Issue Brief

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CMS Issues Proposed Rule to Lower Drug Costs

The Centers for Medicare & Medicaid Services issued a proposed rule that would amend Medicare Advantage program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations "to support health and drug plans' negotiation for lower drug prices and reduce out-of-pocket costs for Part C and D enrollees."

A copy of the 185-page proposal is at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-25945.pdf. The proposal is schedule for publication in the ***Federal Register*** on Friday, Nov. 30. A 60-day comment period ending Jan. 25, 2019, is provided.

PROVIDING PLAN FLEXIBILITY TO MANAGE PROTECTED CLASSES

Current Part D policy requires sponsors to include in 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 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 Jan. 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.

4712 Country Club Drive
Jefferson City, MO 65109

P.O. Box 60
Jefferson City, MO 65102

573/893-3700
www.mhanet.com

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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. CMS says it believes 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.

Under the proposal, step therapy requirements only may 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.

PHARMACY PRICE CONCESSIONS IN THE NEGOTIATED PRICE

CMS also is considering for a future plan year, which may be as early as 2020, a policy that would redefine 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 CMS says it is considering would reduce beneficiary out-of-pocket costs, and improve price transparency and market competition under the Part D program.

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

The following table is from the proposed rule.

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Summary of Costs and Benefits		
Provision	**Description**	**Impact**
Providing Plan Flexibility to Manage Protected Classes (§ 423.120(b)(2)(vi))	CMS proposes to allow the following exceptions related to protected class drugs. (1) allow broader use of prior authorization and step therapy for protected class drugs, including to determine use for protected class indications (2) allow plans to exclude a protected class drug from the formulary if the drug is a new formulation that does not provide a unique route of administration (3) allow plans to exclude a protected class drug from the formulary if the drug had a price increase beyond a certain threshold	The estimated savings to the Trust Fund are $141-$180.5 million in 2020-2024, increasing to $195-$240 million in 2025-2029. The government saves $1.85 billion. Enrollees save $692 million in cost sharing.
E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards (§ 423.160)	CMS proposes to require each Part D plan sponsors' implementation of one or more RTBT of its choosing that are capable of integrating with providers' e-Rx and EMR systems and delivering complete, accurate, timely and clinically appropriate patient-specific real-time F&B information beginning on or before Jan. 1, 2020.	The scoring of this provision is complex. While there is potential for savings to the Trust Fund arising from substitution of lower cost-sharing tier drugs, CMS has no way of quantifying this. Also, CMS says it is uncertain, at this point, of the cost to industry to implement this provision. The implementation most likely would involve plans building their own software or use of third-party vendors. Both these options are very expensive and might outweigh the savings.
Part D Explanation of Benefits (§ 423.128)	CMS proposes to require the inclusion of negotiated drug pricing information and lower cost alternatives in the Part D Explanation of Benefits. The intent of the proposal is to provide enrollees with greater transparency, thereby encouraging lower costs.	There is an estimated cost of $0.2 million in the first year of implementation.
Medicare Advantage and Step Therapy for Part B Drugs (§§ 422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618 and 422.619)	CMS proposes certain new requirements for when MA plans may apply step therapy as a utilization management tool for Part B drugs.	The estimated savings to enrollees due to reduce out-of-pocket costs are between $5 and $7 million for 2020-2024, and are between $7 and $10 million for 2025-2029. The savings to the Trust Fund are between $145 and $185 million for 2020-2024 and between $195 and $240 million for 2025-2029. There is a modest cost to the government and its contractors of $1 to $1.3 million in 2020-2029 due to a projected increased in appeals. These estimates reflect use of step therapy for which CMS announced authority for MA organizations beginning 2019; that is, estimates reflect impact on the Medicare Trust Fund if plans start using step therapy in 2020.
Pharmacy Price Concessions in the Negotiated Price (§ 423.100)	CMS is considering for a future plan year, which may be as early as 2020, to redefine negotiated price as the baseline, or lowest possible, payment to a pharmacy.	If this policy were adopted for 2020 or a future year, there would be an impact on beneficiaries, the government and manufacturers. Beneficiaries would save $7.1 to $9.2 billion over 10 years (2020 to 2029), resulting from reduced cost-sharing, offset by slightly higher premiums. However, the provision would be estimated to cost the government $13.6 to $16.6 billion over that span. Manufacturers also would save about $4.9 to $5.8 billion from 2020 to 2029. Part D sponsors would incur a first year cost of $0.1 million in additional administrative activities related to submission of PDE data.