

Congress of the United States
Washington, DC 20515

June 25, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U. S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure:

Thank you for your partnership to ensure American seniors have access to the medication they need through Medicare's Six Protected Class (6PC) policy. As the Centers for Medicare and Medicaid Services (CMS) implements major policy changes to the Part D program, we want to urge the agency to prioritize continued access to medications for Medicare's most vulnerable beneficiaries by upholding the statutory and regulatory pillars of 6PC.

The United States Congress has a history of longstanding, unanimous bipartisan support for the 6PC policy. 6PC is a fundamental safeguard in Medicare Part D, ensuring that individuals with life-threatening health conditions can access the most effective medications as prescribed by their doctor. Under § 1860D-4(b)(3)(G)(I) of the Social Security Act, "a Prescription Drug Plan (PDP) sponsor offering a prescription drug plan shall be required to include substantially all covered part D medications in the categories and classes identified by the Secretary." The classes, first identified by CMS for plan years beginning in 2010, have remained the same: (I) Anticonvulsants, (II) Antidepressants, (III) Antineoplastics, (IV) Antipsychotics, (V) Antiretrovirals, and (VI) Immunosuppressants for the treatment of transplant rejection.

While CMS conducts rigorous formulary reviews to ensure that Part D plans abide by all applicable laws and regulations, there is little information available on the results of these reviews—insights that could shed light on how plans comply with the 6PC policy. To better understand the agency's process – and provide lawmakers with a clear baseline of current plan compliance against which to assess future compliance – our offices seek additional information on the process around 6PC enforcement.

More specifically, we would like detailed responses to the following questions, and would anticipate that CMS' collection of essential data as an integral part of its formulary review operations will yield this important information:

1. What steps are you taking to proactively ensure that patients have access to drugs in the 6PC considering significant, forthcoming changes to Part D plan benefit design? Please provide a list of all initiatives and the major actions taken or planned for each. If this question is inapplicable or if you are not taking steps to ensure patients have access to 6PC drugs in the future, please explain why.

2. We understand that health plan sponsors can and do use utilization management techniques like step therapy (with the exception of antiretrovirals for HIV/AIDS) and tiering to manage access to certain 6PC drugs under the current law. Do you plan to monitor the use of these techniques or conduct oversight to ensure that they are used only on appropriate drugs properly and in accordance with 6PC law and regulation as Part D redesign changes are implemented? What have you found through this monitoring process to date?
3. When conducting reviews of formulary packages from plan sponsors, do you take into consideration if insurance plan actions (e.g., denials, stringent utilization management) are impacting beneficiaries' access to these drugs? If so, what corrective action, if any, do you take?
4. Does CMS regularly monitor levels of coverage for Part D medications in the 6PC and whether there are reductions year over year? How does the agency do so? Is the agency tracking generic entrants in the market as part of this effort? Is any action taken following an evaluation of annual coverage levels?

Considering that CMS' plan redesign work is ongoing and certain actions may be imminent, we kindly ask for a prompt response within 90 days—timely access to this information is vital to make informed decisions that directly impact healthcare access and outcomes for individuals across the nation including seniors' access to critical medicines.

We appreciate Principal Deputy Administrator Blum's public comments recognizing that 6PC is "clearly settled policy." We strongly urge CMS to proactively defend access to these drugs as the new Part D benefit design is implemented and give top priority to ensuring equitable and fair patient access to these drug categories.

Sincerely,


Debbie Wasserman Schultz
Member of Congress


Brian Fitzpatrick
Member of Congress