

Medicare's Six Protected Classes Explained



In 2003, Congress passed the Medicare Modernization Act (MMA), which created an outpatient prescription drug benefit in the Medicare program. Known as Part D, the prescription benefit is operated exclusively through private insurance plans that contract with Medicare. To ensure that beneficiaries have coverage for the drugs they need Part D plans are required to cover at least two drugs in each therapeutic class. A therapeutic class is a group of medications that are used to treat the same condition.

What are the Six Protected Classes?

The Centers for Medicare and Medicaid Services (CMS) – which implemented the new Medicare drug benefit – acknowledged that, in some cases, Medicare beneficiaries may need access to more than two different drugs within a therapeutic class. CMS identified six “categories and classes of clinical concern,” commonly known as the “six protected classes,” and required Part D plans to cover “all or substantially all drugs” within each of the classes. These six protected classes include: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants. The antineoplastics category includes many oral chemotherapy drugs.

CMS considered implementing significant changes to the Part D six protected classes in 2014,¹ but ultimately declined to adopt the policy change due to overwhelming stakeholder concern.²

What changes are currently being proposed?

In its *American Patients First* Blueprint³ and accompanying Request for Information (RFI),⁴ the Administration is signaling its interest in providing Part D plan sponsors with additional tools to reduce costs for drugs within the six protected classes. Specifically, in the RFI HHS suggests that it may support better negotiation by “[p]roviding plans full flexibility to manage high cost drugs that do not provide Part D plans with rebates or negotiated fixed prices, including in the protected classes.”⁵

ACS CAN Position

ACS CAN opposes policy changes that would limit beneficiary access to prescription drugs in the classes of clinical concern (e.g., the “six protected classes”) for a variety of reasons:

- ***Six Protected Classes Established Since the Beginning of the Part D Program:*** CMS instituted the policy “because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to

¹ Centers for Medicare & Medicaid Services. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program. Proposed Rule. 79 Fed. Reg. 1918 Jan. 10, 2014.

² Centers for Medicare & Medicaid Services. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program. Final Rule. 79 Fed. Reg. 29844 May 23, 2014.

³ Department of Health and Human Services. *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*. May 2018.

⁴ Department of Health and Human Services. *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*. Policy Statement; Request for Information. 83 Fed. Reg. 22692 (May 16, 2018).

⁵ 83 Fed. Reg. at 22695.

mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.”⁶

- *Six Protected Classes Policy Protects Vulnerable Beneficiaries*: Many of these prescription drugs are not necessarily therapeutically equivalent with products within the same class. For example, the class of antineoplastics contains a subcategory of tyrosine kinase inhibitors which have been developed to treat cancer, but each drug within this category may target a different mutation that is relevant to a small subcategory of patients with a given disease. This targeting means that restricting formularies to single drugs within a USP subclass would necessarily leave out many unique drugs that would treat distinct cancers.
- *Six Protected Classes Ensures Availability of Drugs*: If the six protected classes policy was eliminated, Part D plans would be permitted to exclude some of the drugs included in the classes. If a drug were no longer covered under the Part D plan’s formulary, the beneficiary could file an appeal to obtain coverage for the drug, but the appeals process is often cumbersome and could be overwhelmed by additional requests brought in light of this policy change.
- *Part D Plans Already Have Flexibility*: While Part D plan sponsors are not currently permitted to remove a drug within the six protected classes from its formulary, sponsors may tier these drugs on their plans’ formularies – therefore giving plan sponsors some leverage in price negotiations. Part D plans already have more restrictive formularies for drugs covered under the six protected classes relative to commercial plans, suggesting that the current policy does not prevent Part D Plan sponsors from effectively managing formularies within these drug classes.⁷ Further, generic utilization for drugs within the six protected classes is higher than other drug classes (92 percent versus 84 percent).⁸
- *Eliminating Six Protected Classes Policy Could Increase Program Costs*: Even setting aside the negative impact on beneficiaries who rely on this valuable protection, eliminating the six protected classes designation could increase Part A or Part B costs. If beneficiaries are unable to access the prescription drugs most medically appropriate for their condition, they will likely incur higher costs elsewhere in the program, such as additional physician services or emergency room utilization.

⁶ Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual, Ch. 6 – Part D Drugs and Formulary Requirements, sect. 30.2.5, available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.

⁷ *Id.*

⁸ The PEW Charitable Trusts, *Policy Proposal: Revising Medicare’s Protected Classes Policy*, March 2018, http://www.partdpartnership.org/files/resources/DSRI_Policy_Proposal_Revising_Medicare's_Protected_Classes_Policy.pdf.