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Client Alert

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HHS Finalizes Rule Challenging Drug Manufacturer Rebates to PBMs and Payors

Final Rule Closely Resembles Previously Withdrawn 2019 Proposed Rule

INTRODUCTION

On November 20, 2020, as part of a release of several drug pricing rules, the U.S. Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") adopted a Final Rule modifying the Anti-Kickback Statute ("AKS") discount safe harbor and adding two new safe harbors to reform drug pricing in the Medicare Prescription Drug Benefit ("Part D"). The Rule will require pharmacy benefit managers ("PBMs") and Part D Plans ("PDPs") to abandon the use of rebates, unless they are passed on to the consumer at the point of sale. The Final Rule, if it survives inevitable judicial scrutiny, will fundamentally change Part D drug pricing between manufacturers and Part D plan sponsors.

The Rule finalizes, with minimal modification, a similar Proposed Rule first released on January 31, 2019 (which was the subject of a prior Alert that can be found here) and subsequently "withdrawn" on July 10, 2019. The Proposed Rule was initially withdrawn following significant political debate between the White House and HHS over concerns that it would lead to an increase in premiums under Medicare Part D. Despite the government's public statements of withdrawal, however, it appears that the Rule's demise was premature; a withdrawal notice was never listed in the Federal Register, and now OIG has finalized the rule.

The Final Rule creates a new AKS point-of-sale prescription drug price reduction safe harbor that would exempt manufacturer rebates paid to Part D plan sponsors and Medicaid managed care organizations (MCOs) for prescription drugs if those rebates are passed through to the enrollee at the point of sale. The Final Rule also creates a second safe harbor for certain "legitimate" service fees paid by manufacturers to PBMs. These

new safe harbors will be available starting 60 days after publication of the Final Rule in the Federal Register.

In addition, notably, the Final Rule explicitly carves out from discount safe harbor protection rebates and other remuneration in connection with the sale or purchase of prescription drugs from a manufacturer to a Part D plan sponsor (including indirectly through a PBM acting under contract with a plan sponsor). The Final Rule does not explicitly carve out of the discount safe harbor price reductions provided to Medicaid MCOs, in contrast to the Proposed Rule. The changes to the discount safe harbor – including loss of discount safe harbor protection for rebates to Part D plan sponsors – will go into effect on January 1, 2022. Presumably, the purpose of the delayed effective date of the discount safe harbor changes is to allow manufacturers and plan sponsors time to enter into agreements that satisfy the new point-of-sale prescription drug price reduction safe harbor and PBM services fees safe harbor to help avoid scrutiny under the AKS.

OIG claims that the Final Rule will lower prescription drug prices and patient out-of-pocket costs. In OIG's view, the Final Rule will "create incentives for manufacturers to lower their list prices; reduce the incentives for Part D plans to choose high-cost, highly rebated drugs over comparable drugs with lower prices; lower beneficiary out-of-pocket spending; and increase transparency to improve plan choice and program integrity."[1] OIG also argues that the new rule will increase transparency, thereby increasing consumer choice and lowering prices. However, the Office of Management and Budget ("OMB") had indicated that the Proposed Rule was expected to increase PDP premiums for beneficiaries and, although the Secretary has certified that premiums will not rise, it is uncertain what will happen to PDPs starting in 2022.

SUMMARY OF THE MAJOR PROVISIONS

A. New Explicit Carve Out from Discount Safe Harbor Protection

i) The Final Rule

The Final Rule explicitly eliminates protection under the AKS regulatory discount safe harbor that was purportedly previously afforded to rebates paid by a manufacturer to a plan sponsor under Medicare Part D. This exception includes rebate payments made directly to the plan sponsor or indirectly through a PBM acting under contract with a PDP sponsor.

In addition to removing protections under the discount safe harbor for Part D rebates, the Final Rule reiterates HHS's position that any portion of a rebate or discount that a manufacturer pays to a PBM that is not passed through to the "buyer" (as defined in the discount safe harbor) has never been protected under the discount safe harbor, even if that PBM is operating on behalf of a Medicaid MCO.[2] The Rule "clarifies" that the discount safe harbor protects reductions in price to buyers, but PBMs negotiate on behalf of payors and are therefore, not buyers themselves. OIG states further that PBM rebates serve to increase list prices by encouraging Part D PBMs to favor high-cost, highly rebated drugs over comparable drugs with lower list prices. Thus, while it is still unclear that the discount safe harbor ever protected manufacturer rebates paid to a PBM, as of January 1, 2022, it is now certain that neither manufacturers nor PBMs will be able to seek protections under this safe harbor for rebates or other remuneration between the parties.

The impact of this proposed change on manufacturer rebates offered to *commercial* health plans – either directly or through PBMs – is not yet clear. Several comments to the Proposed Rule urged OIG to make clear that the discount safe harbor changes should be applied equally to PBM arrangements that are exclusively within the commercial insurance market; but, OIG noted that it does not have the authority to do so. In other words, OIG acknowledges that manufacturers and PBMs do not necessarily require safe harbor protection from the AKS for rebates that pertain exclusively to commercially insured prescriptions because the AKS does not reach to inducements of prescriptions

that are not reimbursed by a Federal health care program. Nonetheless, OIG expressed optimism that the commercial market will follow the Medicare market without direct regulation.[3] Likewise, even if entities use different discount mechanisms in commercial and Part D contracts, OIG argues that the Final Rule will lower list prices which will spill over and benefit enrollees of commercial plans as well.

Overall, despite its optimism that the Final Rule will alter the rebate structures applicable to commercial insurance plans, OIG notes that its proposed changes will not directly impact discounts to parties other than Medicare Part D plan sponsors and the PBMs that negotiate on their behalf.

OIG reiterated its "long-standing concern" (previously cited in the Proposed Rule) that certain arrangements, such as higher discounts or rebates in commercial plans intended to offset the impact of the Rule, may violate the AKS even if they technically carve out Federal health care program beneficiaries or business generated by Federal health care programs. Specifically, OIG expressed concern that rebates paid only to commercial plans may actually be part of a broader arrangement to induce referrals of Federal health care program business or patients, such that, without safe harbor protection, they may still violate the AKS.[4]

OIG also recognized that the Final Rule has the potential to affect calculations of AMP, Best Price, and the Federal Upper Limits in ways that may be difficult to anticipate.[5] However, OIG did not opine on how chargebacks and other new, non-rebate arrangements would impact drug price reporting metrics, other than to note that the Final Rule does not alter obligations under the Medicaid Drug Rebate Program, including calculations of AMP.[6] Thus, without further guidance, it appears that point-of-sale chargebacks that meet the new safe harbor described below would be included in AMP if made available to AMP-eligible purchasers.

As noted above, the Final Rule's amendments (really, new explicit carve-outs) to the discount safe harbor will not take effect until January 1, 2022. However, for all intents and purposes, new arrangements will need to be finalized by April or May of 2021 so that Part D plan sponsors can submit their bids in early June for the 2022 Plan year.

ii) OIG Responses to Objections to the Proposed Rule

Many commenters suggested changes or requested further guidance related to the Part D program and regulations. For example, OIG received comments related to formulary structure and design, actuarial equivalence determinations, and prescription drug event reporting. OIG brushed off many of those comments as beyond the scope of the AKS safe harbor regulation. However, a Proposed Rule regarding the Part D program is currently pending at OMB (RIN 0938-AT97, CMS-4190) which may further address some of the comments.

Many commenters argued that the Final Rule is not a permissible exercise of the Secretary's authority because it violates the Part D non-interference clause, Social Security Act § 1860D-11(i), 42 U.S.C. § 1395w-111(i), which prohibits the government from interfering in price negotiations between plan sponsors, manufacturers and pharmacies. OIG rejected these comments, stating: "This rule does not interfere in any negotiations between Part D sponsors, manufacturers, and pharmacies… because they do not have any bearing on the ultimate prices negotiated among the parties."[7] This issue is likely to be litigated over the coming months and should be closely watched by interested parties.

OIG also received comments arguing that the Final Rule will not reduce list prices (which do not vary by payor) because rebate arrangements will continue to exist in the commercial market. OIG acknowledged that commercial, private pay, or self-pay arrangements that do not touch Federal health care program beneficiaries in any manner do not implicate the AKS (except in the context of swapping, pull-through, or similar arrangements). OIG recognized that the commercial market is larger than the Part D market, which may make it irrational for manufacturers to lower list prices. Nonetheless, OIG persists in its view that the Final Rule will result in lower list prices either through voluntary

adoption of point-of-sale rebates in the commercial market or through general market pressures to compete for Part D program business.

B. New Safe Harbor for Rebates That Are Passed Through at the Point of Sale

i. The Final Rule

The Final Rule's proposed new point-of-sale rebate safe harbor closely resembles the safe harbor in the Proposed Rule and will become available for use sixty days after publication of the Final Rule.[8] The safe harbor will create new AKS protections for certain price reductions that are passed through to the patient (i.e., the "buyer" in whose name a claim for payment would be submitted) at the pharmacy counter.

The revised safe harbor would now expressly exclude from the definition of "remuneration" a reduction in price from a manufacturer to a plan sponsor under Medicare Part D or a Medicaid MCO if the following conditions are met:

- The price reduction is set in advance with the plan sponsor under Medicare Part D, a Medicaid MCO, or a PBM – meaning that the price reduction is effective at the time of the initial purchase (*i.e.,* the first purchase of the product at the reduced price by the plan sponsor or Medicaid MCO on behalf of an enrollee).
- The reduction in price does not involve a rebate unless the full value of the reduction in price is provided to the dispensing pharmacy by the manufacturer, directly or indirectly, through a point-of-sale chargeback or series of point-of-sale chargebacks, or is required by law; and
- The reduction in price must be completely reflected in the price the pharmacy charges to the enrollee at the point of sale.

Thus, although at least aspects of such arrangements were arguably already protected under the discount safe harbor, under the Final Rule, arrangements wherein enrollees would be able to share in discounts that plans and PBMs negotiate with manufacturers would be more clearly protected. The enrollee's share of the discount would be proportional to their cost sharing obligation. For example, an enrollee in the deductible phase of his or her coverage would receive the entire negotiated discount amount while an enrollee with a 25 percent co-insurance obligation would receive 25 percent of the discount.[9]

ii. Issues Related to Transparently Reflecting Rebates at Point of Sale Requirement

Some commenters expressed concern that requiring the amount of a rebate or discount to be known at the time of sale could present a barrier to certain legitimate discount arrangements, including bundled sale and value-based discounts. OIG acknowledged that a final price would be difficult to present at the point of sale if some types of bundled pricing arrangements were used.[10] However, OIG stated that to the extent the discount can be reflected at the point of sale, the arrangement may qualify for safe harbor protection, and that failure to meet the requirements of the safe harbor does not result in a *per se* violation of the AKS.[11] With respect to value-based arrangements, OIG also acknowledged that it may be difficult to make the value of such discounts known at the time of sale but suggested that other safe harbors may be available (*e.g.*, the personal services and management contracts safe harbor, warranties safe harbor).[12]

iii. Issues Related to Chargeback Administration

Implementation of the Final Rule will be difficult, given the interplay between contract prices, PBM rebates, patient co-pay obligations and passed-through rebates. A new "Chargeback Administrator" entity will need to be created to manage pharmacy reimbursement to accommodate for rebate pass throughs resulting in reduced enrollee payments at the point of sale. More specifically, since pharmacies normally purchase from wholesalers at prices that do not

reflect rebates, but only can collect from enrollees payment that do reflect rebates, the Chargeback Administrator will need to sit between the pharmacies, the Plans and the manufacturers to "true up" the payments and ensure the pharmacies are made whole. The Proposed Rule addressed at length how this Administrator could operate, and who might serve as the Administrator. In contrast, the Final Rule barely addresses implementation of the chargeback regime, other than to respond to stakeholder comments on the Proposed Rule. One or more Chargeback Administrators will need to be formed within the coming year to assist in facilitating implementation of the new rebate landscape, and there may be competition between PBMs, wholesalers, and other entities seeking to serve as the Administrator. Despite prodding, OIG did not provide detailed technical requirements and declined to opine on what type of entity (wholesaler, PBM, not for profit, or other) should be the Chargeback Administrator.[13] However, OIG did make clear that point-of-sale chargeback administration fees would not be protected under the new safe harbor (but may be protected under other safe harbors).[14]

Some commenters expressed concern that the Chargeback Administrator may under-reimburse pharmacies for the appropriate chargeback amount. OIG clarified that it expects the Chargeback Administrator to reimburse pharmacies the full amount of the reduction of price at the point of sale: "the chargeback amount due to the pharmacy must be equal to the reduction in price negotiated by a plan (or PBM operating on its behalf) and the manufacturer of the prescription pharmaceutical product."[15] OIG also clarified that it expects manufacturers to maintain adequate documentation to prove that the full amount of any chargeback was actually administered to the pharmacy.[16]

iv. Other Issues

OIG clarified that point-of-sale rebates used to secure formulary placement are not *per se* AKS violations, and that they can be performed within the scope of the new safe harbors. In doing so, OIG highlighted some areas of compliance risk. For example, OIG clarified that a point-of-sale rebate may not be used to secure formulary placement if it is bundled with required services (*e.g.*, chargeback administration services).[17] Likewise, OIG stated that lump sum payments for formulary placement would be subject to scrutiny.[18] Notably, however, OIG did not address in the Final Rule the protections of the group purchasing organization safe harbor,[19] which the agency has previously stated could be used to protect manufacturer rebates paid to PBMs.[20]

OIG also clarified that passed-through rebates cannot be applied solely to eliminate enrollee cost-sharing. An enrollee may only receive 100% of the discount amount if he or she is in the deductible phase of his or her coverage.[21] Thus, the arrangement is not permitted to operate in a manner resembling a manufacturer coupon or co-payment assistance card. Instead, the pass-through rebates must be consistently applied to all enrollees and must be solely for the purposes of reducing drug costs, as opposed to removing enrollee cost-sharing obligations. In other words, OIG wants to ensure that Medicare Part D enrollees continue to have some "skin in the game" and are not eligible in all cases with a drug to have access without any co-payment or deductible obligations.

C. New Safe Harbor for PBM Services to Manufacturers

The Final Rule also creates a new AKS safe harbor to protect *fixed fee* payments from manufacturers to PBMs for services rendered to the manufacturers (or for the manufacturer's benefit) when certain conditions are met:

- There must be a **written agreement** between the manufacturer and the PBM that:
  - Covers all of the services the PBM provides *to the manufacturer* in connection with the PBM's arrangements with health plans for the term of the agreement, and
  - Specifies each of the services to be provided by the PBM and the compensation for such services.
- The **compensation** paid to the PBM must:

  - Be consistent with **fair market value** in an arm's-length transaction;
  - Be a fixed payment, not based on a percentage of sales; and
  - **Not be determined in a manner that takes into account the volume or value of any referrals or business** otherwise generated between the parties, or between the manufacturer and the PBM's health plans, for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.[22]

- The PBM must disclose in writing to each health plan with which it contracts at least annually, and to the Secretary of HHS upon request, the services it rendered to each pharmaceutical manufacturer that are related to the PBM's arrangements with that health plan and the associated costs for such services.

OIG specifically chose not to create a definition for "pharmacy benefit management services" but provided some examples, including "contracting with a network of pharmacies; establishing payment levels for network pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; performing drug utilization review; and operating disease management programs."[23]

Manufacturers should note that the test for this PBM services safe harbor is different from the seven-prong bona fide service fee test employed for government price reporting. The new tests utilize different criteria. Qualification for the safe harbor does not mean that a PBM service fee is a bona fide service fee, or vice versa. Thus, without CMS guidance to the contrary, services that qualify for the new safe harbor, but fail the bona fide service fee test, would be reportable as price concessions.

The protection of the new service fees safe harbor is expressly limited to payment for services the PBM provides to the manufacturer and does not extend to services the PBM provides to health plans. OIG noted, however, that the safe harbor would not preempt contractual terms between a PBM and a health plan that limit or delineate the PBM's use of the health plan's data.

As with other requirements in the Final Rule, OIG did not provide a specified format for the disclosure of services to health plans. OIG, however, did clarify that PBMs would be required to disclose both the services and the associated fees to the Secretary upon request, and recommended that parties to a service agreement maintain documentation that could demonstrate how each element of the safe harbor (*e.g.*, fair market value, fixed fees) is met.[24] The new safe harbor for PBM services fees becomes effective 60 days after the Final Rule is published in the Federal Register.[25]

COMPLIANCE WITH JULY 24, 2020 EXECUTIVE ORDER

President Trump's July 24, 2020 Executive Order called for the Final Rule but only if the Secretary could certify that the Final Rule would not increase Federal spending, Medicare enrollee premiums, or patients' total out-of-pocket costs.[26] Secretary Alex Azar has made that certification, despite substantial evidence to the contrary.[27] For example, the 2019 Proposed Rule contained numerous fiscal analyses by the HHS Office of the Actuary (OACT) and Milliman, a private consultant retained by HHS, indicating that under virtually any scenario the Rule would cause premiums to increase. Likewise, following publication of the Proposed Rule, OMB estimated that finalizing the Rule would cause significant premium and federal government cost increases.[28]

Secretary Azar's certification contradicted these findings and asserted that because plan sponsors know that Part D enrollees are sensitive to premium price changes, increases to plan premiums are unlikely. Instead, he argues, it is more likely that PBM margins will decline and/or PBMs will negotiate harder and secure greater manufacturer list price concessions.[29] He also suggests that because PDPs must offer premiums below a certain benchmark in order

to be eligible for dual eligible beneficiary auto-enrollment, plan sponsors will compete to keep premiums low. The certification cites no analysis or data other than the Secretary's own experience, despite the fact that his analysis contradicts those described above. Still, it is unclear whether there is a basis for a legal challenge to the certification, given that the Executive Order requirement explicitly does not give rise to any legal obligation or remedy.

VULNERABILITY TO LEGAL CHALLENGE

The Proposed Rule was originally issued on February 6, 2019 and was the subject of heated debate within the Executive Branch, with HHS Secretary Azar strongly supporting the rule, but others in the White House strongly opposing. At one point in the debate, the White House staff prevailed, and on July 10, 2019 the OMB website indicated that the Rule had been "withdrawn." Curiously, the withdrawal, while publicly reported, was never formally published in the Federal Register. Over a year later, in a surprising turn of events, on November 13, 2020, a "Final Rule" was received by OMB from OIG for review. OMB turned the Rule around in record time, and five days later released the Final Rule. Neither OMB nor OIG, however, explained how the Final Rule could be proper given that the Proposed Rule was withdrawn and no new Proposed Rule was released. One notable former OMB official has argued that the Rule must go back through the Proposed Rule stage because the withdrawal was not published in the Federal Register.[30] This unusual procedural issue will likely be litigated in the coming months as plan sponsors bring their legal challenges to the Rule. Even without litigation, there is a subsidiary question about whether the incoming Administration could put a freeze on the Final Rule, since it is expected to be published in the Federal Register on November 30, 2020, less than 60 days before the transition between Administrations.

CONCLUDING THOUGHTS

The Final Rule will almost certainly be challenged in court in the coming weeks. Should the Rule survive judicial review, it seems likely to shift alignment in the manner in which manufacturers and plan sponsors do business. Over the next year – indeed over the next five months, manufacturers and PBMs will need to negotiate new discounts, rebates, and services fees designed to fit within the new point-of-sale rebate safe harbor and new PBM service fees safe harbor. Although PBMs and plan sponsors have anticipated the Rule and have incorporated "hold harmless" provisions into many of their rebate agreements, many rebate arrangements may need to be fundamentally revisited. In the process, stakeholders will need to create a new point-of-sale chargeback mechanism and create solutions to ensure rebates are fully available to enrollees at the point of sale. Manufacturers and PBMs may also enter into service agreements designed to fit into the new PBM service fee safe harbor or explore other protections, such as the group purchasing organization safe harbor. Time will tell whether these changes will stand, and if they do, whether they would result in the near elimination of today's rebate arrangements and actually lower prices.

Plan sponsors may react to the Rule by narrowing their offerings to limit the number of drugs available (so-called "skinny" formularies) or increase enrollee copayments to "make up" for lost rebate dollars. Medicare beneficiaries historically have been insensitive to these types of formulary changes, even though they are highly sensitive to premiums when choosing a Plan. Whether changing formularies will motivate beneficiaries to become better consumers of PDPs remains an open question.

The next six months will be intense for plan sponsors/PBMs and manufacturers, as they will need to renegotiate all rebate and drug pricing contracts to accommodate the January 1, 2022 date when discount safe harbor protection that purportedly exists now is lost. And it is likely that a legal challenge will be pending for much of this time, adding additional uncertainty. Once the bids are in, we will learn whether Secretary Azar's finding that the Final Rule would not increase Federal spending, Medicare enrollee premiums, or patients' total out-of-pocket costs was accurate or not.

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[1] Department of Health and Human Services, Office of Inspector General (OIG), HHS, Fraud And Abuse; 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, RIN 0936-AA08, at 7 available at https://public-inspection.federalregister.gov/2020-25841.pdf ("Final Rule").
[2] Final Rule at 46.
[3] Final Rule at 112.
[4] Final Rule at 64.
[5] Final Rule at 58.
[6] Final Rule at 114.
[7] Final Rule at 29.
[8] The Final Rule is scheduled for publication on November 30, 2020, making the new point-of-sale rebate safe harbor available on January 29, 2021.
[9] Final Rule at 223.
[10] Final Rule at 205-6.
[11] Id.
[12] Final Rule at 167.
[13] Final Rule at 80.
[14] Final Rule at 106.
[15] Final Rule at 156.
[16] Final Rule at 179.
[17] Final Rule at 95.
[18] Final Rule at 80.
[19] 42 C.F.R. § 1001.952(j).
[20] See, Office of Inspector General, Compliance Program Guidance for Pharmaceutical Manufacturers (April 2003).
[21] Final Rule at 88.
[22] A per unit work fee, however, may be permissible. *See* Rule at 245.
[23] Final Rule at 120.
[24] Final Rule at 239; Note that the disclosure requirement applies only to PBMs but it would still be a best practice for manufacturers to document the basis for safe harbor compliance as well.
[25] The Final Rule is scheduled for publication on November 30, 2020 so the new PBM services safe harbor will become available for use on January 29, 2021.
[26] E.O. 13939: Lowering Prices for Patients by Eliminating Kickbacks to Middlemen, 85 Fed. Reg. 45759 (July 24, 2020) *available at* https://www.federalregister.gov/documents/2020/07/29/2020-16625/lowering-prices-for-patients-by-eliminating-kickbacks-to-middlemen
[27] U.S. Dept. of Health and Human Svcs., Secretary Azar Confirmation In Response to Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen available at https://www.hhs.gov/about/news/2020/11/20/secretary-azar-confirmation-in-response-to-executive-order-on-lowering-prices-for-patients.html
[28] Final Rule at 315.

[29] U.S. Dept. of Health and Human Svcs., Secretary Azar Confirmation In Response to Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen available at https://www.hhs.gov/about/news/2020/11/20/secretary-azar-confirmation-in-response-to-executive-order-on-lowering-prices-for-patients.html

[30] See Bridget C.E. Dooling, Going Through Regulatory Withdrawal, Yale Journal on Regulation (October 13, 2020) available at https://www.yalejreg.com/nc/going-through-regulatory-withdrawal/