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New Medicare Advantage and Part D Drug Pricing Proposed Rule

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On November 26, 2018 the Centers for Medicare and Medicaid Services (CMS) issued a **proposed rule, Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses.** This proposed rule is the Trump Administration's latest action to curb prescription drug prices. The proposed rule outlines a number of provisions to for lowering drug prices and reducing out-of-pocket costs in the Part D program that build off the **Administration's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs**. Below details the major provisions within the proposed rule.

Six Protected Classes

One of the most significant changes the proposed rule details involves increasing flexibility for Part D sponsors in their coverage of drugs in the six protected classes. As background, current Part D policy requires Part D plans to include on their formularies all drugs in the following six classes: (1) antidepressants; (2) antipsychotics; (3) anticonvulsants; (4) immunosuppressants for treatment of transplant rejection; (5) antiretrovirals; and (6) antineoplastics. Together these drugs are commonly referred as the six protected classes.

This rule does not change or remove any of the six protected classes. Instead, it proposes three exceptions that would allow Part D sponsors to not cover a protected class drug. Specifically, it would allow Part D sponsors to: (1) implement broader use of prior authorization and step therapy for protected class drugs; (2) exclude a protected class drug from a formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market; and (3) exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period.

In 2014, the Obama Administration proposed removing three of the protected classes (antidepressants, antipsychotics, and immunosuppressants). This rule was never finalized due to criticism by Congress as well as drugmakers and beneficiary advocates. We can expect similar criticism of this new proposal. CMS is seeking comment on considerations that would be necessary to minimize (1) interruptions in exiting therapy, and (2) increases in overall Medicare spending from increased utilization of service due to interruptions in therapy.

Gag Clauses

In October, the President signed the **Know the Lowest Price Act of 2018 (P.L. 115-262)** into law. This law prohibits Part D sponsors from including in their contracts with their network pharmacies "gag clauses." Gag clauses restrict the ability of pharmacies to discuss the availability of prescriptions at a cash price when it is less than the amount that would be charged when receiving the prescription through insurance. This measure will go into effect January 1, 2020. The proposed rule amends Part D regulations to be consistent with this statutory change.

Real-Time Benefit Tool

The proposed rule is also requiring that Part D sponsors implement an electronic Real Time Benefit Tools (RTBT) for providers beginning on or before January 1, 2020. The tool should have capability to inform prescribers when lower-cost alternative therapies are available under the beneficiary's prescription drug benefit.

Part D Explanation of Benefits

The proposed rule also requires Part D plans to include the following information in each members' Explanation of Benefits: (1) the inclusion of drug pricing information and (2) lower cost therapeutic alternatives.

Step Therapy

In August, **CMS published a memo** announcing that MA plans could use step therapy as a utilization management tool for Part B drugs. This proposed rule formally codifies that change. Step therapy can

only be applied to new prescriptions or for enrollees who are not actively receiving the affected medication. MA plans would also be required to use a Pharmacy and Therapeutics committee to review and approve step therapy programs. Additionally, determination and appeals processes for Part B drugs will be subject to shorter adjudication times that mirror Part D timeframes.

Pharmacy Price Concession in the Negotiated Price

The final provision in the proposed rule would re-define “negotiated price.” Negotiated price is the price reported to CMS at point of sale. Under current law, Part D sponsors can generally choose whether to reflect in the negotiated price the various price concessions they or their intermediaries receive. Beneficiary cost-sharing is generally calculated as a percentage of the negotiated price. When pharmacy price concessions and other price concessions are not reflected in the negotiated price at the point of sale, beneficiary cost-sharing increases. The proposed rule is considering to revise the definition of the negotiated price to include all pharmacy price concessions and any dispensing fees, and exclude additional contingent amounts in the negotiated price. This would re-define negotiated price as the baseline, or lowest possible, payment to a pharmacy. Implementation of this change is not certain. However, CMS noted the policy could be implemented as early as 2020.

Next Steps

Comments to the proposed rule can be submitted until January 25, 2019. We can expect significant industry and stakeholder feedback on the proposed rule. Policy changes related to drug pricing are sure to be controversial. What remains to be seen is which changes are so controversial as to lead to sufficient public outcry that it brings down parts of the proposed regulation or all of it.

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