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CLIENT ALERT

Comment Deadline Approaches for CMS's Proposed Changes to Medicare Advantage and Part D Programs for CY 2019:

Part 1: Negotiated Prices for Drugs

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The Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule titled "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program" ("Proposed Rule"), which was published in the *Federal Register* on November 28, 2017.[1] The Proposed Rule contains numerous provisions that propose to revise policies related to drug access and pricing.

In light of the volume of the Proposed Rule, which is nearly 200 pages in length, we have divided our Client Alert into three parts:

- **Part 1** focuses on the provision specifically affecting negotiated prices for drugs.
- **Part 2** will focus on a multitude of other significant provisions in the Proposed Rule affecting beneficiary cost, access, and protection (e.g., Part D tiering exceptions, expedited substitutions of certain generics and other midyear formulary changes, the treatment of follow-on biological products as generics, any willing pharmacy standards, meaningful difference, and the Medicare medical loss ratio).[2]
- **Part 3** will focus on Part D Drug management programs following adoption of the Comprehensive Addiction and Recovery Act of 2016.[3]

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[1] 82 Fed. Reg. 56336 (Nov. 28, 2017), *available at* https://www.federalregister.gov/documents/2017/11/28/2017-25068/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare.

[2] Part 2 of the Client Alert is available at https://www.ebglaw.com/CY2019-2.

[3] Part 3 of the Client Alert is available at https://www.ebglaw.com/CY2019-3.

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In light of the importance of the Proposed Rule, a number of its significant sections are deserving of public comments, which must be submitted to CMS no later than ***5 p.m. EST on Tuesday, January 16, 2018***.

Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

A. Background

The Proposed Rule includes a Request for Information ("RFI") announcing CMS's intention to mandate that Part D plan sponsors pass through a certain proportion of price concessions to beneficiaries through lowered prices for drugs at the point of sale ("POS")—i.e., when the pharmacy dispenses the drug. Such price concessions, which are referred to as "direct and indirect remuneration" ("DIR") under Medicare Part D, take the form of rebates, administrative fees, and various other forms of remuneration that Part D plans receive through their contractual arrangements with manufacturers and network pharmacies.

Under existing Part D law, plans may *choose* to incorporate price concessions into the negotiated prices offered to beneficiaries at the POS, but they are not *required* to pass along any such price concessions. In contrast to CMS's original expectations, most Part D plans have chosen to withhold, rather than pass through, a significant portion of their price concessions in an effort to keep their premiums low. CMS is concerned that Part D plans have been effectively gaming the Part D reimbursement system to shift a large proportion of their drug costs to beneficiaries, drug manufacturers, and the government. With the Proposed Rule, CMS intends to close, or at least dramatically reduce, this loophole by mandating that Part D plans pass through some percentage of price concessions at the POS and thereby realign the competitive balance of the Part D program. The preamble to the RFI, which separately addresses manufacturer rebates and pharmacy price concessions, describes the policy rationale behind CMS's intended policy change, addresses certain related technical components related to a pass-through requirement, and solicits stakeholder input on new policy design and implementation.

B. Manufacturer Rebates at the Point of Sale

CMS is requesting stakeholder input on how to design a policy to require Part D plans to pass through at the POS manufacturer rebates, which comprise the largest share of all price concessions received by plans. To this end, the RFI outlines the potential parameters for such a policy and requests feedback on the associated implications and technical considerations, including the following:

Specified Minimum Percentage: CMS is considering a requirement that Part D sponsors pass through a specified minimum percentage of the cost-weighted average of rebates provided by drug manufacturers for covered Part D drugs in the same therapeutic category or class. This so-called "point-of-sale rebate" would be required to be included in the negotiated price. Stakeholders should also be aware of the following:

- CMS is considering setting the specified minimum percentage at a point less than 100 percent of the average rebate amount for drugs in the same drug category/class. Although CMS does not prescribe a certain percentage level, it seeks comment on what minimum percentage should be reflected in the negotiated price.

- CMS also seeks comment on how and when, if ever, that minimum percentage should be updated by CMS (with analytical justification) and the effect that any such minimum percentage would have on the competition for rebates under Part D and the total rebate dollars received by Part D sponsors and pharmacy benefit managers ("PBMs").

Average Rebate Amount: CMS proposes a methodology to calculate the average rebate amount applied at the POS, based on the following factors:

- *Rebate Year:* The average rebate would be based on the average manufacturer rebates expected to be received for each drug for the current payment year, not historical rebate experience. CMS expects a good faith estimate of any contingent rebates (i.e., contingencies that are not knowable at the POS).

- *Rebated Drugs:* The average rebate amount would be calculated using only drugs for which manufacturers provide rebates. Drugs would be considered on a national drug code ("NDC") basis.

- *Plan Level Average:* The average rebate amounts would be calculated separately at the plan-benefit-package level.

- *Drug Category/Class:* The average rebate amount applied would be based on the plan's average rebate amount calculated for drugs in the same category/class. Plans would be required to calculate the average rebate amount for the therapeutic category/class level (instead of the drug-specific level) to maintain confidentiality of pricing information. CMS specifically requests comments on scenarios where there is only a single drug in a category/class.

- *Weighting:* The average rebate amount for a category/class to be weighted would be based on each drug's total gross drug costs incurred over the relevant time period (to be specified in future rulemaking). For those cases in which a drug has less time on the market than there is cost data for the weighing approach, or the plan has not been active in the Part D program, there would be a requirement that the drug's rebate amount be weighted by a plan's projection of total gross drug costs.

- *Timing:* The average rebate amount would be recalculated periodically based on a time period (e.g., every month, quarter, year, etc.) to be defined in future rulemaking. CMS is seeking comment on how often the average rebate amount should be recalculated.

- *Applicability:* POS rebates would be limited to only rebated drugs by NDC-11 number. Otherwise, manufacturers that do not provide rebates for a particular drug would benefit when one or more of its direct competitors chooses to provide rebates (as the competitor's rebate would be used to lower the negotiated price and thereby potentially increase sales of the non-rebated drug). CMS seeks comment on an alternative approach where sponsors would only be required to provide POS rebates to certain drug categories/classes. Such categories/classes could include those that most directly contribute to increasing Part D costs in the catastrophic phase of coverage or drugs with high price–high rebate arrangements.

Additional Considerations:

- The responsibility for calculating the appropriate POS rebate amount would fall on plan sponsors, given their role in administering the drug benefit. CMS would leverage existing data reporting mechanisms, including prescription drug event ("PDE") records and DIR reports, to review sponsors' rebate calculations.

- CMS expects to impose a chief executive officer, chief financial officer, or chief operating officer attestation requirement relating to the average rebate amount included in the negotiated price and reported on the PDE.

- Regarding enforcement and oversight, CMS seeks comment on what specific mechanisms would ensure compliance with this POS rebate policy.

- CMS also seeks comment on any special considerations needed for Part D employer group waiver plans.

- CMS noted that the negotiated price is the basis by which manufacturer liability for discounts in the coverage gap is calculated. However, CMS is not certain that it has the authority to require sponsors to include in the negotiated price the weighted-average rebate amounts that would be required to be passed through for purposes of determining manufacturer coverage gap discounts.

Comments Specific to Manufacturer Price Concessions:

CMS solicits stakeholder input on the new policy design and implementation, including the following issues, implications, and technical considerations (issues for comment regarding pharmacy price concessions are embedded in the text of that section):

- Does CMS have legal authority to require sponsors to include in the negotiated price the weighted-average rebate amounts that would be required to be passed through for purposes of determining manufacturer coverage gap discounts (in contrast to the negotiated price used to determine the beneficiary's cost share)?

- What minimum percentage of manufacturer rebates should be reflected in the negotiated price (assuming less than 100 percent), and how and when should

the minimum percentage be updated by CMS and on what basis (i.e., analytical justification)?

- With regard to the methodology for the calculation of the average rebate amount to be passed through, CMS proposes that it be calculated using rebated drugs only, based on NDC code, for each plan-benefit-package level, forecast for the current calendar year (including a good faith estimate of contingent rebates). The average rebate amount would be calculated for drugs in the same category/class level by weighting the drug's rebate amount based on its total gross drug costs over the relevant period of time (for confidentiality reasons). But, if there is only a single drug in a category or class, what approach should be taken to avoid disclosure of confidential commercial pricing?

- How often should the average rebate amount be recalculated (e.g., annually, quarterly, or monthly)?

- Should POS rebates be required only for certain drug categories/classes that drive Medicare Part D expenditures?

- What impact will a requirement to pass through a specified minimum percentage have on the rebates received by Part D plan sponsors and/or their PBMs?

- What compliance and oversight mechanisms will ensure a plan sponsor's compliance with its responsibility to calculate, report, and certify the average rebate amount?

C. Pharmacy Price Concessions at the Point of Sale

In the Proposed Rule, CMS separately requests stakeholder input on how to design a related policy to require Part D plans to pass-through pharmacy price concessions in the reported price at the POS. These pharmacy price concessions, which have become a highly contentious issue between pharmacies and plans/PBMs, arise from arrangements in which plan sponsors and their PBMs may adjust a network pharmacy's reimbursement post-POS based on the pharmacy's performance on various measures defined by the sponsor or its PBM. The RFI proposes a means by which CMS could update the requirements to ensure that reported prices at the POS include all pharmacy price concessions; CMS requests feedback on the merits of this approach and on the following associated implications:

Pass-Through of All Pharmacy Price Concessions: CMS is considering requiring all price concessions—as opposed to only a specified percentage (such as would apply to manufacturer rebates)—from pharmacies to be reflected in the negotiated price that is made available at the POS and reported to CMS, even when the concession is contingent upon pharmacy performance.

Definition of "Negotiated Price": The current regulatory definition of "negotiated price" contains an exception for contingent pharmacy payment adjustments that cannot

reasonably be determined at the POS.[4] Based on prior stakeholder input, CMS acknowledges that performance-based pharmacy adjustments cannot be fully known at the POS. Therefore, CMS is seeking comment on how it might update the requirements governing the determination of negotiated prices to better reflect current pharmacy payment arrangements and ensure that the reported price at the POS includes all pharmacy price concessions.

Lowest Possible Reimbursement: To capture all pharmacy price concessions, CMS is considering requiring the negotiated price to reflect the lowest possible reimbursement that a network pharmacy could receive from a particular Part D sponsor for a Part D drug. The price reported would reflect all price concessions that could flow from network pharmacies (i.e., payments that decrease prices) but would exclude additional amounts that could flow to network pharmacies (i.e., payments that increase prices). This policy could lead to reports of negative DIR when a network pharmacy receives a bonus payment for any performance score above the lowest possible score. CMS sees this as a way to move the negotiated price closer to the final reimbursement for most network pharmacies with payment arrangements and, thus, closer to the sponsor's actual drug cost.

Additional Considerations: As mentioned above, CMS expects to leverage existing data-reporting mechanisms applicable to PDE records and DIR reports to review a sponsor's calculations regarding pharmacy price concession amounts. Also, similar to the manufacturer rebates, CMS is not certain whether it has the authority to include pharmacy price concessions in the negotiated price for purposes of manufacturer liability in the coverage gap.

D. Significance and Projected Impact of Proposed Part D Plan Pass-Through Requirement

CMS's announced intent to require a plan pass-through of price concessions at the POS could dramatically impact Part D administration and the dynamics between the program, drug manufacturers, plan sponsors, and beneficiaries. Requiring plans to pass through some proportion of their price concessions would reduce their ability to shift costs. Drug manufacturers would benefit by a reduction in payments under the coverage gap discount program ("CGDP"), as fewer beneficiaries would progress into and through the coverage gap. A pass-through requirement would also generate beneficiary cost-savings at the pharmacy counter and reduce Medicare reinsurance payments tied to catastrophic coverage and low-income subsidies. On the other hand, Part D premiums, which have remained relatively stable for several years, would likely increase.

In the Proposed Rule, CMS provides calculations regarding the projected impacts of a mandated price concession pass-through, which reflect that—with respect to a requirement for a 100 percent manufacturer rebate pass-through—net beneficiary costs would decrease by 8 percent, government costs would increase by 6 percent, and manufacturer liability under the CGDP would decrease by 20 percent over the course of 10 years. Thus, the pass-through requirement would favor beneficiaries and drug

[4] *See* 42 C.F.R. § 423.100.

manufacturers, and it would result in only a relatively modest increase in government costs. On the other hand, Part D plans and their PBMs would stand to be adversely affected by this policy change, because they have been able to shift costs to other stakeholders under the current construct.

Next Steps

Plan sponsors, manufacturers, pharmacies, and other key stakeholders should consider the possible implications of the Proposed Rule with respect to benefits, as well as the products offered under such benefits, including the potential impact of these proposed policies on their business plans, operations, systems, policies, and financial projections/budgeting. Epstein Becker Green is available to assist with drafting and submitting comments to the Proposed Rule and to provide a more detailed understanding of the Proposed Rule's implications and the manner in which particular requirements may be implemented effectively.

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