



Protect Beneficiary Access to their Vital Medications Under Six Protected Classes

The Partnership for Part D Access seeks congressional support for protecting Medicare beneficiaries' access to life-saving and life-enhancing medications. Patient choice and access to medications under the Medicare Part D program is essential to providing quality healthcare and must continue to be guaranteed under the Medicare Six Protected Classes policy.

History of "Six Protected Classes"

During implementation of the Medicare Modernization Act (MMA), which created the Medicare Part D drug program in 2003, CMS (at the urging of Congress) issued sub-regulatory guidance directing prescription drug plans (PDPs), through contract provisions, to cover "*all or substantially all*" medications within six classes and categories that the agency identified. These categories are: Anticonvulsants, Antidepressants, Antineoplastic, Antipsychotics, Antiretrovirals, and Immunosuppressants.

However, in time it became clear that adherence to the sub-regulatory guidance was uneven among plans. Therefore, Congress pursued legislative action, led by Senators Gordon H. Smith (R-OR) and John Kerry (D-MA) to establish a statutory standard for protected classes. In 2008, Congress established under Section 176 of the Medicare Improvements for Patients and Providers Act (MIPPA), the so-called Six Protected Classes of drugs under Medicare Part D. MIPPA codified CMS' existing guidance and carried the force of law. It required Medicare Part D drug plans to include in their formularies access to *all or substantially all* drugs in the six identified classes and categories of priority. MIPPA also specified two statutory criteria that CMS had to use in identifying additional classes of clinical concern:

- 1) restricted access to the drugs in the class would have major or life-threatening clinical consequences for individuals with a disease or disorder treated by drugs in such class; and
- 2) there is a significant need for such individuals to have access to multiple drugs within a class due to unique chemical actions and pharmacological effects of the drugs within a class.

This policy stood unchanged until enactment of the Affordable Care Act (ACA). Under the ACA, Congress provided the Secretary of Health and Human Services (HHS) with authority to "identify, as appropriate, categories and classes of drugs for which the Secretary determines are of clinical concern." It added that the Secretary shall have the authority to develop the criteria used to make the designation. However, the ACA also codified in law the six existing protected classes and categories by name, and expanded coverage to include *all* drugs within these six classes and categories until such time as the Secretary makes changes. The clear intent of Congress was for the six identified classes of medications to maintain protected status.

CMS's Proposed Regulation would have been Catastrophic for Patients

As part of a broader [proposed rule](#) regarding Contract Year 2015 changes to Medicare Advantage and Part D programs in January 2014, CMS proposed limiting and redefining the Part D program's protected drug classes to exclude antidepressants and immunosuppressants for the 2015 coverage year, and antipsychotics in 2016. After strong opposition was mounted by patients, providers and advocates, the agency announced it would not move forward with the changes to the six protected classes policy.

Major Concerns with the CMS Proposed Regulation

- This policy, by CMS's own admission, was focused on the typical individual. However, the Medicare population is comprised of individuals over age 65, who often have multiple chronic conditions, and individuals with significant disabilities. Given the composition of the population, it is essential that policies impacting access to prescription medications account for Medicare enrollees' unique and challenging health characteristics.
- Limiting access to the most appropriate medications would drive higher costs in Medicare Part A and Part B and Medicaid by increasing admittance to in-patient care and emergency departments due to the destabilization of patients' conditions. The costs associated with this care otherwise would not be incurred by Medicare or Medicaid.
- The failure of the appeals and grievance process is well documented, and these current failures do not account for the increase in appeals that are certain to happen if the six protected class policy were to be eliminated. Persons suffering from a severe illness, including those with organ transplant, mental illness, HIV/AIDS, cancer, and epilepsy, must be assured that these systems work before any change to Six Protected Classes is contemplated.
- Eliminating Six Protected Classes would place persons needing organ transplants at risk for severe medical complications. Immunosuppressive medications are not interchangeable. They are prescribed in combinations tailored to meet the unique needs of the individual transplant recipient in order to achieve sufficient immunosuppression while minimizing the toxicity associated with individual agents. Restrictive formularies limit physicians' ability to prescribe the right combination of medications to protect the recipient from organ rejection and other serious side effects. This delicate balance was recognized in the original decision to include these medications under protected status.
- Individuals with both mental illness and HIV represent a large and vulnerable segment of the HIV-infected population. Approximately 50 percent of those in HIV care have some form of a comorbid mental illness. To protect against adverse drug interactions and to limit side effects, which improves adherence, it is important that providers have access to the full range of available antidepressant and antipsychotic medications.
- Mechanisms to contain costs and steer patients toward lower cost options already exist in the program. Part D Plans are allowed to tier the cost of medications, which has proven effective. Research by the Medicare Payment Advisory Committee (MedPAC) has shown that generic utilization among the Low Income Subsidy (LIS) population, particularly for antidepressants, is comparable to rates among non-LIS populations. Though importantly, individuals requiring more expensive or brand name medications are ensured access without appeal under Six Protected Classes.
- According to the American Cancer Society, 1 in 4 individuals with cancer has clinical depression. Studies have also shown that close to 50 percent of individuals with HIV also have a mental health condition. Further, studies have shown that persons with epilepsy have higher rates of depression and suicide. It is important, therefore, that doctors have the ability to choose the right mix of medications for these complicated patients.