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April 5, 2019

The Honorable Daniel R. Levinson
Office of Inspector General
Department of Health and Human Services
330 Independence Avenue, SW
Washington DC, 20201

RE: OIG-0936-P

Dear Inspector General Levinson:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Office of Inspector General (OIG) proposed rule entitled “Removal of safe harbor protection for rebates involving prescription pharmaceuticals and creation of new safe harbor protection for certain point-of-sale reductions in price on prescription pharmaceuticals and certain pharmacy benefit manager service fees,” published in the *Federal Register*, vol. 84, no. 25, pages 2340 to 2363. We appreciate your staff’s work on the proposed rule, particularly considering the competing demands on the office.

OIG’s proposed rule would amend the safe harbor regulation governing pharmaceutical manufacturers’ rebates and discounts, which currently are protected from liability under the federal anti-kickback statute. Under the proposal, the definition of “discount” would be revised to exclude reductions in price or remuneration from drug manufacturers (e.g., rebates and discounts) to plan sponsors in Medicare Part D, Medicaid managed care organizations, or their contracted pharmacy benefit managers (PBMs), unless the price reduction (or rebate) is required by law. At the same time, the proposal would create two new safe harbors. The first would permit rebates set in advance between those same entities so long as the full rebate amount is provided to the dispensing pharmacy through chargebacks and is reflected in the beneficiary’s out-of-pocket (OOP) cost at the point of sale. The second would protect pharmaceutical manufacturers’ ability to pay service fees to PBMs so long as the fees are: 1) consistent with fair market value in an arm’s-length transaction (i.e., in which buyers and sellers act independently and in their own self interest); 2) a fixed payment rather than a percentage of sales; and 3) not determined in a manner that takes into account the volume or value of referrals or business generated between the parties. PBMs would also need to disclose fee arrangements with manufacturers to the health plans with which they contract, as well as to the Secretary upon request.

The Commission supports OIG’s objective of constraining growth in prices and spending for prescription drugs. We recognize that the current gap between drug prices at the pharmacy (what we refer to as point-of-sale (POS) prices) and prices net of postsale rebates and discounts raises serious challenges for beneficiary cost sharing and Medicare program spending.

At the same time, limiting the ability of Part D plan sponsors and their PBMs to use rebates could also lead to uncertain and potentially undesirable outcomes, and thus the Commission has substantial concerns about the proposed changes. In this letter, we describe how rebates are used currently, problems associated with the gap between prices at the pharmacy and prices net of rebates, and potential effects of the proposed rule on beneficiaries and the Medicare program. We conclude by describing policy changes that would improve underlying program incentives in Part D and could potentially help address the current pricing situation.

Rebates are used as a mechanism for price discrimination

For the past several decades, manufacturers have used rebates to negotiate prices for brand-name drugs that are individualized for different purchasers. The approach of charging different prices to different payers—known by economists as price discrimination—is used in many industries from automobiles to airline tickets. For retail pharmaceuticals, payers (such as employers, states, and plan sponsors) and PBMs under contract to them do not directly purchase or take physical possession of drugs from manufacturers or wholesalers. Instead, pharmacies buy medicines and PBMs pay pharmacies for the prescriptions filled by health plan members. However, PBMs directly receive postsale rebates from manufacturers that effectively discount drug prices and may be used to lower enrollee premiums or cost-sharing amounts. The size of specific rebates depends on whether a drug has competing therapies as well as the negotiating leverage of each PBM or payer—which, in turn, depends on the PBM/payer’s ability to deliver a certain market-share goal to the manufacturer. Rebates are structured so that a manufacturer might pay a base rebate to the PBM for placing its product on a plan’s formulary (rather than excluding the drug), but might pay larger rebates if the drug is placed on a preferred cost-sharing tier or if prior authorization requirements are waived. In recent years, payers and PBMs have also negotiated “price-protection” provisions under which the manufacturer agrees to rebate a drug’s mid-year price increases above a specified threshold.

Manufacturers consider rebate amounts highly proprietary because revealing that information could alter their negotiating leverage with other payers. If one payer was able to observe the size of a rebate a manufacturer negotiated with a different payer, the first payer could demand similar rebate terms. For this reason, the Congressional Budget Office, Federal Trade Commission, and other economists have suggested that transparency of specific rebate agreements could set in place conditions for tacit collusion among manufacturers of competing drugs, likely lowering average rebate amounts and compressing the range of final prices net of rebates.¹ At the same time, the opaqueness of rebate agreements between manufacturers and PBMs is one important reason that final drug prices are not transparent to consumers or even to some payers. Some economists

¹ Congressional Budget Office. 2008. *Increasing transparency in the pricing of health care services and pharmaceuticals*. Economic and budget issue brief. Washington, DC: CBO. Federal Trade Commission. 2009. Letter from FTC staff to the Hon. James Seward on N.Y. Senate Bill 58. March. http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf. Danzon, P. 2015. Pharmacy benefit management: Are reporting requirements pro or anti-competitive? *International Journal of the Economics of Business* 22(2): 245–261.

suggest that “contracts with shrouded rebates in a concentrated (PBM) market can result in higher manufacturer prices and increased profits for PBMs.”²

In the commercial market, payers and health plans negotiate with PBMs over whether they will receive a share of manufacturers’ rebates and how much they will pay the PBM for each prescription filled by their members. In previous years, PBMs would often keep most rebate revenue as compensation for their services plus any “spread” (difference) between amounts received from payers and amounts paid to pharmacies. In recent years, however, more payers have negotiated with PBMs to pass through all rebates.³ (Part D requires the pass-through approach.) Other commercial contracts allow PBMs to retain a percentage of rebates if the PBM takes on the risk of guaranteeing the payer predictable rebate payments.⁴ Because there is less or no financial spread under pass-through pricing, PBMs charge payers administrative fees for their services.⁵

Pharmaceutical manufacturers also pay PBMs fees for services such as monitoring patient adherence and administering rebate programs as the PBM adjudicates member claims.⁶ Under Part D regulations, bona fide service fees paid by manufacturers must be priced at fair-market value commensurate with an arm’s-length transaction between unaffiliated parties. Part D plan sponsors must report to CMS the value of fees in excess of fair-market value in the same way that they report manufacturer rebates.⁷

Since the start of Part D, both POS prices for brand-name drugs and postsale rebates and fees have grown rapidly, but rebates have increased at a faster rate. Between 2007 and 2017, spending for brand-name drugs grew by an annual average of 10 percent, while postsale rebates and fees grew by 19 percent annually. Consequently, the gap between brand prices charged at the pharmacy (POS prices) and prices net of postsale rebates and fees has widened considerably. Using Part D plan sponsors’ assumptions about rebates from their 2019 bids, the Medicare Trustees estimated that postsale remuneration—consisting predominantly of manufacturers’ rebates—reduced POS drug costs by 26 percent (averaged across all drugs, including those for which plans do not receive any rebates).⁸ This is a significant increase from about 9.6 percent of POS spending in 2007. This phenomenon is not limited to the Part D program. According to one estimate, in 2017, discounts,

² Garthwaite, C., and F. Morton. 2017. Perverse market incentives encourage high prescription drug prices. *ProMarket* blog. November 1. <https://promarket.org/perverse-market-incentives-encourage-high-prescription-drug-prices/>.

³ In one 2018 survey of employer and union health plans, 63 percent reported using pass-through pricing and 37 percent reported spread pricing. Larger employers were more likely to receive all rebates from their PBMs. Pharmacy Benefit Management Institute. 2018. *Trends in drug benefit design*. Plano, TX: PBMI.

⁴ CVS Health. 2018. *Current and new approaches to making drugs more affordable*. August. <https://cvshealth.com/sites/default/files/cvs-health-current-and-new-approaches-to-making-drugs-more-affordable.pdf>.

⁵ Payers pay PBMs administrative fees for claims processing and other services. Fein, A. 2017. *The 2017 economic report on U.S. pharmacies and pharmacy benefit managers*. Philadelphia, PA: Pembroke Consulting.

⁶ According to manufacturers, these fees have increased rapidly. Pharmaceutical Research and Manufacturers of America. 2017. *Follow the dollar: Understanding how the pharmaceutical distribution and payment system shapes the prices of brand medicines*. Washington, DC: PhRMA.

⁷ CMS refers to rebates and fees paid by manufacturers to plan sponsors and postsale pharmacy fees as “direct and indirect remuneration.”

⁸ Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. 2018. *2018 annual report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds*. Washington, DC: Boards of Trustees.

rebates, and other price concessions reduced overall invoice (list price) spending for all U.S. prescription drugs by 28 percent, from \$453 billion to a net of \$324 billion, a reduction of about \$130 billion.⁹ By comparison, the same researchers estimated that in 2007, the reduction was about \$50 billion, or roughly 17 percent of list prices.

We share the Inspector General's concerns that the current use of rebate arrangements in the prescription drug supply chain may create a barrier to lowering drug costs. At all points along the supply chain, payments for distribution and administrative services are often based on a percentage of the drugs' prices.¹⁰ As blockbuster drugs to treat widely prevalent diseases went off patent and faced generic price competition, manufacturers turned their attention toward specialty drugs and biologics for smaller patient populations. Meanwhile, participants in drug supply and distribution channels grew to rely on price inflation for revenue growth.¹¹ Those factors, combined with the increasing market concentration among participants in the drug supply and distribution channels, have put upward pressure on both prices and rebates. Even employers and other payers have become more reliant on pass-through rebate revenue from their PBMs.¹²

Implications of the gap between POS and net prices in Part D

The widening gap between POS and net prices has garnered attention because of its implications for beneficiary cost sharing and Medicare program spending. In Part D, plan sponsors could use manufacturer rebates to reduce the price of the prescription that generated the rebate at the POS.¹³ Under this approach, enrollees who use drugs for which a rebate is negotiated benefit because the deductible and coinsurance amounts would be based on the discounted price. However, this approach is not practical if the amount of rebate payment is determined retroactively based on performance goals or the magnitude of price increases.

Instead, Part D plan sponsors overwhelmingly opt to use manufacturer rebates to lower plan premiums because beneficiaries evaluate premiums closely when comparing plan options, and

⁹ IQVIA Institute for Human Data Science. 2018. *Medicine use and spending in the U.S.: A review of 2017 and outlook to 2022*. Parsippany, NJ: IQVIA.

¹⁰ Fein, A. 2018. Building a new drug wholesaler compensation model: What happens as brand inflation slows? *Drug Channels* blog. July 24. <https://www.drugchannels.net/2018/07/building-new-drug-wholesaler.html>. Feldman, R. 2018. Perverse incentives: Why everyone prefers high drug prices—Except for those who pay the bills. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3162432. Garthwaite, C., and F. Morton. 2017. Perverse market incentives encourage high prescription drug prices. *ProMarket* blog. November 1. <https://promarket.org/perverse-market-incentives-encourage-high-prescription-drug-prices/>.

¹¹ Fein, A. 2017. McKesson's profit shortfall: How wholesalers benefit from rising drug list prices. *Drug Channels* blog. January 26. <http://www.drugchannels.net/2017/12/the-cvs-aetna-deal-five-industry-and.html#more>. Lopez, L. 2016. These companies you've never heard of are about to incite another massive drug price outrage. *Business Insider*, September 12. Sell, D. 2015. Expect higher prices for generic drugs, says drug wholesaler. *Philadelphia Inquirer*, September 17.

¹² Fein, A. 2018. New disclosures show CVS and Express Scripts can survive in a world without rebates. Are plan sponsors now the real barrier to disruption? *Drug Channels* blog. August 14. <https://www.drugchannels.net/2018/08/new-disclosures-show-cvs-and-express.html>.

¹³ For 2019, one enhanced Part D plan, CVS Health's SilverScript Allure, applies some manufacturer rebates to POS prices at an enrollee premium of \$80 per month. Nationwide, as of February 2019, out of total SilverScript enrollment of about 6.1 million, Allure plans had about 24,000 enrollees.

premiums are the basis on which plans qualify as low-income subsidy (LIS) benchmark plans. Using rebates to reduce plan premiums lowers Medicare program spending because Medicare subsidies pay for a large portion of plan premiums for all enrollees.¹⁴ However, under this approach, because POS prices are not discounted, coinsurance amounts paid by the beneficiary are higher. As a result, a higher proportion of enrollees reaches Part D's OOP threshold—the point at which Medicare's reinsurance pays for 80 percent of benefits. The approach also increases costs for Medicare through higher low-income cost-sharing subsidies. Medicare pays for most of the cost sharing on behalf of LIS enrollees. When plans set cost sharing as a percentage of POS prices, Medicare's low-income cost-sharing subsidy is higher than it would be on a net-of-rebate basis.¹⁵

The Commission has previously discussed how Part D's benefit design can create incentives for plan sponsors to include certain high-cost drugs on their formulary over others, which can increase beneficiary cost sharing and Medicare's spending for the low-income cost-sharing subsidy and reinsurance.¹⁶ In addition, over recent years the amount of rebates and discounts that sponsors received typically has exceeded the amount that sponsors projected in their bids. CMS contends that, under Part D's risk corridors, “any DIR (rebates and discounts) received that is above the projected amount factored into a plan's bid contributes primarily to plan profits, not lower premiums.”¹⁷ Together, Part D's unique benefit design and the current rebate approach provide a financial advantage to plan sponsors. As a result, CMS is concerned that sponsors may have a weak or no incentive to lower prices at the POS and may prefer high cost, high rebate drugs” when available over alternative drugs that have lower net costs. Other analysts have suggested that demand for rebates among plan sponsors has been a factor behind manufacturers' decisions to increase drug prices.¹⁸ PBMs counter that recent increases in rebates have not been correlated with price growth.¹⁹

Uncertainty and the potential for negative financial consequences of the proposal

The Commission appreciates the motivation behind the OIG's proposal to amend the safe harbor regulation regarding rebates under the federal anti-kickback statute. For beneficiaries who use highly rebated drugs, cost-sharing amounts that are based on a percentage of the POS price are too high. The current gap between POS and net-of-rebate prices may lead to poor incentives in formulary decision-making and may further exacerbate drug price inflation. Nevertheless, the Commission recognizes that whether the proposed rule would lead to better incentives for

¹⁴ Medicare also retains a portion of aggregate rebates to offset a share of its payments for individual reinsurance.

¹⁵ LIS enrollees pay nominal cost sharing amounts—typically between \$0 and \$8 per prescription—that are set in law. Medicare's low-income cost-sharing subsidy pays for the difference between the cost-sharing requirements set by the LIS enrollee's plan and the nominal statutory copay amount.

¹⁶ Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

¹⁷ Centers for Medicare & Medicaid Services. 2017. 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. Notice of proposed rulemaking. *Federal Register* 82, no. 227, pp. 56336–56527.

¹⁸ Anderson, G. and G. Bai. 2019. Reforming direct and indirect remuneration in Medicare Part D. *Health Affairs* blog. February 19. <https://www.healthaffairs.org/doi/10.1377/hblog20190215.708286/full/>.

¹⁹ PCMA. 2018. *Reconsidering drug prices, rebates, and PBMs*. Washington, DC: PCMA.

<https://www.pcmanet.org/wp-content/uploads/2018/08/Reconsidering-Drug-Prices-Rebates-and-PBMs-08-09-18.pdf>.

manufacturers and plan sponsors is uncertain, as suggested by the wide range of estimated effects under different behavioral assumptions. In addition, some of the proposal's effects, such as potentially slowing growth in brand prices, may be realized over a longer time period and be less apparent in the near term. Directionally, however, estimates that cover the initial 10 years of the proposed changes suggest that the rule would have negative financial consequences for most enrollees and for the Part D program, while reducing the share of benefit costs assumed by pharmaceutical manufacturers.

Specific effects of the proposal would depend on behavioral responses to the change in policy

The estimated effects of the proposed rule vary widely, reflecting different assumptions and significant uncertainty about the behavioral responses of plan sponsors, PBMs, and pharmaceutical manufacturers. For example, rebate negotiations between plan sponsors or their PBMs and manufacturers would undoubtedly change under the policy. However, the results of those negotiations are difficult to predict. CMS's Office of the Actuary assumed that because rebate amounts would no longer be contingent on a drug's attained market share, manufacturers would offer lower rebates than they do today and instead retain some of those revenues.²⁰ Estimates by other actuarial firms generally assumed that manufacturers would pass all of today's rebates through to beneficiaries at the point of sale.²¹ This behavioral response would affect not only POS prices, but also plan sponsors' formulary decisions, which in turn could change the pattern of drugs used by Part D enrollees.

Another key set of behavioral assumptions relates to whether manufacturers would lower list prices for their drugs across all markets. The proposed rebate policy would apply only to Part D plans and Medicaid managed care organizations, not to commercial health plans. Because any change in a drug's list price (wholesale acquisition cost) would apply to the entire U.S. market, manufacturers that were willing to lower their prices would need to bear in mind the revenue they would lose in commercial sales. Strategic responses would likely vary across manufacturers and might even differ among their products. For example, a manufacturer might choose to launch an authorized generic to allow for differing list prices and rebate strategies for the same drug in different markets.²² Eliminating rebates could reduce the financial benefits of higher prices of both existing and new products, but the magnitude of effects on price levels or growth rates would likely vary across drugs.

Instead of lowering list prices, manufacturers might prefer a strategy of keeping prices at current levels and negotiating individualized discounts with payers in return for formulary placement.

²⁰ Centers for Medicare & Medicaid Services, Office of the Actuary. 2018. Memo on the effects of proposed safe harbor regulation. August 30. In addition, if a drug manufacturer passed along current rebates and competitors were able to observe the discount amount because it was provided at the POS, all manufacturers of competing therapies might begin to offer similar (and over time, potentially lower) discounts.

²¹ Klaisner, J., Holcomb, K., and Filipek, T. 2019. *Impact of potential changes to the treatment of manufacturer rebates*. Brookfield, WI: Milliman. Lambert, J., Courtney, T., and McStanley, D. 2018. *Estimates of the impact on beneficiaries, CMS, and drug manufacturers in CY2020 of eliminating rebates for reduced list prices at point-of-sale for the Part D program*. Tampa, FL: Wakely.

²² <http://www.milliman.com/insight/2019/Changing-the-rebate-game-A-primer-on-the-HHS-proposed-rule-to-shift-drug-rebates-to-POS/>.

Beneficiaries enrolled in plans that charge coinsurance would pay cost sharing on the discounted price. Lower cost sharing, in turn, could lead beneficiaries to fill more prescriptions. Individualized discounts would be consistent with the current approach of price discrimination, which helps manufacturers to expand sales and profits. However, plan sponsors might not prefer that same strategy. Part D enrollees have the opportunity to switch plans annually, and beneficiaries who use high-cost, high-rebate drugs could seek out plans that negotiate the best discounts. As a result, applying discounts to POS prices may result in adverse selection for the plan, and plan sponsors may not have strong incentives to drive a hard bargain with manufacturers for individualized discounts.²³ Instead, plan sponsors would likely prefer that manufacturers lower list prices, which would also benefit commercial clients.

It is also unclear how PBMs would respond to the proposed policy of moving to flat fees for services provided to manufacturers. Today, most PBMs are integrated vertically with health plans, mail-order pharmacies, and specialty pharmacies. If PBMs perceive that fixed fees would reduce their revenues relative to the current approach, they may seek to expand revenues in ways not subject to the proposal. For example, PBMs' mail-order or specialty pharmacies could negotiate for larger rebates, postsale discounts, and fees from manufacturers because the current safe harbor would continue to protect manufacturer price concessions to pharmacies. CMS and plan sponsors that are not vertically integrated with mail-order or specialty pharmacies typically do not observe those types of discounts even though they affect costs for beneficiaries and the Medicare program.

Potential negative financial consequences for most Part D enrollees and the Medicare program

Despite the uncertainty in behavioral responses of manufacturers, plan sponsors, and PBMs, most of the estimated 10-year effects provided with the OIG's proposal were directionally consistent. They generally suggest that most beneficiaries would experience higher OOP costs due to higher premiums and the Medicare program and taxpayers would likely face higher program spending, while pharmaceutical manufacturers would pay lower amounts in coverage-gap discounts.

Most beneficiaries would face increased out-of-pocket costs

Part D plan sponsors generally use rebates to offset benefit costs (i.e., lower premiums for all plan enrollees) rather than to lower POS prices and cost sharing. A policy that shifts some or all rebates to lower prices at the POS would decrease cost-sharing liability for *some* enrollees (i.e., those who use medications with POS rebates or discounts), but would increase premiums for *all* enrollees. Even under the most optimistic scenario where the current level of manufacturer rebates and discounts are fully reflected at the POS, only beneficiaries who use branded prescriptions with POS discounts would see a reduction in their cost-sharing liability. (However, even those beneficiaries benefiting from POS rebates would still have no limit on what they must pay OOP.) Further, only a subset of those beneficiaries is likely to have reductions in cost sharing that exceed

²³ Seeking Alpha. 2019. Humana's CEO Bruce Broussard on Q4 2018 results—earnings call transcript. February 6.

the premium increase.²⁴ For most beneficiaries, the policy would increase their total OOP liability through higher premiums.

Medicare Part D would likely incur higher program spending

Under Part D, Medicare subsidizes about 75 percent of the cost of providing the basic benefit. That subsidy amount is based on the average of bids submitted by plan sponsors that reflect their estimated revenue requirements for providing the benefit, net of expected rebates and discounts. Medicare's subsidy to plans takes two forms: capitated direct-subsidy payments and reinsurance on 80 percent of an individual enrollee's spending in Part D's catastrophic phase.

By requiring rebates and discounts to be reflected as lower POS prices, the proposal would likely increase Medicare's subsidy payments to plan sponsors through higher premiums. Among the three sets of estimates of the proposal's effects, each one found that as premiums increased, so did Medicare's direct subsidy payments and low-income premium subsidies. At the same time, lower POS prices means that fewer enrollees would reach the catastrophic phase, thereby reducing Part D's reinsurance payments. Lower POS prices would also reduce Medicare's low-income cost sharing subsidy payments. On net, however, two of the three sets of estimates prepared for OIG found that Medicare program spending would increase.²⁵ The third set of estimates offered a range of outcomes, from program savings (under the assumption that plans tightened formularies and negotiated larger price concessions from manufacturers) to higher program costs (under the assumption that manufacturers would not lower prices by the full magnitude of current rebates). Very few estimates assumed potential behavioral changes, such as beneficiaries filling more prescriptions for brand-name drugs if their cost sharing was lowered because POS prices reflected the rebate amounts. Some patients might become more adherent to their medication regime because of lower cost sharing, and other beneficiaries might newly decide that they are able to afford the prescribed drug at the lower amount. For some enrollees, that behavioral response may lead to improved clinical outcomes. At the same time, it would also tend to increase Medicare program spending.

Pharmaceutical manufacturers would assume a smaller share of benefit costs

Manufacturers of brand-name drugs and biological products are required to provide POS discounts equal to 70 percent of negotiated prices for all brand prescriptions filled by non-LIS beneficiaries in the coverage-gap phase (known as the coverage-gap discount). Currently, CMS's definition of negotiated prices includes all price concessions from manufacturers and pharmacies to plan sponsors except those amounts that cannot reasonably be determined at the POS. Because manufacturer rebates and discounts (other than the coverage-gap discount) are typically paid after the POS transactions, they are not included in negotiated prices. To the extent that manufacturers

²⁴ Wakely estimated that 30 percent of non-LIS enrollees would have reductions in cost sharing that would more than offset the increase in premiums. Lambert, J., Courtney, T., and McStanley, D. 2018. *Estimates of the impact on beneficiaries, CMS, and drug manufacturers in CY2020 of eliminating rebates for reduced list prices at point-of-sale for the Part D program*. Tampa, FL: Wakely.

²⁵ Wakely estimated that Medicare program costs in 2020 would increase by 3 percent. CMS's Office of the Actuary estimates that between 2020 and 2029, Medicare program spending for Part D would increase by \$196 billion.

and PBMs respond to OIG's proposal by negotiating lower POS prices, this would reduce negotiated prices and, in a corresponding manner, lower the amount manufacturers must pay in coverage-gap discounts. The reduction in coverage-gap discount would likely increase enrollee premiums and Medicare's program spending.²⁶

Effects on other federal programs and other parts of Medicare

In the proposal, OIG notes potential effects on other federal programs that rely on market prices to determine payment rates or mandated rebate amounts. For example, under Part B, Medicare pays for certain drugs based on average sales price (ASP), which reflects the postsale rebates and discounts that most purchasers receive. If the proposed policy affected the broader pharmaceutical supply chain and pricing, payments for pharmaceutical products under Part B and other federal programs that use market prices could increase or decrease.

Alternative approaches for better aligning stakeholder incentives in Part D

The Commission shares the Inspector General's concerns and agrees that a change is needed to ensure Part D sponsors face incentives that align with the program and its beneficiaries. We previously discussed how Part D's benefit design can create incentives for plan sponsors to include certain high-cost, high-rebate drugs on their formulary over others, which can increase beneficiary cost sharing and Medicare spending for reinsurance.²⁷ At the same time, manufacturers may find that, for some products, higher prices allow them to offer larger rebates than their competitors and gain more market share via favorable placements on plan formularies. In this sense, Part D's benefit design may contribute to the inflationary trend in pharmaceutical pricing.

Growth in list prices, combined with rising rebates, has contributed to a relatively slow growth in premiums and a rapid growth in reinsurance payments. Premiums and fixed-dollar copayments are lower for all enrollees when plan sponsors offset their benefit costs with postsale rebates and discounts. However, enrollees who pay coinsurance for their prescriptions do not see any reduction to their cost sharing because coinsurance is based on the price before postsale price concessions are applied. Because Part D's OOP threshold is based on the higher (gross) price, the trend contributes to more beneficiaries exceeding that OOP threshold and increases Medicare's payments for reinsurance.

In 2016, the Commission recommended an integrated set of changes to Part D that would phase in a reduction of Medicare's reinsurance from 80 percent to 20 percent while simultaneously

²⁶ Lower coverage-gap discount payments would be expected to increase plan costs through a reduction in manufacturer contributions toward Part D benefit costs even if the net prices are same under the proposed policy as under current law (if the POS discounts are less than the amounts plan sponsors currently receive in postsale rebates and discounts, the benefit costs would rise further). The result is high bids, which translate into higher government subsidies to plan sponsors and higher beneficiary premiums.

²⁷ Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

increasing capitated payments to plans, among other changes.²⁸ Those recommendations could better align plan sponsors' financial incentives to include lower-priced drugs on their formularies. Beneficiaries would also benefit from lower cost sharing if they select those lower-priced drugs.

The Commission's 2016 package of recommendations, however, relied on indirect effects to address the pricing incentives of pharmaceutical manufacturers. Because plan sponsors would be responsible for a greater share of insurance risk in the catastrophic phase, the Commission expects the recommendations would reduce the financial benefits of including high-price, high-rebate products on their formularies. To the extent that plan sponsors move away from preferring those products, there may be an indirect effect on manufacturers' pricing strategies. Those indirect effects, however, may be limited and would likely vary depending, for example, on the availability of therapeutic competition and the size of the Part D market relative to total U.S. sales for the relevant products.

While Medicare's influence on drug pricing is indirect, its large market share (about one-third of U.S. retail pharmaceutical sales) results in Medicare's payment policies having a significant financial effect on the U.S. health care market, including pharmaceutical manufacturers.²⁹ For example, the amount manufacturers must pay in coverage-gap discounts would be a relatively large share for products with low POS prices but would be a relatively small share for products with high POS prices. That situation may factor into manufacturers' pricing strategies, such as higher price increases or launch prices that already account for the amount they are likely to owe in coverage-gap discount.

One potential policy option that would offer better pricing incentives would be to require manufacturers to provide discounts in the catastrophic phase of the benefit rather than during the coverage-gap phase.³⁰ Under that approach, manufacturers of high-priced products would pay a larger discount, on average, than manufacturers of lower-priced products. Because the size of discount would increase proportionately with price, such an approach may make price increases less attractive to manufacturers. To ensure Medicare's program spending for Part D does not increase, policymakers could choose the rate of manufacturer discount in the catastrophic phase of the benefit that would provide at least as much price discount (in aggregate) as under the current coverage-gap discount policy.

Conclusion

The Commission values the ongoing cooperation and collaboration between OIG and our staff on technical policy issues. We look forward to continuing this productive relationship. If you have

²⁸ Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

²⁹ Kaiser Family Foundation analysis of CMS National Health Expenditure Data. 2019. <https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/>.

³⁰ Hayes, T. O. 2018. *Redesigning Medicare Part D to realign incentives*. Washington, DC: American Action Forum. <https://www.americanactionforum.org/research/redesigning-medicare-part-d-realign-incentives-1/>.

The Honorable Daniel R. Levinson
Inspector General
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any questions, or require clarification of our comments, please feel free to contact James E. Mathews, the Commission's Executive Director, at 202-220-3700.

Sincerely,

A handwritten signature in black ink that reads "Francis J. Crosson M.D." The signature is written in a cursive style with a large, looping initial 'F'.

Francis J. Crosson, M.D.
Chairman