



CONGRESS SHOULD CONTINUE TO SUPPORT THE SIX PROTECTED CLASSES

Every day, millions of Americans rely upon their Medicare drug benefit to help manage their health conditions, including mental illness, organ transplant, epilepsy, Parkinson's Disease, cancer and HIV. Because patients with these illnesses react differently to different medicines, access to the full range of effective medications is a crucial component of successful treatment and recovery. Medicare's "six protected classes" policy has long stood as a guarantee to patients that their access to these critical medications would never be in doubt.

Congress has repeatedly recognized the importance of the "protected classes" policy as a necessary safeguard for patients with complex medical needs. Indeed, from the time these protections were first contemplated in 2003 to the time they were codified in 2008, support from Congress has been bipartisan and bicameral. In 2014, congressional support for the six protected classes was demonstrated overwhelmingly, when every Member of the Senate Finance Committee as well 50 Members of the House Energy & Commerce and Ways & Means Committees sent letters to the Centers for Medicare and Medicaid Services' (CMS) opposing their controversial proposal to limit the protected classes.

THE PROTECTED CLASSES POLICY IS ESSENTIAL FOR COMPLEX AND VULNERABLE PATIENTS

Medicare patients who are elderly and disabled generally have more complex health status. However, those living with a mental health condition, HIV, epilepsy, cancer, organ transplant, or a combination of conditions, have even more challenging medical needs. Therapies for these conditions have complex interactions, contraindications, side effects, and other factors that must be addressed to identify the best course of treatment for an individual patient.

- Many patients living with these illnesses must attempt a variety of therapies before they and their physicians settle on the most appropriate treatment.
- Medicare's six protected classes policy protects Medicare patients from arbitrary restrictions and limitations intended to hinder access to these life-saving and life-enhancing medications.
- Requiring coverage of the six classes of medication has reduced Medicare costs by reducing hospitalizations, emergency care, and other costly interventions.
- Researches have concluded that "profit-maximizing" stand alone drug plans cost Medicare hundreds of millions of dollars because they have no financial incentive to avoid hospitalizations. In covering drugs less generously, they end up costing Medicare \$475 million per year.¹

SIX PROTECTED CLASSES REDUCES OVERALL COSTS

According to independent research performed by Avalere Health, little evidence exists to suggest meaningful cost savings from limiting formulary access. In fact, the opposite impact often is found.

¹ Starc, Amanda, and Robert J. Town. "Externalities and Benefit Design in Health Insurance." Accessed March 6, 2018. <https://kelley.iu.edu/doc/bloomington/business-economics-and-public-policy/seminars/fall-2016/starc-town-fall-2016.pdf>.

- Increases in inpatient and outpatient medical care outweighed any savings on prescription drugs from formulary restrictions.
- The rates of non-adherence increased, especially among older beneficiaries, after formulary restrictions were implemented, and forced some patients to move to new drug treatments.
- Patients who were less adherent or who switched their therapies had higher hospitalization rates. Further, when a non-adherent patient utilized health care services, they required longer hospital stays, higher use of inpatient psychiatric days, and higher frequency of visits.
- MedPAC found that from 2006-2013, prices for protected-class drugs rose more slowly than Part D prices overall.² Cumulative Part D price growth from 2006-2013 was 47% overall and 38% for protected class drugs; after accounting for generic substitution, cumulative prices decreased by 16% for protected-class drugs and increased by 2% for all Part D drugs.³ Accordingly, any theory that protected class drugs have higher prices or lower Part D rebates is unsupported and unproven.

PART D PLANS ALREADY HAVE SUBSTANTIAL FLEXIBILITY

Despite assumptions that Part D plans are restrained in negotiating drug prices for protected classes, plans already have significant latitude in managing the utilization of protected-class drugs and negotiating rebates with drug manufacturers.

- CMS guidance generally permits plans' use of prior authorization and step therapy to manage therapies for any beneficiary initiating therapy with a protected-class drug.
- Generic dispensing rates (GDR) within the protected classes are on par with other therapeutic classes.
- Plans are allowed to utilize tier placement to steer patients toward lower-cost alternatives.
- These existing flexibilities suggest that additional legislative and regulatory action is unnecessary, particularly when beneficiary access to critical medications would be jeopardized.

HISTORY

During implementation of the Medicare Modernization Act (MMA), which created the Medicare Part D drug program in 2003, CMS issued guidance directing prescription drug plans to cover "*all or substantially all*" medications within six classes and categories that the agency identified. These categories included: anticonvulsants, antidepressants, antineoplastic, antipsychotics, antiretrovirals, immunosuppressants. In 2008, Congress codified Medicare's six protected classes policy after realizing that the guidance was not being implemented consistently among Part D plans.

In 2009, through the Affordable Care Act (ACA), Congress intended to provide CMS the authority to *add* new classes of drugs, while also referencing the existing six classes by name in statute and mandating that *all* (not just "*substantially all*") drugs in those classes be covered. Unfortunately, CMS instead attempted to use their new statutory flexibility to *remove* protected status from antidepressants, immunosuppressants (for organ transplant rejection) and antipsychotics (in the following year). After significant opposition from Congress, patient groups, and providers, CMS rescinded its proposed rule, while leaving open the possibility of advancing similar proposals "in future years."

² MedPAC, March 2016 Report to the Congress, Medicare Payment Policy, at 392.

³ *Ibid.*