

Controversial Changes to Medicare Part D Withdrawn by CMS, But For How Long?

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Executive Summary

On March 10, 2014, CMS Administrator Marilyn Tavenner announced the withdrawal of the four most controversial portions of a January 10, 2014 proposed rule (79 FR 1918) to fundamentally change the Medicare Part D drug benefits program. The withdrawal came in response to numerous letters from a broad bipartisan coalition of insurers, drug manufacturers, healthcare providers, pharmacy benefits managers, patient advocate organizations, legislators, and private citizens urging withdrawal of all or part of the proposed rule. The withdrawn portions of the proposed rule include the proposals: (1) to lift the protected class definition on three drug classes (immunosuppressants and antidepressants in 2015 and antipsychotics in 2016); (2) to reduce the number of Part D plans a sponsor may offer to one basic plan and one enhanced plan per region; (3) imposing costly new restrictions on preferred pharmacy and mail-order prescriptions; and (4) allowing CMS to be involved in contract negotiations between plans and pharmacies (i.e., an alteration of the long-standing Part D non-interference provision codified in Section 1860D-11(b)(i) of the Social Security Act.

The biggest industry outcry has been in response to the proposal to eliminate three of the six protected classes of drugs. The proposed rule would revise CMS policy that requires Part D plans to include on their formularies all, or substantially all, drugs within six classes: antidepressants, antipsychotics, antiretrovirals, anticonvulsants, antineoplastics, and immunosuppressants. The rule would create new criteria for determining whether a class of drugs should be protected, i.e., the failure to receive the drug would result in the patient’s hospitalization within seven days and the drugs in the class are not interchangeable. The application of the new criteria by CMS would result in the exclusion of antidepressants and immunosuppressants from protected status beginning in 2015, and antipsychotics beginning in 2016.

CMS’ second controversial proposal, to reduce plan offerings to two per region, is the result of the agency’s belief that seniors have too many Part D plan choices and are getting confused. Opponents of this proposal feel that CMS’ interference with a well-functioning market system simply to reduce choices—not to eliminate poor choices—is bad policy.

Third, CMS would create a minimum savings standard to address its belief that “preferred pharmacy” arrangements are not resulting in cost savings to the Medicare program or beneficiaries. Industry experts contend that this requirement could cause millions of seniors to lose plans that provide discounted prices through a preferred pharmacy network, a part of the program that is projected to save \$9.3 billion over the next ten years.

Finally, CMS proposed that it be allowed to intervene in pharmacy and plan sponsor drug price negotiations. CMS believes that this is necessary to achieve standardization of reporting by drug plans of negotiated prices due to inconsistencies in how prescription drug plans currently report negotiated drug prices. Opponents of the proposal contend that plans have enough leverage with their high number of potential beneficiaries to negotiate effectively without CMS assistance. In addition, opponents feel that should CMS ignore the undisputed Congressional intent behind the long-standing Part D non-interference provision codified in Section 1860D-11(h)(i) of the Social Security Act, the regulatory overreach would set a unhealthy precedent for further administrative intrusion.

In response to the January 10, 2014, publication of its omnibus proposed rule (79 FR 1918) to fundamentally change the Medicare Part D drug benefits program, CMS received numerous letters from a broad bipartisan coalition of insurers, drug manufacturers, healthcare providers, pharmacy benefits managers, patient advocate organizations, legislators, and private citizens urging withdrawal of all or part of the proposed rule.

On March 10, 2014, in a letter to Congress, CMS Administrator Marilyn Tavenner finally succumbed to this pressure and announced the withdrawal of the four most controversial portions of the proposed rule, including the proposals: (1) to lift the protected class definition on three drug classes (immunosuppressants and antidepressants in 2015 and antipsychotics in 2016); (2) to reduce the number of Part D plans a sponsor may offer to one basic plan and one enhanced plan per region; (3) imposing costly new restrictions on preferred pharmacy and mail-order prescriptions; and (4) allowing CMS to be involved in contract negotiations between plans and pharmacies (*i.e.*, an alteration of the long-standing Part D non-interference provision contained in Section 101 of the Medicare Prescription Drug Improvement and Modernization Act (MMA) (P.L. 108-173), as codified in Section 1860D-11(h)(i) of the Social Security Act).

While the Part D proposed rule was not part of the Affordable Care Act (ACA) (P.L. 111-148), the current struggles by the Obama Administration with ACA implementation, the ongoing controversy surrounding the multitude of unilateral ACA changes by the President (see Wolters Kluwer Law & Health Blog: [Unilateral Administration Changes to the ACA: 15 and Counting](#) December 13, 2013), and the fears of incumbent Democrats facing the November mid-term election meant the timing was not good for another health care battle. In addition, it should be noted that Tavenner's letter to

Congress was issued just one day before a House vote was expected on the "Keep the Promise to Seniors Act" (H.R. 4160), a bill to block the proposed Part D changes. The bill was expected to garner bipartisan support.

The announced withdrawal of the four controversial provisions, however, does not mean the proposed rule is completely dead. Instead, according to Tavenner's letter to Congress, after taking into consideration the comments received during the public comment period, CMS intends to finalize the remaining proposals related to consumer protections (ensuring access to care during natural disasters), anti-fraud provisions that have bipartisan support (strengthening standards for prescribers of prescription drugs), and transparency (broadening the release of privacy-protected Part D data).

In addition, and more importantly, it is likely that the four controversial provisions will be back in one form or another at some point. Take careful note of Tavenner's language in her March 10 letter, "Given the complexities of these issues and stakeholder input, we do not plan to finalize these proposals *at this time*. We will engage in further stakeholder input *before advancing some or all of the changes in these areas in future years* [emphasis added]." Since Tavenner has promised to revisit these controversial proposals, it makes sense to be prepared for their reemergence. To be prepared, one must fully understand the proposed changes. An examination of the responses from Congress and industry is helpful in this understanding.

This White Paper first reviews the letters from industry and legislators and then examines each of the four controversial provisions individually.

Industry Response

On February 18, 2014, more than 200 companies and organizations sent a [letter](#) to Tavenner urging withdrawal of the proposed rule because it "will not only fail to achieve its intended goals but will reduce choice and impose higher costs on beneficiaries and taxpayers. Weakening these programs will result in a less healthy patient population and, consequently, increased Medicare costs in the long run." While each of the signatory companies and organizations has concerns with specific provisions of the proposed rule, they unanimously agree on four overarching issues:

- The proposed rule would significantly reduce beneficiaries' choice of plans and medicines and lead to disruptions in care.
- It would fundamentally transform the market-based competitive models that have made the Part D program successful.

- It will impose a large cost burden that will impede the ability of plan sponsors and other health sectors to continue offering affordable, quality care to patients. These new costs will drive higher premiums and higher Medicare costs to the government.
- The timing of the proposed rule has created great uncertainty as preparations for the 2015 plan year have already begun, especially in light the devotion of significant resources to health insurance exchange success.

GOP Congressional Response

One day after the industry letter, on February 19, 2014, Republican House and Senate leaders sent a [letter](#) to HHS Secretary Sebelius and Tavenner questioning the legality of the proposed rule and warning of the harmful effects the changes would have on America's seniors. The crux of the Republican leadership's legality argument is that the proposal rewrites existing statutory law by allowing CMS to interfere with the negotiations between drug manufacturers and pharmacies and prescription drug plan (PDP) sponsors in clear violation of the Part D non-interference clause ([Soc. Sec. Act sec. 1860-11\(h\)\(i\)](#)).

In describing the harmful effects to America's seniors, the Republican leaders write, "The 700-page proposal is a bureaucratic overreach into a highly functioning marketplace that will undermine the success of the Part D program, threatening the prescription drug coverage that provides peace of mind to 35 million seniors across the country and resulting in higher premiums, copayments, and deductibles for seniors while adding unnecessary costs for taxpayers." The Republican leaders requested that the proposed regulations be withdrawn, stating that a failure to do so "will force Congress to evaluate all legislative options necessary to ensure seniors are protected."

Two of the harmful effects to seniors include fewer choices for seniors and higher costs for both seniors and taxpayers.

As evidence of fewer choices and potential PDP loss, the Republican leaders cite Milliman's [Survey Analysis of CMS January 14 Proposed Rule](#) prepared for the Pharmaceutical Care Management Association (a signatory to the industry letter) which estimates that up to 50 percent of Part D plans may be eliminated or materially changed by the proposed rule. In addition, an [Avalere Health](#) report found

that 94 percent of seniors (7.4 million) enrolled in enhanced benefit plans through Medicare Part D could have their plans cancelled or disrupted. Avalere Health also estimates that 214 enhanced plan options would be eliminated or disrupted by the proposed rule.

"Because it is estimated that about half of people living with HIV experience mental illness or substance abuse, we are concerned that people with HIV who rely on antidepressants and antipsychotics will not be able to access their medications."

The [Milliman](#) survey also estimates that 6.9 million non-low-income seniors with Part D coverage may experience significant premium and cost-sharing increases in 2015. The GOP leadership further cites research by Douglas Holtz-Eakin, former Congressional Budget Office Director, and President of the [American Action Forum](#), who estimates that the proposed rule will result in seniors facing a 20 percent premium increase for their prescription drug coverage. The Milliman survey predicts that the rule may cause taxpayers to pay as much as \$1.6 billion more per year on the Part D program.

Bipartisan Senate Response

On [February 28, 2014](#), a letter was sent to Tavenner by Senate Finance Committee Chairman Ron Wyden (D-Ore.) and Ranking Member Orrin Hatch (R-Utah), in which they were joined by 18 colleagues, urging CMS to reconsider the changes proposed to the Medicare Part D prescription drug program. All Republican senators on the Finance Committee signed the letter. Four Democrat committee members did not sign the letter, including Charles Schumer (N.Y.), Maria Cantwell (Wash.), Ben Cardin (Md.) and Sherrod Brown (Ohio).

Eliminating the Protected Status of Three Drug Classes

The biggest industry outcry against the proposed rule has been in response to the proposal to eliminate three of the six protected classes of drugs. The proposed rule would revise CMS policy that requires Part D plans to include on their formularies all, or substantially all, drugs within six classes: antidepressants, antipsychotics, antiretrovirals, anticonvulsants, antineoplastics, and immunosuppressants. The rule would create new criteria for determining whether a class of drugs should be protected, i.e., the failure to receive the drug would result in the patient's hospitalization within seven days and the drugs in the class are not interchangeable.

The application of the new criteria by CMS would result in the exclusion of antidepressants and immunosuppressants from protected status beginning in 2015, and antipsychotics beginning in 2016. CMS contends that many of the drugs within the antidepressants and immunosuppressants classes are interchangeable and will not cause hospitalization if patients do not immediately take them upon receiving a prescription. CMS also determined that even though antipsychotics fail to meet the new criteria, they will not immediately be excluded from protected status. Instead, CMS is soliciting comments on whether a transitional policy for antipsychotics is needed. As such, their protected status will be preserved until 2016.

In addition, while the cost of drugs in these six protected classes are not part of the new CMS criteria, the proposed rule nevertheless discusses pricing, stating that the current protected class policy "substantially limits Part D sponsors' ability to negotiate price concessions in exchange for formulary placement of drugs in these categories or classes."

No group of patients would be greater affected by elimination of the protected classes than AIDS sufferers. In his February 26, 2014 [Congressional testimony](#), Carl Schmid, Deputy Executive Director of The AIDS Institute urged CMS to scrap the proposal to change the "six protected classes" of drugs. According to Schmid, "when Medicare Part D was first implemented, CMS determined that a minimum of only two drugs in a class was simply not enough for certain patients, including those with HIV, mental illness, cancer, epilepsy, and those undergoing organ transplantation. The 'six protected classes' was created so that patients could have access to all the drugs in these classes."

While Schmid is thankful that the proposed rule continued the protections for antiretrovirals (the treatment of HIV normally involves the use of multiple antiretrovirals), he expressed his concern about the elimination of antidepressants and antipsychotics among those suffering from HIV. Schmid testified "Because it is estimated that about half of people living with HIV experience mental illness or substance abuse, we are concerned that people with HIV who rely on antidepressants and antipsychotics will not be able to access their medications. We are also concerned that people with hepatitis who undergo liver transplants will not be able to access their immune suppressants."

Noting that the ACA actually codified the six protected classes, Schmid expressed surprise at CMS' attempt to eliminate three of the six protected classes, concluding that "We see no reason why the protected classes should be changed, and if they were, we would like to see more classes of drugs gain 'protected' status rather than reducing them so that more patients can gain access to the medications that are prescribed by their providers."

Another industry group, the [Medicare Rights Center](#) (MRC), a nonprofit organization that works to ensure access to affordable health care for seniors and the disabled, also opposed the elimination of protected classes. [Congressional testimony](#) by MRC's President, Joe Baker, indicated that current shortcomings of the Part D appeals process and other beneficiary protections, such as formulary transparency and transition supplies, prevent MRC from supporting the protected class changes at this time. Baker suggests that several key changes to Part D would be needed before MRC could support relaxation of any of the six protected classes, to wit:

- **Repair the Part D appeals process.** The multi-step Part D exceptions and appeals process is onerous and time-consuming, according to MRC. Over 33 percent of all calls to the MRC helpline concern coverage denials and appeals. CMS 2011 data indicates that 54 percent of plan-level coverage denials are overturned by the independent review entity (IRE), which makes the first truly independent review. MRC recommends a straightforward approach to improving the appeals process, combining a point-of-sale refusal with a formal request for a coverage determination. This would remove a burdensome step for patients and doctors while expediting the appeals process.
- **Inconsistent access to transition fills.** Transition fills, or coverage for one month when there has been a plan or formulary change, is essential for beneficiaries that rely on continuing treatment. While MRC

applauds CMS for implementing a transition-fill monitoring program, it believes that CMS should wait for the full results of the program, and then publish the results for comment, before relying on transition fills as the complete safety net for securing access to essential protected class medications.

- **Improvement in formulary review and transparency.** CMS believes that beneficiaries can merely review plan formularies on Plan Finder and select plans that cover their current medications. MRC disagrees for three reasons: (1) MRC's helpline experience is that beneficiaries do not review their coverage options; (2) while it may be true that there is no Part D drug that is not included on at least one formulary, the same plan options are not available in all areas of the United States; and (3) a GAO report has found that there is inaccurate and out-of-date information on the Plan Finder. MRC recommends that CMS take steps to improve beneficiary education and the Plan Finder before restricting the protected classes.
- **Targeted interventions are needed for overprescribing in long-term care facilities.** Outside of the documented overprescribing of antipsychotic drugs in nursing homes, CMS presents no evidence suggesting that open access to the six protected classes of drugs results in overutilization. MRC encourages CMS to partner with State boards that oversee nursing home prescribing practices or develop narrow exceptions to the protected class status to allow prior authorization in certain settings before jeopardizing beneficiary access through protected class elimination.

Despite MRC's willingness to consider relaxation of the protected classes if CMS addresses these key changes, The AIDS Institute would not. In an interview with *Wolters Kluwer*, that took place after Tavenner's withdrawal letter to Congress, Deputy Executive Director Carl Schmid reiterated, "we do not want to see any limit to the 6 protected classes, and if there are any changes, we would like to see an expansion."

Limiting Sponsors to Two Plans Per PDP Region

Under the proposed rule, CMS would limit the number of prescription drug plans (PDPs) that could be offered by a plan sponsor to one basic and one enhanced plan per region.

Contrary to much of industry, MRC strongly endorses this proposed change. Joe Baker, President of the MRC, noting that in 2013 beneficiaries on average had 31 PDPs to choose from, [testified](#) there are too many

options and too many variables for seniors to consider. Mr. Baker also believes that enhanced Part D plans are not always meaningfully enhanced.

Baker explains that "Lower income beneficiaries who are enrolled in the Low-Income Subsidy, or Extra Help [program], can receive full subsidies for so-called basic plans—but not for enhanced plans. This means that the less robust enhanced plans will tend to attract a wealthier, healthier population, and be able to offer enrollees lower premiums—while basic plans will charge higher premiums to cover the costs of a by and large less affluent and less healthy population."

"plan sponsors have less competitive incentive to keep basic plan premiums low—premiums which are paid in large part by the federal government through the Extra Help program."

In addition, Baker contends that "plan sponsors have less competitive incentive to keep basic plan premiums low—premiums which are paid in large part by the federal government through the Extra Help program. This is because plans sponsors are currently able to attract healthier, private-paying individuals to a low-premium enhanced plan. Medicare Rights agrees with CMS that this kind of risk segmentation should be avoided."

However, according to [Avalere Health](#), the proposed rule would cause issuers to roll enhanced plans with richer benefits into less generous plans, increasing premiums for existing plans, decreasing the variety of benefits offered, and disrupting the Part D benefits for 94 percent (7.4 million) of individuals enrolled in enhanced plans. In addition, as the [Milliman survey](#) indicates, the reduced plan offerings would result in 50 percent of Part D enrollees seeing their plans cancelled or materially changed.

According to the [Congressional testimony](#) of Douglas Holtz-Eakin, former Director of the Congressional Budget Office (CBO) and current President of the American Action Forum, this proposed reduction in plan offerings to two per region "is the result of concern that seniors have 'too many' choices of Part D plans, and

can get confused. It is not a result of concern that some of these choices are poor or inadequate.” As such, Mr. Holtz-Eakin concludes that “Interfering in a well-functioning market system simply to reduce choices—not to eliminate poor choices, is not good policy.”

The AIDS Institute also opposes this two-plan limit provision, which they believe limits competition.

Restrictions on Preferred Pharmacy and Mail-order Prescriptions

CMS’ proposed rule also seeks to address its belief that “preferred pharmacy” arrangements are not resulting in cost savings to the Medicare program or beneficiaries by creating a minimum savings standard. Part D was initially designed to preserve patient access and choice by permitting any willing pharmacy to participate in a network as long as it met a plan’s terms and conditions. However, over the years, PDP sponsors have formed what CMS refers to as “restrictive preferred pharmacy arrangements.”

In its proposed rule, CMS claims that numerous agency studies have found that current sponsors who utilize preferred pharmacy networks, “...have actually offered little or no savings in aggregate in their preferred pharmacy pricing, particularly in mail-order claims for generic drugs...” In addition, CMS believes that many plan sponsors, and their Pharmacy Benefit Managers (PBM), have conflicts of interest with respect to these pharmacy arrangements. According to CMS, “...most PBMs own their mail order pharmacies, and we believe their business strategy is to move as much volume as possible to these related-party pharmacies to maximize profits.”

Joe Baker of MRC agrees that these practices by plan sponsors and PBMs result in “inappropriate cost shifting to CMS and taxpayers. As a result, Baker states “...we strongly endorse CMS’ proposal to revisit the current preferred pharmacy network structure in favor of a minimum savings standard under a preferred cost sharing system.”

Holtz-Eakin, however, disputes that preferred pharmacy arrangements are intended to be restrictive, stating “these preferred networks are not intended to be exclusionary, but instead are agreements between specific pharmacies in order to ensure a members-only discount.” Holtz-Eakin contends that “This requirement could cause millions of seniors to lose their plans that provide discounted prices through a preferred pharmacy network, a part of the program that is projected to save \$9.3 billion over the next ten years.”

According to Jillanne Schulte, JD, American Pharmacists Association (AphA) Director of Regulatory Affairs,

the APhA, pharmacists, and other pharmacy groups “hate” the preferred network provision. Schulte believes that “The end result is [CMS] breaks up preferred networks.”

“Any willing pharmacy” standards. Under the proposed rule, the “any willing pharmacy” requirement forces preferred pharmacy network (PPN) plans to accept any pharmacy which is willing to meet the terms of their contract.

According to Baker, local pharmacies willing to match competitors’ prices should be allowed to charge the applicable cost sharing. And according to Schulte, despite their opposition to the preferred network provision, the APhA, pharmacists, and other pharmacy groups also support the “any willing provider” provision related to preferred networks.

Holtz-Eakin, however, counters that this requirement could cause millions of seniors to lose their PPN plans. And, according to Holtz-Eakin, the loss of PPNs will “increase costs for Part D through the removal of discounted membership rates, interfere with seniors’ continuity of care, and decrease the quality of coverage. In 2014, the average premium for a basic PDP within a preferred network was 21 percent lower than the average premium for non-preferred network plans.”

Holtz-Eakin also testified that budget estimates in Milliman’s survey “show that the [any willing pharmacy] regulation, if implemented, will raise [Part D] program costs up to \$1.6 billion for the federal government in 2015 alone, increase plan bids by 10 percent, and drive up enrollee cost-sharing, tarnishing the Part D track record of competitive pricing.”

Mail order pharmacy restrictions. The proposed rule includes a new mandated date of shipment requirement for mail order pharmacies. The proposed regulation requires mail order pharmacies to ship prescriptions that do not have any issues or discrepancies within three days and prescriptions that are unclear or require a prior authorization within five days. According to Holtz-Eakin, “This provision directly conflicts with the requirement of mail order pharmacies to receive patient approval prior to shipment of medications,” which adds “another layer of complexity to the mail order process and impose regulations that do not regard patient/prescription specific circumstances.”

Violation of the Part D Non-Interference Provision

The Medicare Part D enabling statute contains a non-interference clause that prohibits HHS from (1) interfering with the contract negotiations between drug

manufacturers and pharmacies and sponsors of prescription drug plans, and (2) from requiring a particular formulary or specific price structure for Part D reimbursement (Section 101 of the MMA as codified in Soc. Sec. Act sec. 1860D-11(h)(i)).

As set forth in a 2004 letter to Congress signed by Holtz-Eakin when he served as Director of CBO, “The clear Congressional intent of the [MMA’s] non-interference provision was to allow for free negotiations between drug manufacturers and pharmacies and plan sponsors.”

The proposed rule would change this interpretation to permit CMS intervention in pharmacy and plan sponsor drug price negotiations. CMS believes that standardization of reporting by drug plans of negotiated prices is needed because of inconsistencies in how PDPs currently report negotiated drug prices. According to CMS, some PDPs report a negotiated price that includes price concessions from the network pharmacy, while other PDPs report a higher negotiated price that excludes price concessions from the network pharmacy, and then wait until the payment year reconciliation process to report concessions as one-off discounts.

In his Congressional testimony, Holtz-Eakin stated his belief that CMS intervention in negotiation would not only be a violation of Congressional intent, but also bad policy. According to Holtz-Eakin, “Plans have enough leverage with their high number of potential beneficiaries to negotiate effectively, and the Secretary would not be able to significantly reduce prices.”

Holtz-Eakin further testified that should HHS ignore the undisputed Congressional intent behind this non-interference provision, the regulatory overreach would set a “disconcerting precedent for further administrative intrusion” which “should be vacated by the federal courts.”

However, without addressing the obvious violation of the non-interference clause, MRC President Baker strongly supports CMS’ involvement in price negotiations in order to “ensure that the reported negotiated price accurately reflects the net agreed-upon price between the network pharmacy and the PDP.” According to Baker, “this practice will not only benefit the Medicare program—and taxpayers—but also improve the accuracy of premium and cost amounts in the Medicare Plan Finder, CMS’ online plan comparison tool, allowing beneficiaries to more accurately gauge plan costs and efficiency.”

Conclusion

Parties will have to reach their own conclusions about these controversial provisions. With regards to (1) limiting sponsors to two plans per PDP region, (2) the restrictions on preferred pharmacy and mail-order prescriptions, and (3) the violation of the Part D non-interference clause

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there has been both support and opposition expressed, with those opposing seeming to be in the majority.

It is quite clear, however, that there is little or no support for eliminating any of the six protected classes of drugs. Only MRC would consider relaxing the protected classes if the following problems are addressed: (1) major repair of the Part D appeals process; (2) inconsistent access to transition fills; (3) improvement in formulary review and transparency; and (4) targeted interventions are imposed for overprescribing in long-term care facilities.

Perhaps the ongoing concern for maintaining the six protected classes is best expressed by the Mr. Schmid, in an interview with Wolters Kluwer, where he stated on behalf of The AIDS Institute, “We are very pleased that CMS, based on the concerns raised by patient groups and Congress, have agreed to withdraw portions of the proposed rule, particularly the part dealing with changing the 6 protected classes. We still do not understand why they made the proposal in the first place. Congress has spoken on this issue in the past and has made clear that they support the six protected classes.”

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