerings. In a similar vein, we appreciated the acknowledgment that the IRA does increase plan liability and is expected to result in potential changes to formulary design as well as stricter use of utilization management tools, both of which have the potential to implicate Medicare's statutory prohibition on discriminatory benefit design. CMS' intentionality in protecting access to the 6PC *in advance* of any potential changes proposed by health plans is key.

We agree with CMS' assertion that plans may make changes to plan design in response to changes under the Inflation Reduction Act (IRA). CMS' commitment to act in advance through the bid process will be paramount. In fact, last year, in our comment letter to the Redesign Instructions for CY 2025, we asked CMS to conduct a rigorous formulary review and not approve formularies if they include lessened access to the 6PC. We were encouraged to see that CMS has explicitly stated in the final instructions that drug plans will only be approved "if the agency 'does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan.'" We appreciate this explicit call-out in the proposal and urge you to add similar language to this year's proposed redesign instructions.

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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/hev.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/10.1016/52352-3018(23)00028-0.

In addition to the oversight CMS has already committed to, we urge you to consider how the formulary review process can be made more transparent. As CMS evaluates each proposed formulary to ensure that categories, tiering, and utilization management (e.g., step therapy, prior authorization, and quantity limits) are appropriate, we encourage you to consider releasing the results of that evaluation for each plan, so that patients and providers can fully understand how plans are treating the 6PC.

Finally, for a number of years, we have advocated for CMS to conduct an analysis of previous bids to establish a baseline of access to 6PC drugs and continue such analysis yearly to analyze any patterns relevant to patient access. We are pleased to see that last year CMS committed to reviews of "year-over-year formulary and utilization management changes."

We recommend that CMS make the results of those reviews public, especially if they are connected to implications about the accessibility of 6PC-covered drugs.

Thank you for your consideration of our comments. We look forward to working with you to ensure continued patient access to vital medications and invite you to send us any questions you may have.

Sincerely,

The AIDS Institute
American Kidney Fund
American Society of Consultant Pharmacists (ASCP)
Cancer Support Community
Epilepsy Alliance America
Epilepsy Foundation of America
HIV+Hepatitis Policy Institute
The Leukemia & Lymphoma Society (LLS)
Lupus and Allied Diseases Association, Inc.
National Council of Mental Wellbeing
PAN Foundation
Texas Kidney Foundation