CMS PROPOSES CHANGES TO MEDICARE ADVANTAGE AND PART D DRUG PRICING

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Health Care Alert

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On November 30, 2018, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule ("Proposed Rule") to revise certain existing Medicare Advantage ("MA") program and Prescription Drug Benefit Program ("Part D") regulations with the goal of achieving lower drug prices through increased negotiation and reduced out-of-pocket costs for patients. [1] The highly anticipated Proposed Rule seeks to implement many of the strategies outlined in President Trump's "American Patients First" blueprint ("Blueprint"), released earlier this year. [2] CMS notes the Proposed Rule aims to combat drug pricing in MA and Part D in the following key areas.

ADDED FLEXIBILITY FOR PLAN D SPONSORS TO MANAGE PROTECTED CLASSES OF DRUGS

Currently, Part D plan sponsors are required to include all drugs in six protected categories on their formularies, with limited exceptions. These protected categories include: antidepressants, antipsychotics, anticonvulsants, immunosuppressants for treatment of transplant rejection, antiretrovirals, and antineoplastics. The Proposed Rule aims to provide greater flexibility for Part D plan sponsors by allowing the following three exceptions to the existing requirement for protected categories:

> 1. Sponsors may implement broader use of prior authorization and step therapy for protected class drugs, including to determine use for protected class indications.
> 2. Sponsors may exclude a protected class drug from a formulary if the drug is merely a new formulation of an existing single-source drug or biologic, regardless of whether the older formulation remains on the market.
> 3. Sponsors may exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold, such as the rate of inflation as measured by the Consumer Price Index for all Urban Customers (“CPI-U”), over a specified lookback period. [3]

CMS believes that these exceptions will help to alleviate some of the prior concerns of Part D sponsors that the protected class policy limited their ability to effectively manage drug spending. Further, CMS notes that an unrestricted, open formulary has limited sponsors' ability to negotiate price concessions in exchange for formulary placement. [4] CMS believes that incorporating these new exceptions into the protected class policy will strengthen the Part D program by allowing sponsors to better manage protected class drugs to help ensure safe

and appropriate use, limit protected class requirements to the intended indications, and negotiate for more competitive pricing, which CMS hopes will flow down to Part D enrollees. [5]

PROHIBITION AGAINST GAG CLAUSES IN PART D CONTRACTS

Consistent with the Know the Lowest Price Act of 2018 [6] enacted by Congress in October 2018, CMS proposes to prohibit Part D plan sponsors from including a "gag clause" in their network pharmacy contracts. [7] The Proposed Rule would amend the Part D regulations to prohibit Part D sponsors from restricting their network pharmacies from informing Part D enrollees of the availability of prescription drugs with a lower cost-sharing amount or a contractually negotiated price that is less than the cost-sharing amount, effective January 1, 2020.

INCLUSION OF PRICING AND COST EFFICIENT ALTERNATIVES IN PART D EXPLANATION OF BENEFITS

CMS is also proposing to expand requirements related to the written explanation of benefits ("EOB") provided by Part D sponsors to their enrollees. Similar to proposals outlined in the Trump Administration's Blueprint, the Proposed Rule would revise the existing EOB regulations to include a new requirement that sponsors include information about negotiated price changes and lower-cost therapeutic alternatives in the Part D EOBs. [8] Specifically, CMS would require that sponsors: (1) include the cumulative percentage change in negotiated price since the first day of the current benefit year for each prescription drug claim in the EOB, and (2) provide information about drugs that are therapeutic alternatives with lower cost-sharing when available (or with the same copayments if the negotiated price is lower) from the applicable approved plan formulary for each prescription drug claim. [9] CMS believes that these changes will provide greater transparency for Part D prescription costs and will empower beneficiaries to initiate conversations with their providers about their prescriptions and make more informed decisions when choosing a prescription. [10]

STEP THERAPY REQUIREMENTS FOR MA PLANS

CMS uses the Proposed Rule as an opportunity to confirm MA plans' existing authority, established in a memo released earlier this year, [11] to implement appropriate utilization management tools, including prior authorization and step therapy, for management of Part B drugs in order to reduce costs for both enrollees and the Medicare program. [12] CMS believes that step therapy and other utilization management tools may allow MA plans to negotiate for better value on Part B drug therapies. However, this authority is not without limitations. CMS proposes to implement a number of safeguards for MA plans, including the following: MA plans would be required to administer the determination and appeals processes under time frames that are similar to those applicable for Part D coverage determinations; MA plans must use a pharmacy and therapeutics ("P&T") committee to review and approve step therapy programs, consistent with Part D requirements; MA plans may only apply step therapy for new prescriptions or administrations of Part B drugs for enrollees not actively receiving the affected medication, with a lookback period of 108 days; and MA plans would be prohibited from using a non-covered drug as a step in the step therapy program. [13]

POTENTIAL CHANGE TO DEFINITION OF "NEGOTIATED PRICE"

Finally, CMS highlights the recent successes of Part D sponsors and pharmacy benefits managers ("PBMs") at negotiating price concessions from network pharmacies and states that it is considering a policy that would redefine "negotiated prices," currently defined at 42 C.F.R. § 423.100. Under the current definition, "negotiated prices" include all price concessions from network pharmacies — except those that cannot reasonably be determined at point of sale. [14] CMS is concerned that pharmacy price concessions, particularly performance-based price concessions, have become an increasingly large share of overall Direct and Indirect Remuneration received by sponsors and PBMs in recent years. Because these price concessions typically occur after the point of sale, they are not calculated in the "negotiated prices" calculation, often resulting in the negotiated price being higher than the final payment to the pharmacies. [15] CMS argues that when pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries may see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing, which may result in the beneficiary paying a larger share of the actual cost of the drug.

Under the proposed definition, "negotiated price" (singular, to make clear that the amount may differ on a drug-to-drug basis) would include all pharmacy price concessions [16] received by the sponsor for a covered Part D drug and would reflect the lowest possible reimbursement a network pharmacy will receive in total. [17] CMS believes that this change would ensure that the prices available to enrollees at point of sale are inclusive of all pharmacy price concessions and will result in lower plan premiums, greater transparency, and increased competition. Notably, CMS does not propose an anticipated effective date for these changes, and instead only solicits comments on whether and how best to make these changes, by CY 2020 or otherwise. [18]

REQUIRED IMPLEMENTATION OF REAL TIME BENEFIT TOOLS FOR PART D SPONSORS

In an expansion of current Part D e-prescribing ("eRx") requirements under the Part D Prescription Drug Program, CMS proposes to establish a real-time benefit tool ("RTBT") requirement for Part D sponsors, effective January 1, 2020, to serve as an adjunct to existing National Council for Prescription Drug Programs ("NCPDP") SCRIPT eRx standards and NCPDP Formulary and Benefits ("F&B") electronic standards. [19] These RTBTs would be required to integrate with a prescriber's eRx and electronic medical record ("EMR") systems to provide compete, accurate, and timely patient-specific F&B information to the prescriber. CMS anticipates that requiring plans to make a RTBT available to prescribers will lead to higher prescriber use of F&B data during the eRx process and may result in lower prescription drug spending and beneficiary out-of-pocket costs as a result of the clinically appropriate information on lower-cost alternative therapies that may be provided by a RTBT. [20]

NEXT STEPS

CMS is soliciting comments on its proposals and the feasibility for plans to meet such proposals by CY 2020. Comments are due no later than 5:00 p.m. EST on January 25, 2019.

K&L Gates' health care practice regularly assists health systems and pharmacies in responding to proposed regulatory changes and can assist in commenting on the Proposed Rule and assessing how such changes to Part

D and MA plans would impact them. We regularly advise clients on compliance matters and facilitate stakeholder engagement with Congress, the Trump administration, and CMS through our public policy and law practice. We will continue to closely monitor developments related to this Proposed Rule, MA and Part D drug reimbursement, and other changes affecting drug pricing.

NOTES:

[1] Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62,152 (Nov. 30, 2018) (hereinafter referred to as the "Proposed Rule").
[2] U.S. Dep't of Health & Hum. Servs., American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (May 2018), https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.
[3] Proposed Rule at 61,257.
[4] *Id.* at 62,156.
[5] *Id.* at 62,157.
[6] Pub. L. 115-262.
[7] Proposed Rule at 62,164.
[8] *Id.* at 62,168.
[9] *Id.*
[10] *Id.*
[11] Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage (August 2018), https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf.
[12] Proposed Rule at 62,169.
[13] *Id.* at 62,169–71.
[14] 42 C.F.R. § 423.100.
[15] Proposed Rule at 62,174.
[16] Part D regulations and current subregulatory guidance do not currently define "price concession." In the Proposed Rule, CMS states that it is considering adding a definition that would include all forms of discounts and direct or indirect subsidies or rebates that serve to reduce the costs incurred under Part D plans, but it does not propose codifying such a definition in this Proposed Rule. Proposed Rule at 62,153.
[17] *Id.* at 62,175.
[18] *Id.* at 62,179.
[19] *Id.* at 62,165.
[20] *Id.*

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