Fact sheet

Contract Year (CY) 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule (CMS-4180-P)

Nov 26, 2018   Legislation, Medicare Part D, Prescription drugs

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The Centers for Medicare & Medicaid Services (CMS) is committed to implementing President Trump's blueprint to lower drug costs and reduce out-of-pocket costs for patients. In line with the policies discussed in the President's blueprint, CMS issued a proposed rule on November 26, 2018 that solicits public comments on potential policies that would remove administrative hurdles to offer lower cost options to seniors and provide support for private sector partners by providing them the tools to lower the cost of prescription drugs.

This fact sheet discusses the provisions of the proposed rule (CMS-4180-P). The proposed rule can be downloaded from the *Federal Register* at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-25945.pdf. In order to be considered, comments must be submitted by January 25, 2019.

Lowering Drug Prices and Reducing Out-of-Pocket Costs for Enrollees

In May 2018, President Trump announced the Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs ("Drug Pricing Blueprint") document, which outlines the Administration's four key strategies for lowering drug prices and reducing out-of-pocket costs in the Part D program: improved competition, better negotiation, incentives for lower list prices, and lowering out-of-pocket costs. CMS is proposing or outlining for consideration by stakeholders a number of provisions that implement these four strategies.

Providing Plan Flexibility to Manage Protected Classes
Current Part D policy requires sponsors to include on their formularies all drugs in six categories or classes: 1) antidepressants; 2) antipsychotics; 3) anticonvulsants; 4) immunosuppressants for treatment of transplant rejection; 5) antiretrovirals; and 6) antineoplastics; except in limited circumstances. The proposed regulatory provision maintains all six protected classes: however, the proposal would provide Part D plans with greater flexibility to negotiate discounts for drugs in "protected" therapeutic classes, so beneficiaries who need these drugs will see lower costs.

The proposal would make 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.

E-Prescribing and the Part D Prescription Drug Program
In order to accelerate the use of electronic Real Time Benefit Tools (RTBT) in the Part D program, CMS is proposing that each Part D plan adopt a provider (i.e. EHR-integrated) RTBT of its choosing beginning on or before January 1, 2020. RTBTs have the capability to inform prescribers when lower-cost alternative therapies are available under the beneficiary's prescription drug benefit, which can improve medication adherence, lower prescription drug costs, and minimize beneficiary out-of-pocket costs.

Medicare Advantage and Step Therapy for Part B Drugs

CMS is proposing a policy similar to the one implemented for 2019, under which MA plans would implement step therapy for Part B drugs as a recognized utilization management tool. We believe that step therapy as a utilization management tool will better enable MA organizations to ensure that Medicare beneficiaries pay less overall or per unit for Part B drugs. The proposed requirements include a number of safeguards that protect beneficiaries and ensure timely access to medically necessary Part B drugs. Under the proposal, step therapy requirements may only apply to new starts of medication, must be reviewed and approved by the plan's pharmacy and therapeutics committee, and coverage requests related to Part B drugs will be subject to shorter adjudication timeframes that mirror the current rules in Part D.

Part D Explanation of Benefits

CMS proposes to amend regulations related to the Part D Explanation of Benefits to require the inclusion of drug pricing information and lower cost therapeutic alternatives in the Explanation of Benefits that Part D plans send members. This information will inform Medicare beneficiaries about possible ways to lower their out of pocket costs but taking a lower cost medication.

Prohibition Against Gag Clauses in Pharmacy Contracts

This provision implements the statutory requirement that restricts Part D sponsors from prohibiting or penalizing a pharmacy from disclosing a lower cash price to an enrollee. This provision supports the President's initiative to help lower out-of-pocket costs of prescription drugs for Medicare beneficiaries by helping inform them about lower cost alternatives.

Pharmacy Price Concessions in the Negotiated Price

CMS is also considering for a future plan year, which may be as early as 2020, a policy that would re-define negotiated price as the baseline, or lowest possible, payment to a pharmacy. The negotiated price for a drug is the price reported to CMS at the point of sale, which is used to calculate beneficiary cost-sharing and generally adjudicate the Part D benefit. With the emergence of performance-based pharmacy payment arrangements, the negotiated price is increasingly higher than the final payment to pharmacies unless it incorporates the large price concessions that result from these arrangements. Higher negotiated prices lead to higher beneficiary cost-sharing and faster beneficiary advancement through the Part D benefit. The policy we are considering would reduce beneficiary out-of-pocket costs, and improve price transparency and market competition under the Part D program.

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Contact us

CMS News and Media Group
Johnathan Monroe, Director
Kelly Ceballos, Deputy Director

press@cms.hhs.gov
202-690-6145

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7500 Security Boulevard, Baltimore, MD 21244