



RESPONSE TO CMS ADMINISTRATOR VERMA'S LETTER ON SIX PROTECTED CLASSES

Recently, Centers for Medicare and Medicaid Services (CMS) Administrator Seema Verma sent a letter to several Members of Congress in response to their concerns about proposed changes to Medicare's six protected classes. This fact sheet includes key substantive excerpts, each of which are followed by important facts and policy details that policymakers should be aware of.

“CMS established the protected class policy primarily to ensure a smooth implementation when the Part D program was started in 2006.”

- While the protected classes policy was first implemented through guidance from CMS to PDPs, it was Congress that instructed the agency to create such protections.
 - As detailed in a November 25, 2003 [colloquy](#) enshrined in the *Congressional Record*, Sens. Chuck Grassley (R-IA), Dianne Feinstein (D-CA), and Max Baucus (D-MT) were explicit in their recognition that “there are certain conditions — like AIDS and epilepsy — where having access to just the right medicine is especially important.”
 - In fact, Sen. Baucus said at the time that, “If a plan can't adequately ensure all of the proper medication for beneficiaries living with HIV/AIDS, epilepsy, and certain mental illnesses, that plan should not be doing business with Medicare.”
- Although the protected classes policy was first implemented through guidance, Congress has consistently recognized the value of this policy and ultimately codified the protected classes in statute.
 - In 2008, as part of the Medicare Improvements for Patients & Providers Act (MIPPA) (see: [Sec. 176](#)), Congress officially required the agency to include “all covered Part D drugs” where: (1) restricted access to the drugs in the class would have major or life-threatening 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), when Congress enshrined in law the six existing protected classes by name, and expanded coverage to include “all” drugs within these classes until such time as the Secretary makes changes (see: [Sec. 3307](#)). The clear intent of Congress was for the six identified classes of medications to maintain protected status.
- Congress' intent was further asserted in 2014 when the Obama Administration contemplated changes intended to limit beneficiary access to medications within the protected classes.

- On February 5, 2014, every member of the Senate Finance Committee sent a [letter](#) to CMS Administrator Marilyn Tavenner rejecting the agency’s approach to implementing the section. Finance Committee members stated that “Since the launch of Part D, Congress and the Administration have recognized that for certain types of conditions and therapies beneficiaries should have access to all available medications” and the members went on to “strongly urge” CMS “to continue this important beneficiary protection as it exists today.”
- On March 4, 2014, the House Energy & Commerce and Ways & Means Committees [followed suit](#), with 50 of the committees’ members sharply rebuking CMS’ proposed implementation of section 3307. The committee members explain that section 3307 “reaffirm[ed]” Congress’s determination that the existing six classes were appropriate for the protected classes policy before noting that CMS’ proposal “will place harmful limits on Medicare beneficiaries’ access to necessary medications.”

“CMS has concluded that despite some formulary and utilization management flexibility, Part D sponsors are not able to negotiate rebates across the protected classes at levels commensurate with other Part D drugs or the commercial market.”

- Medicare Part D is different than the commercial market: perverse incentives among stand-alone drug plans require patient protections such as the six protected classes.
 - Unlike commercial insurance, the [majority](#) of Medicare beneficiaries receive drug coverage through stand-alone prescription drug plans (PDP), which are not responsible for costs associated with utilization of physician, hospital, or skilled nursing facilities. Because of this difference, stand-alone PDPs have significantly less incentive than Medicare Advantage (MA) to manage costs across the spectrum of care.
 - This phenomenon is brought to light in [multiple economic analyses](#), which repeatedly highlight how “profit-maximizing” PDPs are incentivized to limit benefits or increase out-of-pocket costs because they are not responsible for costs incurred by other parts of Medicare, such as hospitalizations.
- Lower-cost generic drugs are already used more frequently in the protected classes than for other Part D drugs.
 - According to a 2017 report of the Medicare Payment Advisory Commission (MedPAC) (see: [pg. 410](#)), the generic dispensing rate across all of Medicare Part D was 85 percent. In comparison, recent [analysis](#) by Avalere of Medicare’s Part D data finds that generic utilization in the protected classes was 91 percent — notably higher than the program at-large.
- CMS has not produced any data defending their claim that rebates within the protected classes are inadequate.
 - While the Proposed Rule does refer to CMS’ own internal analysis pertaining to rebate data, the explanation in the proposal lacks any meaningful or current detail to justify these changes, including aggregate rebate information broken down by the individual protected classes of drugs or products.
 - Further, as HHS moves forward with a proposal to reduce their reliance on rebates, it would be disingenuous to rely on rebate data to defend a proposal that could

significantly undermine medication access for the most vulnerable Medicare beneficiaries.

“The formularies approved by CMS would continue to include drugs that treat all the conditions in the protected classes.”

- Drugs in the protected classes are not interchangeable: It’s not just important that “drugs that treat all the conditions” are available, each unique treatment must be covered. Their therapeutic benefits and adverse effects can vary significantly from patient to patient.
 - Patients living with HIV have resistance to certain treatments, making it crucial from a public health perspective that all HIV patients have access to the full range of therapies.
 - Patients with cancer often need personalized therapies.
 - Epilepsy medications are not interchangeable, and beneficiaries often react quite differently to available treatments.
 - Not all transplant patients tolerate immunosuppressive drugs, even if listed within the same class, in the same way.
 - Patients with mental health disorders often take multiple medications and live with multiple comorbidities, which require doctor discretion to prescribe the most effective and appropriate treatment.

“These safeguards include our current rigorous annual formulary review and approval process... CMS’s current formulary review process and protections ensure that enrollees who have been stabilized on an existing therapy would not have to change to a different drug in order to progress through step therapy requirements.”

- The proposed rule clearly states that that the administration is considering requiring prior authorization and step therapy for patients who are stabilized on existing therapies.
 - As detailed in the [proposed rule](#), “The first proposed exception would allow Part D sponsors to use PA and ST for protected class drugs, including to determine use for protected class indications, without distinguishing between new starts and existing therapies, as is currently allowed for all other drug categories and classes.”
 - Broadening prior authorization and step therapy policies within the protected classes to include patients whose conditions are stable based on an existing treatment regime will create dangerous and costly barriers to beneficiary access to necessary prescription medications. This could undermine adherence to highly effective medication regimens, drive up medical costs for patients and the Medicare program, and increase unnecessary and time-consuming administrative hurdles for patients, their caretakers and providers.
 - As Secretary Azar said in a February 12 [speech](#) at the American Medical Association (AMA), requiring stable patients “to start over again on a step therapy regimen... is not just potentially injurious to their health; it’s also penny-wise and pound-foolish.” Indeed, this is especially true for patients with the most costly, complex chronic conditions — such as those covered under the protected classes.

- CMS' proposal is over reliant upon its largely informal expectations process for how Part D plans would design their formularies and the extent to which they would engage in negotiations with manufacturers of therapies within the protected classes
 - The agency has not added specificity around the clinical criteria that will be applied to its revised formulary review or any additional oversight and monitoring that would be appropriate to ensure the well-being of Part D enrollees with chronic conditions.

“[B]eneficiaries would be able to utilize the existing appeals and exceptions process to ensure access to necessary medications.”

- The Medicare Part D exception and appeals process will not provide sufficient protections for patients facing access challenges.
 - Patients receiving medications from within the protected classes often are the sickest, most vulnerable patients, and typically require immediate access to the medications that they are prescribed. Furthermore, these patients are among the *least* equipped to navigate a process that MedPAC has [called](#) “complex and burdensome.”
 - MedPAC also found “the majority of beneficiaries were not aware that they could ask for an exception or appeal a plan decision, nor could they understand how the appeals process works.”
 - CMS itself has [concluded](#) that for five of the six protected classes, “hospitalization, persistent or significant incapacity or disability, or death likely will result if the initial administration (including self-administration) of a drug in the category or class does not occur within 7 days of the date the prescription for the drug was presented to the pharmacy to be filled.”

What CMS fails to acknowledge in their letter and proposal...

- This proposal could potentially increase costs incurred by the Medicare program as a whole, even if small savings are achieved in Medicare Part D.
 - CMS' aggregate savings estimate did not assess the implications of the proposed Part D changes in their totality, i.e., by assessing potential cost-increasing and cost-shifting interactions within the broader Medicare program (Parts A and B), and to Medicaid. In previous CMS guidance, the agency has articulated that limiting access to the most appropriate medications will drive higher costs in Medicare Parts A and B by increasing admittance to inpatient hospital care and EDs due to the destabilization of patients' conditions. The agency also has [stated](#) that “factors described in our formulary guidance indicated that interruption of therapy in these [protected] categories could cause significant negative outcomes to beneficiaries in a short timeframe.”
 - The savings estimated from additional limits on access does not quantify the beneficiary impact of such changes in modifying established treatment regimens, which may involve the weaning off of dosages and re-titrating to the therapeutic level; delays in filling the new prescription; issues with tolerability of the new prescription — including the presentation of new, unforeseen side effects — or other barriers affecting the beneficiary's propensity to adhere.