CMS Rule Erodes Patient Protections for Medicare's Six Protected Classes

On November 26, 2018, the Centers for Medicare and Medicaid Services (CMS) released a new proposed rule on prescription drug pricing in Medicare Part D and Medicare Advantage (MA). The proposal tracks closely with policy changes outlined in the Trump administration's drug pricing "blueprint," with a focus on providing Medicare plans with levers that will increase their negotiating power to secure additional price concessions from drug manufacturers.

Currently, Part D plans are statutorily required, with limited exceptions, to include all drugs in six classes on their formularies: (1) anticonvulsants, (2) antidepressants, (3) antineoplastics, (4) antipsychotics, (5) antiretrovirals, and (6) immunosuppressants. Under the recently proposed rule, CMS seeks to advance a much more extensive set of exceptions to the protected classes policy than Congress has previously allowed. Doing so would come at the expense of the most vulnerable Medicare beneficiaries and directly contradicts Congress' intent to ensure patients can work with their physicians to determine the therapy or therapies that work best for them.

Subjects Patients to Additional Authorization and Step Therapy Requirements

CMS is proposing to allow Part D plans to implement new utilization management tools on the six protected classes, including broader prior authorization and more restrictive step therapy policies. Under CMS' new policy, starting in 2020, plans may use prior authorization and step therapy policies for protected class drugs even if the patient is already stabilized on a particular treatment regimen.

Currently, when a patient starts a new treatment regimen for a drug in the protected classes, Part D plans can require prior authorization to ensure the drug is being taken for a medically-accepted use. Additionally, a patient beginning treatment within the protected classes may also be subject to other utilization management policies such as step therapy, which plans frequently use to promote cost-effective options within the protected classes.

However, plans currently *cannot* require prior authorization or apply other utilization management tools for patients who are *already* stabilized on a particular treatment within the protected classes. This is true when a patient enrolls in a Part D plan for the first time and when a patient changes from one Part D plan to another.

While the rule cites concerns about the overutilization of protected class drugs as the rationale for these changes, the agency offers no new analysis to validate the concern. Further, a November 2018 analysis performed by Avalere demonstrates that patients receiving medications from within the protected classes, on average, receive a generic medication 91 percent of the time while only 1 percent of medications prescribed are from a specialty tier.

Restricts Patient Access to Cutting Edge Drugs in the Protected Classes

CMS currently requires plans to cover "all or substantially all" drugs in the six protected classes, even though Congress passed legislation that requires Medicare Part D plans to cover "all medications" in the

protected classes. The proposed rule lays out changes that would allow Part D plans to exclude a new single-source drug or biologic product with identical active ingredients that do not provide a "unique route of administration."

Avalere's data demonstrates that plans currently only cover 67 percent of available medications, far below the statutory requirement. Further, CMS offers no scientific evidence and medical standards of practice to support this policy. Instead the agency focuses on the expected impact on cost.

CMS Applies a New Cost-Based Test to Innovative Medications for Vulnerable Patients

CMS would allow plans, starting January 1, 2020, to exclude protected class drugs whose prices rise more quickly than inflation. Prices for this purpose would be defined as wholesale acquisition cost (WAC). Price increases would be measured against the Consumer Price Index (CPI) for all Urban Consumers, a measure of prices throughout the economy, rather than medical CPI.

This exception is grounded solely in the cost of a therapy and fails to meet the statutory requirement to have a basis in scientific evidence and medical standards of practice. Further, it establishes a government threshold versus one determined by the market. CMS offers no indication as to the impact this policy would have on the availability of medications or whether it is a realistic standard by which to measure price increases for medications.

CMS Asserts Congress Intended Statutory Patient Protections were Temporary

CMS has incorrectly stated that Congress, in 2003, encouraged the creation of the protected class policy to transition duals into the Medicare drug benefit. While the protected classes policy initially was implemented via sub-regulatory guidance, numerous statements delivered by Senators at the time the Medicare Modernization Act (MMA) was debated and passed demonstrates that this policy was not intended as a temporary transition for duals. Additionally, Congress, through the Medicare Improvement and Patient Protection Act (MIPPA) and later through the Affordable Care Act (ACA), codified the protected classes policy for all Medicare beneficiaries. Congress has never indicated in the legislative history of the protected classes that it intended for the policy to be temporary or that it supports weakening the protections it affords to Medicare beneficiaries.

New Policies Create Impediments to Therapies for Chronically Ill Patients

While the Partnership appreciates the steps the Department of Health and Human Services is taking to address the cost challenge which threatens to limit patient access to prescription medications, we believe a better balance must be found that protects chronically ill patients' access to the full range of medications in the protected classes. Instead, the proposed rule presents new harm to patients including:

- The new policies will create barriers to prescription medications for Medicare patients with chronic conditions, including patients who are already stabilized on a treatment within the protected classes and patients who are newly starting treatment.
- The new policies have a singular focus on lowering costs to the program and enrollees and are not supported by scientific evidence, clinical rational.
- CMS is over reliant upon its "expectations" for how Part D plans would design their formulary and adequacy of fall back "protections" that would ensure stabilized patients can remain on their current treatment regime.