

Congress Hikes Pressure On CMS to Scrap Proposal Removing Protected Drug Classes

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CMS is facing growing bipartisan pressure from Congress to back off its proposal to remove Medicare Part D protected status for three drug classes, leaving some health care experts to speculate the administration might scrap this portion of its controversial Part D rule while leaving other pieces of the proposal intact. On Wednesday (March 5), House Energy & Commerce and Ways & Means GOP leaders spearheaded a bipartisan letter from nearly 50 lawmakers calling for that segment of the rule to be scrapped. The letter follows a similar one last month from the entire Senate Finance Committee also protesting the protected drug class policy shift.

While Republican lawmakers have drawn some Democratic support for their broader push for HHS to ax the entire Part D rule, the strongest bipartisan backing is attached to arguments against the protected class shift, a shift also opposed by beneficiary and patient advocates. Sources say drug makers and pharmacy benefit managers, who argue alongside Republicans that a separate portion of the rule contravenes Medicare law's non-interference clause and the entire rule should be scrapped, were able to put together a broad coalition in opposition to the rule largely due to other stakeholders' concerns over the protected class piece.

While the [March 5 bipartisan letter](#) was signed by many Democrats from the Ways & Means and Energy & Commerce Committees, not all Democrats lent their support. Ten of 16 Democratic W&M members signed, leaving out Ranking member Sander Levin (MI), Jim McDermott (WA), [Xavier Becerra \(CA\)](#), [Lloyd Doggett \(TX\)](#), [Ron Kind \(WI\)](#) and John Lewis (GA), who did not sign off. And only seven out of 24 Energy & Commerce Democrats signed the letter, leaving out Ranking Member Henry Waxman (CA), John Dingell (MI), Frank Pallone (NJ) and Bobby Rush (IL), among other Democrats.

The latest letter focuses on the Part D proposed rule's proposal to remove protected class status for anti-depressants, immunosuppressants and anti-psychotics, a policy that if finalized would let plans cover only cheaper generic versions. The lawmakers complain the proposed rule if finalized would "place harmful limits on Medicare beneficiaries' access to necessary medications that would otherwise be covered."

CMS, on the other hand, argues the policy shift would lower drug costs in those classes and that beneficiary protections are in place due to an appeals process. But the agency in a recent Frequently Asked Questions document said it was open to stakeholder comments on whether beneficiary protections were adequate.

The bipartisan group of lawmakers' response is no. "(T)he proposed rule relies upon what is widely known to be ineffective exceptions, appeals, and grievance processes to ensure sick individuals enjoy timely access to necessary medications. Removal of protected status for the anti-psychotic, anti-depressant and immunosuppressant classes and allowing coverage of as few as two medications in these classes is certain to overwhelm an already overburdened process under Part D," the letter states.

The March 5 letter, addressed to HHS Secretary Kathleen Sebelius and CMS Administrator Marilyn Tavenner, also raises concerns that dropping protected class status would limit physicians' ability to treat patients. The letter states: "We also believe these policy changes will inextricably tie the hands of physicians who treat these individuals, many of whom have complex medical needs. For instance, limiting the type of immunosuppressants a physician can prescribe places a transplant patient at risk for organ rejection or other health complications. Similarly, hindering access to anti-depressants, and eventually anti-psychotics, may put someone with mental illness at greater risk for suicide and destabilization of their condition. These restrictions on appropriate access also impact persons with other challenging health conditions like cancer, HIV or epilepsy that have higher rates of depression as a comorbidity."

The lawmakers say the six protected class policy is an important reason Part D has been successful. "Created by CMS in 2005 through subregulatory guidance, and later codified by Congress in 2008, the six protected classes policy has enjoyed strong bipartisan, bicameral support. The six classes of medications were deemed by Congress to be the correct classes for inclusion in 2008 and that position was reaffirmed in 2010."

One of the Democrats signing the letter also raised concerns about the policy shift's effect on the biotechnology industry. Rep. Richard Neal (MA), said in a press release accompanying the letter: "The biotechnology community pumps billions of dollars into our economy and employs thousands of people. What are the immediate consequences to this critically important industry?" He said he hopes to raise the issue with the administration "at the earliest opportunity."

The lawmakers note patients are also upset by the proposed rule. "Finally, given the broad public support for increasing patient access to care, especially in the area of mental health, and recognizing further the significant challenges your Department faces in its efforts to implement healthcare reform, we are perplexed by your decision to move forward with such a proposal."

The press release accompanying the letter includes quotes from three advocacy groups representing patients affected by the protected drug classes.

Chuck Ingoglia, senior vice president of the National Council for Behavioral Health, which is spearheading a recently formed Partnership for Part D Access, states: "The proposed CMS rule will decrease access to medication and jeopardize patient health, especially for those beneficiaries living with mental illness. We applaud these members of the House of Representatives for taking this vitally important stand and for helping to protect vulnerable patient populations."

Likewise, Carl Schmid, deputy executive director of The AIDS Institute, says: "Medicare Part D, including the Six Protected Classes, is working. Beneficiaries, including those with HIV, are able to access the medications that their doctors prescribe. We don't understand why the Obama Administration would propose to diminish that access."

The Epilepsy Foundation also weighed in, stating it is "extremely troubled" by the proposed changes from CMS to the protected classes. "Weakening patient protections for some of the most medically fragile Medicare beneficiaries at a time when we should be strengthening access is not only disappointing but dangerous. We strongly urge CMS to not only rescind these changes but consider strengthening the class through policies that ensure there are no unnecessary administrative barriers," said Angela Ostrom, vice president, public policy and advocacy, Epilepsy Foundation.

Separately, community pharmacists announced Wednesday that two Republican lawmakers have come out in support of the Part D rule's contentious pharmacy provisions -- the provisions blasted by Republicans as violating the non-interference clause which prohibits CMS from interfering in industry drug pricing negotiations. Reps. [Trey Gowdy \(R-SC\)](#) and [Sam Graves \(R-MO\)](#) -- who chairs the House Small Business Committee -- [wrote letters](#) lending their support for the preferred pharmacy provision that would start to include "any-willing-provider," opening the door for more independent community pharmacy participation. "For senior beneficiaries who might otherwise have to end their relationships with their nearest local pharmacy, this provision is about preserving choice without undermining the financial underpinnings of these plans," the National Community Pharmacists Association says in a statement.