Health Policy Update – November 26, 2018
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CMS Releases 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule

Today, the Centers for Medicare and Medicaid (CMS) issued a proposed rule to implement changes to the Medicare Advantage (Part C) and Medicare Prescription Drug Benefit (Part D) programs. Many of the policies included in the rule come from the Administration’s American Patients First Blueprint. CMS will be accepting comments on the proposed rule until January 25, 2019.

The proposed rule includes four main policies:

Providing Plan Flexibility to Manage Protected Classes
The proposal would provide Part D plans with flexibility to negotiate discounts for drugs in “protected” therapeutic classes through three exceptions that would allow Part D sponsors to:

1. implement broader use of prior authorization and step therapy for protected class drugs, including to determine use for protected class indications;
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.

Medicare Advantage and Step Therapy for Part B Drugs
CMS is proposing to codify policy that is similar to the one implemented for 2019, which allows Medicare Advantage plans to implement step therapy for Part B drugs as a recognized utilization management tool. The proposed rule acknowledges the potential for utilization management tools like step therapy to create administrative burden and process challenges for network providers. The proposed rule also outlines several patient safeguards including determination and appeals timelines, disclosure requirements, requiring use of a Pharmacy and Therapeutics committee to review and approve step therapy programs, and only allowing step therapy to be applied to new prescriptions or administrations of Part B drugs for patients who are not actively receiving the affected medication.

Requiring Part D Plans to Increase Transparency
CMS is proposing that each Part D plan adopt a real-time prescription benefit tool to inform prescribers when lower-cost alternative therapies are available under the beneficiary’s prescription drug benefit. CMS also proposes to require the inclusion of drug pricing information and lower cost therapeutic alternatives in the Explanation of Benefits for Part D plans to inform Medicare beneficiaries about possible ways to lower their out of pocket costs.

Prohibition Against Gag Clauses in Pharmacy Contracts
The proposed rule implements legislation signed into law earlier this year that restricts Part D sponsors from prohibiting or penalizing a pharmacy’s ability to inform an enrollee about a lower cash price for their prescription.

CMS is also considering for a future plan year a policy that would re-define negotiated price to ensure that the prices available to Part D enrollees at the point of sale are inclusive of all pharmacy price concessions.

To read the proposed rule, CLICK HERE.
To read the fact sheet, CLICK HERE.

To read the blog post from Alex Azar and Seema Verma, CLICK HERE.