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# CMS Proposes Changes to Lower Drug Prices

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On November 30, 2018, the Centers for Medicare & Medicaid Services (CMS) published 83 Fed. Reg. 62152, which proposes changes to Medicare Part D (prescription drug benefit) and drug plans offered by Medicare Advantage (managed care) in an effort to reduce out-of-pocket costs for beneficiaries. The proposed rule is part of the Trump Administration's four part strategy to effectuate its "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," published in May 2018. The Administration's strategy aims to lower prescription drug costs for patients with a mixed approach of "improved competition, better negotiation, incentives for lower list prices, and lowering out-of-pocket costs."[1]

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## Increased Flexibility to Manage Protected Classes

Medicare Part D plans must cover two or more medications in a given therapeutic class. The protected class policy requires that Medicare Part D plan sponsors cover all or substantially all drugs for six specially designated therapy classes. Further, sponsors must list the medications in all six designated therapy classes on their formularies. The designated therapy classes include: (1) antidepressants; (2) antipsychotics; (3) anticonvulsants; (4) immunosuppressants for treatment of transplant rejection; (5) antiretrovirals; and (6) antineoplastics. This protected class policy was implemented when Part D began 12 years ago to provide medication access to beneficiaries while the program was in its early stages. As Part D plans have matured, CMS is now proposing to reduce these protections and increase plan sponsor flexibility with formulary design and negotiating prices for drugs. Specifically, the proposal includes three exceptions to the protected class policy.

- First, the proposal would allow Part D sponsors to use prior authorization and step therapy for protected class drugs. In addition, CMS "would also allow indication-based formulary design and utilization management for protected class drugs."[2] Indication-based formulary design would permit Part D sponsors to create drug formularies based on the disease indications they themselves choose, rather than having to cover all indications approved by the FDA.
- Part D plan formularies designed under this exception would continue to be subject to CMS's annual formulary review and approval process.
- Second, Part D plan sponsors could exclude from their formularies any protected class drugs that are updated formulations of existing protected class drugs, regardless of whether the old formulation remains available.
- The third exception would allow Part D sponsors to exclude protected a class drug from its formulary when the price for such drug rises faster than inflation over a designated period.

## Increased Transparency Regarding Lower-cost Therapy Alternatives

Under the new proposal, Part D plan sponsors would be required to implement a Real-Time Benefit Tool by January 1, 2020. This system alerts prescribers about lower-cost therapy alternatives for their patient under the patient's plan benefits.

In addition, CMS would require that the Part D plan sponsors' Explanation of Benefits sent to beneficiaries include information regarding drug pricing and identify cost effective therapeutic alternatives. CMS anticipates that

providing such information to beneficiaries will enable them to lower their out-of-pocket costs for prescriptions.

## Gag Clause Prohibition

In October 2018, Congress passed the "Know the Lowest Price Act of 2018" (P.L. 115- 262). Beginning on January 1, 2020, this law will prohibit Part D sponsors from restricting pharmacies from discussing the cash price of a drug with patients when it is less than the amount of the his or her insurance copayment for the medication. CMS' current proposal would align the Part D regulations with the 2020 gag clause prohibition.

## Implications

On November 29, 2018, the Partnership for Part D Access (the Partnership) released a study, which casts doubt on the beneficial effects of the new proposal. Specifically, the study concluded that "Medicare's existing protected classes policy is working as intended for Medicare beneficiaries with some of the most complex health conditions: cancer, HIV, transplant recipients, epilepsy, and mental illness among others."[3] Further, the study demonstrated the current system controls costs in a variety of ways such as requiring copayments for expensive brand drugs and promoting generic versions of drugs. As such, changes to the current system motivated solely by overall cost could be detrimental for certain high risk patients who are receiving treatments including cancer, HIV, and kidney transplants that require expensive drugs with high copayments and no generic options.

There is further concern that reducing the protections of certain medications will ultimately lead to their exclusion from Part D plan formularies. Such exclusion would ultimately render drugs inaccessible to Part D beneficiaries and could leave patients in a position where they are unable to afford the medications on which they rely. CMS is accepting comments through January 25, 2019.

## Looking Forward

As a part of its effort to lower prescription drug costs, CMS is also considering a proposal that would "require that the price a beneficiary pays at the pharmacy counter reflects the lowest possible cost."[4] This proposal could eliminate various types of rebates and back-end negotiations strategies. CMS predicts that this requirement could be implemented as soon as 2020 and that it would save beneficiaries between 12 and 15 billion dollars over the next decade.

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[1] https://www.cms.gov/newsroom/fact-sheets/contract-year-cy-2020-medicare-advantage-and-part-d-drug-pricing-proposed-rule-cms-4180-p.

[2] https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-25945.pdf

[3] http://www.partdpartnership.org/newsroom/medicares-six-protected-classes-policy-ensures-patient-access-to-medications-while-simultaneously-driving-high-rates-of-generic-utilization

[4] https://www.cms.gov/blog/proposed-changes-lower-drug-prices-medicare-advantage-and-part-d