Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals
(RIN 0936-AA08)
Summary of Final Rule

On November 30th, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) published in the Federal Register a final rule: 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 Services Fees. (85 *FR* 76666.)

The rule amends the safe harbor that protects certain price discounts provided to individuals and entities, including health care providers, who solicit or receive price reductions, and the individuals and entities who offer to pay them from federal anti-kickback requirements. [1] The final rule eliminates from that safe harbor, rebates provided from a manufacturer to a Part D plan sponsor (including a Medicare Advantage plan offering drug coverage). The rule also establishes two new safe harbors. One protects discounts provided by manufacturers to Part D plan sponsors and Medicaid managed care plans if they are given at point-of-sale. The second protects flat fee service payments that manufacturers make to PBMs for specific activities.

The provisions of this rule become effective on January 29, 2021 except for the changes to the existing discounts safe harbor which will become effective on January 1, 2022.

Table of Contents	Page
I. Purpose and Need for Regulatory Action	1
II. Background	3
III. Provisions of the Final Rule	4
A. Amendment to the Discount Safe Harbor	4
B. New Safe Harbor for Price Reductions at Point-of-Sale	10
C. New Safe Harbor for Certain PBM Service Fees	12
IV. Regulatory Impact Statement	14

I. Purpose and Need for Regulatory Action

HHS describes the purpose of this rule as updating safe harbors to the anti-kickback statute to better reflect changing business practices and to ensure that such safe harbors only protect arrangements that present a low risk of harm to the federal government and to beneficiaries of federal health programs.

HHS also describes the background and need for the changes. Since the passage of the anti-kickback statute, list prices of brand prescription drugs and rebate payments by manufacturers to

[1] Section 1128B(b) of the Social Security Act (42 U.S.C. 1320a-7b(b)).

pharmaceutical benefits managers (PBMs) have both grown substantially. But because of the increasing prominence and size of rebates, net prices have grown more slowly. This difference is called the "gross to net bubble."

These arrangements have resulted in incentives that HHS asserts are a barrier to lowering drug costs. For example, sometimes PBM compensation is based on the difference between the net and list prices making those PBMs insensitive to higher list prices and more concerned with larger rebates. These practices have had the effect of encouraging higher list prices because larger gaps can generate additional compensation. Other times PBMs are held harmless by rising list prices via "price protection" payments from manufacturers.

Impact on beneficiaries. HHS states that these incentives are often harmful to beneficiaries because most rebates do not flow through to the point of sale when a beneficiary obtains their prescription from a pharmacy. Instead, the beneficiary's required payments and copayments are based on the list price. That means they pay higher amounts out-of-pocket when in the deductible phase of their benefit and their co-payments or co-insurance payments are higher than they might be if they were based on net prices.

With respect to the premiums that beneficiaries pay, they are somewhat lower because of the rebates. That is because Part D plan sponsors are required to include estimates of rebates in their premium bids. Evidence is presented, however, that Part D plan sponsors often underestimate those amounts in their bids so Part D premiums often do not reflect the full amount of those discounts.

HHS identifies a number of OIG reports and other research that substantiates these concerns and provides an illustrative example of the higher costs faced by beneficiaries.

HHS further describes the impact on formularies and the paradoxical impact of competition on price because of the rebate arrangements. Instead of formularies being developed based on the list prices of drugs combined with their effectiveness and quality, decisions about formulary placement are often being made on the rebate potential of the drug. In addition, as new drugs are entering the market, instead of lowering the list prices of competitor's products, list prices are increasing to enable larger rebates.

Impact on Federal Health Programs. HHS also presents evidence that the rising rebates have not translated into lower costs, nor lower rates of growth of costs for the Medicare Part D and Medicaid programs. While, HHS acknowledges that the introduction of many new higher-priced products have contributed to higher overall program costs, the growing gross to net bubble is impacting the prices of existing drugs and biologicals as well as new products.

Certain features of the Medicaid drug rebate program protect this increasingly larger gross to net bubble: 1) Rebates, discounts, and other financial transactions paid by manufacturers to PBMs are excluded from the drug prices on which Medicaid rebates are calculated (the Average Manufacturers Price (AMP)); and 2) Maximum rebates under Medicaid are capped at 100% of the AMP.

Lack of Transparency. The terms of rebate agreements between manufacturers and PBMs is considered to be proprietary information and plan sponsors often have limited information about rebate contracts and the amounts negotiated by their PBMs. HHS asserts that this lack of transparency impedes program integrity and the ability of parties to accurately account for rebates where required under program rules.

HHS further presents its changed view that the existing discounts safe harbor should not apply to most rebates paid by manufacturers to Part D plans as those amounts are mostly paid to PBMs.

II. Background

HHS describes the anti-kickback statute including the penalties and fines applicable to whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward the referral of business reimbursable under any of the federal health care programs. As the legislation was intentionally broad, Congress later directed HHS to promulgate regulations providing a safe-harbor for those innocuous commercial arrangements and business practices not subject to sanctions under the anti-kickback statute.[2] Later legislation provided criteria for those safe-harbors[3] and a series of regulations have established a number of them in various areas.

The "discount safe harbor," was created to encourage price competition in the Medicare and Medicaid programs. It was finalized in 56 Federal Register (FR) 35952 and protects discounts that apply to individuals and entities, including providers, who solicit or receive price reductions, and to individuals and entities who offer to pay them. The safe harbor for discounts was expanded in 1999 (64 FR 63518) to include rebates defined as "any discount the terms of which are fixed at the time of sale of the good or service disclosed to the buyer, but which is not received at the time of the sale of the good or service."

In the final rule, HHS eliminates the safe harbor protection for rebates from manufacturers to a Medicare part D plan sponsor (including a Medicare Advantage plan offering prescription drug coverage) including those provided indirectly through PBMs, unless the rebates are required by law. It adds a new safe harbor to protect discounts between those entities if they are given at point-of-sale and meet certain other criteria. It adds a second new safe harbor to protect certain fees that pharmaceutical manufacturers pay to PBMs for services rendered to the manufacturers that relate to PBMs' arrangements to provide pharmacy benefit management services to health plans.

HHS asserts that point-of-sale discounts will be more transparent to both Part D plan sponsors and to beneficiaries than were rebates.

[2] Section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987 (P.L. 100-93).
[3] Section 205 of the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191).

III. Provisions of the Final Rule

A. Amendment to the Discount Safe Harbor

The final rule amends the discount safe harbor at 42 CFR 1001.952(h) by adding new (h)(5)(viii). Under prior rules, a discount, including those in the form of a rebate, were safe from prosecution under anti-kickback rules. The new paragraph eliminates from the discount safe harbor, rebates from a drug manufacturer to a Part D plan sponsor unless the rebate is required by law. HHS had proposed to eliminate rebates from the discounts safe harbor provided to both Medicare Part D plans and Medicaid MCOs but the final rule drops Medicaid MCOs from the provision as explained more below. The final rule also delays the implementation date of this provision until January 1, 2022 in response to the many commenters who argued that their contracts and systems would not be able to be quickly modified in order to comply immediately.

HHS sought comment on whether the amendment to the discount safe harbor should be limited to applying to rebates for prescription drug products payable by Medicare Part D and Medicaid MCOs (which was not finalized), or whether it should also apply to prescription drugs payable under other HHS programs (e.g., Medicare Part B fee-for-service or a Medicaid managed care program operating under waiver authority). As noted above, the final rule limits the amendment to apply only to Medicare Part D and makes no changes to requirements applicable to other federal programs including, Medicaid, the Veterans Health Administration and Medicare Part B.

Under the rule, a Part D "plan sponsor" includes both prescription drug plan sponsors under Medicare Part D as well as Medicare Advantage (MA) organizations offering a MA prescription drug plan.

HHS notes that nothing in the final rule changes the existing exclusion from the safe harbor of price reductions offered to a payer but not to Medicare or Medicaid, particularly when such discounts serve as inducements for the purchase of federally reimbursable products. HHS has a long-standing concern about such arrangements under which parties "carve out" referrals of federal health care program beneficiaries or business generated by federal health care programs from such questionable financial arrangements – describing such practices as disguising remuneration for federal health care program business through the payment of amounts purportedly related to non-federal health care program business.

HHS restates its intent that the discount safe harbor continues to protect discounts offered to other entities including wholesalers, hospitals, physicians, pharmacies, and third-party payers in other federal health care programs. In response to commenters' concerns that the regulatory text could be interpreted to also apply to discounts that manufacturers provide to wholesalers or pharmacies for prescriptions provided to Part D beneficiaries, HHS clarifies the language of new paragraph (viii). The final regulatory text makes clear that those reductions in price that are excluded from the safe harbor are those from a manufacturer to a Part D plan sponsor provided directly to the plan sponsor, or indirectly through a pharmacy benefit manager acting on its behalf.

(1) Definitions

HHS proposed several new definitions in 1001.952(h) most of which are finalized without change. Changes in the final rule are noted below.

- "Manufacturer" is defined as under Medicaid (in section 1927(k)(5));
- "Wholesaler" and "distributor," which are used interchangeably, are defined as "wholesaler" is defined under Medicaid (in section 1927(k)(11));
- "Pharmacy benefit manager" is defined as an entity that provides pharmacy benefits management on behalf of health benefits plans that manage prescription drug coverage. A commenter recommended that HHS distinguish in this definition between a PBM and a Group Purchasing Organization (GPO). HHS declines to do so and notes that it does not prohibit PBMs from potentially qualifying for the GPO safe harbor protection[4] if the GPO meets the qualifications for such safe harbor.
- "Prescription pharmaceutical product" is defined as either a drug or biological as those terms are *described* (instead of *defined* in the proposed rule) under Medicaid (in section 1927(k)(2)(A), (B) and (C)).
- "Medicaid Managed Care Organization" has the same meaning as under Medicaid (section 1903(m)). In the final rule, this definition is moved to a different section (section 1001.952(cc)).

HHS notes that it did not provide a definition of "pharmacy benefit management services" in the regulatory text but listed in the proposed rule's preamble a non-exhaustive list of examples of such services. Commenters recommended, and HHS agreed, to add items to its list as examples of pharmacy benefit management services. In the preamble to the final rule, that list includes: contracting with a network of pharmacies; establishing payment levels for network pharmacies; negotiating rebates and discount arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; performing drug utilization review; operating disease management programs; processing and payment of claims for prescription drugs; adjudication of appeals or grievances related to the prescription drug benefit; and controlling the costs of covered prescription drugs. HHS also clarifies that PBM services under the safe harbor refers to services furnished to health plans and not manufacturers.

Commenters requested CMS issue guidance to distinguish between PBM service fees and "Bona fide service fees" (under Part D with respect to direct and indirect remuneration (DIR) reporting. HHS responds that this request is out of scope of the rule.

HHS notes that it considers discounts such as those under consideration by this rule to be different from across-the-board price reductions that are not meant to incentivize the behavior of a particular buyer, for example, a reduction in the wholesale acquisition cost (WAC). Those types of across-the-board price changes would not be in need of protection from this safe harbor.

[4] The GPO safe harbor at 42 CFR §1001.952(j) protects payments by a vendor for the services of a group purchasing organization from being treated as a criminal offense under anti-kickback requirements so long as certain standards are met.

(2) Response to Comment

HHS received comments from approximately 26,000 commenters including from pharmaceutical manufactures, individuals, pharmacies, PBMs, wholesalers, sponsors of Part D and Medicaid plans, and trade associations. Many commenters agreed with the objective for reducing out-of-pocket pharmaceutical costs but provided mixed feedback on the approach proposed by HHS. Others provided recommendations, or requested clarification or further guidance.

The following sections summarize comments that apply broadly to HHS' finalized amendments.

Antitrust. Some commenters that opposed the proposal suggested that the risk of liability under the Robinson-Patman Act will hinder manufacturers' ability to negotiate up-front discounts. They state that the current rebate system resulted from a settlement in the in *re Brand Name Prescription Drugs* litigation, in which pharmacies sued brand-name prescription drug manufacturers and wholesalers for discriminatory pricing practices that favored large, institutional purchasers. They are concerned that unless the Robinson-Patman Act were to be amended, manufacturers will react by reducing their discounts to pharmacies. The Department states its belief that neither the settlement nor subsequent court rulings distinguished between retrospective rebates and upfront discounts. In response to commenters requesting that the Federal Trade Commission (FTC) or the Department of Justice analyze the rule to provide a Competition Advisory Opinion, HHS states that they may request such an opinion from the FTC.

Transparency. Commenters provided mixed opinions about whether the final rules would improve transparency. Some pointed out that Medicare plans already must report rebates and discounts via Medicare Direct and Indirect Remuneration (DIR) reporting. Some suggested that if HHS seeks to create transparency, it should establish requirements that apply to all parties including pharmaceutical manufacturers, PBMs, and health plans. HHS states that it believes the rule will enhance transparency and will create incentives for manufacturers to lower drug prices.

Commenters provided various recommendations for additional measures to improve transparency which HHS does not adopt including standardized contract terms for PBM services and compensation; requiring additional regular disclosures by PBMs to health plans; disclosure by PBMs to public programs and private plans of discount amounts and other revenue paid to the PBM or related third parties based on the plan sponsor's drug utilization; and an auditable structure that allows plan sponsors to have a complete picture and conduct more fulsome analyses of their drug-related costs and contractual relationships. Recommendations to ban spread pricing – a practice where PBMs negotiate for greater differences between what they charge plans and what they reimburse pharmacies -- are beyond the scope of the rule.

Relationship to Part D. Some commenters stated that the proposed rules violate the Medicare Part D noninterference provision (section 1860D-11(i)). HHS replies that the rules do not interfere with negotiations between plan sponsors, manufacturers, and pharmacies. Many comments related to Part D were outside the scope of the proposed rules – including those recommending reforms to Part D, including implementing rebate pass-through requirements, changes to the definition of average manufacturer price (AMP), clarifying how point-of-sale

concessions apply to AMP, among many others. To commenters requesting additional guidance on how to avoid duplicate 340b discounts, while outside the scope of these rules, the Department reiterates that a violation of the anti-kickback statute must be knowing and willful. Good faith efforts to avoid duplication of discounts will likely not constitute violations.

Commenters raised questions and requested additional guidance related to the interaction of the final rules with number of existing Part D processes and requirements – including application of beneficiary protections, notification of plan changes on account of this rule, changes to formularies, medical loss ratio calculations, bidding processes, the definition of "negotiated price", and other related implementation concerns. While HHS points out that Part D guidance on implementation is outside the scope of OIG's authority, it has coordinated with CMS in the promulgation of the rules and that CMS will work with plan sponsors to minimize disruption.

With respect to concerns that interactions with the Part D bid process will be disrupted by changes on account of the rules, the Department states that by delaying the implementation date of the changes to the existing safe-harbor until January 1, 2022, there should be time to address questions related to Part D bid submissions.

Medicaid. Commenters expressed opposition to including Medicaid MCOs within the scope of the changes to the existing safe harbor. Because most Medicaid beneficiaries pay at most nominal out-of-pocket amounts, the rule changes would not achieve the Department's goal of lowering beneficiaries' out-of-pocket spending, would upset states' supplemental rebates, and would increase administrative burden on states. Upon consideration, HHS agrees that eliminating discount safe harbor protection for reductions in price offered to a Medicaid MCO would have minimal, if any, effect on the amount a Medicaid beneficiary pays when he or she purchases prescription pharmaceutical products at the pharmacy, and therefore does not finalize its proposal to revise the discount safe harbor to exclude rebates offered to Medicaid MCOs. Under this final rule, Medicaid MCOs seeking safe harbor protection for discounts have the option to use either the discount safe harbor or the new finalized safe harbor for point-of-sale reductions in price at paragraph 1001.952(cc) (described below).

Commercial Market. Some commenters recommended for or against extending the rules to the commercial market for insurance. HHS points out that the scope of the anti-kickback statute is limited to payments offered, paid, solicited or received in order to induce or reward Federal health care programs or business. Others raised concerns that the rule will cause drug costs to be shifted to the commercial market. HHS believes, however, that manufacturers will instead lower list prices across both the Part D and commercial markets.

The Departments agree with some commenters' concerns about arrangements where rebates in the commercial market are offered to influence the purchase of products by Federal health care programs. It states that "such 'swapping' arrangements, which essentially shift costs to the Federal health care programs, continue to be of concern. Those arrangements would need to be reviewed for compliance with the anti-kickback statute, but whether a specific arrangement constitutes a problematic swapping arrangement depends on the facts and circumstances. It declines to adopt specific standards or reviews to address the circumstances.

Enforcement Issues. HHS restates that compliance with a safe harbor is voluntary, and arrangements that do not comply with a safe harbor will analyzed based on their facts and circumstances. Failure to meet the conditions of a safe harbor does not automatically subject a stakeholder to criminal penalties. The anti-kickback statute is an intent-based statute; errors or mistakes would not trigger concerns absent other facts evidencing unlawful intent to induce referrals. It further confirms its position that any portion of a payment (whether it is called a "rebate" or something else) that a manufacturer pays to a PBM that is retained by the PBM and not passed through to the buyer never was protected under the discount safe harbor. The discount safe harbor protects a reduction in price *to a buyer*. HHS explains that a PBM is not a buyer, and the portion of a payment from a manufacturer to a payor that is retained by a PBM is not considered a reduction in price.

In response to requests that HHS delay enforcement for some period after the rules become effective while PBMs and issuers alter arrangements and contracts to come into compliance, it states that the delayed effective date of January 1, 2022 should provide sufficient time for a period of adjustment.

State Law Issues. Some commenters raised concerns about state laws that may impact the implementation of the rules. HHS acknowledges that conduct that is lawful under the federal ant-kickback statute or safe harbors may be illegal under state laws.

Other Legal Issues. In response to concerns about whether HHS has satisfied requirements under the Administrative Procedures Act (APA) or that its proposal is arbitrary and capricious, it restates the statutory authorities, and reviews its processes that it asserts are consistent with the APA. Other commenters pointed out that the objective of reducing government costs is not met based on the Department's own regulatory impact analysis that estimates that costs for beneficiaries and premiums could rise. Other commenters pointed out apparently contradictory policies with respect to rebates, citing the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) which recognized that rebates were important to Part D coverage. Also noted is the apparently contradictory definition of "negotiated price" under Part D that permits plan sponsors to determine how much of any price concession is to be passed on to enrollees. The Department simply notes that the new safe harbor regulations impose no new requirements nor mandate any particular behavior and therefore do not conflict with other laws and that simply because prior law has recognized those arrangements, it does not necessarily mean that all rebates were always "legitimate" and did not pose a risk of program abuse. In addition, there is nothing in the Part D statute that limits the Secretary's authority to establish or revise safe harbors for practices that the Secretary determines are abusive to federal programs or beneficiaries.

OIG clarifies that the application of the rules will be prospective.

In response to concerns that that the rule eliminates the value of trade secrets, HHS responds that because the rules don't require any party to take any particular action, there is no property right

being extinguished. Further, there is nothing in this rule that will require federal officers or employees to disclose any information received in the course of their official duties.

Formulary Placement. Requests were made to clarify that reductions in price given to Part D plan sponsors or Medicaid MCOs that are conditioned on formulary placement of a particular drug can qualify for protection under the new safe harbor for point-of-sale reductions in price (and could have been protected for Part D plan sponsors under the discount safe harbor, and can continue to be protected under the discount safe harbor for Medicaid MCOs if all safe harbor conditions are met). HHS states that provided there are no required services (e.g., marketing or switching), and all conditions of the safe harbor are met, the protection still applies. Whether other arrangements would be protected (including a scenario offered by a commenter where a reduction in price is offered in exchange for a formulary not covering a competing drug) would be subject to a case-by-case analysis.

Concerns were raised about the possibility that the rule could result in narrowed provider networks, formulary changes particularly for new or high cost drugs, reduced use of copayments (versus coinsurance), and reduced availability of drugs for rare diseases. Some commenters requested guardrails to prevent such formulary changes and increased monitoring of those changes. While Part D oversight is out of the OIG's scope, HHS notes that OIG has worked closely with CMS in promulgating the rules and that CMS routinely reviews formulary changes.

Impact on List Price. Many commenters raised concerns that the expectation that the rule would result in lower list prices was not supported by historical, economic or competitive market analysis; that rebates help to keep list prices low; and that the most expensive drugs, especially those without competition, tend not to offer rebates. They suggest that the Department should not finalize the proposed changes and instead focus its initiatives on increasing market competition. The Department restates its belief that rebates are driving higher list prices and notes that the new rules will increase transparency and contribute to a more competitive market. It also notes that this rule is one of a number of Department initiatives to address the reasons for high drug prices – other efforts more directly address market competition.

Some commenters suggested that without the rule's application to the commercial market, it will not impact a sufficient portion of drug spending to result in reduced costs. HHS disagrees. It responds that it expects some commercial plans to change their operating structures and transition to using point-of-sale discounts instead of rebates and believes the Medicare market is large enough to potentially influence the commercial market.

Commenters raised the concern that the rule will result in increased premiums and other uncertainties that could result in plans dropping out of the Part D program or that the increased transparency will result in reduced beneficiary access. For example, they might narrow prescription benefits for vulnerable populations or discourage high-cost patients from enrolling. The Department reply that plans have other methods for preventing premium increases and that CMS has in place a robust formulary review and approval process that prevents discriminatory plan design and a risk adjustment process which prevents plans from cherry-picking enrollees.

Monitoring. In response to requests for HHS to monitor the effect of the rule on beneficiaries, PBMs, manufacturers, plans, plan sponsors, pharmacies and other stakeholders, the Department states that it intends to do so.

B. New Safe Harbor for Certain Price Reductions at Point-of-Sale

HHS finalizes as proposed, a new safe harbor, effective 60 days after publication of the final rule, to protect point-of-sale price reductions offered by manufacturers to plan sponsors of Medicare Part D plans and Medicaid MCOs. HHS states that it intends for this safe harbor to apply to Medicare Part D drugs throughout all phases of the benefit.

The conditions for this safe harbor to apply are as follows:

(1) The price reduction must be set in advance, fixed, and disclosed in writing to the plan sponsor by the time of initial purchase. By "initial purchase," HHS means the first purchase of the product at the reduced price by the Part D plan or Medicaid MCO. In the final rule, HHS makes a technical change to this provision to replace the phrase "reduced price" with "reduction in price."

As under existing rules, this safe harbor does not protect price reductions offered to a payer but not to Medicare or Medicaid, particularly when such discounts serve as inducements for the purchase of federally reimbursable products.

(2) The price reduction cannot be a rebate unless its full value is provided at the point of sale to the dispensing pharmacy through a "chargeback."

HHS proposed a definition of chargeback as "payment made directly or indirectly by a manufacturer to a dispensing pharmacy so that the total payment to the pharmacy for the prescription pharmaceutical product is at least equal to the price agreed upon in writing between the Plan Sponsor under Part D, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product." In the final rule, CMS uses the term "point-of-sale chargeback" instead of "chargeback" to differentiate this process from other transactions in the supply chain. In addition, the definition is changed based on commenters' concerns that it could result in gaming that would result in financial losses for pharmacies. In response, HHS amends the definition in the final rule to explicitly state that chargebacks are intended to make pharmacies whole for the difference between acquisition cost, plan payment, and beneficiary out-of-pocket payment.

HHS declines to add additional detail on chargeback administration and notes that requests for guidance from CMS on dispute resolution relating to chargebacks is out of scope of the rule. HHS clarifies, however, that if a pharmacy extends a price reduction to a beneficiary that is not honored by the manufacturer, and the pharmacy: a) made a practice of undercharging beneficiaries for cost sharing under the guise of passing through manufacturer reductions in price, b) with knowledge that the reductions in price

would not be paid by manufacturers (thus providing remuneration to the beneficiaries), and c) did so with the intent to induce beneficiaries to purchase items paid for in part by a Federal health care program, the entity could be subject to liability under the anti-kickback statute. Moreover, while occasional errors in calculations (e.g., a miscalculation of a beneficiary's cost-sharing obligation) would not implicate the anti-kickback statute, a pattern of errors could eliminate the protection of the safe harbor (e.g., if a manufacturer regularly miscalculates the full value of the reduction in price owed to the pharmacy that is required to be provided for safe harbor protection) and would be subject to scrutiny. HHS also clarifies that there should be no situation in which the price at the pharmacy counter is less than zero. A situation in which a beneficiary or a Part D plan sponsor theoretically would be owed money would not be a reduction in price; that would be a payment to a referral source and would not be protected by a safe harbor.

Commenters made a number of recommendations for changes to ensure that pharmacies receive chargebacks owed. HHS notes that to the extent the chargeback process is used, it expects the manufacturer and the plan sponsor to have a written agreement that sets forth the reduction in price negotiated between the parties, which would be equal to the chargeback due to the pharmacy. Similarly, a manufacturer is expected to have documentation to prove that the chargeback actually was administered to the pharmacy and that the amount of the chargeback was equal to the point-of-sale reduction in price agreed upon in writing between the plan sponsor or PBM acting on their behalf.

With respect to which entities may administer chargebacks, commenters made several recommendations. HHS responds that stakeholders in the industry are best positioned to determine the entity that should be responsible for administering those amounts. Some also recommended a timeline for the prompt payment of chargebacks. HHS declines to add a timeline.

(3) The price reduction must be completely reflected in the price the pharmacy charges to the beneficiary at point-of-sale.

Response to Comment. In response to a commenter's concern that plans will need more than 60 days to comply with the safe harbor for point-of-sale reductions, HHS points out that this safe harbor may be used starting 60 days after the final rule is published but it does not require any party to take any particular action within 60 days.

Some commenters raised concerns that the disclosure of discounts would lead to collusion among manufacturers, higher prices, and lowered discounts. Some requested that the Department publish best practices and add safeguards to maintain the confidentiality of proprietary contract data to ensure point-of-sale discounts are not made public. HHS declines to made the changes.

With respect to concerns about common ownership, HHS notes that that arrangements in which PBMs funnel discounts through affiliated or commonly owned entities, or arrangements where it appears that a PBM is channeling kickbacks through a commonly owned entity or otherwise in order to evade this rule, are highly suspect.

HHS confirms that beneficiaries who are in the deductible phase of the Part D benefit would pay 100 percent of the discounted price.

Value-Based Arrangements. Commenters raised the concern that value-based arrangements that offer discounts based on outcomes will not fit into the new safe harbor for point-of-sale reductions in price. The Department notes that some value-based arrangements involving prescription pharmaceutical products could qualify for protection under the new point-of-sale safe harbor but also could qualify under other safe harbors (e.g., the personal services and management contracts safe harbor, the warranties safe harbor).[5] It clarifies that to the extent that manufacturers wish to use the new point-of-sale safe harbor for value-based arrangements, the reduction in price on prescription pharmaceutical products must be in the form of a point-of-sale discount. It also notes that without including all of the features of value-based arrangements, rebates cannot simply be re-defined as value-based payment arrangements. HHS remains committed to promoting value-based arrangements and notes that arrangements that implicate the anti-kickback statute will be analyzed on a case-by-case basis.

A number of additional safeguards for PBMs, manufacturers, pharmacies, and beneficiaries were recommended including prohibiting point-of-sale price reductions that are contingent upon PBM fees, adding transparency or privacy requirements, adding protections for pharmacies' revenues or for manufacturer cost-sharing assistance programs, or implementing conditions to ensure manufacturers lower drug prices. HHS declines to make additions to the provisions based on these recommendations. It does, however, clarify the language requiring POS discounts be "completely applied" at the point of sale. Final (cc)(1)(iii) now states that "the reduction in price must be completely reflected in the price of the prescription pharmaceutical product at the time the pharmacy dispenses it to the beneficiary." In response to a request for clarification, HHS repeats an example from the proposed rule to show how a reduction in price would be reflected at the point of sale consistent with the new safe harbor including for a beneficiary in the deductible phase and in other phases of the Part D benefit.

A commenter raised the concern that manufacturers could interpret this requirement to mean that the entire rebate must apply to a beneficiary's cost sharing. The commenter believed that this is contrary to HHS guidance on the use of coupons. In response, the Department states that this language was not intended to permit a beneficiary to have cost sharing waived or for the beneficiary to receive the entire dollar value of a discount unless the beneficiary is in the deductible phase of the Medicare Part D benefit and is responsible for the full cost of the drug

C. New Safe Harbor for Certain PBM Service Fees

[5] The personal services and management contracts safe harbor (42 CFR 1001.952(d)) protects certain payments made by a principal to an agent as compensation for the services of the agent. The warranties safe harbor (42 CFR 1001.952(g)) protects payment or exchange of anything of value under a warranty provided by a manufacturer or supplier of an item to the buyer (such as a health care provider or beneficiary) of the item as long as certain conditions are met.

HHS finalizes a second safe harbor to protect fixed fees that manufacturers pay to PBMs for services rendered to the manufacturers. The final rule is largely as proposed with several clarifications incorporated in response to comment.

For this safe harbor to apply, several conditions must be met:

(1) The PBM and the manufacturer must have a written agreement that covers all of the services that the PBM provides; and that specifies each of those services and the fees associated with each. HHS declines to specify the format for this agreement. In response to a commenter's recommendation, HHS adds that the written agreements must be signed by the parties.

(2) The final rule adds the condition that the services performed under the agreement cannot involve the counseling or promotion of a business arrangements or other activity that violates any state or federal law.

(3) Compensation to the PBM for the services must be consistent with fair market value; be a fixed payment that is not based on a percentage of sales; and not be set in a way that takes volume, value of referrals, business generated between the parties or the manufacturer and the PBM's health plans into account. Some commenters requested additional specificity about what is meant by a fair market valuation. The Department declines to define the term or provide examples of valuation approaches stating that the parties seeking protection under the safe harbor have experience with the fair market value statute and are expected to use generally accepted valuation methodologies and principles to do so.

(4) The PBM is required to disclose in writing to each health plan with which it contracts at least annually, and to the Secretary on request, the services rendered to each manufacturer that are related to the PBM's arrangements with that health plan and the associated costs for the services.

HHS sought comment on potential additional disclosures that it was considering including requiring PBMs to disclose: the fee arrangements to the health plans; information about valuation and valuation methodology; information demonstrating that fee arrangements are not duplicative of other arrangements for which the PBM might receive duplicative payments ("double-dipping"); and information demonstrating that fee arrangements meet the "volume or value" criterion. While some commenters supported those additions and recommended others as well, HHS declines to finalize additional disclosures.

Response to Comment. Some commenters recommended HHS define the types of services that PBMs provide to manufacturers that would be protected by this safe harbor. HHS declines to make those additions. Some commenters also requested HHS clarify what is meant by providing the safe harbor for PBM fees for services that "relate to" services that the PBM furnishes to health plans. HHS explains that an objective of this proposal is to increase transparency for plan

sponsors to ensure that a PBM's arrangements with pharmaceutical manufacturers are not in tension with the services provided to the health plans and for which the PBM is acting as an agent. Consistent with that objective, this provision requires PBM disclosures regarding only those services relevant to plan to improve transparency for plans. Thus, the safe harbor protects only those fixed fee arrangements between manufacturers and PBMs where plans could and should have visibility into the arrangements.

Some commenters recommended that certain other low risk arrangements between manufacturers and PBMs be protected from the anti-kickback statute as well, and that the scope of the safe harbor be broadened to apply to services that a PBM provides to *or on behalf of* a manufacturer. Others suggested that HHS incorporate the concept of bona fide service fees into the protected fees. In response, HHS states that it finalized clarifications to ensure that only payments for "legitimate" services are protected (although it is unclear to which regulatory language HHS is referring).

HHS addresses a number of questions regarding the existing GPO safe harbor (42 CFR §1001.952(j)) and its interaction with the safe harbor for PBM service fees. HHS clarifies that the GPO safe harbor protects only payment by a vendor to a GPO as part of an agreement to furnish goods or services to an entity. To qualify for the GPO safe harbor, a PBM would have to:

- Meet the definition of a GPO (an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs, and who are neither wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity)); and
- Have a written agreement with each individual or entity for which items or services are furnished that specifies either that the fee the GPO receives will be three percent or less of the purchase price of the goods or services provided by that vendor or specifies the amount the GPO will be paid by each vendor. If the entity that receives the goods or services from the vendor is a health care provider, the GPO must disclose in writing to the entity at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity.

IV. Regulatory Impact Statement

OMB has determined that this final rule is "economically significant" within the meaning of section 3(f)(1) of Executive Order 12866, because it is likely to have an annual effect of $100 million or more in any one year. Accordingly, HHS has prepared a regulatory impact analysis that presents estimates of the rule's cost and benefits.

The Unfunded Mandates Reform Act of 1995 requires that agencies assess any anticipated costs to states if requiring spending in any one year of $100 million in 1995 dollars, updated annually for inflation. That amount is $156 million for 2020. HHS discusses the potential impact on states. Even though the rule does not directly alter any Medicaid drug rebate or best price statutory provisions, it may have an impact on Average Manufacturer Prices (AMP). To the

extent that discounts are shifted from rebates to point-of-sale, AMP could be lowered, which would have the effect of lowering Medicaid drug rebates calculated based on AMP.

In one of the analyses that HHS arranged for, a contractor estimates that the loss of rebates could exceed savings from lowering list prices.[6] HHS actuaries, however, estimate that states' Medicaid costs would rise by $0.2 billion over the 2020 – 2029 period but costs for state employees would decline by $4.3 billion over the period. On net, according to the HHS actuaries, states are estimated to save $4 billion over 10 years.[7] In addition, the actuaries estimate that federal Medicaid costs would rise by $1.7 billion. Some federal savings may arise through Veteran's Health Programs and other federal programs that purchase drugs, but they are not estimated.

HHS states that the overall impact of the rule is difficult to predict but states its intention that it will result in manufacturers lowering their list prices and replacing rebates with point-of-sale reductions in price. Because of the strategic decisions, however, that manufacturers, PBMs, and plans will make, it is possible that all rebates will not be converted into POS price reductions.

HHS describes a CBO analysis of the proposed rule that was, according to HHS, substantially similar to the CMS Office of the Actuary (OACT)'s analysis.[8] CBO expects that rather than lowering list prices, however, manufacturers would offer the renegotiated discounts in the form of point-of-sale chargebacks. CBO's analysis also includes transfer effects related to the costs of implementation of the rule.

Affected Entities

HHS revised its estimates of the administrative burden in response to public comments. Under the new, considerably larger estimates, Manufacturers, PBMs, plan sponsors, and Medicaid agencies would need 5 to 15 hours each to review the rule. The costs of that review, the hours for which are assumed to be divided evenly between managers and lawyers, is expected to total between $13 and $40 million in the first year. If finalized, many of those entities would need to make changes to policies and pricing models, and engage in negotiations with other entities, or restructure contractual arrangements. HHS estimates costs of between $134 and $407 million in the first year, and $12 to $37 million in years two through five to make those changes. Required PBM disclosures would cost between $.7 and $2.1 million each year. Updated IT systems for processing claims by businesses impacted by the rule would cost between $67 and $200 million in the first year following publication of the rule, and between $17 to $50 million per year in years two through five following publication of the final rule.

[6] Milliman. "Impact of Potential Changes to the Treatment of Manufacturer and Pharmacy Rebates." September 2018. The Milliman analysis is posted as supplementary material in the docket for this rule at regulations.gov.
[7] CMS Office of the Actuary. "Proposed Safe Harbor Regulation." August 2018. The OACT analysis is posted as supplementary material in the docket for this rule at regulations.gov.
[8] Congressional Budget Office. "Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections—Supplemental Material for Updated Budget Projections: 2019 to 2029," May 2019, https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf.

Enrollees of Medicare Part D plans are likely to see changes in the characteristics of the plans available to them. HHS estimates that 20% of enrollees will become aware of such changes and will take an average of 30 minutes each to respond to the changes costing an addition $209 million in each of the first five years after publication.

Benefits

HHS identifies and provides a qualitative description of potential benefits of the proposed changes.

- Improved transparency of premiums and out-of-pocket costs and improved formulary designs could lead to beneficiaries making more actuarially favorable decisions.
- Lowered out-of-pocket costs could improve adherence and lower total costs of care.
- Reduced costs for pharmacies to store and track abandoned prescriptions because lower beneficiary copayments will result in fewer beneficiaries abandoning their prescriptions.

Transfers

HHS points out that accounting for the impact on manufacturers' list prices is unpredictable, as is predicting Part D plans' reactions to the changing practices.

Analyses of the Impact

HHS commissioned multiple analyses of the impact of the proposed rule which varied by the amount of rebates converted to discounts at the point of sale and by other behavioral effects of plans, manufacturers, and beneficiaries. It reviews those analyses for the final rule.

- HHS Actuaries assumed that manufacturers would convert 75% of rebates into discounts.
- Milliman and Wakely both provided a non-behavioral analysis that estimated that 100% of current Part D rebates would be converted into list price concessions.
- Milliman also examined additional scenarios in which plan sponsors exert greater formulary control; in which manufacturers include discounts at the point of sale which exceed the amount of rebates offered under existing rules; and in which manufacturers only convert 80% of rebates to discounts.

All but one of the scenarios and estimates conclude that total beneficiary cost-sharing would decline and premiums would rise. In addition, they conclude that the decline in total beneficiary cost-sharing would offset the total increase in premiums across all beneficiaries. However, more beneficiaries would pay more in premiums than would save in cost sharing indicating the uneven impact of these policy changes among different groups of beneficiaries. HHS notes that the out-of-pocket savings are most likely to accrue to those beneficiaries who are using high-cost drugs for which manufacturers provide rebates.

The results of those analyses, which are unchanged from the analyses presented in the proposed rule, of the impact of the policy on costs to beneficiaries and to the federal government are summarized in Tables 2. and 4 and are excerpted below.

In addition, HHS provides estimates of the changes to Part D benefit design parameters under the final rule in Table 3. Those estimates reflect that all of the following parameters would be lower in all years beginning in 2021: the deductible, initial coverage limit, catastrophic limit, and total drug costs at the TROOP (true out-of-pocket). By 2029, those parameters are all estimated to be between 20 and 21% lower than under the baseline.

Table 2. Estimated Impacts on Beneficiaries and the Federal Government

	OACT	Milliman, Scenario 1	Milliman, Scenario 2	Milliman, Scenario 3	Milliman, Scenario 4	Wakely
Modeled Assumptions	• 15% of current Part D rebates retained by manufacturer • 75% of remaining amount applied to per-sponsor/PBM negotiated discounts • 25% of remainder applied as reduction to list price • No beneficiary or plan behavioral changes are assumed	• 100% of current Part D rebates are converted into list price concessions (agnostic on list price reductions versus up front discounts)	• 100% of current rebates are converted into list price concessions • Part D plans exert greater formulary control	• More than 100% of rebates are converted into list price concessions (same agnosticism on how applied) • Part D plans exert greater formulary control	• 20% of current Part D rebates are retained by manufacturers (same agnosticism on how applied) • 80% of current Part D rebates are converted to price concessions (list price or discounts)	• 100% of current manufacturer rebates are converted into reductions in drug costs at the point of sale • No beneficiary or plan behavioral changes are assumed
Beneficiary Impacts, Per Member Per Month, Non-Low Income Subsidy Enrollees, CY 2020 - CY 2029						
Premium	+25%	+$4.03 (+13%)	+$1.27 (+4%)	+$0.61 (+2%)	+$6.84 (+21%)	N/A
Cost Sharing	-18%	-$6.23 (-12%)	-$9.85 (-19%)	-$9.68 (-19%)	-$4.97 (-10%)	N/A
Total	**-4%**	**-3%**	**-10%**	**-11%**	**+2%**	**N/A**
Government Spending Impact, CY 2020 – 2029 ($ in billions)						
Direct Subsidy	+$258.7 (+119%)	+$215.4 (+193%)	+$174.7 (+157%)	+$180.3 (+162%)	+$221.1 (+199%)	Not avail.
Low-Income Premium Subsidy	+$15.4 (+24%)	+$12.0 (+13%)	+$3.8 (+4%	+$1.9 (+2%)	+$20.5 (+21%)	N/A

	OACT	Milliman, Scenario 1	Milliman, Scenario 2	Milliman, Scenario 3	Milliman, Scenario 4	Wakely
Low-Income Cost Sharing Subsidy	-$57.7 (-15%)	-$89.5 (-20%)	-$118.3 (-26%)	-$118.5 (-26%)	-$71.4 (-16%)	N/A
Reinsurance	-$20.3 (-3%)	-$103.1 (-13%	-$139.1 (-18%)	-$163.2 (-18%)	-$30.2 (-4%)	N/A
Total	**+$196.1 (+14%)**	**+$34.8 (+2%)**	**-78.8 (-5%)**	**-$99.6 (-7%)**	**+$139.9 (+10%)**	**N/A**

Source: HPA excerpted from Tables 2 and 4 of the final rule.