



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

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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

AGENCY: Department of Health and Human Services, Office of Inspector General (OIG), HHS.

ACTION: Final rule.

SUMMARY: Discounts for prescription pharmaceutical products are central to this final rule, in which the Department of Health and Human Services (Department or HHS) amends the safe harbor regulation concerning discounts. Amending this regulation changes the definition of certain conduct that is protected from liability under the Federal anti-kickback statute of the Social Security Act (the Act). New regulatory text in the amendment revises the discount safe harbor. By excluding from the definition of a discount eligible for safe harbor protection certain reductions in price or other remuneration from a manufacturer of prescription pharmaceutical products to plan sponsors under Medicare Part D or pharmacy benefit managers (PBMs) under contract with them, the Department modifies the existing discount safe harbor in particular contexts. Existing safe harbors otherwise remain unchanged. Safe harbors are also

created for two additional types of arrangements. The first protects certain point-of-sale reductions in price on prescription pharmaceutical products, and the second protects certain PBM service fees.

DATES: This final rule is effective on [insert date 60 days after the date of publication in the FEDERAL REGISTER], except for the amendments to 42 CFR 1001.952(h)(5), which are effective on January 1, 2022.

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SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose and Need for Regulatory Action as Determined by the Secretary

On February 6, 2019, the Department published a Notice of Proposed Rulemaking in the *Federal Register* (84 FR 2340) (Proposed Rule). In that Proposed Rule, the Secretary set forth his concerns with the modern prescription drug distribution model and, in particular, how the current rebate-based system may be increasing financial burdens for beneficiaries. We refer readers to and incorporate by reference Section I of the Proposed Rule, which sets forth in detail the Secretary's determination of the purpose and need for this rulemaking.

The Trump Administration's *American Patients First* blueprint described a new, more transparent drug pricing system that would lower high prescription drug prices and bring down out-of-pocket costs.¹ The blueprint described four strategies: boosting competition, enhancing negotiation, creating incentives for lower list prices, and reducing out-of-pocket spending.

On July 24, 2020 the President signed an Executive Order² directing the Secretary of Health and Human Services to complete the rulemaking process that was commenced with the Proposed Rule. Section 4 of this Executive Order directs the Secretary

¹ American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, Dep't Health & Human Servs. (May 2018), available at <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>.

² Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen, Whitehouse.gov (July 24, 2020), available at <https://www.whitehouse.gov/presidential-actions/executive-order-lowering-prices-patients-eliminating-kickbacks-middlemen/>. See 85 FR 45759 (July 29, 2020).

of the Department of Health and Human Services to confirm – and make public such confirmation – that the action is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs. The Secretary's

confirmation is available at:

<https://www.hhs.gov/about/leadership/secretary/priorities/drug-prices/index.html>.

This final rule is an important element to achieving the goals of the blueprint and the Executive Order and also works in concert with other regulatory provisions finalized by the Department. For example, this final rule creates new safe harbor protection for point-of-sale reductions in price, which will directly reduce beneficiary out-of-pocket spending at the pharmacy counter. It also increases price transparency, which will enable Medicare beneficiaries to better choose a plan that best meets their needs. This final rule addresses a practice that has increased patient costs at the pharmacy counter and will create incentives for drug companies to lower the list prices of their drugs.

This final rule is also important to beneficiary and government spending in Medicare Part D. Part D rebates and other price concessions grew more than three times faster than gross drug expenditures from 2014-2016. Price concessions, including rebates, have the potential to reduce Part D costs for the Federal government, because Part D plan sponsors subtract their estimated rebates from their plan bids. Lower plan bids

contribute to lower premiums, and lower premiums contribute to lower government spending on premium subsidies. However, the Proposed Rule described how rebates also may create a perverse incentive that rewards manufacturers for increasing their list price, while subjecting consumers to higher out-of-pocket costs. Since beneficiary out-of-pocket costs are often calculated based on the list price of the drug (i.e., before rebates are paid), beneficiaries pay higher cost-sharing than they would if discounts were reflected at the point of sale. Furthermore, high list prices may result in more beneficiaries more quickly reaching the catastrophic phase, where the Federal government bears 80 percent of the drug costs and the Part D plans only cover 15 percent of the drug costs.

The Department is issuing this final rule to 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.

B. Summary of the Major Provisions

i. Discount Safe Harbor

In this final rule, we amend 42 CFR 1001.952(h) to remove safe harbor protection for reductions in price in connection with the sale or purchase of prescription pharmaceutical products from manufacturers to plan sponsors under Part D, either directly or through PBMs acting under contract with them,

unless the reduction in price is required by law. We note that reductions in price negotiated between manufacturers and plan sponsors under Part D (or through PBMs under contract with the plan sponsors) in the form of upfront discounts, rather than after-sale rebates, are eligible for protection under the new safe harbor for point-of-sale reductions in price for prescription pharmaceutical products at § 1001.952(cc).

ii. Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products Safe Harbor

We are finalizing a new safe harbor at § 1001.952(cc) for certain point-of-sale reductions in price offered by manufacturers on prescription pharmaceutical products that are payable under Medicare Part D or by Medicaid managed care organizations (MCOs) that meet certain criteria.

iii. PBM Service Fees Safe Harbor

In this final rule, we create a new safe harbor at § § 1001.952(dd) for fixed fees that manufacturers pay to PBMs for services rendered to the manufacturers that meet specified criteria.

II. Background

A. *The Anti-Kickback Statute and Safe Harbors*

Section 1128B(b) of the Act, the anti-kickback statute, provides for criminal penalties for 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 defined in section 1128B(f) of the Act. The offense is classified as a felony and

is punishable by fines of up to \$100,000 and imprisonment for up to 10 years. Violations of the anti-kickback statute may also result in the imposition of civil monetary penalties (CMPs) under section 1128A(a)(7) of the Act (42 U.S.C. 1320a-7a(a)(7)), program exclusion under section 1128(b)(7) of the Act (42 U.S.C. 1320a-7(b)(7)), and liability under the False Claims Act (31 U.S.C. 3729-33).

Congress's intent in placing the term "remuneration" in the statute in 1977 was to cover the transfer of anything of value in any form or manner whatsoever. The statute's language makes clear that illegal payments are prohibited beyond merely "bribes," "kickbacks," and "rebates," which were the three terms used in the original 1972 statute. The illegal payments are covered by the statute regardless of whether they are made directly or indirectly, overtly or covertly, in cash or in kind, and regardless of the label that parties may affix to the payment. In addition, prohibited conduct includes not only the payment of remuneration intended to induce or reward referrals of patients but also the payment of remuneration intended to induce or reward the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by any Federal health care program.

Because of the broad reach of the statute, concern was expressed that some relatively innocuous commercial arrangements were covered by the statute and, therefore, potentially subject

to criminal prosecution.³ In response, Congress enacted section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93, which specifically requires the development and promulgation of regulations, the so-called safe harbor provisions, that would specify various payment and business practices that would not be subject to sanctions under the anti-kickback statute, even though they may potentially be capable of incenting referrals of business for which payment may be made under a Federal health care program.

Section 205 of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, established section 1128D of the Act, which includes criteria for modifying and establishing safe harbors. Specifically, section 1128D(a)(2) of the Act provides that, in modifying and establishing safe harbors, the Secretary may consider whether a specified payment practice may result in:

- an increase or decrease in access to health care services;
- an increase or decrease in the quality of health care services;
- an increase or decrease in patient freedom of choice among health care providers;
- an increase or decrease in competition among health care providers;

³ See, e.g., Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR 35952 (July 29, 1991).

- an increase or decrease in the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations;
- an increase or decrease in the cost to Federal health care programs;
- an increase or decrease in the potential overutilization of health care services;
- the existence or nonexistence of any potential financial benefit to a health care professional or provider, which benefit may vary depending on whether the health care professional or provider decides to order a health care item or service or arrange for a referral of health care items or services to a particular practitioner or provider; or
- any other factors the Secretary deems appropriate in the interest of preventing fraud and abuse in Federal health care programs.⁴

Since July 29, 1991, there have been a series of final regulations published in the *Federal Register* establishing safe harbors in various areas.⁵ These safe harbor provisions have

⁴ See also section 1102 of the Act (vesting the Secretary with the authority to make and publish rules and regulations, not inconsistent with the Act, as may be necessary to the efficient administration of his functions under the Act).

⁵ Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR 35952 (July 29, 1991); Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Protecting Health Plans, 61 FR 2122 (Jan. 25, 1996); Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements, 64 FR 63504 (Nov. 19, 1999); Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the

been developed “to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements.”⁶

Healthcare providers and others may voluntarily seek to comply with safe harbors so that they have the assurance that their business practices will not be subject to any anti-kickback enforcement action. In giving the Department the authority to protect certain arrangements and payment practices under the anti-kickback statute, Congress intended the safe harbor regulations to be updated periodically to reflect changing business practices and technologies in the healthcare industry.

B. Summary of the Notice of Proposed Rulemaking

On February 6, 2019, we published the Proposed Rule setting forth certain proposed amendments to the safe harbors under the anti-kickback statute. The Proposed Rule also provided substantial background information to explain why the Department believes these amendments are necessary.

Anti-Kickback Statute, 64 FR 63518 (Nov. 19, 1999); Medicare and State Health Care Programs: Fraud and Abuse; Ambulance Replenishing Safe Harbor Under the Anti-Kickback Statute, 66 FR 62979 (Dec. 4, 2001); Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute, 71 FR 45109 (Aug. 8, 2006); Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Federally Qualified Health Centers Arrangements Under the Anti-Kickback Statute, 72 FR 56632 (Oct. 4, 2007); Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 FR 79202 (Dec. 27, 2013); and Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 FR 88368 (Dec. 7, 2016).

⁶ Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR at 35958.

With respect to the proposed amendment to the existing discount safe harbor, we explained that it was designed to address evolving business arrangements and align with the statutory exception's intent to encourage price competition that benefits the Medicare and Medicaid programs.⁷ We also emphasized our longstanding position that a discount must be in the form of a reduction in the price of a good or service based on an arms-length transaction. With respect to rebates, we explained the regulatory history regarding our treatment of "rebates" under the discount safe harbor. Finally, we noted that the discount safe harbor was finalized in 1991 and has not been updated since 2002, and we highlighted that both the Medicare Part D program and comprehensive regulations governing Medicaid managed care delivery systems were enacted in the intervening years. For a more comprehensive discussion of why these amendments to the discount safe harbor are necessary, we incorporate by reference and refer readers to the discussion in the Proposed Rule.⁸

The Proposed Rule also identified certain specific harms that may be caused by the current rebate framework. First, some beneficiaries experience increased financial burdens. For example, if a beneficiary is paying coinsurance on a drug subject to a rebate, the beneficiary pays a percentage of a price that more closely resembles the list price than the net price. Second, the Proposed Rule explained that rebates may be harming Federal health care programs by increasing list prices,

⁷ 54 FR 3092.

⁸ 84 FR 2345-47.

preventing competition to lower drug prices, discouraging the use of lower-cost brand or generic drugs, and skewing formulas used to determine pharmacy reimbursement or Medicaid rebates.⁹ Finally, the Proposed Rule expressed concerns about a lack of transparency in the current system. With respect to rebates, we explained that OIG work showed that some Part D plan sponsors had limited information about rebate contracts and rebate amounts that their PBMs negotiated. A lack of transparency could create a potential program integrity vulnerability because compliance with program rules may be more difficult to verify. We also sought to address a lack of transparency to health plans when the health plans' PBMs are being paid by manufacturers for services that the PBMs render to manufacturers related to pharmacy benefit management services that the PBM furnishes to the health plans.¹⁰

To address the Department's concerns with the current rebate system, the Department proposed and solicited comments on three revisions to the safe harbors. First, the Department proposed to amend the discount safe harbor at 42 CFR 1001.952(h) to exclude from the definition of "discount" at § 1001.952(h)(5) all price reductions from manufacturers on prescription pharmaceutical products in connection with their sale to or purchase by plan sponsors under Medicare Part D, Medicaid MCOs, or PBMs acting under contract with plan sponsors under Medicare Part D or Medicaid MCOs, unless the reduction in price is

⁹ 84 FR 2343.

¹⁰ 84 FR 2349-50.

required by law (e.g., rebates under the Medicaid Drug Rebate Program). The Proposed Rule also proposed definitions at § 1001.952(h)(6)-(10) of the terms "manufacturer," "wholesaler," "pharmacy benefit manager," "prescription pharmaceutical product," and "Medicaid Managed Care Organization."

Second, the Proposed Rule proposed to add a new safe harbor at § 1001.952(cc) to protect reductions in price between the entities that would be removed from the discount safe harbor at § 1001.952(h) if such reductions in price are given at the point of sale and meet certain other criteria. As proposed, this safe harbor would protect reductions in price on prescription pharmaceutical products offered to plan sponsors under Medicare Part D, Medicaid MCOs, or through a PBM acting under contract with either if: (1) the reduction in price is set in advance; (2) the reduction in price does not involve a rebate, unless the full value of the price reduction is accomplished through chargebacks or is a rebate required by law; and (3) the reduction in price is completely reflected in the price the pharmacy charges to the beneficiary at the point of sale.

Finally, the Proposed Rule proposed to add a second new safe harbor at § 1001.952(dd) specifically designed to protect certain fees a pharmaceutical manufacturer pays to a PBM for services rendered to the manufacturer that relate to the PBM's arrangements to provide pharmacy benefit management services to health plans. As proposed, the safe harbor would protect a payment a pharmaceutical manufacturer makes to a PBM for

services the PBM provides to the manufacturer, for the manufacturer's benefit, when those services relate to the PBM's arrangements to provide pharmacy benefit management services to health plans. To receive protection, the proposed safe harbor would require that: (1) the services and compensation be set out in a written agreement; (2) the compensation 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; and (3) the PBM makes annual written disclosures to each health plan with which it contracts regarding the services rendered to each pharmaceutical manufacturer related to the PBM's arrangements to furnish pharmacy benefit management services to the health plan, and make such disclosures to the Secretary upon request.

The Department solicited comments on a range of topics in the course of describing the new proposed safe harbors. For instance, for the proposed safe harbor for point-of-sale reductions in price, the Proposed Rule solicited comments on the sufficiency of the proposed definitions as well as any effects of the proposed safe harbor on competition to the extent pharmacies have sufficient data to reverse engineer the manufacturer's or the PBM's discount structure. For the

proposed safe harbor for certain PBM service fees, the Proposed Rule solicited comments on the interpretation of pharmacy benefit management services and the transparency-related requirements that would be a condition of the safe harbor.

III. Summary of Public Comments and Responses

We received responsive comments from approximately 26,000 distinct commenters, including, but not limited to, individuals, pharmaceutical manufacturers, pharmacies, PBMs, wholesalers, plan sponsors under Part D, Medicaid MCOs, and trade associations representing various individuals and entities. Many of these individuals and entities provided comments on multiple topics. Commenters generally agreed with the Department on the need to lower out-of-pocket costs for consumers on prescription drugs, but they diverged in terms of whether they supported or opposed the Proposed Rule. Comments from both those who opposed the rule and those who supported the rule recommended certain changes or requested certain clarifications. We appreciate the robust feedback from the commenters. We have divided the public comment summaries and our responses into discrete sections: the first section covers general comments and responses that may apply to more than one of our proposals, and the following sections summarize and respond to the comments specific to our proposed amendments to the discount safe harbor and our two new proposed safe harbors.

A. *General*

i. *Antitrust*

Comment: Several commenters were supportive of the Proposed Rule and contended that antitrust laws do not affect the Proposed Rule or that the Proposed Rule will not lead to anti-competitive discriminatory pricing. A commenter explained that antitrust laws related to differential pricing apply equally to upfront discounts as they do to retrospective rebates. Another commenter explained that the Proposed Rule will result in lower cost-sharing amounts for beneficiaries at the point of sale and will allow for the reestablishment of the nexus between price concessions on a product and the actual price paid by consumers for that product.

Response: We appreciate the commenters' support for the Proposed Rule.

Comment: Several commenters addressed whether and how the policies underlying the Proposed Rule intersect with the Robinson-Patman Act. 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. Several of these commenters claimed 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. These commenters pointed out that

under the terms of the 1996 settlement, manufacturers agreed to give pharmacies the same opportunity to earn the favorable discounts given to institutional purchasers, provided that the pharmacies can demonstrate an ability to affect market share in the same or similar manner as the institutional purchasers. The commenters argued that the Department failed to consider this settlement, and stated that absent Congressional action to amend or repeal the Robinson-Patman Act, manufacturers will move to offering lower, unvaried discounts.

Other commenters, however, contended that the antitrust laws do not pose an obstacle to or hinder implementation of the Proposed Rule and that the Proposed Rule would, in fact, further the ultimate goal of antitrust law, which is to promote competition. For instance, one commenter pointed out that the antitrust laws apply equally to up front discounts and retrospective rebates, and the *In re Brand Name Prescription Drugs* litigation did not result in any change in the ability of a prescription drug manufacturer to offer an upfront discount, or create any precedent suggesting that upfront discounts are illegal and retrospective rebates are legal. Another comment similarly questioned the conclusion that moving from a world of PBM rebates to point-of-sale chargebacks would result in anti-competitive discriminatory pricing and pointed out that the Proposed Rule would result in individuals paying less at the pharmacy counter. Yet another commenter contended that

transitioning away from rebates to upfront discounts achieves the intended goals of the 1996 settlement.

Response: The Department is not persuaded that the threat of Robinson-Patman Act litigation will dissuade manufacturers from offering pro-competitive price concessions in the form of upfront discounts. In fact, comments submitted by the major association representing pharmaceutical manufacturers rejected the notion that the Robinson-Patman Act prevents prescription pharmaceutical manufacturers from offering upfront discounts and pointed out that rebates do not occupy a unique position insulated from antitrust scrutiny. The Department agrees that neither the 1996 settlement nor the subsequent court rulings made any distinction between retrospective rebates and upfront discounts and did not result in any decision suggesting that the former are less problematic than the latter. Both retrospective rebates and upfront discounts, to the extent that they are true price concessions, could theoretically be applied in a discriminatory fashion. The Department does not administer antitrust law. However, as the Department understands its application, whether the price discrimination is achieved by something labeled a "rebate" versus something labeled a "discount" would not be relevant for purposes of Robinson-Patman Act liability.

Comment: A commenter requested, and believed it would be helpful for, the Antitrust Division at the Federal Trade Commission (FTC) or Department of Justice (DOJ) to analyze the

Proposed Rule and provide a Competition Advisory Opinion upon which stakeholders could rely.

Response: Parties that want greater certainty may request an advisory opinion from the FTC.

ii. Transparency

Comment: Numerous commenters reiterated the need for greater transparency in our current rebate system, with various commenters asserting that the proposed point-of-sale reduction in price safe harbor would increase transparency and ensure that patients benefit from price reductions. A commenter stated that greater transparency would enable independent pharmacies to negotiate more favorable terms with PBMs and health plan sponsors and inform patients about their drug coverage options, while another commenter stated that greater transparency may put plan sponsors in a better position to exert more influence to lower net drug spending and PBM administrative fees. Another commenter asserted that transparency surrounding discounts would be likely to lower list prices and reduce misaligned incentives. This commenter also stated that patients who know the amount of a plan's discount for a product would be in a better position to select the right plan. Another commenter asserted that this increased transparency surrounding the rebates provided to PBMs and plans would place significant pressure on pharmaceutical manufacturers to lower list prices, stating that manufactures would no longer be able to point to rebates as the reason for high drug prices.

Conversely, other commenters stated that the changes reflected in the Proposed Rule would not increase transparency. Specifically, some commenters asserted that pharmaceutical manufacturers establish drug prices, and that if the rule aims to create transparency, then it should apply to all parties, including pharmaceutical manufacturers, instead of only PBMs and health plans. Another commenter asserted that health plans already provide meaningful transparency surrounding rebates through mechanisms like direct and indirect remuneration (DIR) reporting to CMS, while pharmaceutical manufacturers do not systematically disclose their rebates. Another commenter opposed the proposed point-of-sale reductions in price safe harbor and stated that as long as rebates are a part of our drug pricing system, there will still be confusion among patients and plan sponsors surrounding drug prices.

Response: We appreciate support from commenters who agree that applying manufacturer reductions in price to drug prices at the point of sale would increase transparency. Additionally, we concur that greater transparency surrounding price reductions can enable stakeholders in the drug supply chain to support patients in selecting drugs and plans that minimize their out-of-pocket costs and can lead to lower drug prices.

Many publications document that many Medicare beneficiaries do not make what might appear to be the best decisions when choosing a Part D plan. If the plan premium is the monthly cost of having access to drugs that best meet a beneficiary's needs,

then the beneficiary should have visibility into what kind of discounts are being negotiated on their behalf.

While we understand that plan sponsors under Part D already have DIR reporting requirements, we believe that by excluding certain rebates paid by manufacturers from the discount safe harbor and creating a new safe harbor for point-of-sale reductions in price, there will be enhanced transparency regarding reductions in price that pharmaceutical manufacturers negotiate with plan sponsors under Medicare Part D and PBMs under contract with these plans, especially for the consumer, and create new incentives for manufacturers to lower drug prices.

Comment: Other commenters asserted that blaming PBMs for the lack of transparency in the rebate system is misdirected. A PBM commenter stated that its plan sponsors see their respective drug costs at a unit cost level, as well as the savings the PBM generates for plan sponsors, including rebates, and that its plan sponsors have full audit rights to ensure complete transparency. Another commenter noted that PBMs already offer transparent contracts that allow many large employers to pull through some of the value of negotiated rebates to reduce enrollees' drug-related costs, while another commenter noted that the Proposed Rule did not account for these innovative and transparent models that are taking place within the PBM industry.

Conversely, other commenters claimed that the PBM market lacks transparency. Some commenters indicated that rather than excluding certain rebates from the discount safe harbor, OIG should focus on ensuring that PBMs are completely transparent with health plans regarding rebate payments and pass through 100 percent of all rebate payments to Part D plan sponsors, with a commenter noting that increased transparency with respect to PBM rebates may enable plan sponsors to retain some of these rebates that can be used to benefit plan participants and beneficiaries.

Other commenters discussed the impact of increased transparency on the PBM industry generally. Specifically, a commenter advised OIG to ensure the proposed transparency requirements on top of the other regulations that apply to Medicare and Medicaid will not unintentionally stifle new entrants in the PBM market, noting that more choice in PBMs would benefit patients and the government. Conversely, another commenter asserted that greater transparency will invite competition from new PBM entrants, such as nonprofit PBMs and employer self-administered PBMs.

Response: We understand that some programmatic mechanisms are already in place to foster transparency of rebates and drug prices between PBMs and plan sponsors and to CMS. PBMs will need to consider the new requirements in this final rule and may need to adjust their operations in order to comply with the terms of the applicable safe harbor. However, we are persuaded by the comments suggesting that the additional transparency

provided by this final rule would be useful. Further, as stated in the Proposed Rule, a 2011 evaluation indicated that certain Part D plan sponsors had limited information regarding rebate contracts and rebate amounts negotiated by their PBMs.¹¹ A lack of transparency could contribute to program integrity vulnerabilities by making compliance with program rules harder to verify and by allowing hidden incentives that result in higher list prices. We believe that excluding certain rebates paid by manufacturers from the discount safe harbor and creating a new safe harbor for point-of-sale reductions in price will increase transparency, including transparency to plans and beneficiaries, and improve alignment of incentives among parties that could result in lower list prices and out-of-pocket costs.

Comment: A commenter recommended restricting or banning PBM spread pricing because spread pricing detracts from the goals of transparency and fair pricing by enabling PBMs to profit by charging plans a higher cost for drugs than they reimburse to pharmacies and retaining the difference. To this end, the commenter recommended that OIG or the Department implement penalties for PBMs to discourage this practice and ensure that the full value of price reductions is passed on to plans.

Response: The scope of the changes that we proposed to the discount safe harbor was limited to remuneration from pharmaceutical manufacturers to plan sponsors under Part D, Medicaid MCOs, and PBMs operating on their behalf. Comments

¹¹ 84 FR 2343.

about profits that PBMs may retain by negotiating a difference between what they charge plans and what they reimburse pharmacies are beyond the scope of this rulemaking.

Comment: A commenter suggested that the healthcare system explore other policy actions focused on high list prices, such as prohibiting brand pharmaceutical companies from effectively preventing low-cost generic medications from coming to market. Other commenters noted that our current drug pricing system can only be transparent if beneficiaries are able to predict their out-of-pocket costs and recommended locking in the price of prescription drugs that require coinsurance or requiring at least one drug in each class to be subject to a flat copayment in order to create more stability.

Response: While we appreciate commenters' suggestions for other actions to address high list prices and encourage stability in beneficiaries' out-of-pocket costs, such policy initiatives are outside the scope of this rulemaking.

Comment: Several commenters recommended various additional measures to help promote transparency in the prescription drug supply chain. Specifically, a commenter's recommendations included: standardized contract terms relating to PBM services and compensation; requiring additional regular disclosures by PBMs to health plans with which they contract regarding their business arrangements with drug manufacturers; 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. Another commenter emphasized the need for stakeholders in the prescription drug supply chain to disclose rebate and discount information, financial incentive information, and pharmacy and therapeutics committee information, which the commenter asserted would further improve transparency in this area. Another commenter stated that to further transparency, CMS and OIG should identify, collect, and disseminate data and information that would enable the evaluation of the impact of changes under this rule on beneficiaries.

Other commenters recommended requiring prescription drug manufacturers to be more transparent by making list prices public, with a commenter asserting that patient-level information related to drug pricing must be transparent, democratized, and open source.

Another commenter noted that under the current framework, Medicaid MCOs may negotiate supplemental rebates directly with pharmaceutical manufacturers to minimize costs based on the net cost to the MCO, but the lowest net cost product for the MCO may not always align with the lowest net cost product for the Medicaid program. This commenter recommended mandating transparency of the unit rebate amount (URA) and unit rebate

offset amount (UROA) to Medicaid MCOs to help Medicaid MCOs drive toward the lowest net costs to the system.

Response: We appreciate these commenters' feedback. We note that the new safe harbor for PBM service fees requires PBMs to disclose in writing to each health plan with which it contracts at least annually the services rendered to each manufacturer related to the PBM's arrangements to furnish pharmacy benefit management services to the plan. We are not adopting the commenter's recommendation to require additional regular disclosures by PBMs to health plans regarding business arrangements with drug manufacturers. We believe the requirements under the PBM service fees safe harbor allow for appropriate transparency between the parties in order for the remuneration protected under the safe harbor to be sufficiently low risk. We also are not adopting any of the commenters' other recommendations to increase transparency because they are beyond the scope of the Proposed Rule and, in some cases, outside the authorities under the anti-kickback statute. We are mindful of the importance of monitoring the impact of the final rule on beneficiaries.

iii. Relationship to Part D

a. *Non-interference*

Comment: A number of commenters contended that the Proposed Rule was an impermissible exercise of the Secretary's authority because it violates the Medicare Part D noninterference provision, section 1860D-11(i) of the Act. These commenters

asserted the Proposed Rule seeks to interfere with how manufacturers and Part D plan sponsors negotiate and pay for prescription drugs through the elimination of rebates and the prohibition on using formulary placement as leverage to reduce prices, which are well-established negotiating tools. Commenters also asserted that, by requiring that reductions in price be applied at the point of sale and not applied to premiums, the Proposed Rule violates the prohibition on instituting a price structure for the reimbursement of covered Part D Drugs. A commenter asserted that the proposal, if finalized, also would interfere in Part D plan sponsors' negotiations with pharmacies by mandating that Part D sponsors ensure that pharmacy reimbursement is reduced by the amount of any discounts received by the pharmacy from the manufacturer. In addition, multiple commenters cited CMS rulemakings, which they concluded previously interpreted the non-interference clause as prohibiting the agency from adopting the policies proposed by this rule and asserted that the changed statutory interpretation would require notice and comment.

Response: This rule does not interfere in any negotiations between Part D sponsors, manufacturers, and pharmacies. This final rule changes the circumstances under which certain agreements that implicate the anti-kickback statute fall within the protection of a safe harbor. The parameters of the safe harbor do not institute a price structure, nor do they interfere with negotiations between plans and pharmacies, because they do

not have any bearing on the ultimate prices negotiated among the parties. CMS's longstanding position about the non-interference provision is that all aspects of the non-interference provision must be considered in light of other statutory requirements to implement and oversee the Part D program.¹² It has always been the Department's view that the non-interference provision does not exist in a vacuum and must be read in concert with Part D statutory obligations in connection with, for example, pharmacy network adequacy, consistency in treatment of drug costs, and the provision of adequate formularies. It is no different when one views the non-interference provision in the broader context of the Secretary's other statutory obligations under the Act, including the mandate to establish and modify safe harbors. This rule, as it is being finalized, does not change the Department's interpretation of the Part D non-interference provision.

b. *Impact on Part D Program*

Comment: Some commenters made a variety of recommendations to address pharmacy DIR fees. Other commenters recommended that OIG not finalize the Proposed Rule because it would eliminate DIR.

Response: The administration of pharmacy DIR fees is outside the scope of this rulemaking. Nothing in this final rule changes CMS's rules with respect to DIR.

¹² See, e.g., 79 FR 29844, 29874-75 (May 23, 2014).

Comment: Several commenters recommended that HHS, CMS, and Congress reform the Part D program by, for example: implementing a rebate pass-through requirement as part of the Part D program in lieu of the Proposed Rule; allowing for greater flexibility in calculating deductibles; redefining Average Manufacturer Price (AMP) or clarifying how point-of-sale price concessions or chargebacks might apply to AMP; making adjustments to certain cost-sharing requirements for partial point-of-sale rebate and formulary design options; and permitting manufacturers to offer copayment and coinsurance assistance for single-source drugs.

Response: Comments that request Congressional action, pertain to changes to the administration of the Part D program, or ask for guidance with respect to Medicaid pricing rules are outside the scope of this rulemaking. Manufacturer-sponsored copayment assistance programs are also outside the scope of this rulemaking.

Comment: A commenter recommended that OIG work with the Department to develop guidance and procedures for how to identify and avoid 340B and point-of-sale duplicate discounts in Part D and Medicaid managed care prior to implementation of the proposed safe harbor. For example, the commenter recommended similar requirements that the Department of Defense has implemented, such as (1) requiring the use of a National Council for Prescription Drug Programs (NCPDP) modifier to identify 340B transactions within the new system, or (2) requiring, in the safe harbor text or otherwise, that the PBM or other chargeback

administrator must exchange information and cooperate as necessary to enable manufacturers to determine whether any 340B discounts are also implicated in the transaction. Another commenter requested confirmation that manufacturers may continue traditional duplicate discount avoidance arrangements and that doing so will not put the safe-harbored status of a point-of-sale reduction in price arrangement at risk. The commenter noted that the new point-of-sale reductions in price safe harbor should not require that manufacturers pay chargebacks for Part D point-of-sale reductions in price when doing so would generate 340B duplicate discounts.

Response: We appreciate commenters' feedback on 340B and the potential for point-of-sale duplicate discounts in Part D. Establishment of mechanisms for avoiding duplicate discounts or resolving disputes or errors regarding rebates is outside the scope of this rule, as is compliance with CMS requirements relating to Prescription Drug Event (PDE) reporting for when a claim is re-processed as a result of such mechanisms. The point-of-sale reduction in price safe harbor requires, as a condition of qualifying for the safe harbor, that the reduction in price be completely reflected at the time the pharmacy dispenses the prescription pharmaceutical product to the beneficiary; it does not specifically require chargebacks. In addition, we note that a violation of the anti-kickback statute must be knowing and willful. Good faith efforts to avoid duplication of discounts or resolve disputes or errors, where

such practices are not intending to offer or pay remuneration to induce or reward purchases of federally payable goods or services, likely would not constitute violations.

Comment: Some commenters recommended that OIG review whether and explain how the changes proposed in its Proposed Rule are consistent with a rule that CMS previously proposed, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses."¹³

Response: We thank commenters for their recommendation and note that the rule we are finalizing here makes certain changes to the regulatory safe harbors to the anti-kickback statute, which may impact business arrangements of parties participating in the Part D program but do not amend any program requirements.

Comment: A commenter urged CMS and OIG to advance, in both the final rule and corresponding CMS-issued guidance, plan designs or financing pathways for Medicare Advantage plans that allow for the continuation of Medicare Advantage supplemental benefit programs by offsetting the reduction in rebates that the commenter predicted would result from this rule.

Response: This final rule amends the discount safe harbor and adds two new safe harbors to specify types of arrangements that would be protected from liability under the anti-kickback statute. Additional guidance on plan design or financing pathways for Medicare Advantage plans are outside the scope of this rule.

¹³ See 83 FR 62152 (Nov. 30, 2018).

Comment: A number of commenters identified issues related to beneficiary rights that they asserted will require rulemaking or guidance in order to implement the Proposed Rule. These issues include, but are not limited to: how CMS would expect plans to apply formulary and tiering exceptions policies; how CMS will handle beneficiary complaints, appeal rights, and transition fills; application of percentage price concessions to the higher-tier drug; how CMS would expect plans to apply formulary exceptions when approving a no price concession drug; what changes will be reported in the language of the Evidence of Coverage and model marketing materials; whether enrollees will be told the price concession amount at the point of sale, and how it will be accounted for in the cost component of Medication Therapy Management (MTM) (e.g., might previously qualified enrollees no longer qualify as they no longer meet the cost threshold?); whether a plan's Advance Notice of Changes will have to be revised to reflect changes in rebate status.

Response: To the extent parties elect to structure arrangements to fit into the new point-of-sale reduction in price safe harbor, questions may arise about implementation. Questions related to CMS's administration of the Part D program, however, are outside the scope of OIG's authority and this rulemaking. We have coordinated with CMS in the promulgation of this rule and are informed that their formulary review processes will continue to protect beneficiary access and choice. CMS provides Part D plan sponsors with guidance related to bidding,

formulary submission, and Medicare Plan Finder instructions, and will continue to work with plan sponsors to ensure a smooth transition and minimize disruption.

Comment: Commenters expressed several concerns about formulary structure and benefit design, which the commenters asserted will require rulemaking or guidance from CMS in order to implement changes included in the Proposed Rule, if finalized. For example, a commenter identified various issues related to formulary structure, which the commenter asserted will require rulemaking or guidance by CMS in order to implement the new or amended safe harbors, if finalized. These included: any potential changes to CMS's formulary review process; what the potential effects will be on formularies due to new arrangements; manufacturers using alternate National Drug Codes for existing drugs (e.g., to allow for price concessions or to reauthorize a branded drug as generic or biosimilar); what happens when an LIS enrollee is in different phases of benefit or tiers of a formulary; whether the *de minimis* premium policy for LIS will be increased. Commenters also suggested that CMS finalize its proposal in the 2020 Draft Call Letter to restrict brand and generic drugs to respective brand and generic tiers and more actively track formularies.

Response: As discussed above, questions about CMS's administration of the Part D program (which includes oversight of policies regarding LIS beneficiaries) are outside the scope of OIG's authority.

Comment: A commenter asked if new costs associated with the Proposed Rule (e.g., to update systems, contracts, and staff call centers) will be included in administrative costs for purposes of medical loss ratio compliance. The commenter stated that plans will need to collect higher premiums and make larger claims payments if there is no exception for new costs.

Response: Whether administrative costs should be taken into account when calculating medical loss ratios are outside the scope of this rulemaking.

Comment: Other commenters predicted that the proposal may result in higher premiums for individuals in self-insured plans. In particular, a commenter asserted that self-funded employer group waiver plans (EGWPs) that enroll Medicare Advantage beneficiaries use rebate dollars to reduce premiums and that with fewer rebate dollars, self-funded EGWPs would have to increase premiums substantially for all enrollees by the amount received in rebates.

Response: The intent of the rule includes the elimination of the distortions in the market that drive up pharmaceutical list prices for EGWPs as well as other MA and Part D plans. As discussed elsewhere in this rule, list prices have been rising to increase the rebates. This change will bring transparency to the plan design and allow beneficiaries and employers funding EGWPs to better understand and negotiate, prior to the effective date of this rule, the benefits they are paying for.

Comment: A commenter stated that MA and Part D plan sponsors should have additional flexibility regarding what drugs to exclude from coverage formularies, what criteria and guidance to follow for coverage decisions, and what restrictions they should be subject to. Because plan sponsors must certify the accuracy, completeness, and truthfulness of all data, another commenter stated that CMS should provide plan sponsors with an alternative good faith compliance approach.

Response: Comments requesting that plan sponsors have increased flexibility in the MA and Part D programs are outside the scope of this rulemaking.

Comment: Commenters suggested that the catastrophic phase of the Part D benefit should be reformed or that a cap should be placed on out-of-pocket costs to beneficiaries.

Response: Comments recommending policy changes to the Part D program or amendments to the governing law are outside the scope of this rulemaking.

Comment: A number of commenters expressed concern about the impact of the Proposed Rule on the Part D bid process and stated that rulemaking or guidance by CMS will be necessary to implement the Proposed Rule, including: how would CMS require plan sponsor negotiated price concessions to be allocated in the bid and when would the Bid Pricing Tool be updated for such price concessions; how would CMS revise the out-of-pocket cost values and Total Beneficiary Cost metrics; how will changes in Part D bid amounts be incorporated into MA-PD submission; will

CMS adjust the bidding schedule and beneficiary enrollment period to allow entities to bring their arrangements into compliance; and would CMS require other plan types (e.g., EGWPs) to follow its lead on the bid process? A commenter also recommended certain protections for the 2020 bid submission to limit program disruption and instability such as: adjust the de minimis threshold, rebate reallocation process, supporting documentation requirements for bids, and risk corridor protections; waive the Total Beneficiary Cost and Medicare Part D out-of-pocket cost rules; allow more flexibility in aggregate and product margin tests as well as the desk review and bid audits; and give consideration to the impact of change on EGWP plans.

Response: Comments related to CMS's administration of the Part D program are outside the scope of this rulemaking. We consulted with CMS in the promulgation of this final rule and anticipate that by finalizing this rule with a January 1, 2022 implementation date for the amendments to the discount safe harbor at § 1001.952(h)(5), we have addressed concerns related to the 2020 bid submission.

Comment: A commenter stated that CMS should oversee plan actuarial equivalence determinations to ensure that beneficiaries with copayments receive the intended benefits of the rule through reduced cost sharing. The commenter further stated that CMS should ensure that plan sponsors and PBMs "reduce copayments for the tier on which the prescribed medicine

is placed that maintains actuarial equivalence with the standard benefit design.”

Response: Comments related to CMS’s administration of the Part D program are outside the scope of this rulemaking. However, we are aware that actuarial equivalence requirements in the Part D program may require that plans adjust copayment amounts to reflect discounts that are protected under the point-of-sale safe harbor. Specifically, if the negotiated prices change, the benefit (*i.e.*, cost-sharing structure) must be adjusted to meet actuarial equivalence. Under the defined standard benefit design, lower negotiated prices would result in beneficiaries paying less cost sharing, in absolute terms, in each benefit phase. Under a tiered benefit design, the copayment or coinsurance amounts for the different tiers in each phase could be changed in various ways, as long as the overall cost-sharing structure results in beneficiaries being projected to pay no more in each phase than the beneficiaries’ share required under the defined standard for that phase.

Comment: Commenters raised concerns about the impact that changes included in the Proposed Rule could have on data reporting. Specifically, the commenter identified the following issues that the commenter asserted will require rulemaking or guidance by CMS in order to implement the Proposed Rule, citing Medicare Part D reporting requirements: whether there would be changes to the PDE report, and how claims would be reported where a rebate was provided; what the Proposed Rule’s effect is

on PDE data reporting procedures; whether point-of-sale price concessions would be reported on the estimated rebate fields, how they would be used on market shares, or what process would be used to reconcile over- or under-payments of point-of-sale price concessions to enrollees; how PDEs would be reported when wholesalers are involved; how claims would be reported when a rebate was provided that was later determined to be ineligible (e.g., due to 340B, denial, patient recoupment or duplicate claims); how point-of-sale price concessions or rebates would be reflected in DIR reports, and whether DIR reporting procedures would be revised, including to account for new requirements for PBM service fees; and would CMS need to create an agreement to allow for information to be shared by manufacturers to CMS since confidential data are being collected and reported.

Response: Establishment of mechanisms for avoiding duplicate discounts or resolving disputes or errors regarding rebates is outside the scope of this rule. Comments about CMS's administration of the Part D program, including compliance with CMS requirements relating to PDE reporting for when a claim is re-processed as a result of such mechanisms, are outside the scope of this rulemaking.

Comment: A commenter asked whether CMS will adopt the same definitions as OIG, including the definition of a rebated or discounted drug.

Response: Comments about CMS's administration of the Part D program are outside the scope of this rulemaking. This question would be best addressed by CMS.

Comment: Several commenters stated that D-SNP beneficiaries¹⁴ qualify for low income subsidies that reduce their cost-sharing responsibilities for brand and generic drugs to nominal amounts, so the Proposed Rule will most likely not result in a material change in their experience. These commenters are concerned that if premiums increase it could impact coverage affordability for D-SNP beneficiaries. Other commenters requested adopting a broad interpretation of the term "plan sponsor under Medicare Part D."

Response: We are finalizing the revisions to the safe harbors as they apply to reductions in price or other remuneration in connection with the sale or purchase of a prescription pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D, without distinguishing among Part D plan types.

Comment: Several commenters sought guidance on the interaction of the changes in the Proposed Rule with the Part D definition of "negotiated price." A commenter stated that CMS should update its cost-sharing rules to align with the proposed point-of-sale reductions in price safe harbor. The commenter urged CMS to finalize its definition of negotiated price in the MA and Part D proposed rule, "Modernizing Part D and Medicare

¹⁴ Dual Eligible Special Needs Plans (D-SNPs) enroll beneficiaries who are entitled to both Medicare and Medicaid.

Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses,” and to provide additional guidance. Some commenters stated that the definition of “negotiated price” at 42 CFR 423.100 would need to be revised for several reasons, including: to incorporate price reductions processed via chargebacks itemized at the point of sale, because changes to the Proposed Rule would eliminate a portion of the DIR currently negotiated, or to ensure stakeholders can comply with not only the new safe harbors, if finalized, but also applicable Part D regulations.

Another commenter stated that CMS should clarify the definition of negotiated price to clearly reflect the discounts protected by the new safe harbor. The commenter also stated that CMS should adjust the Part D benefit design to accommodate the reduced negotiated prices. The commenter further asserted that CMS should recalculate the portion of the overall program cost that beneficiaries are responsible for paying by using the reduced negotiated prices. This adjustment, the commenter stated, would lower the deductible, the initial coverage limit, and the catastrophic threshold to reflect the reduced cost of the standard benefit package. The commenter stated that this adjustment also would likely result in Part D plans lowering copayment amounts on specific formulary tiers, since those are also calculated based on the portion of the negotiated price for drugs placed on those tiers.

Response: Comments related to CMS’s administration of the Part D program, including the definition of negotiated price,

are outside the scope of this rulemaking. However, we are aware that actuarial equivalence requirements in the Part D program may require that plans adjust copayment amounts to reflect discounts that are protected under the point-of-sale safe harbor. This rule does not change the definition of "negotiated price" at 42 CFR 423.100.

Comment: A commenter requested guidance on the application of the provisions of the Proposed Rule to various kinds of pharmacies that the commenter indicated will have different applications and expectations, including LTC, mail-order, and specialty pharmacies.

Response: As the commenter did not provide information on which provisions included in the Proposed Rule would affect categories of pharmacies differently, we are unable to respond more fully to this comment. We note that the amendment to the discount safe harbor does not affect discounts on prescription pharmaceutical products offered to entities such as pharmacies,¹⁵ as long as the arrangement meets all the existing requirements of the safe harbor; the amendment only impacts discounts from a manufacturer directly to a plan sponsor under Medicare Part D or indirectly to the plan sponsor, through a PBM acting under contract with it.

Comment: A commenter recommended that independent community pharmacies should assume no liability for implementation of the changes included in the Proposed Rule. For example, if the

¹⁵ 84 FR 2348.

system required fees, the commenter stated, the fees should not be paid by pharmacies. The commenter also suggested that independent community pharmacies' reimbursements should not be affected by price reductions that are agreed upon between the plan or PBM and the manufacturer.

Response: The final rule does not require fees, but only provides a safe harbor from liability under the anti-kickback statute for certain fees or other remuneration, under certain conditions. Whether pharmacy reimbursements are affected by price reductions agreed to between manufacturers and PBMs or plans for purposes of compliance under this rule will depend on the particulars of private contracting between the parties.

Comment: Commenters raised questions about implementing the new safe harbor for point-of-sale reductions in price in light of Part D requirements. A commenter stated that CMS should provide guidance on how point-of-sale discounts apply to Medicare Secondary Payer claims, how point-of-sale discounts will impact vaccine administration fees, and whether point-of-sale discounts would change enrollment eligibility for MTM programs based on exceeding a set annual out-of-pocket cost.

Response: We have coordinated with CMS on the promulgation of the point-of-sale safe harbor to ensure that this rule can operate effectively in conjunction with the Part D program rules. Requests for CMS to issue guidance regarding the Part D program matters raised by the commenters are outside the scope of this rule.

Comment: A commenter recommended amending the proposed safe harbor for point-of-sale reductions in price to require plans' compliance with tiering and coverage requirements for generic and biosimilar products, including automatic coverage of generic and biosimilar medicines immediately after launch, placement of generic-only tiers, and a dedicated specialty tier for specialty generics and biologics.

Response: We do not believe we can make the suggested changes to the proposed point-of-sale safe harbor because we did not propose them. Moreover, even had we proposed them, we do not believe it would be necessary to include compliance with Part D tiering and coverage requirements for generic and biosimilar products in the safe harbor. We believe the conditions in the final safe harbor are sufficient to address program integrity risk with respect to the specific remuneration being protected. Nothing in the final rule changes any requirement of the Part D program, and parties are required to comply with all applicable CMS rules.

iv. Medicaid

Comment: The majority of commenters who addressed Medicaid in their comments strongly opposed including Medicaid MCOs in the scope of the proposed changes to the discount safe harbor, with commenters positing that the change could harm state Medicaid programs, could impose unnecessary costs on states, and could lead states to make significant cuts to other parts of their Medicaid programs. A commenter highlighted that the

changes we proposed would introduce significant uncertainties to states without any clear benefit. Another commenter requested that the Department instead focus on reforming the Medicaid Drug Rebate Program (MDRP).

Several commenters also objected to, or did not understand, the inclusion of Medicaid in the proposed revisions to the discount safe harbor because, according to the commenters, the changes would not achieve the Department's goal of lowering beneficiaries' out-of-pocket spending. Per the commenters, beneficiaries are charged only nominal copayments in Medicaid and, except for a few plans, do not have coinsurance obligations. According to various commenters, because of the limited role of rebates in Medicaid managed care, passing through reductions in price for Medicaid beneficiaries will benefit only a few enrollees by a marginal amount or will be irrelevant. These commenters further questioned whether there would be any incentive for manufacturers to provide point-of-sale price reductions in Medicaid at a level equal to or similar to the savings leveraged through the current framework.

Response: Upon consideration of the comments received, we are persuaded that we should not move forward with our proposal to revise the discount safe harbor to exclude rebates offered to Medicaid MCOs. In the Proposed Rule, the Department articulated its concern that "rebates are often not applied at the point of sale to offset the beneficiary's deductible or coinsurance or otherwise reduce the price paid at the pharmacy counter," which

the Department hypothesized could be increasing financial burdens for beneficiaries.¹⁶ For these reasons, the Department proposed to eliminate protection for rebates provided to Medicaid MCOs and to offer protection for point-of-sale reductions in price for a prescription pharmaceutical product payable, in whole or in part, by a Medicaid MCO. As noted by commenters, however, Medicaid beneficiaries generally have nominal cost-sharing obligations for prescription pharmaceutical products. Additionally, although State Medicaid agencies have flexibility to design alternative cost-sharing arrangements for Medicaid beneficiaries, generally Medicaid MCO contracts must meet cost-sharing requirements for drugs in 42 CFR 447.53. See 42 CFR 438.108. These requirements set maximum allowable cost-sharing amounts for preferred and non-preferred drugs. Given these circumstances and existing regulatory requirements, we believe 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.

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 safe harbor for point-of-sale reductions in price at § 1001.952(cc). As discussed in more detail below, however, we note that neither the discount safe

¹⁶ 84 FR 2341-42.

harbor nor the new safe harbor protects rebates or other reductions in price from a manufacturer that are retained by a PBM, even if that PBM is operating on behalf of a Medicaid MCO.

Comment: Some commenters supported application of the changes to the discount safe harbor to Medicaid as well as to Medicare, other Federal health care programs, and the commercial markets.

Response: For the reasons stated above, we have decided not to move forward with our proposal to revise the discount safe harbor as it applies to Medicaid MCOs.

Comment: Several commenters stated that the changes in the Proposed Rule, if finalized, would create an unlevel playing field in Medicaid programs because they would eliminate safe harbor protection for supplemental rebates negotiated by Medicaid MCOs (or PBMs with which they have contracted) while continuing to protect supplemental rebates received by states directly under Medicaid fee-for-service programs. According to several commenters, because states would be able to negotiate supplemental rebates even if the Proposed Rule were finalized, the changes in the Proposed Rule would incentivize states to carve out the outpatient prescription drug benefit or to adopt a state-mandated preferred prescription drug list to maximize supplemental rebates. A commenter also stated that states may seek larger supplemental rebates, which a commenter noted do not count towards Best Price. Commenters that raised this issue listed several concerns with this result. For example, they

noted that carve-out arrangements inhibit Medicaid MCOs' ability to manage the full range of healthcare items and services for beneficiaries under their care.

Response: We are not finalizing the changes to the discount safe harbor with respect to Medicaid MCOs, which addresses the commenters' concerns.

Comment: Multiple commenters discussed the importance of supplemental rebates to the Medicaid program and Medicaid MCOs. Numerous commenters noted that Medicaid supplemental rebates are an important tool for states in controlling drug spending, with a commenter noting that 46 states and the District of Columbia have supplemental rebate agreements and collected about \$1.2 billion in supplemental rebates during fiscal year 2017.

Additionally, various commenters requested clarification relating to the treatment of supplemental rebates paid by manufacturers to Medicaid MCOs and supplemental rebates paid by manufacturers to state Medicaid agencies. Specifically, several commenters sought clarification as to how Medicaid drug payment provisions in section 1927 of the Act relate to protection for supplemental rebates under the Proposed Rule and, in particular, whether such supplemental rebates are "required by law," which was a carve out to our exception in our proposal to eliminate discount safe harbor protection for reductions in price from manufacturers to Medicaid MCOs. Certain commenters asserted that manufacturers' legal obligations under the MDRP also extend to Medicaid supplemental rebates, which the commenters used to

support the position that the discount safe harbor would continue to protect supplemental rebates negotiated between states and manufacturers. Other commenters recommended that, if OIG moves forward with including Medicaid MCOs in the changes to the discount safe harbor, OIG should clarify that supplemental rebates negotiated by Medicaid MCOs but received directly by state Medicaid agencies are protected.

In addition, several commenters noted that Medicaid MCOs often retain full risk in connection with prescription drug coverage and use supplemental rebates to lower overall costs for state Medicaid programs or to defray capitation costs. Another health plan commenter asserted that with reduced flexibilities to manage drug costs through Medicaid supplemental rebates, the Medicaid program may become less attractive to MCOs, which may decrease health insurance choices for consumers. In the alternative, a commenter recommended that OIG prohibit all supplemental rebates negotiated across Medicaid fee-for-service and Medicaid managed care.

Commenters noted their concerns about the potential for state Medicaid program drug expenditures to increase if the changes in the Proposed Rule limit the existing ability of Medicaid programs to negotiate supplemental rebates. Other commenters estimated that Medicaid costs may rise because of the loss of safe harbor protection for supplemental rebates to Medicaid MCOs, which could lead states to decrease other benefits, cut provider payments, or make other cuts to state

Medicaid programs to make up for these higher costs. Another commenter raised concerns that in the absence of PBMs, states will not be able to adapt and negotiate directly with manufacturers for supplemental rebates. Another commenter noted that many PBMs operating on behalf of Medicaid MCOs already pass through the entire supplemental rebate to health plans they contract with, which are bound by federal and state rate setting and reporting requirements, so eliminating supplemental rebates to Medicaid MCOs will not create any additional transparency in this area. However, another commenter stated that more transparency regarding supplemental Medicaid rebates collected by PBMs and Medicaid MCOs is still needed for states to completely capture the value of Medicaid supplemental rebates paid to PBMs.

Response: As discussed in detail above, we are not finalizing the changes to the discount safe harbor with respect to Medicaid MCOs, which addresses many of the commenters' concerns. We reiterate that this final rule does not alter obligations under the statutory provisions for Medicaid prescription drug rebates under section 1927 of the Act, including without limitation the provisions related to best price, the additional rebate amounts required for certain drugs based on the rate of increase in AMP and the increase in the consumer price index for all urban consumers (CPI-U), or provisions regarding supplemental rebates negotiated between states and manufacturers.

Comment: Several commenters raised a number of concerns about administrative burdens that would be imposed on states and Medicaid MCOs with respect to implementing and operationalizing this rule; for example, a commenter noted that states would be required to set and certify new Medicaid MCO rates. Another commenter stated that affected entities (e.g., Medicaid MCOs, states, PBMs, pharmacies) will all need to renegotiate their contracts, some of which may require state legislative or agency approval. Another commenter explained that Medicaid managed care contracts are generally effective for several years and states often operate on a fiscal year that differs from the calendar year. The commenter believes that providing states limited time to renegotiate multi-year contracts, or to make midyear adjustments, would be potentially unfeasible.

Response: We are not finalizing the changes to the discount safe harbor with respect to Medicaid MCOs, which addresses the commenters' concerns.

Comment: A number of commenters raised various questions or concerns with respect to the implications of the changes included in the Proposed Rule for calculations of AMP, Best Price, and Federal Upper Limits. For example, several commenters stated that the Proposed Rule would result in increased costs to taxpayers because of changes to AMP calculations. According to a number of commenters, if changes in the Proposed Rule lower the AMP, it will result in reductions to drug rebate revenue under the MDRP, which will increase

Medicaid program costs. Similarly, commenters expressed concern that a lower AMP might reduce Federal Upper Limits or the National Average Drug Acquisition Cost invoice pricing data and, in turn, could reduce Medicaid reimbursement to pharmacies. A commenter contended that it is critical that the change to point-of-sale discounts not affect AMP.

As a result of these concerns and questions, a number of commenters requested that CMS issue guidance regarding whether point-of-sale chargebacks are included in calculations of AMP. Commenters who did not want these chargebacks to be included in AMP calculations generally recommended that such guidance explain that point-of-sale chargebacks fit into one of several types of statutorily excluded discounts to AMP. Another commenter posited that the Proposed Rule was ambiguous and could allow a point-of-sale discount to be construed as a PBM or payor concession, a pharmacy concession, or a direct-to-patient concession, which could have AMP and Best Price implications.

With respect to the calculation of Best Price, a commenter stated its position that point-of-sale chargebacks fall within an exemption to Best Price. Other commenters raised concerns that removing the protection for Medicaid supplemental rebates and moving toward point-of-sale discounts would raise Best Price, which the commenters posited would ultimately reduce the amount manufacturers pay in rebates under the MDRP. Another commenter requested that OIG or HHS confirm whether, and how, the final rule may affect existing regulations regarding the

calculations for the Medicaid fee-for-service program Federal Upper Limit calculations as it relates to the formula for the National Average Drug Acquisition Cost and the Cost to Dispense pharmacy dispensing fee.

Response: The Department recognizes that the final rule has the potential to affect calculations of AMP, Best Price, and Federal Upper Limits in ways and to an extent that may be difficult to anticipate. However, we are not finalizing the changes to the discount safe harbor with respect to Medicaid MCOs. We reiterate that the final rule does not alter obligations under the statutory provisions for Medicaid prescription drug rebates under section 1927 of the Act, including AMP, Best Price, and Federal Upper Limits.

Comment: A commenter asserted that brand-name manufacturers launch authorized generics to lower a brand drug's AMP (and thus lower the manufacturer's statutorily required discounts under the MDRP).

Response: We did not propose to alter obligations under the MDRP and the issue raised by the commenters is out of scope of this final rule.

Comment: Commenters raised concerns about the potential effects on value-based arrangements in several Medicaid programs if the Proposed Rule were to be finalized. Several commenters highlighted three value-based contracting models that allow states to align supplemental rebates with outcomes-based and value-based measures.

Response: We believe our decision not to finalize the changes to the discount safe harbor with respect to Medicaid MCOs addresses the commenters' concern.

Comment: A commenter requested that the Department clarify in the final rule that entities that operate under contract with a state are protected under the revised discount safe harbor. The commenter provided an example of multi-state purchasing organizations that create preferred drug lists, and the commenter explained that it is not clear whether these entities would be protected under the revised discount safe harbor because they are not "states."

Response: Because we are not moving forward with the proposed changes to the discount safe harbor with respect to Medicaid MCOs, we believe the commenter's concerns are addressed.

Comment: A commenter specifically requested that OIG clarify whether the final rule would explicitly exclude Puerto Rico's Medicaid rebate system from the amendment to the discount safe harbor, because Puerto Rico's Medicaid program does not currently participate in the MDRP.

Response: Because we are not moving forward with the proposed changes to the discount safe harbor with respect to Medicaid MCOs, we believe the commenter's concerns are addressed.

v. Commercial Market

Comment: Numerous commenters supported the extension of this proposal to the commercial market, stating that plans and drug companies will be motivated to maintain high list prices if rebate arrangements continue to permeate the commercial market. According to the commenters, the benefits associated with the proposal, such as reduced out-of-pocket costs and improved access to medication, will be limited if the proposal is not extended to the commercial market. For example, a pharmaceutical-manufacturer commenter in favor of eliminating rebates in the commercial sector explained that rebates and discounts for its products have increased in Part D and the commercial sector, even though the affordability of drugs continues to be a public health issue. Another commenter was opposed to extending the provisions of the Proposed Rule to the commercial market and stated that rebates are an important tool used by PBMs to negotiate lower prices from drug companies on behalf of employers and private health plans.

Response: The scope of the anti-kickback statute is limited to remuneration that is offered, paid, solicited, or received in order to induce or reward Federal health care program business. Commercial, private pay, or self-pay arrangements that do not touch Federal health care program beneficiaries in any manner do not implicate the Federal anti-kickback statute (except in the context of swapping arrangements or pull-through type arrangements in which discounts might be given only on private

pay business to induce the referral of Federal health care program business). In other words, the anti-kickback statute generally does not extend to arrangements involving purely commercial business; as a result, it is beyond the scope of this rulemaking to extend such safe harbors to the commercial market.

Comment: Several commenters supported future efforts to extend this proposal to the commercial market but recommended ensuring successful implementation of the rule in Medicare Part D before addressing rebates in the commercial market. A commenter noted that the wholesale conversion of both Federal health care programs and the commercial market could cause confusion in the marketplace and disrupt patient access to medications. Specifically, the commenter noted there would be many new operational and system requirements for applying the point-of-sale discount. In addition, the commenter explained that it is vital to see how health plans may change their benefit designs in response to the rule, which could include changes to formularies and greater cost sharing, before this proposal is extended to the commercial market.

Response: Extension of the revised discount safe harbor and the two new safe harbors to the commercial market is beyond the scope of this rulemaking.

Comment: Several commenters asserted that if the Proposed Rule is finalized, drug-related costs will shift to the commercial market, with a commenter noting that employers may change plan offerings for prescription drugs as a result of

these increased costs, which could harm individuals in private plans.

Response: Since the changes under the final rule may result in a range of market responses, the Department respectfully disagrees that drug-related costs will necessarily shift to the commercial market and result in harm to individuals in private plans. Instead, the Department expects that manufacturers will lower list prices, which could result in lower costs across both the Part D and the commercial markets.

Comment: A commenter requested guidance on when rebates that are offered to commercial plans, but not to Medicare or Medicaid, may implicate the anti-kickback statute. Specifically, the commenter requests acknowledgement that OIG rules relating to "swapping" do not apply as long as there is no *quid pro quo* between a manufacturer price concession offered on a plan's or PBM's commercial utilization and a price concession offered on such a plan's or PBM's Federal health care program utilization.

Another commenter raised concerns about the statements in the Proposed Rule that indicated commercial rebates outside of Federal health care programs tied to formulary placement across all plans, including Federal health care programs, may not be protected by the current discount safe harbor or proposed revisions. The commenter claimed that this statement could have a chilling effect on negotiations between private health plans and employers or individuals.

Other commenters expressed concern that if the conditions of safe harbors included the Proposed Rule do not apply to the commercial market, rebates in the commercial market could still be used to induce the purchase of products reimbursed by Federal health care programs. To address this concern, commenters recommended that the Department clearly indicate that rebates in the commercial market will be scrutinized to ensure that they are not being offered to influence the purchase of products by Federal health care programs.

Response: While the anti-kickback statute is not implicated in arrangements that involve only commercial, private pay, or self-pay arrangements, we noted in the Proposed Rule that we have "a long-standing concern about arrangements that 'carve out' referrals of Federal health care program beneficiaries or business generated by Federal health care programs from otherwise questionable financial arrangements."¹⁷ We would have similar concerns with arrangements that involve remuneration offered under the guise of an arrangement limited to commercial-pay or private-pay patients but is, in reality, part of a broader arrangement to induce referrals of Federal health care program business or patients. As we noted in our final rule published in 1999, "such 'swapping' arrangements, which essentially shift costs to the Federal health care programs, continue to be of concern to this office."¹⁸ In any of these circumstances, arrangements would need to be reviewed for

¹⁷ 84 FR 2347.

¹⁸ 64 FR 63528.

compliance with the anti-kickback statute, but whether a specific arrangement constitutes a problematic swapping arrangement depends on the facts and circumstances, and we decline to adopt the *quid pro quo* standard suggested by a commenter. Individuals or entities are free to request protection from sanctions under the anti-kickback statute for specific arrangements through our advisory opinion process.

Comment: A commenter asserted that the Department should not attempt to reform the current commercial market rebate system through the anti-kickback statute and noted that due to the complexity of the commercial market, any changes to the commercial market rebate system should be undertaken carefully and incorporate feedback from a range of stakeholders.

Response: As discussed above, the anti-kickback statute only prohibits remuneration that is offered, paid, solicited, or received to induce or reward Federal health care program business. The statute generally is not implicated when the arrangements involve purely private-pay business.

Comment: Several commenters noted that certain PBMs and insurers have recently announced point-of-sale rebate sharing in the commercial market, which may signify that the infrastructure and capacity to adopt these reforms in the commercial market already exist. However, a commenter indicated that these point-of-sale rebate benefit designs are being offered at a higher premium than standard designs and that it is too early to

determine if enrollment in these options will be robust or limited.

Response: We appreciate the commenters' insights into the dynamics of this market. As we discuss above, we understand that some commercial plans may be operationalizing point-of-sale benefit designs and, as the commenters suggest, we believe that some industry stakeholders have the capabilities to operationalize point-of-sale reductions in price that would be protected under the new safe harbor.

vi. Value-based Arrangements

Comment: Some commenters stated that value-based arrangements would not neatly fit into the new safe harbor for point-of-sale reductions in price because they typically rely on gathering data after the point of sale and making payments after the point of sale. Commenters expressed an interest in allowing value-based arrangements to be protected by a safe harbor, stating that value-based arrangements provide an important opportunity to address drug prices by paying the value of a drug if it achieves the desired outcome, while paying a lower price if it does not work. Other commenters expressed concern that if the changes to the discount safe harbor are finalized but an exception is made so that value-based arrangements continue to receive protection under the discount safe harbor, parties might recast rebate arrangements that otherwise would be prohibited as "value-based arrangements" in order to continue to receive protection under the discount safe harbor.

Response: The Department recognizes the importance of value-based contracting for prescription pharmaceutical products as an evolving tool to improve quality of care and potentially reduce costs.¹⁹ Upon reflection, we agree that not all value-based pharmaceutical arrangements for Part D prescription drugs would fit into the revised discount safe harbor or the new safe harbor for point-of-sale reductions in price. We believe that some value-based arrangements involving prescription pharmaceutical products might 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, warranties safe harbor). To the extent 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. Any value-based arrangement (whether under Part D or another Federal health care program) must be analyzed on a case-by-case basis under the statute and with respect to available safe harbor protection. With respect to the concern about recasting rebate arrangements as value-based arrangements, we note that labeling an arrangement as "value-based" does not necessarily make it so, and any arrangement (whether labeled as value-based or otherwise) must still comply with all conditions of a safe harbor.

¹⁹ See, e.g., 84 FR 55694, 55704 (Oct. 17, 2019).

Comment: Some commenters expressed concern that excluding value-based arrangements from the discount safe harbor may limit the effectiveness of PBMs, plan sponsors, or other third parties that play, or could play, a valuable role in designing effective prescription drug programs, treatments, and therapies, and in ensuring drug manufacturers are held accountable for certain outcomes-based metrics.

Response: We thank the commenters for raising these concerns. As described above, the Department remains committed to promoting value-based arrangements that have the potential to improve the quality of care provided to beneficiaries while lowering overall costs to Federal health care programs. The final rule does not prohibit those entities highlighted by the commenters, including but not limited to PBMs and plan sponsors under Part D, from being able to continue to negotiate value-based arrangements with manufacturers that aim to achieve these goals.

Comment: A commenter suggested that, because value-based arrangements would remain within the safe harbor, value-based arrangements will expand.

Response: As described above, we recognize that the changes to the discount safe harbor may result in certain value-based arrangements no longer being eligible for protection under the discount safe harbor. However, the Department continues to encourage the development and implementation of arrangements

that work to transform the health care system into one that better pays for value.

Comment: Several commenters expressed concern that the proposed revision to the discount safe harbor, without further guidance from OIG on its applicability to value-based arrangements, may deter, chill, or impede drug manufacturers, PBMs, or plans from entering into, developing, implementing, negotiating, or continuing under value-based arrangements. Several commenters expressed concern about and described examples of value-based arrangements that may implicate the anti-kickback statute and not be protected under the safe harbors set forth in the Proposed Rule. For example, under an outcomes-based arrangement, drug manufacturers may or must, contractually, provide rebates or refunds if a specific medication is not effective—or not as effective as indicated—after an individual has used the specific medication. The commenter then posited that a point-of-sale discount would not be practical or possible because the rebate or refund is contingent upon or influenced by a specific outcome and is provided after the point of sale has already occurred. Other commenters requested that OIG allow flexibility or sufficient time after the effective date of the final rule for drug manufacturers, PBMs, and plans to re-negotiate or terminate value-based arrangements that may not satisfy the conditions of the proposed revisions to the existing discount safe harbor or the new safe harbor at 42 CFR 1001.952(cc). Another commenter

expressed concern that, even if value-based arrangements are protected under the proposed amendments to the discount safe harbor and the proposed new safe harbor for point-of-sale reductions in price, drug manufacturers may be deterred from offering certain discounts if competitors know or can determine each other's discount values.

Response: Value-based arrangements, like all arrangements that implicate the anti-kickback statute, must be analyzed on a case-by-case basis. We agree with commenters that not all value-based pharmaceutical arrangements for Part D prescription drugs may qualify for protection under the revised discount safe harbor or the new safe harbor for point-of-sale reductions in price. As we note above, other safe harbors could apply, such as the personal services and management contracts safe harbor or warranties safe harbor. The fact that an arrangement does not fit in a safe harbor does not mean it is necessarily unlawful. The terms of a particular arrangement would drive whether the anti-kickback statute is implicated and any safe harbor that might apply. We remind stakeholders seeking protection for value-based arrangements that the advisory opinion process remains available. Concerns about the effective date and transparency are addressed elsewhere in this preamble.

Comment: Another commenter requested that OIG clarify whether the revised discount safe harbor and/or the safe harbor for GPOs would, in appropriate circumstances, protect value-based contracting between manufacturers and healthcare

institutions or wholesalers/distributors, such as contractual arrangements with hospitals and integrated delivery networks.

Response: Whether the GPO safe harbor is appropriate for value-based contracting is beyond the scope of this rulemaking. Whether a value-based arrangement could use the GPO safe harbor would be a fact-specific determination.

vii. Enforcement Issues

Comment: In discussing the operational challenges of implementing the Proposed Rule, several commenters noted that it would create a new regulatory structure and that any mistakes are subject to criminal penalties under the anti-kickback statute. According to a commenter, this risk may prevent stakeholders from proceeding with implementation. As an example, the commenter explained that pharmacies may not operationalize the chargeback proposal because of potential liability under the anti-kickback statute.

Response: Compliance with a safe harbor is voluntary, and arrangements that do not comply with a safe harbor—because of mistakes or otherwise—are analyzed based on their facts and circumstances. The failure to meet the conditions of a new safe harbor does not automatically subject one to criminal penalties. The anti-kickback statute is an intent-based statute; mere errors or mistakes would not trigger concerns absent other facts evidencing unlawful intent to induce referrals. In addition, as with our other safe harbors, the advisory opinion process remains available for parties that seek to determine if an

arrangement or proposed arrangement satisfies the criteria of the safe harbor.

Comment: A commenter recommended that OIG work with several agencies, including the DOJ and the FTC, to develop guidance for the industry with respect to a final rule. The commenter explained that this guidance is particularly important as it renegotiates contracts in order to avoid possible civil and criminal penalties. As one example, the commenter requested guidance on various types of swapping arrangements. Another commenter asked for affirmative guidance from OIG on a number of enforcement-related topics. For example, the commenter requested that OIG declare in the final rule that it expects industry-wide compliance with the anti-kickback statute with respect to the reductions in price and service fee arrangements covered under the new safe harbors. The commenter also asked OIG to state that it will subject PBMs to heightened scrutiny for any arrangements conditioned on formulary placement that do not fit within the new safe harbors.

Response: The Department regularly collaborates with our government partners, as appropriate. Any requests for the Secretary to issue sub-regulatory guidance jointly with other agencies or to issue affirmative guidance is outside the scope of this safe harbor rulemaking. OIG publishes guidance from time to time on its webpage.

OIG agrees with the commenter that the proper question is whether entities are in compliance with the anti-kickback

statute; we reiterate, however, that compliance with a safe harbor is voluntary. Any arrangement that implicates the anti-kickback statute and does not satisfy an exception or safe harbor would be subject to scrutiny; as discussed in more detail below, we reiterate our concern about any kind of payment to buy or provide remuneration tied to formulary placement that is not a safe harbored reduction in price.

Comment: Several pharmaceutical manufacturer commenters raised concerns with respect to PBMs' response to the new safe harbor, stating that PBMs may take aggressive positions on interpretations of the anti-kickback statute or the new safe harbors and require manufacturers to accept that legal position to access the PBMs' beneficiaries. For example, the commenters stated that a PBM might interpret the anti-kickback statute to permit rebates to PBMs or might take the position that safe harbor compliance is not required.

Response: With respect to the commenters' concerns surrounding PBMs' interpretation of changes to the safe harbor provisions, we emphasize that, while compliance with the terms of a safe harbor is voluntary, an arrangement is protected only if all conditions of a safe harbor are met. We want to take this opportunity to confirm our position, as stated in the preamble to the Proposed Rule, 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.²⁰ The discount safe harbor protects a reduction in price to a buyer. 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 a reduction in price. Dating back to the 1991 Final Rule,²¹ we have made a distinction between (i) fees that would fall under personal services contracts and (ii) discounts; a discount is a reduction in price, not payment for a service. Payments to a PBM for services could be protected under other safe harbors if all relevant safe harbor conditions are met.

PBMs can provide valuable services for health plans and manufacturers and can be compensated for those services. To the extent such compensation implicates the anti-kickback statute, it can be structured to comply with a safe harbor (such as the personal services and management contracts safe harbor or new PBM service fee safe harbor). However, we note generally that we would have significant concerns with arrangements for services that are not necessary, are worthless, or are duplicative and that operate as shams designed to reward a party for referrals of Federal health care program items or services; these concerns apply with equal force to both the payor and the recipient of remuneration, and our approach to enforcement has and will, as business practices and incentives evolve, continue to reflect that. Such arrangements would not be protected under any safe harbor.

²⁰ 84 FR 2343 n.36.

²¹ 56 FR 35952.

Comment: Several commenters requested that OIG engage in some type of enforcement discretion during implementation of a final rule, with a commenter citing to the final rules in 1991 and 1999 as examples of instances where the Department has considered enforcement discretion. A commenter suggested that, if the rule is finalized, OIG should issue a statement of non-enforcement for a period of two years because Part D bids will be based on safe harbor rules in effect at the time of the bids, while the plans may operate under different safe harbors in the plan year. A commenter requested that OIG publish a policy statement that it will not enforce the anti-kickback statute where PBMs serve as point-of-sale chargeback administrators that implement the point-of-sale discounts. Another commenter asked that the Department permit the distribution of rebates where the terms of the rebate arrangement were set prior to January 1, 2020.

Response: As explained elsewhere in this final rule, the amendments to the discount safe harbor at § 1001.952(h)(5) do not take effect until January 1, 2022. We recognize that many parties have previously structured their arrangements based on the advice of an attorney and in good-faith belief that their arrangements were legal under the discount safe harbor, and any arrangements that comply with that safe harbor remain protected until that effective date. The new safe harbor for point-of-sale reductions in price will be effective and available for use 60 days after publication of this final rule. The Department

encourages parties to use the new safe harbor as rapidly as possible. We are not issuing an enforcement discretion policy given the length of time parties have under the final rule to come into compliance with the amended safe harbor. We also decline to adopt the commenter's suggestion to exercise enforcement discretion where PBMs serve as point-of-sale chargeback administrators that implement the point-of-sale discounts.

viii. State Law Issues

Comment: Several commenters raised concerns about various state laws, such as state trade secrets or privacy laws, that could be implicated by the Proposed Rule.

Response: We are not in a position to respond to comments on state laws. As we stated in our 1991 rulemaking, "[i]ssues of state law are completely independent of the federal anti-kickback statute and these [safe harbors]. . . . Thus, conduct that is lawful under the federal anti-kickback statute or [safe harbors] may still be illegal under State law."²² Similarly, state laws governing trade secrets or privacy issues are outside the scope of this rulemaking.

ix. Other Legal Issues

Comment: Some commenters raised Administrative Procedure Act (APA) concerns. For example, a commenter urged the Department to adhere to the duty to review and take into account public comments received. Another commenter stated that the

²² 56 FR 35957.

Proposed Rule fails to provide clear examples of the harm that it would remediate. In particular, the commenter claimed that the rule describes a policy rationale, but it does not explain what type of "inducement" the Proposed Rule would prevent. A commenter suggested that aspects of the Proposed Rule do not meet the APA's requirement to include sufficient detail to allow for meaningful comment. For example, the commenter stated that the preamble does not provide enough detail to explain how chargebacks would work so that industry stakeholders can meaningfully comment.

Response: The Department reviewed all comment letters, took into account all relevant public comments, and considered relevant impacts and program integrity concerns in developing this final rule. With respect to the questions set forth by commenters about the substantive sufficiency of the Proposed Rule, we respectfully disagree. Discounts of any kind serve as an inducement to purchase an item or service, and the anti-kickback statute specifies that a "rebate" is a form of inducement. The Proposed Rule sets forth the authority from Congress for establishing or modifying safe harbors, two of which include an increase or decrease in access to healthcare services and any other factors that the Secretary deems appropriate in the interest of preventing fraud and abuse in Federal health care programs.²³ The Proposed Rule extensively describes the problematic incentives with the current rebate

²³ 84 FR 2345.

system, including, but not limited to, the incentive to include higher-priced prescription drugs on formularies to capture larger rebates and the impact of higher list prices on beneficiaries.²⁴ In other sections of the Proposed Rule, such as the discussion of “chargebacks” that a commenter referenced, we not only made specific proposals but we also solicited comments on a number of issues. In fact, we received detailed and meaningful comments on chargebacks from almost 50 commenters, to which we respond elsewhere in this final rule. We did not include in the proposed safe harbor overly technical requirements about the administration of the chargeback process in order to provide private parties with the flexibility to design these systems, while offering numerous opportunities to comment.

Comment: Some commenters alleged that the Proposed Rule is arbitrary and capricious for a variety of reasons. For example, a commenter asserted that the Proposed Rule is arbitrary and capricious because it treats similar situations differently by continuing to protect rebates in Medicare Parts A and B without an adequate explanation. A commenter also asserted that there is not a rational connection between the concerns identified in the Proposed Rule and the proposed changes to the safe harbors. In support of this claim, the commenter asserted that a stated objective of the Proposed Rule is to reduce government program costs, but the regulatory impact analysis shows that costs will

²⁴ See, e.g., 84 FR 2340-44.

rise and noted that the rule expresses concern for beneficiary out-of-pocket costs while the impact analysis predicts increased beneficiary premiums. This commenter also claimed the proposed rule was asserting contradictory purposes in seeking to reduce the spread between list and net prices while also seeking to replace rebates from manufacturers to PBMs with discounts provided to beneficiaries at the point of sale. Another commenter expressed concern that the Proposed Rule may be arbitrary and capricious because, in the commenter's view, significant impacts, consequences, and results were overlooked or discarded in developing the Proposed Rule, such as potential effects on future enrollment in Part D and Medicaid MCOs, possible impacts on MCO-negotiated supplemental rebates and the antitrust implications of up-front discount negotiations. A commenter suggested that estimates of the time entities will spend updating systems to comply with the rule was underestimated.

Response: We believe the changes to the safe harbor protections that we are finalizing here are a reasonable and appropriate response to address harmful effects of rebates on beneficiaries in Medicare Part D and other Federal health care programs and will help to ensure that safe harbor protection is available only for non-abusive arrangements that are transparent and reflect an alignment of incentives among plan sponsors, manufacturers, beneficiaries, and the government. We appreciate the concern that the changes we proposed could be construed as

treating similar situations differently by removing protection for rebates in some Federal health care programs but not others. However, this characterization disregards the fact that many safe harbors, including the discount safe harbor, differentiate between the protection afforded to arrangements involving different Federal health care programs in order to target protection to non-abusive arrangements. The Proposed Rule was developed in response to certain abusive rebate arrangements that have been identified in the specific context of Medicare Part D, and therefore the proposal was structured to remove protection for those abusive arrangements. Moreover, we solicited comments on whether the amendment also should apply to prescription pharmaceutical products payable under other Federal health care programs.²⁵ As we discuss elsewhere in this final rule, commenters agreed that the amendment should not be expanded to other programs. Accordingly, we concluded that the amendment should not be expanded to other programs. In particular, as explained above, we are not finalizing our proposal to apply the amendment to Medicaid MCOs.

Similarly, we believe the final rule rationally and effectively advances the regulatory goals of transparency and "alignment of incentives."²⁶ Specifically, the rule addresses the problem that rebate arrangements among Part D plan sponsors, pharmacy benefit managers, and pharmaceutical manufacturers are not transparent to the government or beneficiaries and

²⁵ 84 FR 2347.

²⁶ 84 FR 2343-44.

incentivize higher list prices for drugs contrary to the interests of the Federal health care programs or beneficiaries. Accordingly, we proposed to eliminate the existing safe harbor protection for those abusive arrangements. We disagree that there is any conflict between seeking to lower list prices and concurrently working to ensure that any negotiated reductions to the list prices of drugs are provided in the form of discounts to beneficiaries at the point of sale. As discussed in the Proposed Rule, the current rebate framework for prescription pharmaceutical products does not appear to translate into lower Medicare per beneficiary spending on prescription drugs, when age and inflation are accounted for. The existing structure may be one of the factors driving list prices higher, which harms patients and Federal health care programs. The final rule directly addresses these issues.

Likewise, we disagree with the commenter who suggested that we ignored or disregarded certain impacts of the proposed changes to safe harbor protection for rebates. In the Proposed Rule, we expressly identified and solicited comment on the potential impacts of our proposals in the areas the commenter alleged we overlooked, including potential effects on future enrollment in Part D and Medicaid MCOs, possible impacts on MCO-negotiated supplemental rebates, and the antitrust implications of up-front discount negotiations. Furthermore, as discussed elsewhere in this final rule, we have taken commenters' feedback into account and have made adjustments to our proposals to

ensure that in each of these areas, the impact of the policies adopted in this final rule is not inconsistent with the Department's policy goals, including by narrowing the scope of the amendment to the existing discount safe harbor to allow for continued safe harbor protection of rebate arrangements between manufacturers and Medicaid MCOs.

Comment: Some commenters questioned OIG's authority to promulgate this rule because commenters suggested that the resulting rule would conflict with other Federal laws. For example, a commenter asserted that the Secretary is proposing a rule under one section of the Act that the commenter contends conflicts with another section of the Act, and in doing so it violates a tenet of administrative law (that an agency exceeds its authority when it promulgates a regulation that conflicts with a Federal statute). Another commenter asserted that even if section 1102 of the Act allows the Secretary to interpret terms in a criminal statute, such authority is limited to establishing rules consistent with the Act. This commenter stated that the Proposed Rule is inconsistent with the statutory discount exception and with statutory provisions governing Part D that are within the Act.

Response: We respond to comments highlighting differences between the Proposed Rule and specific statutes elsewhere in this rule. In general, however, we note that the safe harbor regulations are voluntary. Individuals and entities that choose to comply with a particular safe harbor have assurance that

their business practice will not be subject to an anti-kickback enforcement action. However, the safe harbor regulations “impose[] no requirements on anyone” and therefore do not put stakeholders in a position where they cannot comply with both a safe harbor and a Federal law.

Comment: Certain commenters highlighted specific Federal statutes with which they claim the proposed changes conflict and suggested that the statutes would control. For example, a commenter stated that Congress recognized when enacting the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) that “price concessions, such as discounts, ...[and] rebates” were important factors with respect to providing Part D coverage. Because the MMA specifically allows for different types of price concessions, the commenter asserted that the Department does not have the authority to require that all manufacturer price concessions be passed on at the point of sale. Another commenter noted that the MMA was enacted decades after the anti-kickback statute and includes several references to rebates in the Part D program and, as such, if there was a conflict in the Part D statute and the anti-kickback statute, then Part D's approval of rebates would control, both because it is more specific and because it was later-enacted. Several commenters stated that the proposed changes to the discount safe harbor directly conflict with the Part D program's statutory definition of “negotiated price.” Commenters stated that CMS has consistently interpreted the definition of “negotiated

price" and related Part D disclosure requirements as permitting Part D sponsors to choose how much of the price concessions they negotiate with manufacturers would be passed through to beneficiaries. A commenter stated that Congress confirmed CMS's interpretation in the Patient Protection and Affordable Care Act (PPACA) when it established the Coverage Gap Discount Program, which defines "negotiated price" to include rebates that the Part D sponsor has elected to pass through at the point of sale.

Response: For reasons stated elsewhere in this final rule, we disagree that the amendment of the safe harbor regulations conflicts with other Federal statutes. As stated previously, the safe harbor regulations impose no requirements and do not mandate any particular behavior, and thus do not conflict with other laws. The Department acknowledges that the Part D statute references manufacturer rebates and that CMS has viewed manufacturer rebates as an important factor in Part D sponsors' provision of the Part D benefit. However, it does not follow that because the Part D statute contemplates, and the Part D program historically has involved, manufacturer rebates, such rebates are always legitimate. Similarly, neither the statutory definition of "negotiated price" enacted in the MMA nor the subsequent adoption of another definition of "negotiated price" in the PPACA have any bearing on whether manufacturer rebates pose a risk of program abuse. As noted elsewhere in this rule, in recent years manufacturer rebates have become problematic.

It would be unreasonable to construe the Part D statute to permit under the anti-kickback statute rebates that the Secretary has determined pose a risk of program abuse pursuant to authority under the anti-kickback statute simply because they are mentioned in the Part D statute. Therefore, comments contending that the Part D statute "controls" are unpersuasive. The Part D statute does not - either expressly or by implication - limit the Secretary's authority to establish and revise safe harbors to curb rebating practices that the Secretary determines are abusive to Federal health care programs and beneficiaries.

Comment: Certain commenters claim that aspects of the Proposed Rule conflict with OIG guidance documents. For example, a commenter was concerned that the language in the point-of-sale reduction in price safe harbor requiring that the reduction in price must be completely applied to the price of the prescription pharmaceutical product charged to the beneficiary at the point of sale could lead manufacturers to apply the entire rebate to a beneficiary's cost sharing, which is contrary to OIG guidance on the use of coupons. Similarly, a commenter requested that the final rule preserve certain pricing exclusions, for example, the value of manufacturer-sponsored drug discount card programs, manufacturer coupons, manufacturer copayment assistance programs, and manufacturer-sponsored programs providing free goods if the benefit is not contingent on other purchases, which are excluded from AMP, Average Sales Price, and Best Price reporting. Other commenters cited the

2003 Compliance Program Guidance for Pharmaceutical Manufacturers,²⁷ noting that this guidance implicitly acknowledges that price reductions can be contingent on formulary placement by explicitly stating that lump sum payments for formulary placement would be subject to scrutiny. A commenter also stated that OIG has not previously challenged the practice of conditioning discounts on formulary placement. Another commenter noted that the use of formulary position to negotiate reductions in price is a long-recognized practice by plans.

Response: We thank the commenters for their insights. In this final rule we have revised the language of the safe harbor to clarify what we meant in the Proposed Rule when we said that the reduction in price must be completely reflected in the price the pharmacy charges the beneficiary at the point of sale. As we further explain elsewhere, 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 and responsible for paying the full cost of the drug). Our intent was for the reduction in price to be applied to the price of the drug upon which any beneficiary cost sharing is calculated. The issues related to AMP, ASP, and Best Price, and linking reductions in price to formulary placement are addressed elsewhere in this preamble.

²⁷ 68 FR 23731 (May 5, 2003).

Comment: Certain commenters cited to fundamental rules of fairness or generally urged OIG to acknowledge that the principles set out in the Proposed Rule are a change in law and would apply only prospectively. A commenter noted that OIG states in the Proposed Rule that many financial arrangements would "no longer" meet the discount safe harbor and that OIG has well-documented its awareness of rebates paid to PBMs. Another commenter stated that the Proposed Rule is an abrupt change in our longstanding interpretation of the statutory exception.

Response: We agree with commenters and acknowledge that the revisions to the discount safe harbor are a change with respect to certain rebates that the discount safe harbor at § 1001.952(h) will no longer protect. Enforcement of these changes would be prospective. However, as explained elsewhere in this final rule, not all payments labeled "rebates" are (or ever were) reductions in price. We address the statutory exception in section III.B.i below.

Comment: A commenter asserted that an agency's narrowing of protected conduct, resulting in expansion of criminal conduct, is not authorized and is impermissible. To the extent there is ambiguity, the commenter noted that the Rule of Lenity should apply and resolve ambiguity in favor of a defendant. The commenter cited to a Supreme Court case that held that "criminal laws are for courts, not for the Government, to construe."

Response: Revisions to the discount safe harbor at § 1001.952(h) do not expand the scope of the anti-kickback statute or remove protections offered under the statutory exceptions.

Comment: A commenter suggested that the Proposed Rule requires disclosure of rebates and price information and that such disclosure and potential for the public to access the information eliminates the value of these trade secrets, thus extinguishing a property right. Therefore, compliance with the Proposed Rule without compensation would violate the Takings Clause of the Fifth Amendment. Similarly, a commenter stated that any proposal that requires even a specific portion of manufacturer rebates to be passed through at the point of sale would expose confidential information in direct violation of the Trade Secrets Act.

Response: As a threshold matter, we reiterate that safe harbors were intended to evolve with changes in the health care industry, are voluntary, and do not require any party to take any action, including any disclosure of rebate or pricing information. Therefore, no property right is being extinguished and this final rule does not implicate the Takings Clause. Moreover, even for parties seeking to comply with the point-of-sale reduction in price safe harbor, we fail to see how the Trade Secrets Act at 18 U.S.C. 1905 would be implicated. That law prohibits certain Federal officers or employees from disclosing certain types of information received through the course of their employment or official duties, except where

authorized by law. Nothing about this safe harbor requires disclosure of rebates or pricing information to a Federal agency, so the law would not be implicated.

Comment: A commenter expressed concern that the chargeback system set forth in the Proposed Rule might incentivize manufacturers to deal only with a subset of pharmacies who agree to contract terms that are more stringent than what safe harbor compliance would require. The commenter noted that this would limit the effect of the any willing pharmacy provisions of the Part D program.

Response: Nothing about this final rule exempts any party from complying with other legal obligations, including any willing pharmacy provisions. We further note the point-of-sale reduction in price safe harbor requires that the reduction in price be completely reflected at the time the pharmacy dispenses it to the beneficiary.

Comment: Some commenters requested that we implement procedures outside of the advisory opinion process where parties can request interpretive guidance regarding the new safe harbors.

Response: We decline to implement procedures for parties to request individualized interpretive guidance related to the new safe harbors. OIG periodically issues materials (e.g., special advisory bulletins, special fraud alerts) that provide guidance on compliance with Federal health care program standards to relevant stakeholders.

x. Formularies

c. Formulary Placement

Comment: We received a number of comments related in some way to the Proposed Rule's statement that "[r]ebates paid by drug manufacturers to or through PBMs to buy formulary position are not reductions in price."²⁸ Several commenters stated that OIG's assertion that rebates negotiated in exchange for formulary position do not qualify as "a discount or other reduction in price" under the statutory exception conflicts with the statutory exception and is inconsistent with Federal price reporting rules and the agency's own past statements. Commenters requested clear guidance on the extent to which manufacturers and plans may consider formulary positioning and other utilization management techniques in negotiating discounts under the proposed point-of-sale reduction in price safe harbor, asserting that negotiating point-of-sale discounts that are contingent on formulary placement is an important tool for plans, or their PBMs, under the new point-of-sale reduction in price safe harbor and would provide an opportunity to lower patients' out-of-pocket expenses. A commenter further requested that OIG clarify whether a reduction in price for one drug contingent on formulary placement or other condition related to another drug would be protected under the proposed safe harbor, so long as the price reduction to patients applied at the point-

²⁸ 84 FR 2340.

of-sale is consistent with, for example, the allocation methodology used for price reporting purposes.

In contrast, other commenters recommended that OIG eliminate safe harbor protection for point-of-sale reductions in price conditioned on exclusive or preferred formulary placement when there are generic or biosimilar competitors and for multi-year formulary arrangements that preclude a plan sponsor or PBM from adding a generic or biosimilar to a formulary. In particular, commenters requested that OIG preclude point-of-sale discounts on a branded product in exchange for a plan not covering a competing generic or biosimilar product or placing the generic or biosimilar on the same or higher cost-sharing tier compared to the brand.

Response: We recognize that some statements in the Proposed Rule may have been misinterpreted, and we are taking this opportunity 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). As noted by commenters, we believe reductions in price contingent on formulary placement can foster competition among manufacturers to the ultimate benefit of beneficiaries and Federal health care programs, provided that

safety and efficacy considerations are not disregarded. Accordingly, under this final rule, we confirm that point-of-sale reductions in price can be conditioned on formulary placement and nonetheless qualify for protection under the new safe harbor at § 1001.952(cc), provided that there are no required services (e.g., marketing or switching), and all conditions of the safe harbor are met. Whether other arrangements would be considered a "service" that would not be protected, such as the scenario suggested by a commenter (conditioning a reduction in price on a formulary not covering a competing drug), would be subject to a case-by-case analysis.

Comment: Some commenters recommended prohibiting, through additional safeguards in the proposed safe harbor for PBM Service Fees or otherwise, drug manufacturers from tying any service fees or other compensation paid to PBMs to formulary placement. A commenter recommended this prohibition unless the compensation is paid by the manufacturer in exchange for services a PBM performs on a manufacturer's behalf to support the safe and effective use of medicines, for example, through risk evaluation or mitigation strategies. Another commenter recommended that OIG ensure payments for chargeback processing related to point-of-sale reductions in price are not disguised kickbacks related to formulary placement or exclusive arrangements.

Response: We agree with the commenters' concern about linking PBM service fees or point-of-sale chargeback

administration fees to formulary placement. As we stated in the 2003 Compliance Program Guidance for Pharmaceutical Manufacturers (2003 CPG), “[l]ump sum payments for inclusion in a formulary or for exclusive or restricted formulary status are problematic and should be carefully scrutinized.”²⁹ We reiterate here that any type of a “fee” (which would include any payment retained by a PBM) is not a discount or other reduction in price and therefore will not meet the discount safe harbor at § 1001.952(h) or the new safe harbor for point-of-sale price reductions at § 1001.952(cc) if it is tied to formulary placement. Similarly, the PBM service fee safe harbor protects fees for services that PBMs provide to manufacturers; developing a formulary is a service that a PBM provides to a plan. Therefore, those fees cannot be tied to formulary placement.

d. Impact on Formulary

Comment: Several commenters raised concerns relating to narrow formularies, with a commenter noting that plans may look for ways to minimize some of the cost increases caused by the loss of rebates by moving to exclusive contracts with manufacturers where only one manufacturer will be on the formulary in exchange for keeping discount levels stable. Another commenter posited that higher-cost prescription drugs may be placed on higher tiers or removed from formularies altogether.

²⁹ Office of Inspector General, *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 FR 23726, 23731 (May 5, 2003), available at <https://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>.

Several commenters predicted that it could take several years following the rule's implementation before formularies stabilize, while other commenters noted that the possibility of major formulary changes should be an essential aspect of any impact analysis and considered before the rule is finalized.

Response: OIG does not administer the Part D program; this responsibility lies with CMS. We are informed by CMS that they have and will diligently oversee a robust formulary review process to ensure sufficient inclusion of all necessary Part D drug categories or classes for Medicare beneficiaries. As part of this review, CMS assesses the adequacy of a Part D sponsor's formulary drug categories and classes along with the plan's formulary drug list to ensure that the formulary offers an appropriate range of Part D drugs.³⁰

Comment: Another commenter asserted that the forced application of point-of-sale reductions in price to brand drugs may lead beneficiaries to use more expensive brand drugs instead of generics. The commenter indicated that not only will this increase overall program costs and disrupt efforts to promote the use of generics, but it may incentivize plans to minimize the opportunity for brand drugs to capitalize on this circumstance by developing narrower formularies with fewer brand drugs.

Response: First, we reiterate that safe harbors are voluntary and do not mandate any conduct. In particular, the

³⁰ 79 FR 1918, 1939 (Jan. 10, 2014).

new safe harbor for point-of-sale reductions in price provides a pathway to protect certain types of price reductions, but it does not require price reductions. Second, the final rule does not affect other drug utilization tools that plans have at their disposal, such as moving generics to a lower tier or moving brands to higher tiers. Furthermore, sponsors have an incentive to promote utilization of the lower net cost drug, regardless of whether the drug is a generic or brand. Reductions in price applied at the point-of-sale will remove an incentive for plan sponsors to game rebates in their bidding, as well as create an incentive for plans to include more generic drugs of equal safety and efficacy on their formularies.

Comment: A commenter indicated that under the Proposed Rule, Part D plans could further reduce or even eliminate their use of fixed copayments since simply converting all of their cost sharing to coinsurance may make it considerably easier to pass through rebates at the point of sale and ensure compliance with the changes included in the Proposed Rule. This shift, the commenter further contended, would directly expose beneficiaries to drug manufacturers' pricing and be particularly problematic for beneficiaries taking brand drugs without a rebate.

Response: We appreciate commenters' concern that there could be a transition to coinsurance for more drugs. Nothing in this final rule compels plans to discontinue their use of copayments, which many consumers prefer; further, upfront discounts on drugs subject to copayments can comply with the

final point-of-sale safe harbor, so long as the discounts are reflected in the point-of-sale price the beneficiary is paying and accounted for when setting the copayment amount at the time of bidding. Comments related to CMS's administration of the Part D program are outside the scope of this rulemaking. However, CMS has indicated that actuarial equivalence requirements in the Part D program may require that plans adjust copayment amounts when setting them at the time bids are submitted to reflect discounts under the point-of-sale safe harbor. Additionally, for beneficiaries taking brand drugs with a rebate, it is possible that the coinsurance amount for some highly rebated drugs may be very close to the current copayment amount and that even patients in plans with no deductibles and paying only copayments could save as a result of this final rule. When accounting for the trends in utilization and costs by phase for Part D beneficiaries taking high-cost drugs with high rebates, these analyses also suggest it is likely that beneficiaries taking high-cost, high-rebate drugs in copayment-based plans will see a decrease in their overall out-of-pocket costs.

Comment: Another commenter discussed the impact of the Proposed Rule on those with rare diseases. Noting that manufacturers have less of an incentive to offer rebates to secure placement on a formulary for therapies for rare diseases since these treatments have fewer competing products, and that within the context of Medicare, many rare disease therapies fall

within the six protected classes that must be included on a formulary, the commenter asserted that as a result, there is limited use of rebates for rare disease therapies, so any benefits expected under the Proposed Rule would be diluted for patients on these treatments.

Response: As stated in the Proposed Rule, we understand that beneficiaries using high-cost drugs in protected classes may be less likely to benefit from a reduced pharmacy purchase price, because manufacturers generally offer low or no rebates to plans for these drugs, since drugs in protected classes must be included on Part D plan formularies.³¹ While we also recognize that manufacturers generally do not offer rebates on drugs where there are no competing products, the Proposed Rule was only intended to address circumstances where rebates are used. Furthermore, the Department believes that reductions in price that are completely reflected in the price of the prescription pharmaceutical product at the time the pharmacy dispenses it to the beneficiary may also benefit consumers in poorer health or with higher drug costs who are on treatments where rebates are used by decreasing their out-of-pocket spending at the pharmacy. The Department also believes that the enhanced transparency of premiums and out-of-pocket costs that the safe harbor encourages will support beneficiaries in making more actuarially sound decisions.³² Thus, while the final rule may have a differing

³¹ 84 FR 2358 (Feb. 6, 2019).

³² 84 FR 2355 (Feb. 6, 2019).

impact on certain patient groups, the Department believes many patients will experience benefits.

Comment: A health plan commenter requested that Medicare Advantage and Medicare Part D plan sponsors have the ability to temporarily exclude all new, high-cost medications from coverage formularies for at least six months. According to the commenter, this approach prevents pharmaceutical manufacturers from driving any utilization before appropriate price concessions are negotiated to better reflect the new drug's actual clinical value.

Response: Recommendations to change Part D program rules are beyond the scope of this rulemaking.

Comment: Various commenters recommended that following the implementation of the final rule, CMS actively monitor formulary changes and utilization management protocols in order to prevent patient discrimination and to ensure patients are able to access needed treatments. Several commenters noted that the Proposed Rule, in conjunction with previously proposed changes to allow greater utilization management for the six protected classes of drugs within Medicare Part D, could result in restrictions that would interrupt care regimens for those with certain diseases.

A commenter noted that as a requirement for formulary approval, the MMA requires that the Secretary of HHS cannot find that a plan's categorization system discourages enrollment by a group of beneficiaries. This commenter also recommended various guardrails that CMS should consider when evaluating formularies

under this proposal, including tracking formularies for increases in product exclusions due to the heightened potential for adverse selection, aligning formularies to existing clinical guidelines, including a wide range of drug treatments on formularies, and monitoring formularies for significant changes from copay to coinsurance.

Response: We have coordinated with CMS, which administers the Part D program, in promulgating this rule. We agree that it is critically important that patients' access to needed treatments be protected, that patients not be discriminated against, that patients receive critical care uninterrupted, and that plans not discourage enrollment impermissibly. Plans should comply with all Part D rules and take appropriate actions to guard their enrollees against these harms. We are informed by CMS that they have and will diligently use a robust formulary review and approval process, which entails in-depth checks to ensure sufficient inclusion of all necessary Part D drug categories or classes for Medicare beneficiaries, preventing discriminatory benefit designs. As part of this review, CMS assesses the adequacy of a Part D sponsor's formulary drug categories and classes along with the plan's formulary drug list to ensure that the formulary offers an appropriate range of Part D drugs.³³ The formulary review and approval process, risk adjustment, and anti-discrimination rules each serve to mitigate the incentive for health plans and PBMs to narrow prescription

³³ 79 FR 1918, 1939 (Jan. 10, 2014).

benefits for vulnerable populations and to discourage enrollment among high-cost patients.

Comment: In order to prevent narrower formularies and increased cost sharing, a commenter recommended that in the next payment notice for Medicare Part D plans, CMS include discussion of cost-sharing and utilization management rules to ensure the changes included in the final rule do not lead to violations of existing protections or result in decreased access to necessary medicines.

Response: Suggestions for CMS to issue guidance in the next payment notice are outside the scope of this rulemaking.

Comment: Other commenters discussed the influence of rebates on formulary placement. A health plan commenter indicated that while net prices factor into the overall value proposition of a drug, review of clinical evidence is the essential first step of formulary development, and a drug's clinical performance relates in this way to the potential magnitude of a rebate, if any. Another health plan commenter stated that rebates are only considered for drugs that are in competitive classes, where two or more therapeutically similar or equivalent drugs exist, and that in the overwhelming number of cases, plan determinations regarding drug formulary treatment are well-justified by the underlying drug characteristics and economics.

However, other commenters asserted our current rebate system may result in PBMs placing more expensive products in a

preferred formulary position over less expensive equivalents and that eliminating rebates would correct their impact on formulary design.

Other commenters discussed the influence of rebates on the placement of biosimilars on formularies and asserted that PBMs generally give preferred formulary placement not to the product with the lowest list price, or to the product that provides the lowest cost to the patients, but to the product that will provide the PBM with the greatest rebate. These commenters stated that because of a biosimilar's lower price, it may not have preferred placement on a formulary, which can be particularly harmful to patients with chronic illnesses that rely on biosimilars. Another commenter was concerned that the absence of rebates, combined with the impacts of beneficiary cost-sharing differences and Part D subsidies/program design, may make generic or biosimilar drugs less lucrative to PBMs or plan sponsors, which could result in Part D plans giving preferential or equivalent-tier placement to higher-cost brand drugs.

Another commenter emphasized that decisions about which drugs are chosen for formulary inclusion should be based upon the drug's effectiveness, safety, and ease of administration, rather than financial arrangements like rebates. Other commenters raised concerns that PBMs lead to formulary disruptions.

Response: The Department agrees with commenters asserting that clinical factors should be paramount in formulary development and with commenters asserting that the current rebate system may result in more expensive products or products offering PBMs the largest rebates receiving preferred formulary placement, rather than products with lower list prices or lower costs to beneficiaries. This concern about inappropriate financial influence on formulary placement is an important element of the Secretary's decision to finalize the Proposed Rule. Nothing in this rule changes any Part D requirements with respect to formularies, including which types of drugs should be included in a formulary and criteria for including the drugs on the formulary. These are matters for CMS under the Part D program. However, as we clarify throughout this final rule, we agree with commenters' suggestion that formulary placement may be a factor in determining the type or extent of a reduction in price that may be available for a particular drug. As we also clarify throughout this rule, any portion of a so-called "rebate" that was retained by a PBM was not and is not protected under the discount safe harbor, nor will it be protected under the safe harbor for point-of-sale reductions in price; such remuneration is a payment for a service, not a reduction in price, for purposes of the discount safe harbor.

Comment: Other commenters raised concerns relating to chargeback services and formulary placement. A few commenters asked OIG to clarify that when a third-party unrelated to a PBM

is being paid to perform point-of-sale chargeback administration services, PBMs cannot require pharmaceutical manufacturers to pay chargeback administration fees, chargeback adjudication fees, or similar service fees as a condition for formulary placement or position, due to the potential chilling effect on third-party chargeback administrators entering into the market.

Response: Point-of-sale chargeback administration fees or similar service fees would not be covered under the new safe harbor for point-of-sale reductions in price at § 1001.952(cc), regardless of whether such fees are fair market value; however, payment for these services might, depending on the facts and circumstances, be covered by another safe harbor. We agree with the commenter that only the party performing the point-of-sale chargeback administration should be paid for that service. As explained elsewhere in this rule, payments to PBMs for formulary placement, or any kind of payment for a service, are not covered by either the discount safe harbor or the safe harbor for point-of-sale reductions in price.

xi. Impact on List Price

Comment: Many commenters believed that removing rebates would correct distorted incentives and lower list prices. These commenters expect that removing rebates and moving to upfront discounts will consolidate the procurement process and lead to reduced costs, which could be passed on to customers. These commenters also expected that manufacturers would respond to added competitive pressures from plan sponsors with more

competitive pricing, and potentially introduce new drugs at lower price points.

Response: We agree with commenters' suggestion that removing the existing safe harbor and creating the two new safe harbors should promote a more transparent and rational pharmaceutical market that may reduce drug prices through competition.

Comment: Many commenters expressed concern that the rule would be unlikely to lower list prices for new drugs or limit price increases for existing drugs. These commenters felt that the rule would be more likely to either increase drug prices or not significantly affect list prices at all.

Response: We appreciate commenters' concern that the rule may not lower list prices. There are a wide range of potential behavioral changes from all parts of the prescription pharmaceutical product supply chain. The amendment to the discount safe harbor removes the positive incentives that come with higher list prices for manufacturers, PBMs, and payors. With these incentives removed, and with the incentive to get the drug for the lowest possible net price retained, the Department believes it is likely that list prices will decrease and price increases for existing drugs may be more limited.

Comment: Many other commenters expressed concern that the expectation that the rule would result in lower list prices is not supported by historical, economic, or competitive market analysis. These commenters noted that there was not enough

support for the conclusion that rebates are the primary cause of high list prices and that drug manufacturers have given no indication that they would lower drug prices if the rule were finalized.

Response: We disagree with commenters' feedback that there is no evidence that rebates are a primary cause of high list prices. Rebate arrangements in the prescription drug supply chain have been cited as a barrier to lowering drug costs.³⁴ We also disagree that manufacturers have given no indication that they would lower drug prices if the rule were finalized.³⁵ Finally, while we acknowledge that there are a range of potential behavioral changes that could result from the rule, we do not agree with the assumption that PBMs will start paying a higher net price simply because of the transition from rebates to point-of-sale discounts. PBMs and manufacturers already know the current net prices that they have negotiated for drugs and PBMs have proven to be extremely effective negotiators over the past 15 years. Therefore, the Department expects PBMs to continue to work to get the best possible deals for their customers, with one likely result being lower list prices.

Comment: Several commenters asserted that not only would the Proposed Rule fail to lower list prices, but rebates do not contribute to high list prices nor do they prevent manufacturers

³⁴ See, e.g., A perspective from our CEO: Gilead Subsidiary to Launch Authorized Generics to Treat HCV. Gilead Pharmaceuticals, available at <https://www.gilead.com/news-and-press/companystatements/authorized-generics-for-hcv>.

³⁵ See Drug Pricing in America: A Prescription for Change, Part II, Hearing Before the U.S. Senate Comm. on Finance (Feb. 26, 2019), available at <https://www.finance.senate.gov/imo/media/doc/37143.pdf>.

from lowering prices. These commenters specifically argued that list price increases are primarily driven by drug manufacturers' revenue and profit goals and that rebates assist in keeping list prices from being even higher. These commenters noted that list prices are increasing at a faster rate for drugs with small rebates than for drugs with larger rebates.

Response: The Department believes rebates are an important driver of increased list prices. Rebates and price protection payments increase when list prices increase.³⁶

Comment: Many commenters remarked that the Proposed Rule contains no mechanism to bring down list prices, and that absent additional rulemaking, the changes included in the Proposed Rule would further embolden manufacturers to keep prices high.

Response: We appreciate commenters' concern that the rule does not have a mechanism to lower list prices. As discussed above, the Department believes that rebates are a major driver of high list prices, and that, by removing the incentives of the rebate system, PBMs and payors will have a strong incentive to negotiate lower net prices and manufacturers will lower list prices. The Department agrees with the many commenters that commend the existing competitive market and praise the effectiveness of PBMs as negotiators that have carefully managed net prices. The amendment to the discount safe harbor should add transparency to an extremely competitive market, which will translate into lower list and net prices.

³⁶ Pharmacy manufacturer rebate negotiation strategies: A common ground for a common purpose. Milliman. Nov. 17, 2015.

Comment: Several commenters suggested that high list prices and drug costs would be better addressed through increased competition among drug manufacturers. These commenters noted that most of the most expensive drugs have no competition from other manufacturers and offer no rebates. The commenters also noted that there are few meaningful legal or economic restrictions on drug manufacturers' ability to set and increase prices, arguing that drug manufacturers frequently engage in anti-competitive behavior that must be addressed for list prices to come down, such as securing longer periods of patent exclusivity and pay-for-delay settlements.

Response: We agree with commenters that high list prices and drug costs are an important issue that requires a multifaceted response. We further agree that action taken to promote competition in the prescription pharmaceutical product space has the potential to curb rising drug prices. This final rule is one of many Department initiatives that build on each other to lower list prices and reduce out of pocket costs, as outlined in the American Patients First blueprint.³⁷

Comment: Several other commenters remarked that because the safe harbors and amendments included in the Proposed Rule would not apply to commercial markets, list prices are not likely to be lowered. These commenters noted that commercial markets represent a majority of the U.S. drug market, and therefore,

³⁷ American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, Dep't Health & Human Servs. (May 2018), available at <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>.

drug manufacturers have little incentive to lower list prices where a majority of the industry would remain unchanged.

Response: We acknowledge that the commercial market is not covered by this final rule, and that there are a range of potential behavioral responses as a result of this rule. While it is possible that the market will respond by keeping rebates in the commercial market, as commenters suggest, it is also possible that the commercial market will follow the Medicare market without direct action. It may be difficult to maintain a bifurcated market between commercial and Medicare Part D, so plans may prefer to negotiate based on the same discount mechanism for efficiency. We note that some commercial plans have already begun to pass discounts on to patients at the point of sale. While the commercial market is a larger portion of U.S. spending on prescription pharmaceutical products than Medicare, Medicare is an important part of the market and the commercial market often tracks policies implemented in the Medicare program. The Department believes it is likely that as parties change their operating practices to comply with the safe harbors with respect to Medicare Part D business, there may be a spillover effect on their practices in the commercial market, and that list prices would decline as a result.

Comment: A few commenters expressed skepticism that switching to point-of-sale reductions in price would not translate to lower list prices for various reasons, including: there is lack of meaningful competition; intellectual property

and Food and Drug Administration laws empower monopolistic pricing; clinicians have a strong influence over prescribing; coverage and reimbursement laws create price floors; and the healthcare industry as a whole generally fails to assess effective lower-cost alternative drugs.

Response: We agree with the commenters that there are a number of complex factors that have led to high list prices for prescription pharmaceutical products, and that the Department will have to use a multifaceted approach that addresses many of these issues to meaningfully lower list prices and reduce out-of-pocket costs for patients. This final rule is addressing the incentives in the existing rebate framework that drive up list prices while net prices stay neutral or increase only slightly. The Department believes this is an important and foundational step for other reforms that can help to lower list prices and reduce out-of-pocket costs, as outlined in the American Patients First blueprint. The Department will continue to consider further reforms to address issues described by the commenters.

Comment: A commenter argued that the Proposed Rule seems to suggest that HHS would prefer a lower list price drug with a net higher cost over a drug with a lower net cost and that such a situation would increase costs for both beneficiaries and taxpayers.

Response: We disagree. The Department expects that the net price of prescription pharmaceutical products would largely be the same with point-of-sale discounts as it has been through the

use of rebates. The Department expects that PBMs will continue to be effective negotiators in a competitive market and does not see any reason why PBMs would accept higher net prices.

Instead, the Department expects that the rule will result in lower list prices and lower out-of-pocket costs for patients through point-of-sale reductions in price.

Comment: Several commenters expressed concern that because the MDRP calculates mandatory rebates using the AMP of a product (which is impacted by a product's list price), lower list prices could reduce rebates states receive under this program.

Response: The Department recognizes that the final rule has the potential to affect calculations of AMP in ways and to an extent that may be difficult to anticipate. We reiterate that the final rule does not alter obligations under the statutory provisions for Medicaid prescription drug rebates under section 1927 of the Act, including AMP.

xii. Definitions

In the Proposed Rule, we asked for comments on the definitions that are necessary to implement the new safe harbors. We received several comments that we discuss below.

General Comments on Definitions

Comment: Many commenters suggest that a number of terms introduced in the Proposed Rule, such as "affiliate," "negotiated price," "pharmacy negotiated price," "fair market value," "chargeback administrators," "administrative fees," and "manufacturer reporting requirements," must be more fully

defined by the Administration to ensure that operational changes that will be required by the Proposed Rule are reflected in the common understanding of the rules for these programs.

Response: We appreciate commenters' feedback on the terms that require a definition to implement this final rule regulation. We provide the definitions of the terms that are within the scope of this rule below. We provide additional information on terms such as "point-of-sale chargebacks" and "value-based arrangements" in other parts of this rule. We believe this rule includes the necessary definitions for affected entities to comply with the new safe harbors.

Pharmacy Benefit Manager

The Proposed Rule proposed to define "pharmacy benefit manager" as "any entity that provides pharmacy benefits management on behalf of a health benefits plan that manages prescription drug coverage." A number of commenters provided feedback on the definition.

Comment: One commenter noted that health benefits plans may engage PBMs to provide a limited suite of pharmacy benefits management services, such as a limited authorization to provide rebate contracting services on behalf of the plan. In addition, PBMs may be engaged to provide services with regard to prescription drugs dispensed under the medical benefit, such as physician administered drugs where a POS discount could not be implemented, and thus, such engagements should continue to be covered by the existing discount safe harbor. The commenter

recommended the following definition: "For purposes of this paragraph (h), the term pharmacy benefit manager or PBM means any entity that provides pharmacy benefit management services, or a subset thereof, to a prescription benefit plan."

Response: The definition of a PBM requires that the PBM provide "pharmacy benefit management." This definition does not require that a PBM provide a full range of pharmacy benefit management services; it might provide a subset of such services. This is consistent with the definition we are finalizing, and we are not making a change to the regulatory text.

Comment: Many commenters recommended that we use a functional definition of "PBM." While some of these commenters agreed that the role of a PBM may evolve over time, they suggested that if we do not use a more detailed definition, the scope of the safe harbor would be unclear and PBMs would structure their arrangements to fall within or outside of the safe harbor based on their preferences. To develop the more detailed definition, commenters recommended including a non-exhaustive list of PBMs services. Many commenters specifically referenced the definition proposed by a trade association:

"Pharmacy Benefit Manager" means any person, business, or other entity that, pursuant to a written agreement with plan sponsors under Medicare Part D, either directly or through an intermediary, acts as a price negotiator on behalf of plan sponsors under Medicare Part D or manages the prescription drug benefits provided by plan sponsors

under Medicare Part D, including but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, controlling the cost of covered prescription drugs, or the provision of services related thereto. Under this definition, any person, business, or other entity that carries out one or more of the activities above or any entity that is owned, affiliated, or related under a common ownership structure with such a person, business, or entity is a "pharmacy benefit manager." Such entity is not a purchasing agent and therefore is not a GPO as defined in paragraph (j) of this section.

Other commenters recommended additional services (discussed below) be included in the definition. Commenters notes that the list should not include "services" such as "negotiating rebate arrangements," that are core functions of a PBM's job for its plan customers, because the new safe harbor should protect only fees that are paid for a specific service that the manufacturer legitimately needs and that are provided to the manufacturer, independent of services a PBM provides to its plan customers.

Response: We decline to define "pharmacy benefit manager" with the level of specificity suggested by the commenter, e.g., by defining a PBM through a list of pharmacy benefit management

services, by incorporating a common ownership element, or by referencing the definition of "GPO." We do not see value in including a list of services in the regulatory text, given the variety of potential services; we believe the term "pharmacy benefit management" is clear and commonly understood, and would include both price negotiation and management of benefits. We separately provide a non-exhaustive list of potential pharmacy benefit management services in this preamble that PBMs provide to health plans, and we are adopting some of the commenters' suggestions for the preamble list. The list may be useful to parties determining whether they are a PBM, and particularly, whether the services they provide to a manufacturer for purposes of the PBM services fee safe harbor are related to the pharmacy benefit management services that the PBM furnishes to one or more health plans, which is a requirement of that safe harbor. As commenters acknowledge, the role of PBMs may evolve over time, which could make it problematic to use a functional definition. We address common ownership elsewhere in this preamble.

Comment: One commenter recommended that the PBM definition should further distinguish between the functions of PBMs and GPOs to foreclose protection of PBM services arrangements under the GPO safe harbor.

Response: We are not prohibiting PBMs from potentially qualifying for the GPO safe harbor protection. As we explain in greater detail in section III.D.vii below, if a PBM otherwise

meets the qualifications, and follows the limitations, for the GPO safe harbor, then it may be able to use that safe harbor.

Comment: Some commenters noted that the Proposed Rule may lead entities to vertically integrate. These commenters expressed concern that as PBMs continue to evolve in the market, e.g., by vertical integration, merging with other entities, and/or spinning off certain business units, there could be new entities that fall outside the Proposed Rule's definition for "PBM," but that influence the PBM negotiation process.

Response: This final rule relates only to safe harbor protection under the anti-kickback statute; safe harbors protect specified arrangements that implicate the anti-kickback statute. Any entity seeking protection for an arrangement must meet all conditions of a safe harbor, including any applicable definitions. If an arrangement does not fit in a safe harbor, it would be subject to case-by-case review under the anti-kickback statute. It strikes us as unlikely that this final rule itself would lead parties to favor arrangements that do not qualify for safe harbor protection.

Pharmacy Benefit Management Services

Under the Proposed Rule, the services provided to the manufacturer must relate to the "pharmacy benefit management services" that the PBM furnishes to one or more health plans.

The Proposed Rule proposed a non-exhaustive preamble list of examples of pharmacy benefit management services furnished to plans, such as 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. In the Proposed Rule, we proposed that we would not create a definition for "pharmacy benefit management services" with the understanding that these services could evolve over time. We did not propose a definition for the term "pharmacy benefit management services." In the Proposed Rule, we solicited comments on the approach of providing examples, but not providing a definition.

Comment: Many commenters recommended including the list of the pharmacy benefit management services in the definition. Services recommended for the definition in addition to those listed in the Proposed Rule include processing claims for prescription drugs, adjudication of appeals or grievances related to the prescription drug benefit, controlling the costs of covered prescription drugs, and provision of services related to the services listed. These commenters stated that "negotiating rebate arrangements" should not be included in the list of services, since they are prohibited by the new safe harbor.

Response: We accept, with a modification explained below, the commenters' recommendations for additions to the preamble list of potential pharmacy benefit management services that PBMs furnish to plans and to change the listed service related to negotiation of rebate arrangements to negotiation of discount arrangements. Accordingly, the following is a non-exhaustive list of pharmacy benefit management services that PBMs furnish to plans for purposes of this final rule: 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. To be clear: this is not a list of services PBMs furnish to manufacturers, but a list of examples of pharmacy benefit management services that PBMs furnish to any type of health plan. For the purposes of this rule, we are listing "negotiate rebate or discount arrangements" in recognition that PBMs may negotiate both discounts and some types of rebates.

Comment: Some commenters noted that it is unclear how the PBM service fee amounts compare with the current definitions of "Bona Fide Service Fees" (BFSFs) under the Medicare Part D and the MDRP. One commenter noted that the definition of BFSFs

includes additional conditions, meaning that it is not entirely consistent with the terms of the safe harbor, which creates questions regarding the reporting of these fees by Part D sponsors under Part D as well as by drug manufacturers in regards to their determinations of best price and AMP under the MDRP. Likewise, PBMs are required to account for BFSFs in reporting the aggregate amount of price concessions they negotiate that are attributable to patient utilization under a Part D or MA-PD plan. This commenter asked that CMS issue guidance regarding any differences between these two types of fees and the reporting and FMV implications under Part D and the MDRP.

Response: These comments are outside of the scope of this rule, which does not address compliance with CMS requirements relating to DIR reporting for when a payment may be considered within the point-of-sale safe harbor but not a bona fide service fee for purposes of DIR reporting.

Comment: One commenter noted that PBMs do not conduct many of the services outlined in the examples for pharmacy benefit management services, listed in the Proposed Rule, on behalf of manufacturers. In fact, some of the activities attributed to PBMs involve the practice of pharmacy which is overseen by state boards of pharmacy. Specifically, the commenter noted that negotiating pharmacy networks is an activity that is typically done by PBMs on behalf of plans and for which community pharmacies pay a type of pharmacy DIR fee to participate in such

a network (known as a pay-to-play fee). In the PBM-manufacturer relationship, PBMs typically receive administration fees from manufacturers for acting as a purchasing agent for the underlying plans to which PBMs provide services (and also for the provision of data). The commenter recommends revising definition of "pharmacy benefit management services" and narrowing any further description of PBM services to the actual services PBMs provide to manufacturers so that PBMs do not create a de facto rebate composed of new classes of fees charged to manufacturers.

Response: We clarify that term "pharmacy benefit management services" as used in the safe harbor at 42 CFR 1001.952(dd), and the non-exhaustive list of such services provided above, refers to services furnished to health plans, not manufacturers. We agree that we do not want to create de facto rebates composed of new classes of fees charged to manufacturers. We believe that the condition in the new safe harbor for PBM service fees that requires predetermined flat fees that are not tied to volume provides a necessary safeguard to prevent abuse of these fees.

Manufacturer

The Proposed Rule proposed to define "manufacturer" with the meaning ascribed to it in Social Security Act section 1927(k)(5), which defines manufacturer as any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from

substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

We did not receive any comments on the definition of manufacturer, and we are finalizing the definition of "manufacturer" as proposed.

Wholesaler/Distributor

The Proposed Rule proposed to define the terms "wholesaler" and "distributor" as terms that are used interchangeably and carry the same meaning as the term "wholesaler" as defined in Social Security Act section 1927(k)(11). Section 1927(k)(11) defines "wholesaler" as a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including (but not limited to) manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer's and distributor's warehouses, chain drug warehouses, and wholesale drug warehouses) independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

We did not receive any comments on the definition of "wholesaler" and "distributor," and we are finalizing the definitions of "wholesaler" and "distributor" as proposed.

Medicaid Managed Care Organization

The Proposed Rule proposed to define "Medicaid managed care organization" or "Medicaid MCO" with the same meaning ascribed to these terms in section 1903(m) of the Social Security Act. We did not receive any comments on the definition of Medicaid MCOs in the Proposed Rule. While we are moving this definition to § 1001.952(cc), we are otherwise finalizing this definition as proposed.

Prescription Pharmaceutical Product

The Proposed Rule proposed to define "prescription pharmaceutical product" as either a drug or a biological as those terms are defined in sections 1927(k)(2)(A), (B), and (C) of the Act.

Comment: One commenter noted that the definition of prescription pharmaceutical product states that the terms "drug" and "biological" are defined at Section 1927(k)(2) of the Social Security Act, but this is not the case. A commenter recommended that this definition be revised to read as follows: "For purposes of this paragraph (h), a prescription pharmaceutical product means any drug, biological or insulin product that falls within the scope of Social Security Act section 1927(k)(2)."

Response: We agree that "defined" is inaccurate. We are updating the definition to use the word "described" instead of "defined." In addition, because insulin is considered to be a biological product, we are not adopting the commenter's recommendation to list that term in this definition.

"Fair market value" and "arm's-length transactions"

In the Proposed Rule, we stated that the new safe harbor for certain PBM service fees would be available for fees if they are consistent with "fair market value in an arm's-length transaction." Many commenters provided feedback on the definition of "fair market value" and "arm's-length transaction."

Comment: Multiple commenters recommended that OIG provide guidance on certain issues related to fair market value compensation in an arm's-length transaction. At least one of these commenters recommended that OIG (i) clarify that PBMs are obligated to negotiate services arrangements in good faith based on the bona fide needs of manufacturers, (ii) clarify the scope of safe harbor protection available for arrangements in which a PBM provides services on behalf of an affiliated health plan, and (iii) clarify that individual health plans that do not provide pharmacy benefits management services to plan sponsors under Part D may not attempt to use the safe harbor to negotiate administrative fees from manufacturers.

Another commenter recommended definitions of "fair market value" and "arm's-length" that would set guardrails for purposes of negotiations between manufacturers, PBMs, Part D plans, and chargeback administrators and would provide further transparency on how HHS intends these fees to be determined. Specifically, the commenter recommended that OIG clarify that the fair market value standard is neither intended to allow free rein for third-party entities to continue to keep a disproportionate share of

pricing concessions that should be used to reduce beneficiary cost-sharing nor to tie fees to the list price of a medication.

Response: We decline to provide further guidance on fair market value compensation in an arm's-length transaction. The safe harbor is an affirmative defense for criminal violations of the anti-kickback statute, so it is the entity's obligation to prove that the remuneration meets the conditions of the safe harbor based on the terms outlined in this final rule. Moreover, these terms are used in several existing safe harbors.

Comment: One commenter recommended that OIG clarify the requirement that payments be "consistent with fair market value in an arm's-length transaction" by providing a non-exhaustive list of examples of valuation approaches that meet this standard and specify that PBMs must negotiate in good faith based on manufacturers' bona fide needs, refraining from tactics that would be inconsistent with an arm's-length transaction. The commenter asserted that OIG should require that PBMs inform manufacturers when seeking manufacturer compensation for services also compensated by health plans. This disclosure would enable manufacturers to evaluate whether to pay for the services and what a fair market value rate might be.

Response: We decline to provide a non-exhaustive list of examples of valuation approaches. We expect that parties seeking protection under this safe harbor have experience with the fair market value standard and would use generally accepted valuation methodologies and principles in any determination of

“fair market value.” We also decline to include a requirement that the PBM inform a manufacturer when the PBM is receiving compensation from a health plan for a service. This safe harbor protects only payment by a pharmaceutical manufacturer for services the PBM provides to the manufacturer, not payment for services a PBM provides to a health plan; because we have included additional conditions in the safe harbor aimed at clarifying that only payment for legitimate services would be protected, we do not believe this requirement is necessary.

xiii. Comments Outside the Scope of Rulemaking

Above we respond to certain comments addressing matters outside the scope of this safe harbor rulemaking. We received additional comments that are outside the scope of this rulemaking. For instance, several commenters recommended that Congress pass legislation or the Department create new regulations related to certain issues the Proposed Rule appears to address, such as lowering cost-sharing and out-of-pocket costs for consumers; promoting competition of generics and biosimilars; and ensuring beneficiaries have access to negotiated prices through point-of-sale rebates. Requests for Congress to pass legislation are outside the rulemaking authority; the other matters raised by commenters are programmatic and outside the safe harbor authority. Another suggestion involved extending safe harbor protection to the commercial market; as noted above, purely commercial arrangements generally do not implicate the Federal anti-

kickback statute. Commenters requested that OIG or CMS establish certain programs or other forms of guidance, including creating a rebate index that would provide parties with data on the range of rebates currently used in the market for each drug receiving rebates under Part D. Another commenter recommended focusing on the lack of competition in the drug market and restrictions on beneficiary choice rather than trying to reform the rebate system; as noted above, this rule is part of a larger set of Department actions undertaken and under consideration with respect to lowering drug prices. Other commenters requested that OIG create a new safe harbor protecting value-based arrangements or proposed specifically including value-based arrangements in existing safe harbors. OIG has proposed safe harbors for certain value-based arrangements in separate rulemaking.³⁸

B. Discount Safe Harbor Amendment

i. Statutory Exception

Comment: Several commenters stated that, under the terms of a rebate arrangement, a manufacturer offers remuneration to a Part D plan sponsor or Medicaid MCO to induce the purchase of federally reimbursable products, thus implicating the anti-kickback statute. However, commenters further asserted that, although the statutory discount exception does not explicitly refer to rebates, the language encompasses any reduction in price as long as it is properly documented, which would include

³⁸ 42 FR 55694 (Oct. 17, 2019)

rebates administered by PBMs. Because a rebate is a "reduction in price" obtained by Part D plan sponsor "under a Federal health care program," and they are "properly disclosed" to CMS and "appropriately reflected" in costs submitted to CMS, including through statutorily required and CMS-established processes for reporting DIR, commenters assert that they are protected under the statutory discount exception. Similarly, a commenter alleged that the Proposed Rule was based on incorrect and incomplete assumptions regarding the conduct protected by the statutory discount exception.

Response: The legislative history of the statutory exception states that the exception is intended to protect discounts that are properly disclosed and appropriately reflected, and notes that providers are encouraged to "seek discounts as a good business practice *which results in savings to [M]edicare and [M]edicaid program costs.*"³⁹ As explained elsewhere, as the market has evolved in recent years, we do not believe that the way many types of rebates have been used in the Part D program function as reductions in price. While we believe that the changes that we are finalizing to the safe harbors reflect statutory intent and provide a clear pathway to protection, we reiterate our longstanding guidance that safe harbors are voluntary. If a party believes in good faith that a particular arrangement does not implicate the anti-kickback

³⁹ See H.R. Rep. No. 95-393, pt. 2, at 53 (1977) (emphasis added).

statute or meets the terms of a statutory exception, there is no mandate to comply with a safe harbor.

Comment: A commenter noted that the Department has acknowledged that Congressional intent was to protect price reductions in the normal course of business and that post-point-of-sale manufacturer price reductions are precisely the type of discounting that occurs in the normal course of business. Another commenter noted that Congress did not give the Department authority to transform practices that are protected under the statutory discount exception into a crime; the Secretary's regulatory authority is limited to protecting conduct that would otherwise be illegal.

Response: We agree with the commenter that Congress gave the Department authority to protect certain practices that occur in the normal course of business. We further agree that the Department does not have authority to narrow the reach of the statutory discount exception, and that is not our intent. We note, however, that the mere fact that a certain practice is performed in the normal course of business does not make it legal. As a threshold matter, to be protected under the discount exception, an arrangement must involve a reduction in price. For example, an arrangement between a manufacturer and a plan sponsor to increase the amount of the rebate to the plan sponsor by increasing the list price of the drug would be suspect and subject to scrutiny under the statute. Given the variety of "rebate" arrangements that have been created over the

past several years between pharmaceutical manufactures and Part D plan sponsors (directly or through PBMs), many of which are not reductions in price, the Secretary has determined that rebates to Part D plan sponsors do not pose a low risk of fraud and abuse and should not be protected by a regulatory safe harbor. We reiterate that falling outside of a safe harbor does not make an arrangement criminal; each arrangement would need to be examined on a case-by-case basis.

Comment: A commenter stated that the Proposed Rule impermissibly infringes on protections afforded by the statutory discount exception because, taking together the changes to the discount safe harbor and the addition of the new safe harbor for point-of-sale reductions in price, the Proposed Rule effectively eliminates post-point-of-sale manufacturer price reductions, which limits the types of price reductions a Part D plan sponsor, a Medicaid MCO, or a PBM could accept from a manufacturer. The commenter stated that the new safe harbor for point-of-sale reductions in price imposes requirements beyond those in the discount exception's text.

Response: In this final rule, we are carving out a narrow class of arrangements that the Secretary believes poses a higher risk of fraud and abuse and the potential for increased costs to both beneficiaries and Federal health care programs, and we are creating a new safe harbor to protect certain reductions in price that pose lower risk. This new safe harbor has its own conditions, specific to the particular arrangements that are the

subject of the safe harbor, and it is not intended to mirror the discount exception or safe harbor. As noted above, this final rule has no impact on the statutory exception.

Comment: Other commenters asserted that rebates or other payments by drug manufacturers to PBMs may be structured to fit under the GPO safe harbor, 42 CFR 1001.952(j), as well as the managed care safe harbors 42 CFR 1001.952(m), (t), and (u), and noted that these safe harbors have corollary statutory exceptions under the anti-kickback statute (the statutory GPO exception, and the statutory shared risk exception). Commenters asserted that the elimination of these statutory protections through revisions to the regulatory discount safe harbor inappropriately reads out of the anti-kickback statute the multiple protections available to MCOs under other relevant statutory exceptions.

Another commenter asked OIG to issue guidance or revise the managed care safe harbors 42 CFR 1001.952(m), (t), and (u) to ensure they do not protect reductions in price or other remuneration that is excluded under the discount safe harbor.

Response: As a threshold matter, and as we discuss in detail above, rebates from manufacturers to PBMs were not protected by the discount safe harbor. If a payment arrangement can be structured to fit within any one safe harbor, it would be protected by that safe harbor regardless of any changes to a different safe harbor. Amendments to the managed care safe

harbors, 42 CFR 1001.952(m), (t), and (u), are beyond the scope of this rulemaking.

ii. Effective Dates

We received many comments on the proposed January 1, 2020 effective date for the revisions to the discount safe harbor.

Comment: Various commenters supported the proposed effective date. Some of these commenters noted that it would be challenging to make all necessary updates to systems and agreements and that significant resources would be required across the industry to meet a January 1, 2020 effective date, but that the proposed effective date is attainable. Some commenters noted that guidance from OIG and CMS and cooperation from stakeholders would be required to meet that timeline and minimize patient, pharmacy, and supply chain disruptions.

Response: Based on the comments received and further consideration of the appropriate timeframe for implementation, we have modified our proposal, and the changes to § 1001.952(h) (5) of the discount safe harbor will be effective January 1, 2022, which should provide adequate time for parties to come into compliance and to minimize any disruption.

Comment: A commenter strongly supported a January 1, 2020 effective date, but the commenter recommended that it be coupled with both a flexible 36-month transition process to facilitate implementation and guidance issued before the effective date on chargebacks and other issues. Other commenters suggested delaying the effective date and testing efforts to reform the

rebate system before the Proposed Rule is implemented across Medicare Part D. Other commenters that did not support a January 1, 2020, effective date noted that the April 5, 2019 Memorandum from CMS provided some guidance, but not enough to submit an actuarially sound bid. Another commenter urged OIG to delay the effective date of the final rule until 2022 or, alternatively, to issue a statement that it will not begin to enforce the new safe harbors until after the period of the announced CMS demonstration. A commenter also noted that the demonstration program would need to be expanded, for example, to account for enhanced benefits to EGWP plans. This commenter further stated that if CMS does not expand the demonstration program, CMS would have to require plans to submit two bids (one to account for rebates, one to account for POS discounts). Another noted that this effective date would place an enormous burden on CMS to issue required guidance, which could lead to beneficiary disruption if key events leading to the open enrollment period are delayed. A commenter requested that OIG clarify whether manufacturers, PBMs, and pharmacies can leverage existing mechanisms for exchanging data to support point-of-sale reductions in price, noting that the January 1, 2020 effective date is more feasible if extensive systems changes are not necessary.

Response: Based on the comments received and further consideration of the appropriate time frame for implementation, we are finalizing our proposal for the changes to §

1001.952(h) (5) of the discount safe harbor to be effective January 1, 2022. The CMS demonstration referenced by the commenter was contingent on a change in the safe harbor rules effective in 2020; because our changes to § 1001.952(h) (5) of the discount safe harbor will be effective January 1, 2022, requests for modifications to that demonstration are no longer applicable.⁴⁰ Additionally, we confirm that the safe harbor does not mandate any particular system or process for implementing point-of-sale reductions in price.

Comment: Several commenters noted that the proposed January 1, 2020 effective date is particularly problematic for Medicaid MCOs because many states' contracts are not renewed annually and often work on a July 1-June 30 fiscal year. A January 1 change could require mid-year rate adjustments to ensure that capitated payments to managed care plans are actuarially sound. Other commenters noted that the proposed January 1, 2020, effective date would not give states enough time to substitute directly negotiated supplemental rebates for current Medicaid MCO rebates. Additionally, a state health department commenter indicated that a January 1, 2020, effective date would make it challenging to prospectively set Medicaid Managed Care capitation rates that appropriately account for anticipated price reductions for prescription pharmaceutical products, while another commenter stated that the proposed January 1, 2020,

⁴⁰ Letter from Seema Verma, Administrator, CMS, to Part D Plan Sponsors (Apr. 5, 2019), available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2019-Apr-5th.pdf>.

effective date would significantly disrupt current arrangements among manufacturers, PBMs, Medicaid MCOs, and pharmacies.

Response: Based on the feedback we have received from commenters and further consideration of the appropriate timeframe for implementation, we are finalizing the modifications to § 1001.952(h)(5) of the discount safe harbor to be effective on January 1, 2022. Additionally, we are not finalizing our proposal with respect to Medicaid MCOs, which we believe addresses the commenters' concerns.

Comment: Various commenters stated that the effective date should be delayed for some period of time (e.g., at least until 2022) to give plan sponsors time to understand the impact of the rule. A commenter noted that the changes set forth in the Proposed Rule would occur simultaneously with many other changes being proposed to or implemented in the Part D benefit, including new indication-based formularies. The commenter stated that other pending rules would impact Part D protected classes, pharmacy DIR changes, shifting drugs from Part B to Part D, and others, all of which would make a January 1, 2020, effective date more challenging. Commenters noted that, depending on what is finalized, plans may need to adjust bids, renegotiate contracts, and make systems changes. Another commenter noted that both PBMs and plans will have to contract with vendors, who will have to develop, test, sell, and have operational products, which the commenter asserts cannot happen by 2020. Another commenter indicated that the safe harbor

changes proposed in the Proposed Rule would require fundamental changes to the way drugs are negotiated, reimbursed, and adjudicated at the point of sale, which would include new NCPDP electronic health care transaction codes for pharmacy claims.

Commenters suggested that both the proposed January 1, 2020, effective date and alternative effective date of January 1, 2021, were unreasonable, indicating additional time would be needed to implement the point-of-sale reduction in price structure, and that the chargeback system referenced in the Proposed Rule would be far more complex and require more coordination than what currently exists. Others suggested that the same changes would take one year and recommended an implementation date of 2021, with a commenter noting that an additional year would help protect patients from the negative consequences of market disruption and allow more time to educate beneficiaries on any finalized changes. Another commenter asserted that the proposed effective date of January 1, 2020 should be delayed to allow the market to have an opportunity to respond to the new rule. A health plan commenter also recommended delaying the effective date of the rule beyond January 1, 2020, noting that even with CMS's risk corridor assurances, there is still too much uncertainty, which will lead to disparities in 2020 bid pricing.

Response: The final rule is one of many complementary initiatives targeted around lowering list prices and reducing out-of-pocket costs, as outlined in the American Patients First

blueprint. These initiatives are meant to build on each other to create a more rational and competitive prescription pharmaceutical product market. Based on the comments received and further consideration of the appropriate timeframe for implementation, we are finalizing the changes to § 1001.952(h)(5) of the discount safe harbor to be effective January 1, 2022.

Comment: Several commenters objected to the proposed effective date because of the statutory Part D bid deadline. Commenters stated that plans expected all final guidance for the upcoming year to be released by CMS in early April 2019 because Part D bid submissions for calendar year 2020 were due by June 3, 2019. If a final rule were released without sufficient lead time, the commenter cautioned that there will be large financial losses for plans and for CMS (who would have to make substantial payments when plans enter the risk corridor). A commenter expressed concern about the ability to submit an actuarially sound bid by the bid deadline.

An effective date of January 1, 2020, does not provide a reasonable amount of time after issuing a final rule for re-negotiating agreements involving pharmaceutical manufacturers, pharmacies, health plans, and PBMs. Several commenters raised concerns that a January 1, 2020, effective date would make it difficult for the online Medicare Plan Finder tool to reflect accurate information about premiums, deductibles, and cost-sharing and requested that CMS prioritize updates to the

Medicare Plan Finder and other notices to patients. Some commenters also noted that a January 1, 2020, effective date could cause significant disruptions in coverage or benefits and confusion for beneficiaries. This confusion, a commenter argued, may make it difficult for patients to understand and utilize their prescription drug benefits or could cause patients to search for new plans.

Other commenters noted that formularies for Medicare Part D plans must be complete by early May for the June bid submission, and that given the timing of the rule, an effective date of January 1, 2020, would make it extremely challenging to meet the bid requirements.

Response: Comments related to CMS's administration of the Part D program are outside the scope of this rulemaking. We are finalizing the changes to § 1001.952(h)(5) of the discount safe harbor to be effective January 1, 2022.

Comment: A commenter stated that a 2020 effective date would harm beneficiaries enrolled in MA-PD plans, especially if the rule is finalized after bids are submitted on June 3, 2019. The commenter suggested that, in order to mitigate losses from the change in rebates after premiums and bids have been set, MA-PD plans would have to reduce costs in other areas. The commenter stated that it would take years for plan sponsors to recover from these losses, threatening improvements in quality performance, Star measures, and the benefits of care coordination over an extended period.

Response: We appreciate commenters' feedback and note that we are now finalizing an effective date of January 1, 2022, for the amendments to § 1001.952(h)(5) of the discount safe harbor, which should avoid the disruptions and potential harm described by the commenters. Under the final rule, parties are not being asked to change their practices after bids and premiums have been set for the 2022 plan year.

Comment: A health plan commenter indicated that if OIG requires point-of-sale reductions in price, health plans will have to determine benefit configuration, and there will likely be several formulary configuration changes. A PBM commenter indicated that significant system development and testing would be required, including system modifications to apply formulary exceptions, and that PBMs would need to make dramatic formulary changes just prior to the 2020 plan year which, according to the commenter, may result in member disruption and dissatisfaction.

Response: We thank the commenter for sharing this concern and note that the effective date of the modifications to § 1001.952(h)(5) of the discount safe harbor will be January 1, 2022, providing additional time for stakeholders to address these and other potential implementation concerns.

Comment: A commenter noted that employers, including state employers, would not receive any benefits from the changes we proposed, and they would face additional costs if premiums increase. The commenter indicated that this is particularly unfair for public employers such as state governments that rely

upon taxpayers to help fund public employee and retiree health benefit coverage. The commenter requested either an exemption from the proposed rule for governmental employee benefit plans, which are not subject to ERISA, or if an exemption is not granted, then a delay in the effective date specifically for non-ERISA plans to January 1, 2021.

Response: We thank the commenter for sharing this concern and note that the finalized effective date of January 1, 2022 for modifications to § 1001.952(h)(5) of the discount safe harbor should provide sufficient time to address these and other implementation concerns. We do, however, disagree with the commenter's suggestion to remove employee benefit plans from the final rule. The Department believes that the transition from rebates to point-of-sale reductions in price can happen based on existing infrastructure, and these plans will benefit from the lower list prices that may result from the final rule.

iii. Expand to other Federal Health Care Programs

The Proposed Rule stated that the changes proposed were intended to exclude from discount safe harbor protection rebates from manufacturers to plan sponsors under Medicare Part D and Medicaid MCOs, whether negotiated by the plan or by a PBM or paid through a PBM to the plan or Medicaid MCO. The Proposed Rule clarified that the Department intended for the discount safe harbor to continue to protect discounts on prescription pharmaceutical products offered to other entities, including, but not limited to, wholesalers, hospitals, physicians,

pharmacies, and third-party payers in other Federal health care programs. Commenters provided feedback about whether payments for prescription pharmaceuticals paid for by other Federal health care programs should be excluded from the safe harbor.

Comment: Some commenters noted that if Medicaid MCOs, but not Medicaid fee-for-service, are excluded from the existing safe harbor, the Department would be treating these programs differently and would potentially put Medicaid MCOs at a disadvantage. Most of these commenters recommended removing Medicaid MCOs from the proposed exclusion of the existing safe harbor. A few commenters were indifferent on whether or not Medicaid MCOs were excluded from the existing safe harbor or not, but they recommended that Medicaid MCOs and Medicaid fee for service be treated the same way.

Response: As discussed above, the final rule removes Medicaid MCOs from the exclusion of the existing safe harbor, which addresses these comments.

Comment: Several commenters agreed with our proposal that the amendment to the discount safe harbor should not apply to prescription pharmaceutical products payable under Medicare Part B. These commenters noted that Part B drugs are reimbursed under Medicare fee-for-service based on the average sales price (ASP), which already accounts for rebates and other price concessions. There were no comments recommending that payment for drugs billed by Part B fee-for-service providers be excluded from existing safe harbors.

Response: We are finalizing our proposal that the amendment to the discount safe harbor should not apply to prescription pharmaceutical products payable under Medicare Part B for the reason noted by the commenters.

Comment: A commenter recommended that OIG remove the safe harbor protection for rebates paid to Medicare Advantage plans with respect to their coverage of Part B drugs because an increasing number of Medicare beneficiaries are covered by Medicare Advantage plans, and these plans can use rebates, similar to Part D plans, to manage Part B drug costs. Additionally, according to the commenter, many of the most expensive, high-spend drugs are physician-administered biologics.

Another commenter noted that Medicare Advantage generally pays for Part B drugs as part of the medical benefit, and because of underlying Medicare rules, these drugs are generally not subject to the same type of formulary placement negotiations and patient cost-sharing patterns as in the Part D prescription drug benefit.

Finally, additional commenters stated that there are differing levels of cost-sharing in Medicare Advantage for Part B drugs and that it is likely not necessary to extend the proposed changes to Part B drugs. However, they recommend that OIG evaluate how Medicare Advantage plans are reflecting potential savings on Part B covered medicines in beneficiary cost-sharing.

Response: We thank the commenters for their recommendations. We are finalizing our proposal that the amendment to the discount safe harbor should not apply to prescription pharmaceutical products payable under Medicare Part B for the reasons noted by the commenters.

Comment: One commenter noted that the Department of Veterans Affairs (VA) could use this rule as an opportunity to assert a self-serving interpretation of the definition of the non-Federal average manufacturer price (non-FAMP). The commenter would like OIG to clarify that any transactions governed by the final rule would constitute "Federal" prices and should thus be excluded from the determination of a "non-Federal" average manufacture price. For the VA to determine that these are not "Federal" sales would be inconsistent with the Veterans Health Care Act.

Response: In the Proposed Rule, we noted that the VA, Department of Defense, Coast Guard, and the Public Health Service (including the Indian Health Service) are eligible to purchase drugs under the Federal Ceiling Price (FCP) Program. The FCP is calculated as a percentage of non-FAMP. Eligible programs can purchase drugs using the lesser of the Federal Supply Schedule (FSS) Price and FCP. Although it is difficult to determine the operation of the Proposed Rule on FSS users or entities entitled to FCPs, if the overall effect of lowering list pricing is achieved and that results in lower prices to commercial customers (and wholesalers) or pricing components of

non-FAMP, it is possible the VA may realize some additional savings. This final rule does not change the requirements of the FCP and whether Federal programs, such as the VA, count transactions governed by this final rule as "Federal" prices is outside the scope of this rulemaking.

iv. Scope of Amendment

Comment: A commenter asserted that, as written, the proposed amendment to the discount safe harbor would apply not only to rebates on prescription drugs dispensed by a community pharmacy but also to physician-administered drugs covered in the Medicaid program. According to the commenter, Medicaid MCOs would no longer be able to collect rebates on these drugs as there is no avenue to pass the rebate on at the point of sale. The commenter explained that the change could lead to "white-bagging" (*i.e.*, where providers purchase a pharmaceutical product from a specialty pharmacy in order to receive a discount), which the commenter believes raises a number of operational and program-integrity concerns. The commenter also noted this change could create an access issue for members in rural locations.

Response: As discussed in detail elsewhere in this final rule, we are not finalizing the changes to the discount safe harbor with respect to Medicaid MCOs, which we believe addresses the commenter's concerns.

Comment: A number of commenters requested clarification regarding what specific types of rebates and discounts would

still be protected under the discount safe harbor. According to these commenters, the Proposed Rule, as drafted, could be read to remove protection for common purchase discounts that manufacturers provide to wholesalers or pharmacies, if those discounted products are later dispensed by the pharmacy to a Part D or Medicaid MCO enrollee. A commenter requested that the final rule clarify that discounts to wholesalers are protected.

Another commenter requested clarification that pharmacy purchase discounts received by any mail-order pharmacy, specialty pharmacy, or retail pharmacy owned by a plan sponsor under Part D, Medicaid MCO, or a PBM operating on behalf of either, regardless of whether these discounts are dependent on formulary placement, are protected, as the proposed language could be read to exclude such discounts.

Response: We note initially that we are not finalizing our proposal to amend the discount safe harbor to exclude protection for reductions in price to Medicaid MCOs, which we believe partially addresses the commenter's concerns with respect to pharmaceutical products dispensed to Medicaid enrollees as well as the comments regarding pharmacies owned by Medicaid MCOs or their PBMs.

We confirm in this final rule our statement in the Proposed Rule that we "intend[]" for the discount safe harbor to continue to protect discounts on prescription pharmaceutical products offered to other entities, including, but not limited to, wholesalers, hospitals, physicians, pharmacies, and third-party

payors in other Federal health care programs.”⁴¹ Further, we clarify that protection is available for these discounts (including rebates) even if the prescription pharmaceutical product is ultimately dispensed to a Part D enrollee (provided all safe harbor conditions are met). We have revised the language in § 1001.952(h)(5)(viii) to state that the term excludes “[a] reduction in price or other remuneration in connection with the sale or purchase of a prescription pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D either directly to the plan sponsor under Medicare Part D, or indirectly through a pharmacy benefit manager acting under contract with a plan sponsor under Medicare Part D, unless it is a price reduction or rebate that is required by law.” We believe this revised language addresses commenters’ concerns and reflects our intent as articulated in the Proposed Rule.

Discounts offered or given to pharmacies owned by a plan sponsor under Part D or a PBM generally could qualify under the discount safe harbor if all conditions of the safe harbor are met. However, remuneration that is labeled as a “discount” but that is given to pharmacies or other entities owned by or affiliated with a plan sponsor under Part D or a PBM to reward the plan or the PBM for referrals of other Federal health care program business would be suspect. These arrangements would

⁴¹ 84 FR 2348.

appear to have many of the same features as problematic swapping arrangements discussed elsewhere in this rule.

Comment: A commenter requested that OIG clarify in the final rule that all rebates are still protected under the discount safe harbor, except for formulary rebates paid by pharmaceutical manufacturers to health plans or PBMs.

Similarly, a commenter requested that OIG confirm that the Proposed Rule does not affect discounts offered to other entities (e.g., pharmacies).

Response: As we stated in the Proposed Rule and confirm in this final rule, “[t]he Department intends for the discount safe harbor to continue to protect discounts on prescription pharmaceutical products offered to other entities, including, but not limited to, wholesalers, hospitals, physicians, pharmacies, and third-party payors in other Federal health care programs.”⁴² As discussed above, we are finalizing our proposed revisions to the discount safe harbor with a slight modification to ensure that the regulatory text is consistent with our statement in the Proposed Rule. Specifically, the revisions to the definition of “discount” apply only to reductions in price or other remuneration in connection with the sale or purpose of a prescription pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D or through a PBM acting under contract with the plan sponsor under Medicare Part D, unless it is a price reduction or rebate that is required by law. In

⁴² 84 FR 2348.

other words, the revisions apply only to reductions in price offered from manufacturers to plan sponsors under Medicare Part D or a PBM acting under contract with such entities. For reasons explained above, the revisions to the discount safe harbor in the final rule do not apply to discounts offered to Medicaid MCOs.

Comment: A commenter recommended that OIG clarify that manufacturer rebates and discounts may remain protected under other safe harbors. The language of any proposed point-of-sale reduction in price safe harbor and related amendments should specifically provide that the subject remuneration may still receive protection under other available safe harbors.

Response: If a party enters into an arrangement that fits squarely within a safe harbor—any safe harbor—the party would be protected from liability under the anti-kickback statute.

v. Impact on Volume or Prompt Pay Discounts

Comment: A commenter expressed concern that the finalizing changes that we proposed to the discount safe harbor would enable other entities to engage in the exact same practice that the Department is trying to eliminate with PBMs; specifically, it will allow other entities in the supply chain to be compensated for the provision of services based on volume and a percentage of list prices.

Response: We noted in the Proposed Rule that we intended for the discount safe harbor to continue to protect discounts on prescription pharmaceutical products offered to other entities,

including, but not limited to, wholesalers, hospitals, physicians, pharmacies, and third-party payors. However, we reiterate that the discount safe harbor protects only the reduction in the amount a buyer is charged for an item or service; it does not protect payments for services.

vi. Impact on Beneficiary Access

Comment: A number of commenters were supportive of the Proposed Rule. These commenters contended that the Proposed Rule would reduce out-of-pocket costs for beneficiaries; safeguard and increase access to necessary and affordable treatments and therapies and increase patient adherence to those treatments and therapies; and lower list prices for drugs or, at least, address the increasing cost of drugs.

Other commenters contended that the Proposed Rule addresses the perverse incentives for manufacturers to provide rebates, which affects affordability of drugs; curbs PBMs' practices of preferring high-cost drugs; shifts practices so that drug choices are based on what is best for patients; and addresses PBMs' role in reducing the availability of drugs, patients' access to drugs, and patients' freedom to choose certain drugs.

Response: We thank the commenters for their support. The commenters describe goals this rule is intended to achieve.

Comment: A commenter requested that the Department ensure that some form of rebates remain protected to maintain prescription drug choice and savings for their enrollees.

Response: The new safe harbor for point-of-sale reductions in price offers a clear pathway for manufacturers to offer price reductions to Part D plan sponsors and Medicaid MCOs. In addition, reductions in price to Medicaid MCOs remain eligible for safe harbor protection under the discount safe harbor.

Comment: Several commenters were concerned that finalizing the changes in the Proposed Rule could result in higher premiums. Some of these commenters were specifically concerned that an increase in premiums will decrease or deter Part D enrollment, delay enrollment by beneficiaries and, therefore, cause them to incur penalties for late enrollment, or cause beneficiaries to dis-enroll or drop Part D coverage altogether. Other commenters were concerned that uncertainty in the Part D program caused by the Proposed Rule, including risks of an older and sicker population and higher-than-projected premiums, may cause smaller plans to drop out of participation in Part D because they may be unable to handle the increased risk, which could, in turn, reduce beneficiary choice of plans. Some commenters suggested that an increase in premiums may result in a decrease in beneficiary access to medically necessary medicines. Commenters stated that an increase in premiums could result in changes to beneficiaries', including dual-eligible beneficiaries', supplemental benefits, contending that an increase in those costs may deter enrollment. A commenter suggested that an increase in costs, generally, would reduce beneficiary access to plans and plan choices.

Response: We understand commenters' concerns. The Department notes that premiums in the Part D program have historically increased at a slower rate than inflation, while the list prices of drugs and government expenditures have increased more rapidly. Additional information about impacts of this rule in areas predicted by the commenters can be found in the Regulatory Impact Statement. The Department does not believe that the risk of increased premiums or the other uncertainties raised by the commenter will lead to plans dropping out of the Part D program because Part D plans have methods for preventing premium increases, such as tougher negotiation or lower overhead, and that plans will be able to share in the savings under this final rule.

Comment: Several commenters raised concerns that, without adequate or timely updates to the Medicare Plan Finder, beneficiaries may not be able to find appropriate plans and could, potentially, dis-enroll from Part D. The same commenters, as well as another commenter, are also concerned that beneficiaries may be confused about their cost-sharing obligations and may, incorrectly and based on inaccurate or unreliable information, assume that they should benefit from lower cost-sharing amounts. Commenters requested that the Department create mechanisms for beneficiaries to be provided or have access to information about cost sharing, discounts received at the point of sale, and the amounts reimbursed to pharmacies dispensing the medicine. A commenter suggested that

one way to mitigate their concerns is to, for example, update the Medicare Plan Finder or to ensure that pharmacies and prescribers have sufficient information to provide beneficiaries about their cost-sharing obligations at the point of sale.

Other commenters recommended the use of electronic tools, such as Real Time Benefit Tools, that would allow prescribers to access specific information on patients' formularies and out-of-pocket costs for prescription drugs.

Response: We agree with commenters that it is important for beneficiaries to have access to information needed to make informed health care decisions. The Department believes the reduced price at the point of sale will create the appropriate amount of transparency, and that separately providing the amount of the reduction in price is not necessary for transparency to be achieved. While the creation of mechanisms for beneficiaries and prescribers that provide information about cost sharing, out-of-pocket costs, and discounts received at the point of sale would be programmatic tools that are outside the scope of this rulemaking, we point commenters to a May 2019 final rule published by CMS entitled "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses" under which CMS requires Part D plans by 2021 to adopt Real Time Benefit Tools that provide complete, accurate, timely, clinically appropriate and patient-specific real-time formulary and benefit information to prescribers that they can discuss with their patients. CMS has also noted that Medicare

beneficiaries or their representatives can search an online interactive drug plan comparison tool, the Medicare Plan Finder, to find formulary and cost-sharing information for Part D plans. Additionally, CMS has informed us that through their eMedicare initiative, which is a multi-year initiative intended to empower patients and update Medicare resources to meet beneficiaries' expectation of a more personalized customer experience, the Medicare Plan Finder will continue to be improved over time to enhance access to information.⁴³

CMS has also advised us that it will ensure that beneficiaries receive adequate and timely information about cost-sharing obligations under Medicare plans, and that the Medicare Plan Finder will reflect any necessary updates before the final rule's implementation.

Comment: A commenter is specifically concerned that the increased transparency that results from a final rule may pressure PBMs to reduce overall costs in ways that may disadvantage beneficiary access. The commenter is concerned that health plans and PBMs may narrow prescription benefits for, e.g., vulnerable populations, or discourage high-cost patients from enrolling altogether. Other commenters also raised concerns relating to narrow prescription benefit design and increased cost sharing, indicating that if the amended and new safe harbors are finalized, plans and PBMs will have increased

⁴³ Centers for Medicare & Medicaid Services (CMS), CMS announces new streamlined user experience for Medicare beneficiaries, (Oct. 1, 2018), available at <https://www.cms.gov/newsroom/press-releases/cms-announces-new-streamlined-user-experience-medicare-beneficiaries-0>.

pressure to reduce costs, which may result in some plans and PBMs significantly narrowing formularies, using utilization management tools to a greater extent, and/or increasing cost-sharing on brand-name drug tiers in order to prevent enrollment by beneficiaries who have costly conditions or take certain medications. Other commenters asserted that mandatory point-of-sale reductions in price could lead to adverse risk selection, where beneficiaries with a specific condition select the one plan with the lowest upfront discounted price for their specialty drug, which the commenters asserted could result in significant formulary and coverage changes.

Expressing similar concerns, another commenter stated that CMS should enhance its review of Part D benefit design to ensure the patient protections of Part D are not undermined and that plans are not restricting access to medicines in a manner that would violate the non-discrimination protections in Part D. Another commenter suggested that having safeguards in place to protect patients who are currently stable on a medication will be important and requested that OIG or the Department provide certain additional safeguards.

Response: We appreciate and share commenters' concerns that beneficiaries be protected from discriminatory practices, including improper restrictions on access to drugs. As stated elsewhere in this rule, CMS is responsible for administering the Part D program. We are informed by CMS that it has a robust formulary review and approval process, which entails in-depth

checks to ensure sufficient inclusion of all necessary Part D drug categories or classes for Medicare beneficiaries, preventing discriminatory benefit designs. As part of this review, CMS assesses the adequacy of a Part D sponsor's formulary drug categories and classes along with the plan's formulary drug list to ensure that the formulary offers an appropriate range of Part D drugs.⁴⁴ This formulary review process also includes a review of utilization management tools to ensure plans do not restrict beneficiary access to necessary medication. The Secretary cannot approve a prescription drug plan if the plan's design and its benefits, including any formulary and tiered formulary structure, are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan.⁴⁵

CMS also employs risk adjustment where Medicare plan sponsors receive higher payments for beneficiaries who are higher risk (as determined by health status). Risk adjustment is intended to minimize the incentive for Medicare Part D plan sponsors to engage in practices that would result in the enrollment and retention of beneficiaries with expected cost below the average, although individual plan experience may differ based on the plan's mix of beneficiaries relative to the national average and the specific costs that they face relative to the national average. CMS believes that the formulary review and approval process, risk adjustment, and anti-discrimination

⁴⁴ 79 FR 1918, 1939 (Jan. 10, 2014).

⁴⁵ Social Security Act section 1860D-11(e)(2)(D)(1).

rules each serve to mitigate the incentive for health plans and PBMs to narrow prescription benefits for vulnerable populations and to discourage enrollment among high cost patients.

Comment: A commenter stated that the changes included in the Proposed Rule could prevent Part D plan sponsors and PBMs from penalizing manufacturers for lowering list prices by removing drugs from formularies or imposing significant utilization management requirements.

Response: We agree with the commenter that it is inappropriate to penalize lower prices; a key goal of this rulemaking is to encourage lower drug prices.

Comment: Several commenters recommended that, before implementing the final rule, the Department or OIG conduct certain demonstrations, pilot programs, focus groups, or other assessments or evaluations to determine whether and how beneficiaries will benefit from, or be adversely affected by, the proposed changes.

Response: While we appreciate the commenters' suggestions, we are not conducting any particular pilot programs or assessments prior to finalizing the rule. We analyzed anticipated impacts to beneficiaries in the regulatory impact analysis and refer readers to that section for further information.

vii. Additional Safeguards

Comment: Several commenters recommended OIG, CMS, or HHS monitor, or implement mechanisms to monitor, the effect of the

final rule on beneficiaries, PBMs, drug manufacturers, plans, plan sponsors, dispensing pharmacies, and other stakeholders in the drug supply chain. Some of these commenters recommended that data be gathered on the effect of the final rule, specifically related to drug prices, beneficiaries' costs, utilization management, access to drugs, chargeback amounts, the contracts PBMs enter into with drug manufacturers and plans and the terms of those contracts, and formulary changes. A commenter specifically recommended a mechanism for stakeholders in the drug supply chain to report non-compliance with any of the proposed safe harbors. Another commenter specifically requested that the data gathered by OIG, CMS, or HHS through its monitoring mechanisms be publicly available. Finally, a commenter recommended that OIG require pharmaceutical manufacturers to confidentially disclose their drug rebates before the Proposed Rule's changes are finalized so policymakers can compare net costs for drugs before and after the proposed changes go into effect.

Response: The Department recognizes that, due to the complexity of the drug supply chain, the final rule has the potential to affect stakeholders in ways and to an extent that may be difficult to anticipate. The Department declines the commenter's request to require manufacturers to disclose rebate amounts prior to issuance of the final rule. The Department intends to monitor the effects of this rule. As an independent, objective oversight entity, OIG regularly reviews the Part D and

other HHS program and has identified ensuring that HHS prescription drug programs work as intended as a priority area. OIG's reports are routinely made public and available on our website at <https://oig.hhs.gov/reports-and-publications/index.asp>. With respect to a mechanism for reporting non-compliance with the requirements of a safe harbor, the OIG website provides detailed instructions for reporting violations of law, including violations of the anti-kickback statute, at <https://oig.hhs.gov/fraud/report-fraud/>. We note, however, that an individual or entity's failure to comply with the requirements of a safe harbor does not per se constitute a violation of the anti-kickback statute. The conduct in question must otherwise meet the elements of a violation of that law.

Comment: Some commenters requested OIG include safeguards in the amendment to the discount safe harbor. For example, a commenter requested OIG ensure that the only price concessions available to health plans, PBMs, or the affiliates in their vertically integrated business in Part D are those point-of-sale reductions in price under the new safe harbor for point-of-sale reductions in price.

Response: Arrangements are protected from liability under the anti-kickback statute if they meet all the requirements of a safe harbor. Parties are free to enter any arrangements that do not violate the anti-kickback statute or other federal or state law.

viii. Alternative Recommendations

Comment: A commenter recommended that, in lieu of removing rebates to Part D plans and Medicaid MCOs from the discount safe harbor, OIG should modify the existing safe harbor by allowing rebates only when a minimum percentage, for example 50 percent, is reflected at the pharmacy point-of-sale, while the remaining savings continue to be spread across monthly premiums for all consumers served by the health plan.

Response: We thank the commenter for this proposal, but we decline to adopt this revision. We did not propose this approach, we do not believe it would be practical to implement, and we do not believe it would achieve the goals of this rulemaking.

Comment: A commenter recommended that OIG expand the proposed amendment to the discount safe harbor to permit manufacturers to offer copayment and coinsurance assistance to Part D beneficiaries for single-source drugs where the patient has no other choice and thus cannot be induced to select one drug over another, while still allowing plan sponsors to decide whether to cover drugs under existing rules and effectively manage utilization for appropriate patient care and while allowing patients who need innovative therapies and cannot afford the copayment due to the circumstances of Part D's benefit design to be able to access manufacturer copayment support. By contrast, a commenter recommended that OIG narrow the existing discount safe harbor to prohibit rebate

arrangements as a percentage of list price while still allowing for price concessions in the form of rebates that are beneficial for the healthcare system, including those that would yield a fixed net price for a drug over time and those that reimburse plans when a drug does not work as promised.

Response: We decline to adopt the changes proposed by commenters. First, we did not propose or solicit comments on including any protection for cost-sharing supplements from manufacturers to beneficiaries, and we have longstanding concerns with such assistance. With respect to the second suggestion, we believe that some value-based arrangements involving prescription pharmaceutical products might 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, warranties safe harbor). We decline to continue protection under the discount safe harbor for rebate arrangements between pharmaceutical manufacturers and Part D plans (directly or through their PBMs) that might yield a fixed price over time. It is unclear how we could separately protect such rebates, and beneficiaries would not be able to share in the benefit of the lower cost. We note other rebates may be permitted under the discount safe harbor, and certain price concessions are permitted under the new point-of-sale reduction in price safe harbor at 42 CFR 1001.952(cc).

Comment: Some commenters recommended that CMS monitor formulary changes by plan sponsors, and one of those commenters

recommended specifically monitoring for the potential emergence of "discount walls." A commenter recommended that CMS monitor medical exceptions (which, according to the commenter, are ways for beneficiaries to access new innovator products that are blocked from formulary access (i.e., non-contracted) by rebate walls) to ensure plan sponsors do not tighten controls for or restrict access to these medical exceptions as a way to manage costs in the absence of rebates. The same commenter recommended that CMS ensure that the final rule does not affect "non-medical switching" (which, according to the commenter, involves switching between branded products and across therapeutic classes in a medically stable patient solely for cost savings and potentially without the patient's or provider's consent) so that formulary changes made by plan sponsors do not affect patients undergoing therapy.

Response: We have coordinated with CMS in promulgating this rule. As described above, CMS has informed us that it has and will use a robust formulary review and approval process.

C. Safe Harbor for Certain Price Reductions on Prescription Pharmaceutical Products

Comment: We received a comment that expressed concern about the new safe harbor for point-of-sale reductions in price taking effect 60 days after the rule is finalized. The commenter stated that 60 days is not enough to adjust bids and amend contracts for compliance.

Response: The new safe harbor for point-of-sale reductions in price does not require any party to take any action within a

particular timeframe. The safe harbor may be used starting 60 days after the final rule is published, but it is just another option for protecting discounts.

i. Point-of-Sale Chargebacks

Comment: Several commenters requested that OIG revise the definition of "chargeback" proposed in the Proposed Rule. A commenter requested that OIG amend the definition to prohibit entities that control Part D or Medicaid MCO formularies from processing chargebacks. Another commenter recommended that different chargeback amounts should not be negotiated for chain pharmacies, community pharmacies, and specialty pharmacies.

With respect to the term "chargeback," a commenter suggested defining it as "a payment made directly or indirectly to the dispensing pharmacy that is equal to the price reduction negotiated between the manufacturer and the plan or PBM." A commenter representing pharmaceutical manufacturers recommended that OIG specify that the total payment to the dispensing pharmacy be equal to: (1) the payment to the pharmacy from the plan or PBM; (2) the point-of-sale chargeback due from the manufacturer; and (3) the beneficiary cost-sharing amount. The commenter recommending these changes expressed concern that OIG's proposed definition could result in gaming by other entities that would result in pharmacies dispensing medicines at a financial loss. Several commenters requested that we change the term to "point-of-sale chargeback" to avoid confusion with how that term is used elsewhere in the distribution channel.

While a commenter asked for the definition of "chargeback" to include a payment agreed upon by the pharmacy, and not just Part D issuers and/or PBMs, another commenter expressed support for chargeback to be defined as proposed in the rule but requested clarification on whether a chargeback is to be based on the pharmacy actual acquisition cost or on Wholesale Acquisition Cost (WAC). Another commenter proposed amending the definition of "chargeback" to confirm that chargebacks are separate and apart from the agreed upon reimbursement to the pharmacy.

Response: We appreciate the range of suggestions received in response to our request for comment on the proposed definition. As we noted in the Proposed Rule, "the use of chargebacks [makes] pharmacies whole for the difference between acquisition cost, plan payment, and beneficiary out-of-pocket payment" ⁴⁶ Further, we are mindful of concerns about pharmacies dispensing prescription pharmaceutical products at a loss. We agree with the commenter above who recommended clarifying that a chargeback is equal to the amount of the discount negotiated by 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. We are revising the definition to eliminate any confusion on this point. The revised definition is consistent with our goal expressed in the Proposed Rule to protect point-of-sale price

⁴⁶ 84 FR 2361.

reduction arrangements in which consumers share the full benefit. Any point-of-sale chargeback, as defined in this rule, is part of the total reimbursement to the pharmacy for the prescription pharmaceutical product.

With respect to the request that OIG confirm that different types of pharmacies must receive the same chargeback amount, as described above, 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. If a manufacturer and a plan (or a PBM acting on its behalf) have negotiated a point-of-sale reduction in price for a prescription pharmaceutical product that complies with the safe harbor, we would expect the chargeback to the pharmacy to be the same, regardless of the type of pharmacy.

Finally, we agree with those commenters who recommended that we revise the term from "chargeback" to "point-of-sale chargeback" to differentiate this process from other transactions in the pharmaceutical supply chain with the same name. We have revised the term in the final regulations at § 1001.952(cc).

Comment: A number of commenters raised concerns about the need for CMS to promulgate or revise regulations and to issue technical guidance applicable to the chargeback administration process if the new rule is finalized. Several of these commenters requested that OIG consult with CMS because of its

oversight and administration of the Part D program. For example, a commenter requested that CMS issue guidance regarding how to incorporate chargebacks into the Medicare Plan Finder files. Another commenter provided an extensive list of Part D regulations that it believes would need to be revised and topics for sub-regulatory guidance that it believes would need to be published in order to implement the chargeback construct.

Several commenters also posited that significant involvement by CMS would be required because there is currently no regulatory structure or oversight mechanism in Part D for these chargebacks, for example, there is no structure for invoicing, reconciliation, or auditing and recovery functions. As one example, a commenter expressed concern that there are no requirements for pharmacies to disclose chargeback amounts to CMS and there is no requirement for pharmacies to provide evidence that the point-of-sale reduction in price benefited the beneficiary. A commenter recommended that there be regulatory oversight of the chargeback process by relevant agencies. Furthermore, according to commenters, under Part D there is no existing regulatory authority over or oversight of wholesalers or other entities that could be facilitating the chargeback administration process.

In addition, several commenters requested guidance from CMS on error adjudication or dispute resolution processes. A commenter indicated the error adjudication process would be used in those instances where a manufacturer erroneously remits a

chargeback to a pharmacy or where there are errors in the amount that a beneficiary pays. Other commenters suggested that pharmacies should not be required to reverse and rebill original claims if a price reduction is applied in error because it could result in a beneficiary's cost-sharing obligation increasing, and a commenter requested guidance from the Department explaining that plan sponsors and PBMs are not required to collect additional cost-sharing from beneficiaries under these circumstances. A number of commenters raised concerns or questions about the impact that changes included in the Proposed Rule would have on pharmacies. For example, a commenter requested guidance on dealing with non-collectible rebates (e.g., if a beneficiary is given a discount at the point of sale, which the manufacturer later does not honor, must the pharmacy attempt to collect the disallowed amount from the beneficiary?).

Similarly, a commenter requested clarification on the role of pharmacies in dispute resolutions involving point-of-sale reductions in price and asked that there not be any retroactive adjustments for chargebacks paid to pharmacies. Another commenter requested guidance on administering chargebacks to pharmacies where the value of the chargeback exceeds the ingredient cost.

Response: This rule provides flexibility for parties seeking safe harbor protection to structure back-end, point-of-sale chargeback processes that result in fully passed-through

point-of-sale discounts. Moreover, were we to include detailed technical requirements, we would make it more difficult for parties to use and comply with the safe harbor for its intended purposes. While we have consulted with CMS in this rulemaking, any requests for CMS to issue guidance related to the chargeback administration process (e.g., guidance related to dispute resolution processes) and questions about CMS authority to do so are outside the scope of this rulemaking, as are CMS requirements related to PDE reporting and correcting known discrepancies in cost-sharing charged to beneficiaries in the event of a mistake or error in the calculation of the point-of-sale price.

With respect to the comments regarding the circumstances under which a pharmacy extends a price reduction to a beneficiary that is not honored by the manufacturer, we note that if an entity made a practice of undercharging beneficiaries for cost sharing, under the guise of passing through manufacturer reductions in price, with knowledge that the reductions in price would not be paid by manufacturers (thus providing remuneration to the beneficiaries), and 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 for intent.

We also clarify 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.

Comment: A commenter requested additional safeguards related to chargebacks for small business community pharmacies, including but not limited to the right to: appeal chargeback decisions, inquire about missing chargeback payments, utilize audit processes, and engage in dispute resolution. A commenter recommended that, if other parties violate the requirements under the Proposed Rule and the anti-kickback statute, then community pharmacies should be held harmless from such conduct. This commenter stated that independent community pharmacies should have the opportunity to do business with any trading partner in the supply, billing, or reconciliation chain.

Response: Nothing in this rule restricts the ability of pharmacies to do business with other parties in the supply, billing, or reconciliation chain. While we appreciate the commenter's concerns, we decline to provide additional safeguards in the safe harbor that are specific to community

pharmacies; the articulated concerns are not unique to any particular type of pharmacy, and we believe the safe harbor contains the right combination of conditions to protect programs and patients from abusive kickback schemes. We note that many of the commenter's requests, e.g., the right to appeal chargeback decisions, are outside the scope of this rulemaking, which addresses the conditions necessary for protection under the anti-kickback statute. Nothing in this rule limits pharmacies' ability to inquire about missing chargeback payments or to enter into contracts that provide for appealing chargeback decisions, utilizing audit processes, and engaging in dispute resolution. We further note that community pharmacies would not necessarily be liable under the anti-kickback statute if other parties violate the anti-kickback statute. Whether a party is subject to liability under the anti-kickback statute depends upon the actions and intent of that party and not solely upon the actions and intent of other parties to an arrangement.

Comment: Several commenters requested that the Department facilitate the exchange of information for purposes of implementing the chargeback process. For example, a commenter requested that CMS allow for the electronic sharing of data so that pharmacies will know patients' cost-sharing obligations and create a mechanism for pharmacies to receive point-of-sale chargebacks. Another commenter asked that OIG require as a safe harbor condition that plans, PBMs, and other entities involved

in the chargeback administration process exchange information and cooperate as necessary to ensure transparency.

Several commenters raised concerns or questions related to the claims-level data needed for chargeback administration. For instance, some commenters asked that the Department develop processes and claims-level data elements to allow manufacturers to administer chargebacks to pharmacies. A commenter requested that HHS implement updates to existing data and communications file formats to assist with the chargeback verification and correction process.

Other commenters commented on the need for pharmacies to have visibility into various claims-level data. For example, a commenter explained that pharmacies should have full visibility into the total and final reimbursement due the pharmacy and any final amounts due as chargebacks so that they can predict their cash flow. A commenter indicated that while other parties in the drug supply chain may argue that these chargeback amounts are proprietary, access to this information is vital to a pharmacy's ability to operationalize its business and support the Proposed Rule. Another commenter noted that transparent, timely, and plan-validated communication of claims-level chargeback amounts due to the pharmacy will enable wholesalers to effectively adjudicate the chargeback payment to pharmacies. A commenter recommended that the chargeback administrator be required to furnish electronic remittance advices with all chargeback amounts detailed at the claim level so as to allow

pharmacies to substantiate the total and final reimbursement. Other commenters had various requests for pharmacies to have full visibility into plan-adjudicated claims, for example, to allow the pharmacies to extract chargeback data or to track price reductions made by an entity who will be paying the pharmacies (if the entity making payment is not a plan sponsor under Part D or a PBM).

Response: We do not intend for this rule to stipulate the data that must be shared among the parties administering the point-of-sale chargebacks. As we stated above, this rule provides flexibility for the industry to develop and implement arrangements for the administration of chargebacks as necessary to meet the conditions of the safe harbor.

While we encourage such flexibility, we note that point-of-sale chargebacks are defined as a payment made directly or indirectly by a manufacturer to a dispensing pharmacy. To the extent the chargeback process is used, we expect the manufacturer and the plan sponsor under Part D, Medicaid MCO, or PBM to have a writing that sets forth the reduction in price negotiated between the parties, which would be equal to the chargeback due to the pharmacy.

Similarly, we would expect a manufacturer to have sufficient 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 under Part D,

the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer. While we are not specifying the form of this documentation, it would be prudent for manufacturers to maintain appropriate documentation to show that the condition in (cc) (1) (ii) has been met, if applicable.

We decline to adopt the commenter's request to create a condition in the safe harbor related to the exchange of information and cooperation among the parties. While increased transparency is an important goal of this final rule, we believe such a condition in the safe harbor would be vague and would result in significant stakeholder confusion.

Comment: Several commenters noted that NCPDP would need to be consulted in order to implement new minimum transaction standards related to chargebacks. A commenter posited that a new version of the standard transaction is not required but expedited code values would be required. Several commenters suggested that every approved pharmacy claim (adjudicated through the standard transactions developed by NCPDP) should include an itemized chargeback amount due to the pharmacy. One of these commenters explained that a number of sources (e.g., a manufacturer, a health plan, a pharmacy switch) could potentially provide the claims-level chargeback data. Another commenter raised concerns, however, that manufacturers and wholesalers do not currently have access to the final adjudicated claim or to other enrollee-level data, which the

commenter believes would be necessary to implement the chargeback processing system.

A commenter that is a not-for-profit standards development organization provided guidance on three possible options for chargebacks to be administered in accordance with the HIPAA standards for electronic healthcare transactions. In two methods, a PBM would administer the chargeback process and in the third method a non-PBM entity would serve as the chargeback administrator. According to the commenter, two of the possible methods for administering chargebacks (one involving a PBM and one involving a non-PBM entity) would require near-term modifications to the standard transaction through additional expedited code values added to the existing HIPAA standard. The commenter stated that ten-to-twelve months from the date of a final rule would be necessary for the standards development process, with additional time needed for modification of industry operations. The commenter requested that OIG and the Department provide guidance as to which of these methods would support the definition of a "chargeback."

Response: We appreciate the commenters highlighting changes to the HIPAA standard transactions that might be required for certain parties to administer point-of-sale chargebacks, although we will note that the Department is agnostic as to which entities may choose to implement the point-of-sale chargeback process. We thank the commenter for the estimate that ten to twelve months would be necessary for

standards development and implementation. While we do not endorse that estimate, we do believe the revised effective date of January 1, 2022 for the amendments to § 1001.952(h)(5) of the discount safe harbor will provide adequate time for the standards development process and for implementation of industry operations to provide the chargeback function.

Comment: A few commenters requested that OIG provide flexibility as to the entities that may administer the chargebacks described in the point-of-sale reductions in price safe harbor, with various commenters highlighting that existing systems used by PBMs, pharmacy switch models, and wholesale distributors, among others, could be leveraged to operationalize this process. A commenter requested that OIG allow market forces to determine the most efficient revenue streams under this new system. Another commenter requested that OIG clarify those entities that can have a role in the chargeback administration process, and whether entities that have formulary decision-making responsibility (directly or indirectly) could serve as chargeback administrators. A commenter highlighted, however, that the safe harbor only protects reductions in the price charged by a manufacturer, which the commenter noted could unintentionally limit the chargeback process to wholesalers because manufacturers typically only "charge" these entities.

Several commenters supported the use of wholesalers to effectuate chargebacks to pharmacies. For example, a trade association representing pharmaceutical distributors explained

that existing distributor systems could be leveraged to process point-of-sale reductions in price and to route chargebacks to pharmacies. More specifically, some commenters posited that wholesalers are best-positioned in the distribution channel to facilitate point-of-sale discounts because of their existing capabilities and infrastructure, and their prior experience with chargeback transactions. According to these commenters, the wholesaler system would create a "cash-less" discount model and would move the industry towards net prices for patients, would enhance transparency, and would minimize payment delays to pharmacies. A wholesaler commenter noted that the use of wholesalers to effectuate chargebacks would increase transparency and would ensure wholesaler accountability because pharmacies have the discretion to choose a different wholesaler with which to do business. However, the commenter emphasized that there is a need for additional accountability principles to be set, such as requirements to relay accurate information and credits throughout the channel promptly so as not to impede manufacturers, wholesalers, or other entities from the proper administration of chargebacks. Another wholesaler commenter stated that a new remittance transaction would need to be established for the payment of the chargeback by the wholesaler to the pharmacy once it is authorized by the manufacturer.

A PBM commenter raised a number of concerns with wholesalers serving as chargeback administrators. For example, the commenter expressed concern that using a wholesaler-led

system could lead to pricing collusion. Another commenter raised its concerns that wholesalers that administer chargebacks may be incentivized to ignore utilization management requirements and pay discounts because, unlike plans or PBMs, they are paid per unit sold. A commenter also cautioned against unintended consequences of using wholesalers to facilitate chargebacks; specifically, the commenter stated that using these entities would decrease the AMP and, as a result, would lower the amount that states and the Federal government receive under the MDRP.

Other commenters requested that PBMs be designated to administer chargebacks because they are able to use existing infrastructure and relationships with manufacturers, plan sponsors, and pharmacies. However, a trade association representing community pharmacists supported a model in which PBMs would not participate in the chargeback administration process. According to the commenter, interactions between pharmacies and PBMs have led to a non-transparent environment that may hinder patient care. Another commenter cautioned against making pharmacies the chargeback administrator, as it would require the pharmacy to be privy to a significant amount of new information, such as information about the beneficiary's plan, benefit structure, position in the benefit parameters, and costs, as well as information about the discount negotiated. The commenter also cautioned that such responsibilities would significantly change the role of a pharmacy.

Response: The Department recognizes that stakeholders in the pharmaceutical industry are best positioned to determine what entity or entities should be responsible for the point-of-sale chargeback administration process. In addition, the Department wants to encourage current and future innovation and seeks a level playing field so that a variety of entities may engage in the chargeback administration process. For these reasons, and so as not to be overly prescriptive, the final rule does not require a specific category or categories of entities to serve as chargeback administrators.

We did not intend for the use of the word "charged" in the safe harbor to imply that only wholesalers may effectuate the chargeback process, and that term has been changed in the regulatory text. So long as all conditions of the safe harbor are met, any entity may administer the chargeback process for purposes of compliance with the safe harbor.

Comment: Many commenters raised concerns about the costs, coordination, and development that would be required for all Part D stakeholders (e.g., manufacturers, wholesalers, and pharmacies) to create and implement new systems to operationalize chargebacks. For example, several commenters noted that pharmacies would be required to develop mechanisms to track payments at negotiated discount rates and to operationalize chargebacks. To address these concerns, a commenter requested that OIG minimize burden and financial risk for pharmacies and suggested that the responsibility for

calculating the total payment due to the pharmacy rest with the plan sponsor. On a similar note, a commenter raised concerns about the burden on pharmacies to determine beneficiary out-of-pocket cost-sharing amounts.

Commenters noted that entities would incur significant financial costs through, by way of the commenters' examples, upfront investments in IT; development of systems for invoicing, reconciliation, and recovery; and new systems (specific to pharmacies) to collect reimbursement from the PBM and chargeback administrator. Such system modifications also would be required across the entire drug supply chain to incorporate and analyze utilization information at the beneficiary level. In addition, some commenters noted that the existing wholesaler chargeback systems in place are much simpler and very different than what would be required in the retail pharmacy context and would need to be modified for this context, potentially requiring significant infrastructure changes and material investments.

Commenters also noted that all parties involved would have to renegotiate existing contracts or enter into new contracts to operationalize this system, which they posited would be a time-consuming and resource-intensive process. A commenter also requested confirmation from CMS that the renegotiation of the terms and conditions of contracts between pharmacies and plans (or PBMs) implicates the any willing pharmacy provisions of the Act.

Commenters highlighted that the new chargeback infrastructure would need to undergo rigorous testing to avoid adverse impacts, and a commenter noted that the proposed deadline does not provide sufficient time for stakeholders to develop, test, and deploy these new chargeback systems. According to a commenter, requiring pharmacies to implement these new processes increases administrative costs for, and requires significant upfront investment by, these entities, with no added benefit. Several commenters noted that these burdens, challenges, and risks would be worse for independent community pharmacies and specialty pharmacies.

Response: While we recognize that some system changes may be required in order to administer point-of-sale chargebacks, we note that nothing in the point-of-sale reduction in price safe harbor requires parties to utilize this process. While the Department encourages rapid adoption of point-of-sale price reductions, we note that we are finalizing a later effective date than originally proposed for the amendments to § 1001.952(h)(5) of the discount safe harbor, which should help address commenters' concerns about implementation timelines. As we set forth in § 1001.952(cc)(1)(ii), the reduction in price must 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. We view this criterion of the safe harbor as

applying only if a rebate is involved (in the form of a point-of-sale chargeback). If the pharmacy receives the full value of the reduction in price at the time of sale of the prescription pharmaceutical product to the beneficiary, then a chargeback (and the requirements for chargebacks under this safe harbor) would not be needed.

We are not providing specific guidance and rules around reimbursement methodologies or processes in the safe harbor to allow flexibility, as further explained below. If the chargeback process is used, then in order to receive protection under the safe harbor the payment must be made from the manufacturer (directly or indirectly) to the pharmacy, and the amount of the payment must be equal to the reduction in price negotiated between the plan sponsor and the manufacturer. Moreover, we agree that the new safe harbor should not restrict patient access to drugs because of delays in reimbursement at the pharmacy.

Comment: A commenter raised concerns that the chargeback system may allow manufacturers to access pharmacy systems for auditing purposes, which the commenter believes raises privacy issues.

Response: Nothing in this final rule would alter in any aspect existing obligations of Covered Entities under the HIPAA privacy and security rules. We would expect such entities to structure their interactions in full compliance with applicable laws.

Comment: A commenter asked if payments to pharmacies will be subject to prompt payment rules, particularly with regard to chargeback payments where, according to the commenter, CMS has no regulatory authority over wholesalers. The commenter noted that if the chargeback system fails to timely compensate pharmacies at the point of sale, pharmacies may refuse to participate in Part D plans or networks that rely on chargebacks rather than existing PBM-facilitated transaction systems, decreasing beneficiary access to medicines at pharmacies.

Commenters also noted that there could be a significant delay between a pharmacy's dispensing of a product and receipt of a chargeback, which the commenters believe will create significant financial burdens, substantial operational challenges, and increased financial risk for pharmacies. A commenter asked for clarification as to what entity holds the financial risk in the period between when the price reduction is applied at the point of sale and when pharmacies are made whole. According to the commenters, this lag also could jeopardize patient access to needed medications.

Commenters suggested solutions to this issue such as tracking systems to account for each specific discount, applying chargebacks as credits due from the wholesaler to the pharmacy, immediate communication of the discount at the time of invoicing, or daily adjudication for rebate payments. Several commenters posited that pharmacies may choose not to participate

in the Part D program if they are not compensated in sufficient time or are required to implement these new operations.

Some commenters recommended that CMS amend its regulations to apply the Part D prompt-payment requirements to point-of-sale reductions in price, while another commenter opposed application of these regulations to chargeback payments. At least one commenter requested that the safe harbor require as a condition of protection that any chargeback process be consistent with prompt payment laws. Similarly, a commenter requested that pharmacies be permitted to charge interest for delayed payment of chargebacks in addition to being paid in full for the total and final reimbursement.

Response: We thank commenters for highlighting these issues. As a threshold matter, the Proposed Rule did not propose prompt payment as a condition of meeting the safe harbor condition regarding chargebacks. We did not propose this condition, and, in any event, it would add unnecessary technical detail to the safe harbor to stipulate the specifics related to the timing of any payments made via the chargeback process or which party assumes the financial risk during the process. In large part, these comments concern questions that must be resolved through arrangements negotiated by the relevant parties. The Part D program is a private sector-based program in which the participating entities negotiate with their partners to make what they believe are the most effective arrangements to participate in the Part D market. Entities have

been and continue to be required to establish these arrangements in compliance with programmatic requirements as well as the anti-kickback statute.

We expect terms related to chargebacks to be in the agreements between the relevant parties, but we note that, to the extent the chargeback process is used, the chargeback must be made from the manufacturer to the pharmacy, directly or indirectly, in order for the safe harbor to protect the reduction in price.

Comment: A trade association representing pharmacy benefit managers stated that the rule, if finalized, would require parties to create a new system to handle chargeback transactions unless rebates can be transferred through a PBM. In lieu of the Proposed Rule, the commenter provided a detailed description of an alternative in which PBMs would be responsible for administering price concessions at the point of sale.

Response: The Department does not intend for this rule to prescribe those individuals or entities that may serve as chargeback administrators, and we see no compelling reason to do so. The Department believes that PBMs as well as other individuals or entities (including entities that currently or may in the future participate in the pharmaceutical supply chain) would be able to develop the means and infrastructure necessary to effectuate the chargeback process. By remaining agnostic in this safe harbor, the Department believes that

innovation and competition will be encouraged in the marketplace.

Comment: A commenter requested that HHS modify Medicare and Medicaid policy to ensure point-of-sale chargebacks will continue to be treated as plan discounts because they are established through manufacturer-plan relationships, rather than being treated as pharmacy discounts because this may affect pharmacy reimbursement.

Response: We have consulted with CMS as part of this rulemaking and are informed that point-of-sale chargebacks should be treated as plan discounts.

Comment: A commenter noted that key portions of the Proposed Rule related to the chargeback process are vague and ambiguous, which heightens enforcement concerns for these parties under the anti-kickback statute. The commenter requested that OIG re-propose the rule with additional clarifications.

Response: While we appreciate the commenter's concerns, we respectfully disagree that the portion of the proposal related to the chargeback process is vague and ambiguous. By design, the proposed safe harbor is not overly prescriptive with respect to the chargeback process to allow for private sector flexibility, competition, and innovation, and to avoid creating technical barriers to the safe harbor's utility. We intend for this safe harbor to provide flexibility in terms of the parties

responsible for chargeback administration as well as how that process is operationalized.

Comment: Several commenters requested that OIG revise the safe harbor for point-of-sale reductions in price to add disclosure requirements for chargeback administrators that mirror the disclosure requirements in the PBM service fees safe harbor.

Response: We decline to accept the commenter's suggestion. As we explained in the Proposed Rule, the "transparency requirement is important to ensure that PBM's arrangements with pharmaceutical manufacturers are not in tension with the services that the PBM provides to the health plans for which it is acting as an agent." We believe the transparency requirement is important for purposes of the PBM service fee safe harbor because of the agency relationship and functions in that safe harbor, because of the potential for a wide variety of services and compensation structures and amounts, and because there are defined parties (*i.e.*, the pharmaceutical manufacturer, the PBM, and the health plans to which the PBM provides pharmacy benefit management services). Because the point-of-sale reductions in price safe harbor specifically requires the point-of-sale chargeback (if used) to be equal to the discount negotiated between the manufacturer and plan and is agnostic as to the entity that serves as chargeback administrator, and because a range of individuals and entities could potentially be involved

in this process, we believe the same disclosure requirements are not appropriate or necessary for purposes of this safe harbor.

Comment: Commenters who commented on the chargeback process raised a number of questions about fees that may be charged to administer chargebacks. For instance, a commenter recommended that pharmacies not be responsible for any chargeback administration fees, and another commenter recommended that pharmacies be held harmless for these processing fees. Commenters also asked that the compensation and disclosure requirements set forth in the new PBM service fees safe harbor apply with respect to fees for chargeback administration services. A commenter recommended that OIG establish a form for a chargeback administration fee (e.g., specify that the fee must be on a per-chargeback basis), and recommended that OIG mandate that chargeback administration fees not vary substantially by manufacturer or by drug.

Response: We did not propose, and are not finalizing in this rule, requirements regarding chargeback administration arrangements. We note, however, that chargeback fee arrangements should not be used to reward the generation of Federal health care program business and would need to comply with the anti-kickback statute. Other existing safe harbors (e.g., the personal services and management contracts safe harbor) could be used to protect such arrangements. We note that chargeback administration fees based on the cost of the drug, or that vary substantially by drug, would share many of

the same problematic features of those rebate arrangements that are no longer protected under the discount safe harbor and would be suspect.

ii. Reverse Engineering

Comment: Various commenters expressed concerns that the proposed point-of-sale reduction in price safe harbor would provide sufficient data to reverse engineer the manufacturer's or the PBM's discount structure, with certain commenters asserting that point-of-sale reductions in price would not likely be incentivized because disclosure of sensitive price and bargaining information inhibits competition. However, another commenter noted that this reverse engineering may allow stakeholders to have a better understanding of drug discounts and pricing and may result in increased competition and lower prices.

Response: We appreciate commenters' concerns about price transparency and agree that providing the market with additional information could have unintended effects in certain, limited circumstances. However, the Department is not persuaded, on net, that this would increase overall program costs or reduce competition. Price transparency lowers a key barrier to entry and increases competition in most competitive markets. Additionally, as commenters suggest and program performance indicates, PBMs have been extremely effective negotiators in the Medicare Part D program, and the Department does not anticipate that additional price transparency would weaken their

negotiating leverage and ability to obtain price concessions. PBMs are aware of the rebates they currently receive, and, in the Department's view, they are unlikely to accept higher net prices going forward as they compete to attract Medicare beneficiaries.

Comment: Numerous commenters were concerned that requiring the disclosure of discounts would, for example, lead to collusion among manufacturers; higher prices; and lower, unvaried discounts because, in part, negotiation leverage diminishes, manufacturers will be able to determine the contract terms offered by their competitors to each plan, and manufacturers will lose the incentive to negotiate the lowest possible discounts, in order to protect market share. In support of these assertions, several commenters cited statements from the FTC indicating that, if pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors, tacit collusion among manufacturers is more feasible.⁴⁷

Several commenters recommended that OIG consider implementing commercial best practices and safeguards that maintain the confidentiality of proprietary contract data and ensure point-of-sale discounts that manufacturers negotiate with plans and their PBMs are not made public. A commenter also requested that CMS not display the value of rebates on Medicare

⁴⁷ U.S. FTC, Letter to Assembly Member Greg Aghazarian, 2004, available at https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf.

Plan Finder but only require display of the final discounted drug prices, net of any pharmaceutical manufacturer discounts.

By contrast, a commenter asserted that, while some stakeholders fear full price transparency will undermine the negotiating power of payers and increase the potential for collusion, the disclosure of price concessions represents the best way of assuring plan sponsors that formulary development is not being influenced by rebates.

Response: We appreciate commenters' concerns that manufacturers may raise their prices or engage in tacit collusion as a result of this final rule. However, the Department has seen very limited evidence that this will occur.

Additionally, although we recognize that the pharmaceutical market is different than other markets in some respects, in most consumer markets where prices are known, transparency increases competition, rather than harms it. In the Department's experience, a hallmark of the prescription drug market is that manufacturers are less concerned about other manufacturers knowing the level of discounts they offer. Indeed, manufacturers can generally estimate the discount their competitors are offering, based on negotiations they have won or lost. Manufacturers are more concerned about each PBM knowing the discount the other PBMs have received, because that will enable PBMs to seek the lowest discount offered by a manufacturer for a particular product. This places downward pressure on net prices, rather than enabling collusion.

Echoing a sentiment of many commenters, the Department recognizes that PBMs are extremely effective negotiators. Nothing in this final rule takes away a PBM's ability to negotiate lower drug prices in exchange for better formulary access, and the Department expects that PBMs will continue to be effective negotiators.

iii. Common Ownership

Comment: Various commenters raised concerns regarding changes proposed in the Proposed Rule and common ownership between PBMs, pharmacies, and health plans. Commenters noted that many of the largest PBMs have vertically integrated business lines, such as health plans or pharmacies. Some commenters asserted that OIG's proposed definition of "PBM" might allow vertically integrated organizations to circumvent the proposed requirements, with a commenter noting that this potential loophole could give PBM-affiliated pharmacies improper competitive advantages over non-PBM-affiliated pharmacies. Another commenter highlighted the potential anti-competitive behavior of PBMs, including requesting that drug manufacturers provide higher discounts for drugs sold through PBMs' own pharmacy operations.

To address this issue, commenters recommended that OIG adopt a functional definition of PBM that includes any person, business, or other entity that carries out specified PBM services to a manufacturer, where directly or through an owned, affiliated, or other related entity under a common ownership

structure with a PBM, with a commenter recommending that PBM- and plan-affiliated pharmacies be able to access non-abusive purchase discounts, such as those on generics. A commenter suggested that PBMs be required to provide the same conditions and same reimbursement to independent, non-vertically integrated pharmacies as are provided to PBM-owned pharmacies, while another commenter recommended that all discounts and rebates from any source and PBM service fees be disclosed at the point of sale and PBM service fees paid by the pharmaceutical industry be disclosed and separated from any discounts and rebates provided to PBM-owned pharmacy operations.

However, another commenter noted that only extending the revisions proposed in the Proposed Rule to PBM-owned pharmacies could raise anti-competitive issues with non-PBM-owned competitors. This commenter recommended expanding the scope of the amendment to include all intermediaries involved in drug distribution and payment transactions, whether or not they take possession of the drugs. Another commenter specifically noted that the provisions in 42 CFR 1001.952(dd)(2)(iii) for PBM services must also include language to prohibit the PBM's activity between the manufacturer and another business entity in which the PBM has operational control or an ownership interest.

Another commenter suggested that the changes we proposed could result in unfair competition because they would exclude from safe harbor protection all purchase discounts received by any mail-order pharmacy, specialty pharmacy, or retail pharmacy

owned by a PBM or a plan sponsor, regardless of whether the purchase discounts (offered to the buyer in its capacity of a dispensing pharmacy, not in the capacity of a formulary manager) are dependent on formulary placement of the manufacturer's pharmaceutical product. The same commenter is concerned that, if purchase discounts are not offered to PBM-owned and plan sponsor-owned pharmacies because of the safe harbor exclusion, class-of-trade pricing could prevent manufacturers from offering purchase discounts to any mail-order pharmacy, specialty pharmacy, or retail pharmacy.

Response: We appreciate the comments on any potential issues that ownership interests might create under our proposed revisions to the discount safe harbor and suggestions on how best to address these issues. However, we intend for the discount safe harbor to continue to protect discounts on prescription pharmaceutical products offered to entities other than plan sponsors under Medicare Part D (directly or through a PBM), including, but not limited to, wholesalers, hospitals, physicians, and pharmacies. As explained previously, we are not expanding the amendment to include entities other than plan sponsors under Medicare Part D, such as PBM-affiliated pharmacies. We note, however, 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. The anti-kickback

statute prohibits remuneration offered, paid, solicited, or received, *directly or indirectly*, to induce or reward referrals of, or the purchase (or arranging for the purchase) of, an item or service paid for in whole or in part by Federal health care programs. If a discount offered to a pharmacy is for the purpose of inducing a commonly owned entity, e.g., a PBM, to arrange for the purchase of a drug paid for by Federal health care programs, through formulary placement or otherwise, then the discount would not be protected by the discount safe harbor.

Finally, while we appreciate the commenter's suggestion to require disclosure of all discounts and rebates from any sources and PBM service fees paid by the pharmaceutical industry, we note that this safe harbor is limited to reductions in price by manufacturers for prescription pharmaceutical products payable by a plan sponsor under Medicare Part D or a Medicaid MCO. The safe harbor does not protect discounts or rebates offered to or from other sources and it does protect any service fees. Given this limited scope of this safe harbor, we decline to adopt the commenter's suggestion for broader disclosure requirements.

Comment: Other commenters recommended that OIG monitor for inappropriate business practices involving PBMs and PBM-affiliated entities, with several pharmaceutical company commenters pointing to price concessions from manufacturers to specialty pharmacies that are owned by or affiliated with PBMs and may be used to subvert the requirements set out in the Proposed Rule. A commenter also encouraged OIG to assert in the

preamble to the final rule that these types of price concession arrangements will be viewed as highly suspect if certain facts are present.

Response: We acknowledge the issues that common ownership interests between PBMs and other entities may cause and understand that this may be a potential area of risk following the implementation of the final rule. We reaffirm that this rule is intended to explicitly exclude from the discount safe harbor certain reductions in price and other remuneration offered by manufacturers of prescription pharmaceutical products to Part D plan sponsors that may pose a risk to certain Federal health care programs and beneficiaries. As discussed above, pricing arrangements that enable PBMs to retain these types of discounts through an affiliated or commonly owned entity, instead of flowing to Part D plans, are excluded from the discount safe harbor and would not qualify for protection under the new point-of-sale reductions in price safe harbor. The determination as to whether a particular pricing arrangement would receive safe harbor protection would be dependent upon the facts of that particular case.

Comment: Some commenters recommended that DOJ monitor and increase its scrutiny related to vertical and horizontal mergers, especially given that three PBMs appear to control a majority of the market, allowing the PBMs to leverage their market power to the detriment of plan sponsors (government and commercial), providers, and consumers.

Response: We appreciate the commenters' feedback. This issue is outside the scope of this rule.

Comment: A commenter stated that pharmaceutical companies should provide to all pharmacies in the same circumstances, irrespective of their ownership, access to the same drug product's actual acquisition cost and discounts.

Response: The amendment to the discount safe harbor and the two new safe harbors promulgated in this final rule do not address discounts or other pricing arrangements between manufacturers and wholesalers, pharmacies, or other entities.⁴⁸

iv. Incentives for Point-of-Sale Reduction in Price

Comment: Several commenters were uncertain how manufacturers, health plans, and PBMs would react to the new safe harbor for point-of-sale reductions in price for and how those reactions would affect the prescription drug marketplace. These commenters were generally unsure whether the new safe harbor would incentivize point-of-sale reductions in price and requested that HHS further analyze how manufacturers may alter pricing strategies, particularly longer-term impacts, before enacting a final rule.

Response: We appreciate commenters' concerns regarding uncertainty. The Department intends to monitor the effects of this final rule. However, we note that the new safe harbor for point-of-sale reductions in price is designed to offer more flexibility for manufacturer discounts and several manufacturers

⁴⁸ See 84 FR 2348.

commented that they would be incentivized to offer point-of-sale reductions in price, noting their support for lowering out-of-pocket costs for beneficiaries.

Comment: A few commenters questioned whether manufacturers would provide point-of-sale reductions in price to fully offset the rebates that would be prohibited if the amendment to the discount safe harbor were finalized, especially because point-of-sale reductions in price have been offered by PBMs for some time in the commercial market, and there has not been widespread adoption.

Response: We appreciate commenters' observations about the dynamics of the commercial market. As we discuss elsewhere in this rule, we are aware that some commercial plans may be operationalizing point-of-sale benefit designs and believe that at least some industry stakeholders have the capabilities to operationalize point-of-sale reductions in price that would be protected under the new safe harbor.

Comment: A commenter requested clarification on how PBMs will negotiate for discounts without using rebates. For example, the commenter requested clarification on what compensation would be available to PBMs, how PBMs would be incentivized to negotiate lower prices for patients, and how drug manufacturers would negotiate for formulary placement, all in the absence of rebates.

Response: This rule does not require any particular method of negotiation of discounts, and parties are free to pursue all

lawful forms of negotiation. With respect to negotiations between PBMs and manufacturers, PBMs are supposed to be acting as an agent of health plans and, in this role, we would expect them to negotiate with manufacturers on behalf of plan sponsors under Part D for point-of-sale reductions in price. We leave it to the applicable parties to determine how negotiations of point-of-sale reductions in price will evolve and how financial arrangements will be structured between these parties to comply with the anti-kickback statute.

Comment: A few commenters expressed concern that errors or delays in the implementation of point-of-sale reductions are likely, which could leave beneficiaries without prescriptions at all or with prescriptions at higher costs. Commenters questioned whether a pharmacy would be liable for such errors via retroactive reconciliation. Without clarity on these issues, commenters believed manufacturers were not likely to be incentivized to offer point-of-sale reductions in price.

Response: Questions regarding billing errors are outside the scope of this rulemaking. However, we note that while all conditions of a safe harbor must be met to ensure protection, falling outside a safe harbor does not necessarily result in liability under the statute. Moreover, mere errors do not create liability under the anti-kickback statute.

Comment: A couple of commenters questioned whether point-of-sale reductions in price were viable as constructed under the Proposed Rule as they would require significant operational

changes, ultimately discouraging point-of-sale reductions in price from being offered. These commenters recommended that the Department should require Part D plans to provide a point-of-sale rebate plan as one of their plan offerings instead.

Response: We appreciate the commenters' concerns regarding the viability of point-of-sale reductions. The Department believes that industry stakeholders have or can develop the capabilities to operationalize point-of-sale reductions in price that would be protected under the new safe harbor. Regarding commenters' recommendation that the Department require Part D plans to provide a rebate plan, we note that changes to Part D rules related to required plan offerings are outside the scope of this rulemaking.

Comment: A few commenters expressed concern that manufacturers would not likely be incentivized to offer point-of-sale reductions in price unless HHS clarified whether discount safe harbor protection will continue to be available for formulary and utilization management arrangements.

Response: As we explain above, reductions in price to a plan sponsor or Medicaid MCO that are conditioned on formulary placement and utilization management tools can qualify for protection under the new safe harbor for point-of-sale reductions in price.

Comment: A few other commenters expressed concern that manufacturers were not likely be incentivized to enter into arrangements to offer point-of-sale reductions in price unless

the Department clarified whether manufacturers have an option to provide these discounts via plans, directly to each pharmacy, or through another mechanism.

Response: We thank commenters for their concern. We note that the discount safe harbor continues to protect discounts on prescription pharmaceutical products offered to other entities, including, but not limited to, wholesalers, hospitals, physicians, pharmacies, and third-party payors in other Federal health care programs. We clarify, however, that under the new safe harbor at § 1001.952(cc), the reduction in price must be set in advance with a plan sponsor under Medicare Part D, a Medicaid MCO, or a PBM acting under contract with either. While a chargeback may be paid directly to the pharmacy, the Medicaid MCO or Part D plan is the anticipated recipient of the reduction in price.

Comment: A few other commenters expressed concern that manufacturers were not likely be incentivized to enter into arrangements for point-of-sale reductions in price unless HHS clarified whether point-of-sale discounts are required to be uniform across all stages of the benefit design.

Response: We appreciate the commenters' concern. We clarify that because the reduction in price must be set in advance with a plan sponsor under Medicare Part D, a Medicaid MCO, or a PBM acting under contract with either, we would expect the point-of-sale reduction in price to be uniform across all stages of the benefit design, and would not expect the reduction

in price to be negotiated on a beneficiary-by-beneficiary basis. Any such arrangement would be difficult to know at the point of sale and thus could not be applied accurately to the point-of-sale price, creating risk of violating the requirements of the new safe harbor for point-of-sale reductions in price.

Comment: Another commenter expressed concern that manufacturers would not likely be incentivized to provide point-of-sale reductions in price, or only provide limited reductions at the point of sale, because manufacturers would more likely set single discount levels across all payers due to the increased transparency requirements.

Response: As we discuss in more detail in the Regulatory Impact Statement, we acknowledge that there may be a wide range of behavioral changes throughout the prescription pharmaceutical product supply chain. However, PBMs will continue to have access to important negotiation tools, such as formulary placement. Additionally, PBMs know the net prices that plans paid before the revisions to the safe harbors. Accordingly, the Department believes it is unlikely that parties will dramatically change the prices they negotiate due to transitioning from rebates to point-of-sale reductions in price.

Comment: A few commenters noted that since drugs are not typical consumer products, offering point-of-sale reductions in price would not likely impact demand; therefore, manufacturers would not likely be incentivized to offer them. However, another commenter expected that the new safe harbor would increase

competition and create a strong behavioral response among plans and manufacturers. Another commenter believed that some manufacturers would be highly incentivized to offer point-of-sale reductions in price if the drug was already in a highly competitive market.

Response: We thank commenters for their insights into the dynamics of drug markets. We agree that manufacturers are more likely to be incentivized to offer point-of-sale reductions in highly competitive drug markets and less likely to be incentivized in drug markets with less competition, as was the case with rebates. However, as explained elsewhere in this final rule, we believe there is a decreased risk of fraud and abuse when the reductions in price are offered at the point of sale rather than as rebates.

v. During 100 Percent Cost Sharing

Comment: A commenter noted that the Proposed Rule did not address how point-of-sale discounts would apply to beneficiaries with 100 percent cost sharing. Other commenters provided examples of how they interpreted the point-of-sale discount to apply during phases with 100 percent cost sharing, e.g., the deductible phase. A commenter suggested that such beneficiaries should pay 100 percent of the discounted net cost. The commenter provided the following example: if a drug's list price is \$200 and a beneficiary's plan sponsor under Part D has negotiated a point-of-sale reduction in price of 10 percent, then the price of the drug is \$180. According to the commenter,

during a period of 100 percent cost sharing, the beneficiary would pay \$180.

Response: We agree with the example offered by the commenter. Specifically, if a drug's list price is \$200 and a plan sponsor under Part D has negotiated a point-of-sale discount of 10 percent, the price of the drug for enrollees of that plan is \$180. If a beneficiary is in the deductible phase, the beneficiary would pay the full discounted price of the drug (*i.e.*, \$180) at the pharmacy counter.

vi. Additional Safeguards

Comment: A commenter recommended OIG require entities to "refrain from doing anything that would impede" their contracting counter-party from meeting its own obligations under the safe harbor. The commenter noted that this is a condition of the discount safe harbor.

Response: The proposed safe harbor for point-of-sale reductions in price for prescription pharmaceutical products differs from the discount safe harbor at 42 CFR 1001.952(h), in that the latter has separate sets of requirements for buyers and sellers or offerors of discounts. Because the ability of the buyer to meet its obligations under the discount safe harbor depends in part on cooperation of the seller or offeror, the safe harbor includes requirements that the seller or offeror refrain from impeding the buyer from meeting the buyer's own obligations. Because the proposed safe harbor for point-of-sale reductions in price does not include conditions that similarly

require the cooperation of other parties to the transaction, we did not propose to include this safeguard, and we decline to include it in the final rule.

Comment: A commenter recommended that the point-of-sale reductions in price not be contingent upon agreement between the manufacturer and the PBM as to PBM service fees.

Response: We did not propose, and therefore are not finalizing in this rule, a condition of the point-of-sale reduction in price safe harbor that would prohibit a reduction in price being contingent upon agreement between the manufacturer and the PBM on PBM service fees. We note, however, that the point-of-sale reduction in price safe harbor protects only the reduction in price; it does not protect a demand or request for concession with regard to a PBM service fee arrangement. Such a demand or request itself could constitute a solicitation for remuneration (the remuneration being the service fee agreement, or a concession on the terms of the service fee agreement) prohibited by the anti-kickback statute that would not be protected by any safe harbor.

Comment: Some commenters recommended revising the proposed safe harbor for point-of-sale price reductions to require any individual or entity administering point-of-sale chargebacks to meet the same compensation requirements set forth in the proposed PBM service fees safe harbor.

Response: We did not propose, and therefore are not finalizing in this rule any requirements for payments related to

chargeback administration. We note, however, that the point-of-sale reduction in price safe harbor protects only a reduction in price by a manufacturer for a prescription pharmaceutical product that is payable, in whole or in part, by a plan sponsor under Medicare Part D or a Medicaid MCO; it does not protect any payment arrangements that parties may enter into for services such as chargeback administration.

Comment: Several commenters requested that OIG require certain transparency requirements, for example: plans or PBMs should be required to exchange information to enable manufacturers to validate that the full value of the reduction in price is provided to the dispensing pharmacy; data from plans and PBMs should be available to manufacturers to confirm that patients receive point-of-sale reductions in price; information from plans or PBMs be available to patients and pharmacies at the point-of-sale; and information from plans or PBMs, including chargeback amounts due and paid, be available to pharmacies in real time. By contrast, some commenters opposed general transparency requirements and requested that OIG ensure that point-of-sale reductions in price remain confidential by explicitly stating that transparency is not required for this proposed safe harbor. For example, pharmacies are not parties to the agreements between plans, PBMs, and manufacturers and, thus, should not be allowed to know their terms.

Response: We appreciate the commenters' suggestions for and concerns about certain transparency requirements for the

proposed point-of-sale reductions in price safe harbor. As explained elsewhere in this final rule, we believe that creating a new safe harbor for point-of-sale reductions in price will increase transparency, including transparency to plans and beneficiaries, and improve alignment of incentives among parties that could result in lower list prices and out-of-pocket costs. However, as explained earlier in this rule, we decline to adopt the commenter's request to create a condition in the safe harbor related to the exchange of information and cooperation among the parties, such as the suggested disclosures to manufacturers.

Comment: Some commenters recommended that OIG ensure that pharmacies are further protected by, for example, ensuring that a reduction in revenue for PBMs is not compensated by reduction in payment to pharmacies not affiliated with the PBM, or ensuring that the chargeback accounts for costs incurred by the pharmacy or that pharmacies are reimbursed for medication costs and costs to acquire, handle, and dispense medications.

Response: We are not specifying the reimbursement terms of an agreement between a PBM or plan and a pharmacy for prescription pharmaceutical products in the final safe harbor. To the extent point-of-sale chargebacks are used, the payment from the manufacturer to the pharmacy must be equal to the reduction in price negotiated between the manufacturer and the plan or PBM. As we stated in the Proposed Rule, we intend for the point-of-sale chargeback to make "pharmacies whole for the

difference between acquisition cost, plan payment, and beneficiary out-of-pocket payment.”

Comment: A commenter requested that OIG clarify the meaning of “completely applied” as set forth in paragraph (cc)(1)(iii). Another commenter requested OIG revise paragraph (cc)(1)(iii) to indicate that the reduction in price must be completely applied to the price upon which the patient’s out-of-pocket spending at the point-of-sale is based. Another commenter recommended revising paragraph (cc)(1)(iii) to ensure that the rule does not inadvertently permit point-of-sale reductions in price to operate like a branded drug manufacturer coupon program for Medicare and Medicaid beneficiaries.

Response: We agree with the commenter’s interpretation of “completely applied” as it was set forth in paragraph (cc)(1)(iii) of the Proposed Rule and confirm that a protected reduction in price cannot operate like a coupon program. We have revised the language for clarity in this final rule. The reduction in price is from the manufacturer to the plan sponsor under Medicare Part D or a Medicaid MCO, but the reduction in price negotiated by a Part D plan sponsor or Medicaid MCO (or a PBM on the plan sponsor’s or Medicaid MCO’s behalf) must be reflected at the pharmacy counter. The amount paid by a beneficiary at the pharmacy counter will depend on the benefit design of a particular plan, the phase of the benefit year in which the prescription is filled, and the price negotiated by the plan sponsor or PBM for the prescription pharmaceutical

product that may include, *e.g.*, reductions in price negotiated with the pharmaceutical manufacturer or dispensing fees negotiated with the pharmacy. For example, if a pharmaceutical product has a list price of \$120 and the manufacturer gives a reduction in price of \$20, then that entire \$20 would need to be reflected completely in the price upon which the beneficiary's cost-sharing obligation is based. We are informed by CMS that their guidance allows for this reflection of the entire discount at the point of sale.⁴⁹ For purposes of safe harbor protection, the reduction in price must be completely reflected at the point of sale.

If a Part D beneficiary has a 20 percent coinsurance obligation, the beneficiary typically would pay 20 percent of \$100, or \$20, at the pharmacy counter (plus any portion required by the benefit design for, *e.g.*, dispensing fees). If the beneficiary were in the deductible phase at the time the prescription was filled, the beneficiary would pay \$100 at the pharmacy counter (plus any portion required by the benefit design for, *e.g.*, dispensing fees). If, however, the beneficiary's plan used copayments instead of coinsurance, then the beneficiary would pay the copayment amount according to Part D rules. Part D plan sponsors must meet actuarial equivalence standards when designing plans and benefit structures during the Part D bidding process. The reduction in price must be reported

⁴⁹ CMS, Medicare Prescription Drug Benefit Manual, ch. 5, section 20.6 (describing that Part D plan sponsors must provide enrollees with access to negotiated prices for covered Part D drugs as part of their qualified prescription drug coverage).

in accordance with existing rules and regulations governing the reporting of discounts and other reductions in price under the Part D program. We reiterate that if a PBM operating on behalf of a Part D plan sponsor or Medicaid MCO retains any portion of the reduction in price, the remuneration retained by the PBM would not be protected under this new point-of-sale safe harbor.

To provide additional clarity for stakeholders, we include the following example from the Proposed Rule regarding the current rebate framework and then explain how a reduction in price would be reflected at the point of sale consistent with the new safe harbor. Consider a branded prescription drug dispensed at a retail pharmacy that has a WAC/list price of \$100. A manufacturer sells the drug to a wholesaler at a 2 percent discount from the WAC. Thus, the drug is sold to the wholesaler at \$98. The wholesaler in this example sells the drug to a pharmacy for \$100. A PBM negotiates on behalf of a plan both a negotiated reimbursement rate with a pharmacy that dispenses the drug and a rebate from the manufacturer for including the drug on the plan's formulary, tier placement within the formulary, etc. Under its contract with the PBM, the pharmacy agrees to be paid a negotiated rate such as, by way of example only, $1.20 \times \text{WAC/list price} - 15\%$ plus a \$2 dispensing fee.

When a patient has a prescription for the medication, the pharmacy files a claim on behalf of the patient to the patient's prescription insurance. This claim is processed by the plan

and/or the PBM on the plan's behalf. The PBM determines what they pay the pharmacy and the amount remaining for the patient to pay the pharmacy. In this instance, the pharmacy is paid \$104 for the drug. After the transaction, the plan and/or PBM may also receive rebates from the manufacturer, and in some cases, pay the pharmacy less than the original amount.

In this example, the PBM has negotiated a rebate with the manufacturer, of 30 percent of the WAC/list price (\$30), which is passed on entirely to the plan sponsor. This rebate does not reduce the price charged at the pharmacy counter or the beneficiary's out-of-pocket cost, and the beneficiary's \$26 coinsurance is actually 35 percent of the net cost of the drug (\$104-\$30), compared to the 25 percent coinsurance described in the benefits summary (which is based on negotiated pharmacy reimbursement and not net price). Thus, in this example, the plan receives back \$30 in rebates, reducing the net cost for the drug to \$74 (*i.e.*, \$104-\$30). This process is reflected in the following chart, which has been revised slightly with technical edits:

Transaction	Brand	Notes
List Price	\$100	(A) .
Pharmacy Reimbursement/POS Price	\$104	(P) .
Manufacturer Rebate to Plan	\$30	(B) = 30% of (A) .
Net Drug Cost	\$74	(C) = (P) - (B) . ⁵⁰
Patient Coinsurance	(\$26)	(D) = 25%* (P) .
Net Cost to Plan	\$48	(E) = (C) - (D) .
Patient's Share of POS Price	25%	(H) = (D) / (P) .
Patient's Share of Net Cost	35%	(I) = (D) / (C) .

⁵⁰ The Federal government shares in the rebates received by PBMs and Part D plan sponsors. See also <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>.

The difference in the patient's cost sharing relative to that of the plan is even more acute when the beneficiary is in the deductible phase and is fully responsible for the total pharmacy reimbursement. In this case, the beneficiary pays the full \$104, more than 40 percent higher than what the plan negotiated, but never paid any fraction of it. In fact, the plan netted \$30 when the beneficiary picked up the prescription.

Transaction	Brand	Notes
List Price	\$100	(A).
Pharmacy Reimbursement/POS Price	\$104	(P).
Manufacturer Rebate to Plan	\$30	(B) = 30% of (A).
Net Drug Cost	\$74	(C) = (P)-(B).
Patient Coinsurance	(\$104)	(D) = 100% of (P).
Net Cost to Plan	(\$30)	(E) = (C)-(D).
Patient's Share of POS Price	100%	(H) = (D)/(P).
Patient's Share of Net Cost	140%	(I) = (D)/(C).

As we stated in the Proposed Rule, this example reflects the Department's concern that, under the current rebate-based system, beneficiaries may not receive the benefits of reduced prices and costs that other parties do. The Department recognizes that parties to prescription drug sales are frequently paid based on a percentage of the WAC/list price and therefore, as the list price increases, so does the revenue to these parties. For example, in the context of branded prescription drugs, the absolute net revenue to the PBM and manufacturer generally may increase as the WAC increases. The net revenue to the pharmacy also may increase, but that would be contingent on the pharmacy's contract with the PBM. While the insurer's costs will increase as the WAC increases, under the

current system, PBMs often offset the increase for insurers via a higher rebate from the manufacturer. In contrast, when a beneficiary is in the deductible phase, their out-of-pocket spending is more closely related to the WAC price than the net price. The rebate from the manufacturer is not utilized to offset beneficiary's out-of-pocket costs. Similarly, the beneficiary's coinsurance, which is often partly a percentage of WAC, will often increase as list price increases. Under the current system, rebates are often not applied at the point of sale to offset the beneficiary's deductible or coinsurance or otherwise reduce the price paid at the pharmacy counter.

Under this final rule, beneficiaries would be able to share - at the pharmacy counter - in the discounts that plans and PBMs negotiate with manufacturers. Using the examples above, if the rebate were fully reflected in the point-of-sale price, the beneficiary's cost-sharing obligations would drop from \$104 to \$74 if the beneficiary were still in the deductible phase, and from \$26 to \$18.50 if she had a coinsurance obligation of 25 percent. The plan's share of the discount would be proportional to the coinsurance: the plan would get no share of the discount if the beneficiary were to pay full cost, but it would get 75 percent of the discount if the beneficiary had 25 percent coinsurance. The following provides an illustration of this point:

Transaction	100 Percent coinsurance (deductible)	25 Percent coinsurance
List Price	\$100	\$100
Pharmacy Reimbursement	\$104	\$104

Transaction	100 Percent coinsurance (deductible)	25 Percent coinsurance
Negotiated POS Discount	(\$30)	(\$30)
Net Drug Cost/POS Price	\$74	\$74
Patient Coinsurance	\$74	\$18.5
Net Cost to Plan	\$0	\$55.5
Patient's Share of POS Price	100%	25%
Patient's Share of Net Cost	100%	25%

Comment: A commenter recommended that OIG restrict, through a revision to the proposed safe harbor, the provision of identifying patient and prescriber information the drug manufacturer can receive from a Medicaid MCO or PBM acting on behalf of a Medicaid MCO in exchange for providing a price reduction. Specifically, the commenter recommended that a new paragraph (cc)(1)(iv) be added: (iv) The reduction in price does not involve the provision of identifying patient or prescriber information to the pharmaceutical manufacturer by a Medicaid MCO, or the PBM acting under contract with it.

Response: Nothing in this final rule affects obligations under existing privacy and security rules. We do not expect manufacturers to need patient- or provider-specific information. The plan sponsor under Part D, Medicaid MCO, or PBM must have a writing with the manufacturer that sets in advance the reduced price for a prescription pharmaceutical product. The plan sponsor under Part D, Medicaid MCO, or PBM is best positioned to ensure that the reduction in price is completely reflected in the price of the prescription pharmaceutical product at the time the pharmacy dispenses it to the beneficiary, and we would expect these parties to maintain documentation showing that

these reductions in price were completely reflected at the time of dispensing.

Comment: A commenter requested that OIG clarify that under the point-of-sale safe harbor, point-of-sale reductions in price can be made contingent on bundled sales arrangements. Such arrangements can provide additional value to patients by expanding the types of discount arrangements available to manufacturers and payors. Another commenter recommended that any point-of-sale reductions in price that are contingent on bundled sales arrangements are passed along to consumers in a non-allocated, disaggregated fashion. This commenter further stated that if a method for allocating bundles at the point-of-sale is needed, OIG should look to CMS's definition of "bundled sale" at 42 CFR 447.502 and that OIG should encourage manufacturers and PBMs to agree upon a written method for estimating and allocating, in advance, effective rates for products subject to a bundle and that these effective rates are provided to the dispensing pharmacy. This commenter also recommended that price protection payments are passed along as point-of-sale chargebacks.

Response: The conditions of the new safe harbor for point-of-sale reductions in price do not limit the types of negotiation methods the parties may use, as long as the reduction in price can be completely reflected at the point of sale. Elsewhere in this final rule, we make clear that a reduction in price must be simply a reduction in price and not

payment for a service. Therefore, making a reduction on price contingent on a bundled sale arrangement (e.g., by providing for a reduction in price for one drug contingent on formulary placement of another drug) is not prohibited. However, we caution that to be protected under the safe harbor, the reduction in price must be reflected in the price of the product at the point of sale and a reduction in price that is not known at the time of sale (and therefore cannot be reflected at the time of sale) would not meet this condition of the safe harbor. For example, we could see a bundled arrangement based on formulary placement (such as in the example above) to be feasible; the parties will know at the time of sale, what the reduction in price would be. However, some types of bundling arrangements (e.g., an arrangement that might be contingent on volume of sales of different items in a bundle) would make it difficult to reflect the final price at the time of sale, and therefore would not be consistent with the requirements of the safe harbor. We also clarify 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.

Comment: A commenter suggested that OIG coordinate with the FTC to identify and address anti-competitive rebate schemes, such as rebate walls (which, according to the commenter, block

competition by coupling volume-based discounts across multiple indications with retaliatory measures, such as the clawback of rebates by a market leader), when they run afoul of antitrust law.

Response: We appreciate the commenter's feedback. We work closely with our Government partners, including the FTC, as appropriate.

Comment: A commenter proposed an alternative model relating to point-of-sale reductions on drugs covered under Federal health care programs—namely, safe harbor protections for manufacturer cost-sharing assistance programs that provide point-of-sale reductions on prescription drugs covered under Federal health care programs when there is no less expensive and equally effective generic available, such as for biologics.

Response: We did not propose to protect manufacturer cost-sharing assistance programs and have long-standing concerns with these types of arrangements; for these reasons, we decline to adopt the commenter's suggestion in this final rule.

Comment: Some commenters requested that OIG clarify how the point-of-sale discounts should be structured. For example, a commenter requested that OIG clarify whether manufacturers would be required to or have the option to provide the point-of-sale discounts by plans directly to the pharmacies, individually, or through another mechanism.

Response: If safe harbor protection is desired, point-of-sale reductions in price can be structured in any way that

complies with the requirements of this safe harbor and any other applicable law. We note, however, that the safe harbor protects the price reduction from the manufacturer to the plan (directly or through a PBM). Discounts to pharmacies are not included in this safe harbor, but they are eligible for protection under the discount safe harbor if all safe harbor conditions are met. We have made minor changes to the regulatory text at § 1001.952(cc)(1) to clarify this point.

Comment: Some commenters recommended that patients with higher cost sharing be provided preferential treatment. A commenter requested that OIG provide manufacturers with the ability to pass through differential discounts to patients with, for example, copayments or higher cost sharing. Another commenter requested that patients with copayments, specifically, pay the lesser of the negotiated price of the drug, after it is reduced to reflect the point-of-sale discounts, or a reduced copayment reflecting a reduction that must, at a minimum, be proportional to the point-of-sale discount.

Response: We have clarified above the treatment of copayments under this final rule. We are not providing specifically for differential discounts under the safe harbor. We note, however, that this safe harbor protects reductions in price that manufacturers offer to plan sponsors under Part D and to Medicaid MCOs; the amount that gets passed through to beneficiaries is part of a plan's design and would not be determined by the manufacturer.

Comment: Several commenters identified that there is no mechanism in the proposed safe harbor to influence or even monitor drug manufacturer behavior, particularly related to lowering drug prices. Some commenters recommended that OIG require manufacturers to lower drug prices, while another commenter recommended that drug manufacturers be required to "price drugs fairly" as a condition for receiving government-funded research monies. A commenter recommended that OIG enforce penalties for "egregious price increases" that have the effect of increasing costs for plans, Federal health care programs, or patients. Another commenter recommended that OIG require not just manufacturers, but also PBMs and payors to lower drug prices. Another commenter recommended that CMS leverage the condition of participation standards by implementing new conditions on drug manufacturers that (1) would limit price increases for existing drugs to a measure of healthcare cost inflation and (2) allow managed care companies the option to exclude new drugs from their formularies if their price is higher than existing, peer drugs, but the differences in their clinical effectiveness relative to existing, peer drugs are not statistically different. A commenter recommended that the Department establish requirements on drug manufacturers that are similar to the medical loss ratio, for example, drug manufacturers should be held to standards based upon a ratio of expenditures on research and development and required to provide detailed reports of their expenses with penalties or other

consequences for non-compliance. A commenter recommended that OIG require not only manufacturers, but also PBMs and payors, to lower drug prices.

Response: OIG does not have the authority to require that manufacturers or others lower drug prices, and comments recommending CMS take certain actions are outside the scope of this rulemaking. This final rule is limited to the issue of safe harbor protection under the anti-kickback statute for certain arrangements that implicate the prohibition on referral payments but pose an acceptably low risk of fraud or abuse. To that end, we have revised the discount safe harbor and added two new safe harbors. We have not required any particular level of discounts or price reductions.

Comment: Several commenters were concerned that the changes included in the Proposed Rule would not influence manufacturers' behavior and would not impose requirements on manufacturers to engage in good faith negotiations with all entities of the supply chain.

Response: As we stated in the Proposed Rule, it is difficult to predict any particular manufacturer's behavior. We are finalizing a safe harbor that permits manufacturers to offer reductions in price that meet certain conditions, including that the reduction be completely reflected in the price of the prescription pharmaceutical product at the time the pharmacy dispenses the drug to the beneficiary. Like all safe harbors,

this safe harbor is optional and does not require manufacturers to offer discounts.

Comment: A commenter identified that the Proposed Rule does not provide a mechanism by which manufacturers can monitor or validate whether the reductions in price from manufacturers are passed through at the point of sale. Thus, the commenter recommended that OIG allow for manufacturers to be insulated from liability if certain discounts are not passed through at the point of sale, until OIG can establish a mechanism for monitoring and validating the pass through actually occurs.

Response: We decline to adopt this suggestion. Under the anti-kickback statute, parties are always required to comply with the law regardless of whether the OIG monitors for compliance with it. With that said, we recognize that each party has certain responsibilities for complying with the safe harbor. Whether a party has complied with the law is a fact-specific inquiry, including with respect to the intent of the parties.

Comment: Some commenters recommended that OIG require all participants or intermediaries in the drug supply chain be regulated and subject to the proposed safe harbor.

Response: For reasons explained elsewhere, we are not expanding the scope of the safe harbor beyond what we proposed. The commenters' suggestion would be impractical. Further, a safe harbor offers protection under the Federal anti-kickback

statute for the remuneration described in the safe harbor; it does not generally regulate parties in the industry.

D. Safe Harbor for Certain PBM Service Fees

The Proposed Rule proposed a safe harbor to protect remuneration in the form of flat, fixed fees that manufacturers pay to PBMs for services the PBM provides to a manufacturer.

Comment: Many commenters who commented on the proposed safe harbor for PBM service fees were generally supportive of the safe harbor and its requirements. According to a commenter, the conditions limit the potential for PBMs to perform services with the incentive to increase costs for beneficiaries and programs. Another commenter supporting the proposal stated that it will allow parties to receive appropriate payment for the value of their services, rather than the volume or value of the pharmaceutical products.

Response: We appreciate the commenters' support for this safe harbor.

Comment: Some commenters raised concerns about or opposed the proposed safe harbor for PBM service fees. For example, according to a commenter, the proposed safe harbor does not address what the commenter believes to be a conflict of interest when a PBM provides services to plan sponsors and patients while profiting from their relationships with manufacturers. The same commenter also said that manufacturers and PBMs can mislead parties by how they classify rebate payments and service fees in their financial arrangements.

Another commenter said that the safe harbor will not lower the surplus that PBMs with market power receive because, according to the commenter, such PBMs can demand a flat fee as easily as they can negotiate for percentage-based fees under the current rebate system. According to this commenter, payments from manufacturers to PBMs should first flow to the payor before being split between the payor and the PBM.

Response: We appreciate the commenters' responses. While we agree that PBMs can negotiate for flat fees just as they can negotiate for percentage-based fees, this safe harbor includes safeguards to reduce the risks associated with remuneration that may be tied to referrals. For example, the fees must be consistent with fair market value in an arm's-length transaction and cannot be determined in a manner that takes into account the volume or value of referrals or business otherwise generated between the parties, or between the manufacturer and the PBM's health plans that is payable, in whole or in part, by a Federal health care program. In addition, protected fees would be only for services that the PBM provides to the manufacturer, not for services provided to health plans. Fees for services furnished to health plans may be structured to comply with the personal services and management contracts safe harbor at § 1001.952(d).

Comment: Several commenters requested that OIG clarify the meaning of "services the PBM provides to the pharmaceutical manufacturer related to the pharmacy benefit management services that the PBM furnishes to one or more health plans," and

requested that OIG specify the types of services protected by the proposed safe harbor. A commenter recommended OIG narrow the list of "pharmacy benefit management services" listed in the preamble to the Proposed Rule so that, for example, PBMs do not create rebates composed of new classes of fees, or otherwise disguise rebates as fees, charged to and paid by manufacturers. Another commenter recommended OIG restrict PBM services to adjudicating claims only. Other commenters suggested that OIG issue guidance on the types of PBM services that OIG views as appropriately compensated by plans instead of by manufacturers, with a commenter pointing to claims adjudication and utilization management as examples of services performed for plans, and member aggregation as an example of a service appropriately provided to manufacturers.

Response: We are not specifying the services to be protected under the PBM service fees safe harbor because we do not want to set a static list of services that will be protected. Moreover, the types of services a PBM might provide to a health plan are not necessarily the same types of services that a PBM might provide to a manufacturer. Using the commenter's example, adjudicating claims is a service that a PBM performs for a health plan, but not for a manufacturer; further, while member aggregation might be one type of service provided by PBMs to manufacturers, to the extent that any compensation for such services is determined based on the volume or value of Federal health care program business, the compensation would not

be protected by this safe harbor. We decline to specify a list of services that the PBM provides for plans as opposed to manufacturers. We believe it should be clear to the contracting parties whether the PBM is providing a service for a manufacturer or a plan.

i. Scope of Protected Fees

The Proposed Rule proposed a new safe harbor to protect certain PBM service fees that were flat service fees manufacturers make to PBMs for services the PBMs provide to the pharmaceutical manufacturers, for the manufacturers' benefit, when those services relate in some way to the PBMs' arrangements to provide pharmacy benefit management services to health plans. This safe harbor would protect only a pharmaceutical manufacturer's payment for those services that a PBM furnishes to the pharmaceutical manufacturer, and not for any services that the PBM may be providing to a health plan. 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. The Proposed Rule provided a non-exhaustive list of "pharmacy benefit management services," but proposed not to create a definition

because the role of the PBM may evolve over time. We address the definition of pharmacy benefit management services in the definition section. This section discusses the scope of the protected fees.

Comment: Some commenters suggested clarifying that the services must be performed "on behalf of" the manufacturer instead of "to the manufacturer" or "for the manufacturer's benefit." Commenters also recommend that the safe harbor be limited to fees for services "that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement."

Response: For purposes of this safe harbor, and in this context, we believe that "to the manufacturer" is sufficiently clear. The PBM would be providing a service to a manufacturer (which also might be on behalf of the manufacturer). While we are not incorporating the particular language suggested regarding the services that the manufacturer would otherwise perform (or contract for), we agree that the safe harbor protects payment only for legitimate services.

Comment: Several commenters recommended broadening the proposed safe harbor related to PBM Service Fees to all fees, especially all PBM arrangements with manufacturers. These commenters wanted to ensure that the "related to" language does not unduly limit the scope of the safe harbor or risk noncompliance if manufacturers contract with PBMs for services

that may not clearly "relate to" the PBM services that they typically provide to health plans.

Response: We thank the commenter for this suggestion but decline to accept it. If a service does not relate to pharmacy benefit management services that the PBM provides to a health plan, then it is unclear how the PBM could meet the condition that requires certain annual disclosures to health plans. As we note elsewhere, other services that PBMs provide could be protected by other safe harbors, including the GPO and personal services safe harbors.

Comment: One commenter recommended that OIG clarify the PBM services covered by the safe harbor by removing the requirement that the services must "relate to" services the PBM furnishes to health plans and clarify the types of PBM services that might be provided for the benefit of the manufacturer.

Response: We decline to remove the requirement in the new safe harbor for PBM service fees that the fees for which safe harbor protection is sought "relate to" pharmacy benefit management services that the PBM furnishes to health plans. This proposed condition fosters transparency for health plans. As we stated in the Proposed Rule, the Department believes that PBMs are agents of the health plans with which they contract and that transparency is important to ensure that a PBM's arrangements with pharmaceutical manufacturers are not in tension with the services it provides to the health plans for which it is acting as an agent. Disclosures of specific

services will allow a plan to see what services a PBM is contracting with a manufacturer that relate to the health plan. Thus, we proposed to protect only those fixed fee arrangements between manufacturers and PBMs where plans could have visibility into the arrangements, in other words, arrangements related to services the PBM was providing the plans. We solicited comments on limiting the safe harbor to fees that pharmaceutical manufacturers pay to the PBMs that relate to the PBM's arrangements to provide pharmacy benefit management services to health plans.

The language of the final rule clarifies that the fees for which safe harbor protection is available are fees for services provided for the benefit of the manufacturer who is paying for them. As noted in the Proposed Rule, such services might include services rendered to a manufacturer that depend on or use data gathered from PBMS from their health plan customers (whether claims or other types of data), subject to all applicable privacy and security rules. PBMs also might provide services for manufacturers to prevent duplicate discounts on 340B claims. Nothing in this rule preempts any contractual terms that a PBM has with health plans that limit uses of health plans or enrollees' data.⁵¹

Comment: As noted in the definition section, many commenters recommended that the PBM services and their related fees be tied to bona fide services. Additionally, these

⁵¹ 84 FR 2349-50.

commenters recommended that the services be itemized to clearly show that the fees are paid for specific services at a market value. These commenters recommended that this guidance clarify that these services cannot be negotiated as a fixed suite of services or services that are applied on an "all or nothing basis."

Response: As we explain above, we have included additional conditions aimed at clarifying that only payment for legitimate services would be protected. We did not propose, and are not finalizing, a specified format for disclosure of the services to health plans, nor would PBMs be required to disclose the fees to health plans. However, PBMs would be required to disclose both the services and associated fees to the Secretary upon request. Therefore, it would be a best practice to maintain documentation that could demonstrate how each element of the safe harbor (e.g., fair market value, fixed fees) is met.

Comment: One commenter recommended that the safe harbor fees be narrowed to protect only service fees paid for the purposes of administering point-of-sale reductions in price and related chargebacks.

Response: We decline to adopt this suggestion. The safe harbor for point-of-sale reductions in price protects a different stream of remuneration (i.e., the reduction in price from a manufacturer to a plan sponsor under Part D or a Medicaid MCO). This safe harbor for PBM service fees is not related to the safe harbor for point-of-sale reductions in price and

therefore should not be limited to arrangements protected under it.

Comment: A commenter requested that OIG protect only fees paid to PBMs independent of services a PBM already provides to plans.

Response: The PBM service fees safe harbor protects payments "for services the PBM provides to the pharmaceutical manufacturer." Services provided to plans are not services provided to manufacturers, and therefore payments for services to plans are not protected by the safe harbor.

ii. Fair Market Value

Comment: A commenter recommended that the fair market value of the payment to PBMs reflect the value of the services, not the value of the products involved.

Response: By its terms, the proposed safe harbor for PBM service fees protects compensation paid for services performed by a PBM for a pharmaceutical manufacturer. The safe harbor provides that the compensation must (1) be consistent with fair market value in an arm's-length transaction; (2) be a fixed payment, not based on a percentage of sales; and (3) not be determined in a manner that takes into account the volume or value of Federal health care program business. We believe it is clear from this context that the compensation must reflect the fair market value of the service rendered, and not the value of the products involved.

Comment: Several commenters requested that OIG clarify the meaning of "fair market value." A commenter asked OIG to provide examples of valuation approaches to meet the standard. Other commenters requested that OIG either adopt CMS's statements regarding fair market value in the context of CMS's *bona fide* service fees guidance for the MDRP or clarify the "fair market value" standard is consistent with CMS's statements. Another commenter asserted that in order to establish fair market value, PBMs and manufacturers should provide specific disclosures and demonstrate that the performed services are of real value to manufacturers, instead of simply showing that many manufacturers are willing to pay PBMs comparable amounts of money for general, nondescript services.

Response: The requirement that compensation paid for PBM service fees be "consistent with fair market value in an arm's-length transaction" is nearly identical to a requirement of the safe harbor for personal services and management contracts, 42 CFR 1001.952(d), which has been in effect since 1991. 56 FR 35952 (July 29, 1991). In addition, both the personal services and management contracts safe harbor and the proposed PBM service fees safe harbor include a requirement that the compensation not be determined in a manner that takes into account the volume or value of any Federal health care program business. (Because of this requirement, a fair market value determination cannot be made through comparison to transactions where compensation may have taken the value of referrals into

account.⁵²⁾ The proposed PBM service fees safe harbor also specifically excludes from protection compensation based on a percentage of sales. In addition, as we explain elsewhere, we include certain additional requirements similar to the personal services and management contracts safe harbor at 42 CFR 1001.952(d).

We decline to provide further guidance on the setting of compensation for PBM service fees, nor do we adopt the guidance provided by CMS in a different context.⁵³

iii. Take into Account Volume or Value

Comment: Commenters suggested that, if OIG does not believe that all fees based on volume or value would generate a

⁵² See, e.g., Letter from D. McCarty Thornton, Associate General Counsel, Inspector General Division, to T. J. Sullivan, Office of the Associate Chief Counsel, Internal Revenue Service, Dec. 22, 1992 ("When considering the question of fair market value, we would note that the traditional or common methods of economic valuation do not comport with the prescriptions of the anti-kickback statute. Items ordinarily considered in determining the fair market value may be expressly barred by the anti-kickback statute's prohibition against payments for referrals. Merely because another buyer may be willing to pay a particular price is not sufficient to render the price paid to be fair market value. The fact that a buyer in a position to benefit from referrals is willing to pay a particular price may only be a reflection of the value of the referral stream that is likely to result from the purchase."), available at <https://oig.hhs.gov/fraud/docs/safeharborregulations/acquisition122292.htm>.

⁵³ A commenter on the Proposed Rule cited CMS's response when asked to provide guidance on the meaning of "fair market value" as used in its definition of "bona fide service fees." 81 FR 5170, 5179-5180 (Feb. 1, 2016). Among the comments cited in that rulemaking was one that "encouraged CMS to acknowledge that many or most fee arrangements common in the industry tend to be percentage based agreements and that manufacturers can establish a fair market value rationale for a percentage based fee through industry benchmarking by comparing types of specific services outlined in an agreement with ranges of payments observed throughout the industry." 81 FR 5179. While CMS did not respond to this particular comment and declined to further define fair market value for purposes of the bona fide service fee definition, it stated its belief that manufacturers should retain flexibility in determining whether service fees are paid at fair market value. We are not adopting CMS' terminology nor its definition of "bona fide services fees," for purposes of this final rule. To the extent that CMS's guidance on the topic of service fees leaves room for percentage-based arrangements, it should be noted that percentage-based arrangements are expressly excluded from protection under the PBM service fees safe harbor.

significant risk, OIG should adopt clear guidance excepting lower risk arrangements from the volume or value requirement. More specifically, several commenters recommended that OIG exempt any arrangement that involves varying numbers of transactions, provided that the fee for each individual transaction is fixed in advance and consistent with fair market value in an arms-length transaction, as it presents a low risk of fraud. This would facilitate practical service fee arrangements between manufacturers and PBMs. Alternatively, commenters suggested that the rule could clarify that the reference to volume or value of business "otherwise generated" between parties means that payment terms under the PBM service fee arrangement in question should not take into account other arrangements outside of the contract, but would not preclude per-unit fees based on volume or value of the services furnished under the service fee agreement itself. According to commenters, these types of arrangements present a low risk of fraud or abuse if certain safeguards are incorporated into the safe harbor. Specifically, a few commenters recommended including the factors identified in OIG's Advisory Opinions 10-14 and 11-18⁵⁴ to deem certain fair market value, arms-length, per-unit fees as not taking into account the volume or value of referrals or other business generated between the parties. A commenter requested that the safe harbor protect fees where PBMs

⁵⁴ Advisory Opinion 11-18 was terminated on April 1, 2014.

are paid less per claim as the number of claims increases in light of certain fixed costs.

Response: We agree with the general premise of the commenters' concerns, that compensation for services may be determined on a per-unit of work basis and thus vary with the volume of work performed. This particular safe harbor condition excludes compensation that takes into account the volume or value of referrals or other business that are payable in whole or in part under a Federal health care program. For example, if a per-unit-of-work fee is fixed in advance at fair market value for services actually provided to the manufacturer and is not based on volume or value of Federal health care business, then that arrangement could be protected, so long as the unit-based compensation does not vary during the course of the compensation arrangement in any manner that takes into account referrals or other Federal business generated. On the other hand, the safe harbor would not protect per unit compensation that varies with either increases or decreases in volume (e.g., X amount per unit for the first 1,000 units, X + 1 per unit for additional units), as we believe that compensation determined in this manner is not low risk. In addition, we emphasize that this safe harbor would not protect any per-unit-of-work fee that is based on or otherwise connected with drug prices.

Comment: According to a commenter, the Proposed Rule would allow all entities (other than PBMs) in the drug supply chain that supply services to manufacturers to be compensated for the

provision of services based on volume and a percentage of list price. The commenter recommended requiring all payments by manufacturers for services provided by third parties to be applied equally and to be set in advance, fixed, and based on fair market value.

Response: In the Proposed Rule, we proposed a new safe harbor specifically to protect fees paid from manufacturers to PBMs for services rendered to the manufacturers, if all the conditions of the safe harbor are met. This safe harbor does not "allow" payments to other entities that do not meet these conditions; it simply does not protect them, whether they meet the conditions or not. Manufacturer payments to entities other than PBMs may be protected by other safe harbors, such as the safe harbor for personal services and management contracts, 42 CFR 1001.952(d). (This safe harbor also requires that compensation be set in advance, consistent with fair market value in arm's-length transactions, and not determined in a manner that takes into account volume and value of Federal health care program business.) However, compliance with the terms of each safe harbor is voluntary. If parties choose not to comply with such requirements with regard to particular arrangements, it may be that they do not believe that these arrangements implicate the anti-kickback Statute or that they otherwise comply with the law.

iv. Fixed Fees

Comment: Several commenters were supportive of the condition in the safe harbor requiring that the compensation paid to a PBM be a fixed payment rather than a payment based on a percentage of sales. A commenter noted that this proposal may increase the placement of less expensive drugs on preferred formulary tiers and could reduce out-of-pocket costs for certain patients. Some commenters noted that a flat-fee system aligns fees with the value of the services provided.

Response: We appreciate the commenters' support for this condition of the safe harbor. Based on the comments received, we are finalizing this condition, as proposed.

Comment: Several commenters suggested changes to the scope of fees that can be protected under the PBM service fees safe harbor. For instance, several commenters recommended that the safe harbor apply to fees for any service a PBM provides to or on behalf of a manufacturer. Many commenters either requested that the safe harbor protect fees for all *bona fide* services provided by PBMs to manufacturers or asked that we incorporate (or consider incorporating) the standards from the *bona fide* service fee definition under the MDRP (42 CFR 447.502). According to at least one commenter, if we do not limit the scope of the safe harbor to *bona fide* services, PBMs may seek to convert costs and lost revenue to service fees.

Response: We are finalizing a modification to the new safe harbor to protect payments by a pharmaceutical manufacturer to a

PBM for legitimate services the PBM provides to the pharmaceutical manufacturer related to the pharmacy benefit management services that the PBM furnishes to one or more health plans with certain conditions. We share commenter's concerns about the use of this safe harbor to convert costs and lost revenue to service fees. Therefore, we are clarifying in the regulatory text that the safe harbor applies only to "legitimate" services; thus, this safe harbor does not protect arrangements between manufacturers and PBMs for services that are not necessary, are worthless, or are duplicative. Because we are not adopting or incorporating by reference the term "bona fide service fee," as CMS may use that term, we wanted to use a different term to convey a similar concept.

Comment: A commenter requested clarification as to how fixed fees would be structured to comply with this safe harbor. In particular, the commenter raised concerns that a fixed-fee model could lead PBMs to pass down higher administrative costs to Medicaid MCOs that could, in turn, increase costs for states and the Federal Government. Another commenter raised concerns that flat fees will be used by manufacturers as another way to encourage utilization of their products. According to these commenters, the fixed fees are a mechanism for entities to offset rebate losses.

Response: We appreciate the commenter's concerns about how a fixed-fee model could affect costs for states and the Federal government, and we do not intend for this safe harbor to protect

fixed fees that serve only as a mechanism for entities to offset rebate losses. As discussed above, we are finalizing a modification to the new safe harbor to protect payments by a pharmaceutical manufacturer to a PBM for legitimate services the PBM provides to the pharmaceutical manufacturer related to the pharmacy benefit management services that the PBM furnishes to one or more health plans with certain conditions. If the fee arrangement does not meet all safe harbor conditions, then it would not be protected.

Comment: A commenter sought clarification from OIG that the PBM service fees protected under the safe harbor would replace the existing administrative fees received by PBMs that are based on a percentage of WAC. Additionally, the commenter requested that OIG not protect any administrative fees based on a percentage of WAC that are paid to PBMs or any other intermediaries.

Response: We proposed to add, and are finalizing, a new safe harbor specifically designed to protect certain fixed fees 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. With respect to the commenter's second request, we note that nothing in this final rule is intended to affect any existing protections that may be available under other safe harbors for the types of administrative fee arrangements the commenter described.

Comment: A commenter disputed OIG's assertion that a PBM service fee becomes a kickback because the basis for setting it is a percentage of list price, especially since this is typically the best measure of fair market value. To address this concern, the commenter recommended a prohibition on any manufacturer requirement that the service fees be dependent on formulary placement. This would permit specifying that service fees tied to a fixed percentage of sales may qualify as a permitted fixed fee under the rule.

Response: Our Proposed Rule stated that service fees tied to a product's price "could function as a disguised kickback." Whether a service fee based on a percentage of list price rises to the level of an unlawful kickback under the anti-kickback statute would depend on the facts and circumstances. As we noted in the Proposed Rule, we proposed a safe harbor that would protect flat fees because they "pose lower risk of abuse and conflicts of interest." Because of these concerns, we decline to adopt the commenter's suggestion to protect service fees tied to a fixed percentage of sales.

v. Disclosure Requirement

Comment: Many commenters expressed general support for PBM disclosures arguing that plans should have full information about PBM relationships with manufacturers, including fees that manufacturers pay to PBMs.

Response: We appreciate the commenters' support. To promote transparency, we are finalizing our proposals that

information about both the services and the associated fees be disclosed to the Secretary upon request. In the Proposed Rule we said we were considering and solicited comments on requiring additional information about the fee arrangements, including information about valuation, valuation methodologies, compliance with the "volume or value" criterion, and other characteristics. For purposes of compliance with the final safe harbor, we are not requiring disclosure of each of these additional elements. However, maintaining documentation of these elements would be prudent to demonstrate safe harbor compliance.

Comment: Many commenters recommended additional disclosure requirements, including: requiring PBMs to disclose service fee arrangements with plans to manufacturers; requiring PBMs to disclose all arrangements with manufacturers and wholesalers that are related to health plans; requiring PBMs to disclose all information related to the fees PBMs are paid for the services protected under the safe harbor; requiring PBMs to disclose to manufacturers when they seek manufacturer compensation for services also compensated by a plan; requiring PBMs to annually disclose to the Department information that explains their valuation methodology and demonstrates their fee arrangements meet the volume and value criteria; and requiring PBMs to disclose service fees that are separated from any discounts or rebates. A commenter requested clarification regarding the specific information that must be included in the disclosures under the new safe harbor, particularly as it related to the

"additional information about fee arrangements" that PBMs would be required to disclose to the Secretary." See 84 FR 2350.

Another commenter requested that PBMs' written agreements with pharmaceutical manufacturers be made publicly available on both the manufacturer's and PBM's websites and that CMS should also compile and display these agreements on the agency's website.

Response: Although we appreciate commenters' suggestions, we did not propose transparency requirements for agreements between PBMs and health plans or wholesalers and, therefore, could not finalize such requirements here. Moreover, the additional disclosure requirements suggested by the commenters exceed what we believe should be necessary for safe harbor compliance, given the overall structure of the safe harbor, and to protect against abusive fee arrangements between manufacturers and PBMs. Additionally, we see no need to require the public disclosure of this type of private agreement between two parties as a requirement under the safe harbor. However, we note that under the final rule, PBMs would disclose to the Secretary upon request the services provided and fees paid for the services. Of course, to the extent a PBM was subject to an enforcement action and asserting the safe harbor as a defense, the PBM would have to show that it met each element of the safe harbor. Therefore, as a best practice, the PBM should have documentation of how it met each element (e.g., a fair market value analysis for the fees).

Comment: A commenter proposed that beneficiaries should have similar access as health plans to information regarding PBM contracts and another commenter requested clarification as to whether the PBM disclosures would be required to the pharmacy or beneficiary.

Response: We did not propose and are not finalizing any requirement for PBMs to make disclosures to pharmacies or beneficiaries. We believe the safe harbor conditions we are finalizing provide the appropriate protections against abusive kickback schemes.

Comment: Another commenter proposed that disclosures of contracts and service fees should be made at the time of agreement rather than annually, because obtaining the information earlier would aid plans in contemporaneously addressing possible conflicts in PBMs' recommendations. The same commenter recommended adding a new subsection to prohibit Medicaid-identifying patient or prescriber information from being provided to the manufacturer.

Response: We appreciate the commenter's suggestion, but we decline to delete the requirement for PBMs to report on arrangements with manufacturers annually. We believe that this information can change over time and should be updated. Medicaid-identifying patient or prescriber information is not part of the disclosure requirement and its disclosure may be governed by other laws.

Comment: A commenter supported general disclosure of the types of services that PBMs may provide to manufacturers but objected to disclosures of specific services provided to manufacturers on the grounds that such disclosure would be unwieldy and provide no additional transparency. Another commenter objected to the disclosure requirements, because PBMs and their clients already engage in arm's-length negotiations, including what is disclosed and not disclosed, and called any additional disclosure requirements unnecessary, burdensome, and invasive.

Response: Although we appreciate the commenters' concerns, we respectfully disagree. The transparency requirement is important to ensure that a PBM's arrangements with pharmaceutical manufacturers are not in tension with the services it provides to the health plans for which it is acting as an agent. Disclosures of specific services will allow a plan to see what services a PBM is contracting with a manufacturer for on its behalf.

Comment: A commenter requested clarification regarding the scope of "associated costs" and "associated compensation" for services rendered to pharmaceutical manufacturers that are to be disclosed under the new PBM service fees safe harbor. The commenter objected to the disclosure to plan sponsors of fees paid by manufacturers to PBMs, stating that the disclosure of fees to plan sponsors would not provide any additional transparency and would negatively affect competition due to

widespread dissemination of the fees paid by each manufacturer to each PBM.

Response: We appreciate the commenter's concern. The terms "costs" and "compensation" as used in the Proposed Rule were meant to be synonymous. We further note that while we considered and solicited comments on whether PBMs should be required to disclose fee arrangements to health plans, we are not finalizing this requirement. We are, however, finalizing the proposal that PBMs are required to disclose fee arrangements to the Secretary upon request.

Comment: Regarding "additional information about fee arrangements" to be disclosed to the Secretary upon request, a commenter recommended that PBMs disclose information to the Department that demonstrates fee arrangements do not duplicate other arrangements for which the PBM might receive payments. Conversely, other commenters cautioned that duplicative services may not always constitute "double dipping" and that duplicative services may not necessarily indicate that an arrangement is fraudulent or abusive. As an example, these commenters noted that "PBMs may provide the same data to more than one entity, and such data could represent value to each recipient, even if the data is also received by others."

Response: In the Proposed Rule, we said we were considering and solicited comments on a range of additional information we might require be disclosed to the Secretary, upon request, including information related to duplicative payments and

double-dipping. However, we are not requiring that the PBM proactively disclose information that specifically demonstrates a lack of duplicate services. The safe harbor requires that a PBM disclose to the Secretary upon request the services it rendered to each pharmaceutical manufacturer related to the PBM's arrangements to furnish pharmacy benefit management services to the health plan and the fees paid for such services. We believe this disclosure requirement will provide sufficient transparency and that additional disclosure requirements are not necessary to achieve the goals of the safe harbor. The requirement to provide information about services and the fees paid for those services to the Secretary on request does not constitute a determination that any particular arrangement is abusive. We recognize that particular fees and services cannot be examined in a vacuum, and we would look at the totality of facts and circumstances in reviewing an arrangement.

Comment: A commenter argued that, as proposed, the definition of pharmacy benefit manager services eligible for protection under the proposed safe harbor meets the definition of a *bona fide* service fee and urged HHS to specify that if administrative service fees meet the *bona fide* services fee definition they would no longer be treated as reportable price concessions.

Response: Determinations of what services are or are not reported as price concessions are the purview of CMS, which administers the Part D program.

vi. Scope of Agreement

We solicited comments regarding whether the safe harbor for pharmacy benefit manager fees should specify the format of any such agreement (e.g., whether it would be sufficient for a PBM to have one agreement with a manufacturer that covers all of the services the PBM provides to that manufacturer, or whether separate agreements for services that relate to each health plan would be necessary).

Comment: A commenter recommended that the rule should not dictate the format of a PBM agreement, which could vary based on the services to be provided and the preferences and standards desired by the parties. The commenter suggested that requiring separate agreements for each of a PBM's plan sponsor clients would impose tremendous costs on the parties while providing no benefit or protection to Federal health care programs. The commenter also pointed out that PBMs may need separate agreements for Federal and commercial business.

Response: The final rule does not specify the format of a PBM service fee agreement and does not mandate that the PBM have separate agreements with each health plan with which it contracts.

vii. Statutory Exception and Safe Harbor for Group Purchasing Organizations

Comment: Various commenters asked OIG to affirmatively rescind statements from its 2003 CPG that indicate rebates or other payments to PBMs may be structured to fit under the GPO

safe harbor at 42 CFR 1001.952(j)⁵⁵ and to indicate in revised guidance that these statements have been superseded and replaced by the point-of-sale reductions in price and PBM service fees safe harbors, as of the effective date of the final rule.

Another pharmaceutical manufacturer commenter asserted that allowing PBMs to rely on the GPO safe harbor would create a loophole to the new safe harbors and reduce uptake of point-of-sale discount arrangements and service fees based on flat, fair market value payments.

Commenters also asked for clarification as to whether OIG still recognizes the GPO safe harbor as a possible source of protection for rebates or other payments by manufacturers to PBMs. Similarly, other commenters recommended that OIG clarify or revise the 2003 CPG in light of the final rule because of the potential for confusion by stakeholders on the status of rebates or other payments paid by manufacturers to PBMs.

Conversely, a PBM commenter indicated that it intends to continue to utilize the GPO safe harbor, 42 CFR 1001.952(j), to protect the receipt of administrative fees from manufacturers. Another commenter stated the GPO safe harbor also has a corollary statutory exception that would protect these payments.

⁵⁵ Specifically, several commenters requested OIG rescind the following statements from the "Payments to PBMs" section in 68 FR 23736: "Any rebates or other payments by drug manufacturers to PBMs that are based on, or otherwise related to, the PBM's customers' purchases *potentially* implicate the anti-kickback statute. Protection is available by structuring such arrangements to fit in the GPO safe harbor at 42 CFR 1001.952(j). That safe harbor requires, among other things, that the payments be authorized in advance by the PBM's customer and that all amounts actually paid to the PBM on account of the customer's purchases be disclosed in writing at least annually to the customer.

Response: To qualify for protection under the GPO safe harbor, certain requirements must be met. First, the safe harbor protects only payment by a vendor to a GPO as part of an agreement to furnish goods or services to an entity. Second, the GPO must 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 (or if not known, the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO). Third, if the entity that receives the goods or service from the vendor is a health care provider of services, 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. In addition to meeting the requirements above, a PBM, as a threshold matter, 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).⁵⁶

Thus, for a PBM to qualify as a GPO acting as a purchasing agent on behalf of its members, the PBM could not wholly own the members, nor could the members be wholly owned by the same parent corporation as the PBM. This may limit the utility of the safe harbor for many PBMs. The propriety of any particular arrangement and whether it can fit under a safe harbor is highly dependent upon the facts and circumstances of each particular case. Any statements in this final rule should be not construed as approval of an individual arrangement. PBMs and manufacturers wishing to use the GPO safe harbor should closely scrutinize their arrangements for full compliance with all safe harbor conditions and definitions, including all requirements relating to written agreements and disclosures.

Requests for amendments to the regulatory safe harbor for GPOs are beyond the scope of this rulemaking. In addition, as we state above, fees to PBMs are not protected by the discount or point-of-sale reduction in price safe harbors, so nothing in this rule would suggest those amendments would replace or supersede a PBM's ability to have fees protected by a different safe harbor. The new PBM service fee safe harbor is an additional avenue for protection for arrangements between pharmaceutical manufacturers and PBMs that meet the conditions of that safe harbor. As with any safe harbor, only offers or

⁵⁶ 42 CFR 1001.952(j)(2).

payment of remuneration that meet all safe harbor conditions, including any applicable definitions and disclosure requirements, would be protected.

Comment: Another commenter encouraged OIG to clarify and distinguish the GPO safe harbor term "purchasing agent" from PBM in the final rule or future rulemaking. The commenter asserted that the term "purchasing agent" is used but not defined in both the GPO statutory exception and safe harbor. The commenter requested that OIG define the term "purchasing agent" narrowly, e.g., as an entity that is distinct from a PBM and represents members that take title and possession of purchased products, which, the commenter asserted, would better ensure the objectives of the Proposed Rule. Similarly, another commenter encouraged OIG to clearly distinguish PBMs from GPOs based on the types of entities that they represent and services they perform for those entities.

Response: Defining the term "purchasing agent" and distinguishing between GPOs and PBMS as those terms are used in the GPO statutory exception and safe harbor is outside the scope of this rulemaking, which does not address the GPO safe harbor.

viii. Additional Recommendations

Comment: Several commenters requested that OIG clarify, expand, or restrict the definition of PBM for purposes of the proposed safe harbor for various reasons. For example, some commenters recommended a definition that is based on an entity's function or incorporates the types of services an entity

provides, rather than the label of its name. A commenter recommended that a definition of "PBM" not include "negotiating rebate arrangements" because it could create the impression of protecting PBM services provided to manufacturers that are not legitimate and/or necessary. Some commenters recommended OIG include in the definition all PBM-owned and PBM-affiliated entities, including PBM-owned pharmacies.

Response: We thank the commenters for their suggestions. We decline to expand or limit the definition of "PBM" that we included in the Proposed Rule. We included only the core function of a PBM in the definition because we recognize that one PBM may perform more or fewer services than another PBM, and we do not want a defined term to dictate a business model for purposes of safe harbor protection. We also decline to include all PBM-owned or PBM-affiliated entities in the definition. Other safe harbors (such as the personal services safe harbor) might be available to protect services performed by other types of entities.

Comment: Some commenters requested that OIG clarify or remove altogether the "related to" aspect of the proposed safe harbor so that the safe harbor protection could be more broadly available to, for example, all PBM services arrangements with manufacturers.

Response: We are not adopting this suggestion. The conditions in this safe harbor are designed to ensure that protection is offered only for service fees if the services are

related or (*i.e.*, connected in some way) to pharmacy benefit management services that the PBM provides to health plans. If there is no connection to health plan services, certain conditions in the safe harbor would be inapplicable (*e.g.*, the requirement to make certain disclosures to health plans). We note, however, that other safe harbors, such as the personal services and management contracts safe harbor at § 1001.952(d) may be available to protect other types of service arrangements between PBMs and manufacturers.

Comment: Some commenters recommended that OIG incorporate certain requirements of the personal services and management contracts safe harbor to the PBM service fees proposed safe harbor. Specifically, the commenters recommended requiring that (1) the agreement for the service be signed by the parties; (2) the services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law, and (3) the aggregate services contracted for do not exceed those that are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

Response: The proposed safe harbor for PBM service fees includes certain safeguards adapted from the personal services and management contracts safe harbor, including a requirement that compensation be fair market value for services rendered.

With regard to the suggestion that the safe harbor include a requirement that the agreement for PBM services be signed by

the parties, we believe that such a requirement is implicit in the requirement that the agreement be in writing in order to establish and memorialize the agreement of the parties. However, we acknowledge that the personal services and management contracts safe harbor includes an explicit requirement of signatures. For the sake of consistency, and to avoid any implication that an inconsistency on this point means no signatures are required for compliance with the PBM service fees safe harbor, we are adding this explicit requirement to the final rule.

As noted by commenters, the personal services and management contracts safe harbor also includes a requirement that the services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law. While the proposed PBM service fees safe harbor did not include such a requirement in regulatory text, we think it is obvious that the proposed safe harbor was not intended to protect payments for the counselling or promotion of illegal activities. For the sake of clarity, we are adding this explicit requirement to the final rule.

The commenters also noted that the personal service and management contracts safe harbor requires that "the aggregate services contracted for do not exceed those that are reasonably necessary to accomplish the commercially reasonable business purpose of the services." While we are not including this

specific condition in the final rule, we note that considering whether services are commercially reasonable would likely be useful in meeting the condition that payments protected by the safe harbor be "for services the PBM provides to the pharmaceutical manufacturer related to the pharmacy benefit management services that the PBM furnishes to . . . health plans" and not for favorable treatment of the manufacturers' products.

Comment: A commenter recommended that OIG provide guidance stating that companies will be held accountable for their own compliance, noting that the discount safe harbor requires entities to "refrain from doing anything that would impede" their contracting counter-party from meeting their own obligations under the safe harbor. The contractor further noted that the 1999 preamble to the discount safe harbor states that, if a seller meets its obligations under the safe harbor in good faith, while the buyer fails to meet its obligations, the seller would be protected by the safe harbor. 64 FR 63518, 63527 (Nov. 19, 1999).

Response: The safe harbor for PBM service fees differs from the discount safe harbor at 42 CFR 1001.952(h), in that the latter has separate sets of requirements for buyers and sellers. The PBM service fee safe harbor has only one condition that is the responsibility of only one party: the PBM is responsible for certain disclosures, which we believe it is able to make without the assistance of any other party to the agreement. We

confirm that, provided that all other requirements of the safe harbor are met, and provided that the manufacturer party to an agreement with a PBM has taken no steps to discourage or impede the PBM from meeting the disclosure requirements, the PBM's failure to meet the disclosure requirement will not, by itself, cause the manufacturer to lose the protection of the safe harbor. We note, however, that if the manufacturer were aware of a failure to disclose and took no steps to remedy it, liability might attach to the manufacturer through various legal theories, depending on all the facts of the arrangement and the conduct of the parties.

Comment: A commenter explained that *bona fide* payments for services performed by PBM intermediaries should be converted to fee-for-service arrangements that are tied to the fair market value of the services performed rather than a percentage of WAC. The commenter requested that OIG provide similar protections for pharmacies, wholesalers, and outpatient providers.

Response: The commenter did not explain how the referenced service arrangements with pharmacies, wholesalers and outpatient providers implicate the anti-kickback statute while posing low risk of abuse, and therefore are suitable for protection by a safe harbor. If the arrangements do not fit in a safe harbor, they would be analyzed on a case-by-case basis for compliance with the statute.

Comment: Some commenters requested that pharmacies' reimbursement not be affected by the negotiated rate between

plans or PBMs and manufacturers and that pharmacies not be expected to pay any of the service fees owed by manufacturers to PBMs.

Response: There is no expectation under the final rule that pharmacies pay any of the service fees owed by manufacturers to PBMs. Pharmacy reimbursement from plan sponsors and the relationships between pharmacies and manufacturers are beyond the scope of this rulemaking. However, we note that the PBM service fee safe harbor protects only payments to PBMs by manufacturers, provided all conditions of the safe harbor are met. Payments that are made by pharmacies, even indirectly through reimbursements to manufacturers, are not protected by the safe harbor.

Comment: Some commenters requested that OIG clarify what "arm's-length transaction" means. In particular, a commenter specifically requested that OIG clarify: (1) that PBMs are obligated to negotiate services arrangements in good faith based on the bona fide needs of manufacturers; (2) the scope of safe harbor protection available for arrangements in which a PBM provides services on behalf of an affiliated plan; and (3) that individual health plans that do not provide pharmacy benefits management services to plan sponsors under Part D may not attempt to use the safe harbor to negotiate administrative fees from manufacturers.

Response: The term "arm's-length transaction" has appeared in safe harbor regulations since 1999⁵⁷ and has been subject to interpretation in advisory opinions and other OIG guidance,⁵⁸ as well as court cases,⁵⁹ since that time. We decline to provide further interpretation here.

Comment: A commenter suggested that alternative, transparent, flat-fee based pharmacy benefits models that reduce costs already exist (and were not considered by OIG or HHS) that generate savings, which are used by health plans in a variety of ways, including (1) reducing plan spending and/or providing member savings, such as offsetting premium costs; or (2) lowering copayments for enrollees and not charging an enrollee more than the cost of the drugs themselves.

Response: The Proposed Rule does not prohibit the use of other models but only provides protection from liability for PBM service fees, in certain circumstances, because they implicate the anti-kickback statute and are considered to be low-risk.

Comment: A commenter urged OIG to clarify that, if an arrangement fell under the protection of other safe harbors, including discount, personal services and management contracts, managed care, and GPO administrative fee, those arrangements can only now be protected under the proposed PBM service fees safe harbor.

⁵⁷ See, e.g., 64 FR 63518 (Nov. 19, 1999).

⁵⁸ See, e.g., 2003 CPG, Special Advisory Bulletin: Contractual Joint Ventures (April 23, 2003, available at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVentures.pdf>).

⁵⁹ See, e.g., U.S. ex rel. Gale v. Omnicare, Inc., 2013 WL 3822152 (N.D. Ohio, July 23, 2013).

Response: An arrangement that satisfies all conditions of any safe harbor can be protected without satisfying conditions of other potentially applicable safe harbors. Thus an arrangement between a PBM and a manufacturer that does not satisfy the conditions of the safe harbor for PBM service fees could be protected by a different safe harbor, if the arrangement met all the conditions of that other safe harbor.

E. Technical Comments

We received several comments requesting that we make technical revisions to certain provisions in the regulatory text. We summarize the comments received below.

Comment: Commenters requested that we revise "reduced price" to "reduction in price" in § 1001.952(cc)(1)(i) to ensure consistency with the term used in § 1001.952(cc).

Response: We agree with the commenters and have made the technical correction.

Comment: Commenters noted that we use the term "health benefits plan" in the proposed definition of "pharmacy benefit manager" but use the term "health plan" throughout the rest of the Proposed Rule. The commenters requested that we avoid introducing inconsistency and use the term "health plan" in this definition.

Response: We agree with the commenters and have made the technical correction.

IV. Provisions of the Final Regulation

This final rule incorporates, in large part, the amendments to the discount safe harbor and the new safe harbors we proposed in the Proposed Rule, but with some changes to the regulatory text.

A. Revision to the Discount Safe Harbor

We are finalizing, with certain revisions, our amendments to the discount safe harbor (42 CFR 1001.952(h)). In the Proposed Rule, we proposed to exclude from safe harbor protection a reduction in price or other remuneration from a manufacturer in connection with the sale or purchase of a prescription pharmaceutical product to a plan sponsor under Medicare Part D or to a Medicaid MCO. In response to comments, we are not finalizing our proposal to exclude from protection those reductions in price from pharmaceutical manufacturers to Medicaid MCOs.

B. New Safe Harbors

We are finalizing, with certain revisions, a new safe harbor in § 1001.952(cc) to protect point-of-sale reductions in price by a manufacturer for a prescription pharmaceutical product that is payable, in whole or in part, by a plan sponsor under Medicare Part D or a Medicaid Managed Care Organization. In addition, we are finalizing, with minor revisions, a new safe harbor that protects payment by a pharmaceutical manufacturer to a PBM for services the PBM provides to the pharmaceutical

manufacturer related to the pharmacy benefit management services that the PBM furnishes to one or more health plans.

C. Technical Corrections

We are correcting a numbering error in the new safe harbor in § 1001.952(dd). Specifically, we inadvertently failed to include a (1) before the opening language for § 1001.952(dd). In this final rule, we have inserted the (1) and renumbered the subsequent paragraphs accordingly to correct this oversight.

V. Regulatory Impact Statement

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects of \$100 million or more in any one year.

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations "to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." The Department believes that this rule is a significant regulatory action as defined by Executive Order 12866 that imposes costs, and therefore is considered a regulatory action under Executive Order 13771. The Department estimates that this rule generates

\$78.0 million in annualized costs at a 7 percent discount rate, discounted relative to 2016, over a perpetual time horizon.

The Regulatory Flexibility Act (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, non-profit organizations, and government agencies. Based on subsequent analysis, the Secretary does not believe that this rule will have significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. The Secretary has determined that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of \$100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately \$156 million. The rule may have effects on states

through its effects on the MDRP, under which rebates are shared between the Federal Government and the states based on the Federal Medical Assistance Percentage (FMAP) for each state.

The rule does not alter obligations under the statutory provisions for Medicaid prescription drug rebates under Section 1927 of the Act that are calculated as percentages of AMP plus the difference between the rate of increase in AMP and the increase in the consumer price index for all urban consumers (CPI-U). It also does not alter Section 1927's provisions for Medicaid rebates based on the Best Price available to other payers for innovator drugs or for supplemental rebates negotiated between states and manufacturers, nor does the rule alter the regulations and guidance to implement Section 1927 provisions.

Although it is difficult to anticipate the final rule's potential effects on AMP, if the rule reduces AMP, it will also reduce Medicaid prescription drug rebates calculated as percentages of AMP plus the difference between the rate of increase in AMP and the increase in the CPI-U. The Milliman analysis includes an extended example demonstrating that the loss of revenue from these rebates can exceed the savings from lower list prices.⁶⁰

⁶⁰ Milliman, Inc., Impact of Potential Changes to the Treatment of Manufacturer Rebates (Jan. 31, 2019). This citation is corrected from the Proposed Rule and reflects the document that was posted as supplementary material in the docket for this rule at regulations.gov in February 2019.

The VA, Department of Defense, Coast Guard, and the Public Health Service (including the Indian Health Service) are eligible to purchase drugs under the FCP Program. The FCP is calculated as a percentage of non-FAMP. Eligible programs can purchase drugs using the lesser of the FSS Price and FCP. Although it is difficult to determine the effects of the final rule on FSS users or entities entitled to FCPs, if the overall effect of lowering list pricing is achieved and that results in lower prices to commercial customers (and wholesalers) or pricing components of non-FAMP, it is possible the VA may realize some additional savings.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this regulation does not impose any direct costs on State or local governments, preempt State law, or otherwise have federalism implications, the requirements of Executive Order 13132 are not applicable.

Comment: One commenter suggested that the Proposed Rule did not comply with the requirements under EO 13771 to offset costs of significant rules by eliminating costs from at least two prior final rules and suggested the EO 13771 cost estimate was calculated incorrectly.

Response: We appreciate the comments but disagree. The Proposed Rule complied with the requirements under EO 13771, as described in more detail in OMB guidance.⁶¹

A. *Need for Regulation*

As described above, manufacturers paying rebates to PBMs may be a factor in list prices rising faster than inflation. This phenomenon may also be causing PBMs to favor higher-cost drugs with higher rebates over drugs with lower costs and discouraging the adoption of lower-cost brand drugs and biosimilars. As a result, rebates may increase costs for consumers, because their out-of-pocket costs during the deductible, coinsurance, and coverage gap phases of their benefits are based on the retail price derived from pharmacy acquisition costs with negotiated additional markups and dispensing fees. Rebates may also increase costs for the government, which pays a portion of the premium, cost-sharing, and reinsurance payments associated with the use of highly rebated drugs instead of less-costly alternatives.

Prescription drug spending can be measured based on WAC price (also referred to as list price or invoice price) and the so-called "net price" (which accounts for all price concessions).⁶² According to the IQVIA Institute for Human Data

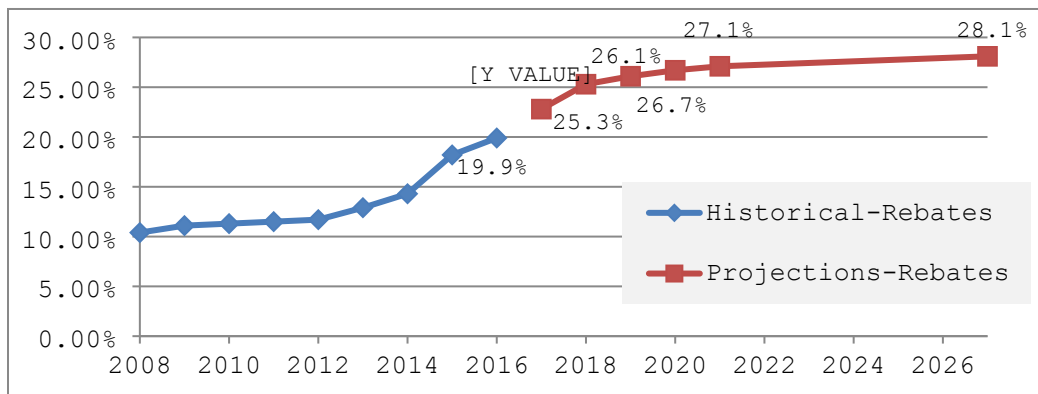
⁶¹ For general guidance, see <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf>. For guidance on accounting methods, see https://www.reginfo.gov/public/pdf/eo13771/E013771_accounting_methods.pdf.

⁶² "Net price" is industry jargon. Each PBM or plan sponsor may treat payments and price concessions differently. Thus the "net price" of a drug is more difficult to define than the Wholesale Acquisition Cost set by the manufacturer.

Science (a private research organization affiliated with the human data science and consulting firm IQVIA that uses proprietary data from IQVIA), the difference between total U.S. invoice spending (the amount paid by distributors) and net spending (which accounts for all price concessions) across all distribution channels has increased from approximately \$38 billion in 2009 to \$135 billion in 2018 for retail drugs.⁶³

Department analysis shows that within Medicare there has been a similar trend of growing differences between list and net prices. Manufacturer rebates grew from about 10 percent of gross prescription drug costs in 2008 to about 20 percent in 2016 and are projected to reach 28 percent in 2027 under current policy (Figure 1). Reinsurance spending and gross drug costs, after rising in tandem with premiums in the early years of the Part D benefit, are now growing much faster than premiums.

FIGURE 1: MANUFACTURER REBATES AS A PERCENT OF GROSS DRUG COSTS, 2008 TO 2027 (PROJECTED)



Source: 2018 Medicare Trustees Report, Table IV.B8

Comment: One commenter suggested that the Proposed Rule does not adequately justify the need for regulation, does not

⁶³ IQVIA Institute for Human Data Science, *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023*, May 2019, p. 20.

adequately describe and assess the impacts of alternatives, and does not carefully weigh effects on stakeholders.

Response: We appreciate the commenter's feedback and additional information but disagree with the conclusion. One of the purposes of the Proposed Rule was to get feedback and information from the public that we could not otherwise access. We have updated the regulatory impact analysis and the rule based on the comments, and the regulatory impact analysis represents our best thinking in these areas with consideration of these comments. We note that while we only had qualitative evidence on benefits in the Proposed Rule, the Department now quantifies some of these benefits, and these benefits exceed the rule's cost estimates.

B. Background on Costs, Benefits, and Transfers

This rule eliminates safe harbor protection for rebates received by plan sponsors, or PBMs under contract with them, from manufacturers in connection with Medicare Part D prescription pharmaceutical products and offers new safe harbor protection for certain price reductions offered at the point of sale. As a result, manufacturers will have an incentive to lower list prices, PBMs will have greater incentive to negotiate larger discounts from manufacturers, and beneficiaries will benefit from more transparency enabling them to better choose a plan that meets their needs. The goal of this policy is to lower out-of-pocket costs for consumers, reduce government drug spending in Federal health care programs, and create

transparency that increases choice, competition, and program integrity.

The full magnitude of these savings is difficult to quantify, and the Office of Management and Budget has specific definitions of costs, benefits, and transfers. As such, a brief summary of potential effects of this rule is provided here. More information about these effects may be found in the respective costs, benefits, and transfers sections.

Notably, the Department intends for this rule to result in manufacturers lowering their list prices and replacing rebates with point-of-sale reductions in price. One way to quantify this impact is to simply replace all manufacturer rebates paid to PBMs with point-of-sale reductions in price to consumers and estimate the effect of this transfer on stakeholders. However, this approach does not consider the range of strategic behavioral changes stakeholders may make in response to this rule, including the extent to which manufacturers lower list prices or retain a portion of current rebate spending, PBMs change benefit designs or obtain additional price concessions, and the impact on consumer utilization of lower-cost drugs. The section below describes the current system and the potential system that could result from finalizing this rule, based on current Medicare Part D spending and a range of potential behavioral changes, including the manufacturer pricing changes and PBM negotiation practices described above. In some places, the analysis in this section is premised on the proposed

effective date of January 1, 2020. We recognize that impacts will not occur in 2020, but did not feel that updated analyses would significantly change the discussion of the range of potential impacts or resolve uncertainty around estimates from the proposed rule stage. Impacts will occur at a later point in time, relative to the proposed rule, due to the delayed effective date. As at the proposed rule stage, the precise timing of impacts depends on external factors, such as when regulated entities implement adjustments to their business arrangements.

Today, prescription drug manufacturers prospectively set the WAC, or list price, of the drugs they sell to wholesalers and other large purchasers. Manufacturers also retrospectively make payments to PBMs or other customers who meet certain volume-based or market-share criteria. The difference between the list price of a drug and the rebate amount is referred to in industry parlance as the "net price." Since the passage of the anti-kickback statute and the establishment of the various safe harbors, the list prices of branded prescription drugs, and the rebates paid by manufacturers to PBMs, have grown substantially. The phenomenon of list prices rising faster than "net prices" is referred to as the "gross to net bubble."

Research suggests that the approval of a new drug can lead to higher list prices for existing drugs in the therapeutic

class.⁶⁴ PBMs may favor drugs with higher rebates over drugs with lower costs, or otherwise discourage the adoption of lower-cost brand or generic drugs and biosimilars. As a result, rebates may increase costs for consumers (who experience out-of-pocket costs more closely related to the list price than the rebated amount during the deductible, coinsurance, and coverage gap phases of their benefits) and the government (which pays a portion of the premium, cost-sharing, and reinsurance payments associated with the use of higher-rebated drugs instead of less-costly alternatives). This rule seeks to correct the incentives that have created the widening gaps between gross and net prescription drug costs and between gross prescription drug costs and Part D premiums.

This rule removes safe harbor protection for rebates from a manufacturer of prescription pharmaceutical products to plan sponsors under Part D (either directly or indirectly through PBMs under contract with them), and creates two new safe harbors protecting certain reductions in price at the point of sale by manufacturers and protecting certain flat fees paid by manufacturers to a PBM for services that the PBM renders to the manufacturer. To the extent that this rule results in manufacturers reducing the list price of drugs, it will impact all cash flows throughout the system.

⁶⁴ Hartung DM, et al. The cost of multiple sclerosis drugs in the US and the pharmaceutical industry: Too big to fail? *Neurology* 2015; 84(21):2185-92; Alliance of Community Health Plans, *The Spike in Drug Costs: Rheumatoid Arthritis*, available at https://www.achp.org/wp-content/uploads/Rheumatoid-Arthritis_Final.pdf; Alliance of Community Health Plans, *The Spike in Drug Costs: Diabetes*, available at https://www.achp.org/wp-content/uploads/Diabetes_FINAL_Revised-12.7.15.pdf.

The intent of this rule is to remove discount safe harbor protection for rebates and other reductions in price from manufacturers to plan sponsors under Part D or PBMs under contract with those sponsors and to provide a new avenue for point-of-sale reductions in price that will benefit beneficiaries at the pharmacy counter. This change will impact the price that many patients pay for prescription drugs. As part of their health insurance coverage, many consumers pay some cost-sharing for the use of health care services. For many plans, consumers first pay a deductible. This typically means that the consumer pays the full cost of services until the deductible is met. After the consumer has met the deductible, cost sharing often takes the form of coinsurance, in which consumers pay a percentage of the cost of the covered health care service or product, or copayments, in which consumers pay a fixed amount for a covered health care service or product. A recent IQVIA report found that in 2017 more than 55 percent of commercially-insured consumer spending on branded medicines was filled under coinsurance or before the deductible is met.⁶⁵ For most health care services, consumer deductibles and coinsurance are based on the prices that health insurers negotiate with their network providers. However, for prescription drugs, often the price the plan ultimately pays is based on rebates that are paid after the point of sale to the consumer, whereas the

⁶⁵ IQVIA, Patient Affordability Part One: The Implications of Changing Benefit Designs and High Cost-Sharing (May 18, 2018), *available at* <https://www.iqvia.com/locations/united-states/patient-affordability-part-one>.

consumers' deductible and coinsurance payments are based on the list price.

With a reduced price used to adjudicate the benefit, patients with coinsurance or deductible plans will likely experience reductions in cost-sharing for rebated brand-name drugs at the point of sale. Because of actuarial equivalence requirements in the Part D program, patients with fixed co-payments may also see changes in their cost-sharing at the point of sale outside of the deductible, coverage gap, or catastrophic phases of their benefits. These effects will accrue to some beneficiaries through lower out-of-pocket costs and to all beneficiaries through more transparent pricing. If this rule closes the gap between list and net prices and leads to additional price concessions, as the Department anticipates, the benefit of lower premiums and out-of-pocket costs would accrue to all beneficiaries with individual out-of-pocket savings varying by beneficiary prescription drug utilization. If this rule closes the gap between list and net prices but leads to fewer price concessions, all beneficiaries could experience higher premiums with only some experiencing lower out-of-pocket costs. The potential impact of these distributional changes is described in the transfers section of this regulatory impact analysis.

Consumers also select health insurance plans based on their understanding of relevant plan characteristics, including premiums, cost-sharing, formulary coverage, and in-network

providers. Research shows that consumers often do not understand their health insurance plans and would better understand a simpler plan.⁶⁶ Research specific to Medicare Part D suggests beneficiaries place a greater weight on premiums than out-of-pocket costs, are most likely to choose the plan with the lowest premiums.⁶⁷ Oftentimes they select the plan with the lowest premiums when plans with higher premiums and more comprehensive coverage were actuarially favorable.⁶⁸ However, consumers in poorer health or with higher drug costs are more likely to anticipate their future drug spending and choose a plan that places them at less financial risk. Also, as stated earlier, a beneficiary paying 20 percent coinsurance on a drug with a \$100 WAC and 30 percent rebate effectively pays 28 percent of the plan's cost after accounting for payments made by the manufacturer to the PBM. Thus, the publication of premiums and cost-sharing amounts that more accurately reflect the discounted price of a prescription drug could help align consumer understanding of health insurance benefits with reality and help consumers to choose the health insurance plans that best meet their needs. These effects are described in the benefits section.

The Federal government pays a significant portion of the premium for every Medicare Part D beneficiary and subsidizes the

⁶⁶ Loewenstein G et al. Consumers misunderstanding of health insurance. *Journal of Health Economics*. 32 (2013) 850-62.

⁶⁷ Abaluck and Gruber. Evolving Choice Inconsistencies in Choice of Prescription Drug Insurance. *Am Econ Rev*. 2016 Aug., 106(8): 2145-84.

⁶⁸ Heiss, Leive, McFadden and Winter. Plan Selection in Medicare Part D: Evidence from Administrative Data. *J Health Econ*. 2013 Dec., 32(6): 1325-44.

cost-sharing of beneficiaries eligible for the Part D Low Income Subsidy (LIS). If this rule increases or decreases premiums, Federal spending on premium subsidies will also increase or decrease, potentially outweighing estimated Federal savings associated with this rule. These potential effects are described in the transfers section of this regulatory impact analysis.

Stakeholders involved in the manufacture, sale, distribution, and dispensing of prescription drugs, as well as those who provide prescription drug coverage, will need to review this policy and determine how it affects them. They may also need to make changes to existing business practices, update systems, or implement new documentation and recordkeeping requirements. These effects are described in the costs section of this regulatory impact analysis.

After the close of the comment period, CBO independently estimated the impact of the Proposed Rule.⁶⁹ The CBO analysis was substantially similar to the CMS Office of the Actuary (OACT) analysis of the Proposed Rule. One significant difference is that CBO expects that rather than lowering list prices, manufacturers would offer the renegotiated discounts in the form of point-of-sale chargebacks. In addition, the CBO analysis includes transfer effects related to the costs of

⁶⁹ 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>.

implementation of the rule. Despite these differences, the transfer effects of the rule estimated by CBO are within the range of estimates presented in the Proposed Rule, and as a result, we do not provide additional substantial discussion of CBO's estimates of these transfers in the final rule.

The CBO analysis also includes additional analysis not conducted for the Proposed Rule. Part of this analysis related to guidance on Part D bids for the 2020 plan year and a CMS demonstration that was contemplated, but not finalized, in 2019. CBO analyzed the impact of the rule on Medicare Part A, B, and D utilization. On net, these changes are expected to reduce Medicare spending. According to the CBO analysis, the rule will increase prescription drug utilization, resulting in increased Part D spending. This increase in Part D spending is estimated to be offset by savings in Medicare Parts A and B. As previously described in detail in this impact analysis, the range of actuarial estimates for this rule range from \$100 billion in reduced federal spending if more than 100 percent of rebates are converted into list price concessions and Part D plans exert greater formulary control, to \$196 billion in increased Federal spending, if manufacturers reduce price concessions in Part D. There is wide variation in the analyses conducted that makes it difficult to project with certainty the impact of the policy change on federal spending. The Secretary, in applying the modeling assumptions and the range of available estimates, coupled with the fifteen-year history of the program

(including its competitive dynamic), has projected that there will not be an increase in federal spending, patient out-of-pocket costs, or premiums for Part D beneficiaries as required by the Executive Order. The Department further believes that the rule will make beneficiary medications more affordable and lead to lower cost sharing for patients.

The Department has considered the wide variation of potential transfer impacts in the analyses conducted and has decided to proceed with this rulemaking based on its view that the rule will have significant transparency and prescription adherence benefits for Medicare beneficiaries.

Comment: Multiple commenters suggested that impact estimates indicate that premiums for plans will increase, but the estimates do not account for how this will affect enrollment. One commenter noted that a study shows that a \$100 increase in MA-PD premiums leads to 34 percent increase in plan switching.

Response: We appreciate commenters' feedback but would note that a change of \$100 in monthly premiums is several orders of magnitude outside the range of potential impacts discussed in this rule. We would further note that since the inception of the Medicare Part D program, the base beneficiary premiums have ranged from \$27 to \$35, but the number of enrollees in Medicare Part D have increased every year.⁷⁰

⁷⁰ CMS, 2020 Annual Report, Boards of Trustees Fed. Hospital Ins. & Fed. Supp. Medical Ins. Trust Funds, available at <https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf>.

Comment: One commenter noted that the estimates rely on the standard plan design (full deductible and 25 percent coinsurance) on all non-low-income beneficiaries in the initial coverage limit and coverage gap, when in reality, the majority of Part D plans use actuarial equivalents of the standard benefit that have smaller deductibles. This commenter suggested that estimates of beneficiary cost-savings are overstated because they assume 100 percent deductibles for all patients.

Response: We disagree with the commenter. Use of the standard benefit design does not inherently build any bias into the estimates. All basic plans must provide coverage that is actuarially equivalent to the standard benefit so the net effects on the modeling are at most modest.

Comment: One commenter stated that the estimates suggest that the transition to a chargeback system will result in \$170.9 billion in extra Federal spending that will provide a net benefit to manufacturers.

Response: We agree with the commenter that several of the estimates included in the proposed rule estimated transfers from the Federal government to manufacturers. OACT estimated that there will be \$196.1 billion in additional Federal spending that will partly reduce individuals' out-of-pocket spending and will partly result in additional manufacturer revenue. However, other actuarial estimates based on strategic industry responses to this final rule range from \$99 billion in reduced federal spending (Part D plan sponsors increased formulary controls and

obtained additional price concessions) to \$140 billion in increased Federal spending (if manufacturers reduced price concessions in Part D to offset list price decreases in other markets).

Comment: One commenter noted that the estimates do not account for transfers related to the administrative burden necessary for a transition to a wholesaler chargeback system.

Response: We agree in part with the commenter that a wholesaler-led chargeback system is a possible outcome of this rule and note that CBO's estimate does account for changes in premiums related to administrative burden, and CBO's estimates are well within the range of estimates provided in the Proposed Rule. OACT did not make any explicit assumptions with respect to potential additional administrative expenses in administering the wholesaler chargeback system.

C. Affected Entities

Comment: One commenter suggested that the Department underestimated the number of entities (specifically, PBMs and pharmaceutical wholesalers) affected by the rule, underestimated the categories of entities affected by various categories of impacts, and offered suggestions for improving discussion of the impact on pharmacies.

Response: We agree that wholesalers are affected by this rule but lack concrete data to estimate the number of affected wholesalers. The commenter suggested ten wholesalers are affected. To ensure we do not undercount, we will estimate that

approximately twenty wholesalers are affected by the rule. The commenter suggests 66 PBMs, rather than the 60 estimated in the Proposed Rule, are affected by the rule. We are unable to verify the source underlying this information and retain the estimate that approximately 60 PBMs are affected by the rule. The commenter suggested small pharmacies largely use 20 pharmacy services administration organizations (PSAOs) to provide administrative services, such as negotiation, on their behalf. As a result, we have adjusted estimates to assume that costs affecting pharmacies occur at each pharmacy and drug store firm and each of 40 PSAOs to ensure we do not undercount. We have also revised the analysis to reflect that a broader pool of entities may be affected by impacts in all categories discussed below.

This rule will affect the operations of entities that are involved in the distribution and reimbursement of prescription drugs to Medicare Part D prescription drug benefit enrollees. According to the U.S. Census⁷¹ and other sources,⁷² there were 67,753 community pharmacies (including 19,500 pharmacy and drug store firms and 21,909 small business community pharmacies), 1,775 pharmaceutical and medicine manufacturing firms, and 880 direct health and medical insurance carrier firms operating in the U.S. in 2015. In 2018, there were 44 PBMs listed in the

⁷¹ U.S. Census Bureau, *Statistics of U.S. Businesses*, available at <https://www.census.gov/programs-surveys/susb.html>.

⁷² Qato, Zenk, Wilder, et al. PLoS One. 2017 Aug 16;12(8).

Pharmacy Benefit Management Institute directory.⁷³ Organizations are required to pay a fee if they choose to register, and therefore we estimate that participation in the directory is incomplete and that the total number of PBMs operating in the U.S. is approximately 60. As described above, we estimate that the rule affects approximately 20 pharmaceutical wholesalers. Finally, a 2013 GAO study⁷⁴ identifies 22 PSAOs, and notes there may be more in operation. We adjust this upward and estimate the rule affects 40 PSAOs. As noted previously, we assume that costs affecting pharmacies are incurred at each pharmacy and drug store firm and each PSAO.

We note that this rule no longer amends the discount safe harbor to exclude rebates offered to Medicaid MCOs.

Finally, the rule will affect Medicare prescription drug enrollees. CMS reports there were 44,491,003 enrollees with Part D prescription drug coverage in December 2018.⁷⁵ CMS reports there were 80,184,501 beneficiaries in Medicaid in 2016, 65,005,748 of which were enrolled in any type of managed care plan. However, these beneficiaries are less likely to be significantly affected, given Medicaid's low beneficiary cost-sharing requirements and the decision not to finalize inclusion of Medicaid MCOs in the amendment to the discount safe harbor.

⁷³

https://www.pbmi.com/PBMI/Directory/Pharmacy_Benefit_Manager_Directory.aspx, last accessed July 13, 2018.

⁷⁴ <https://www.gao.gov/products/GAO-13-176>.

⁷⁵ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/Medicare-Enrollment/Enrollment%20Dashboard.html>.

The Department estimates the hourly wages of individuals affected by this rule using the May 2016 National Occupational Employment and Wage Estimates provided by the U.S. Bureau of Labor Statistics.⁷⁶ We note that, throughout, estimates are presented in 2016 dollars. We use the wages of Medical and Health Services Managers as a proxy for management staff, the wages of Lawyers as a proxy for legal staff, and the wages of Network and Computer Systems Administrators as a proxy for information technology (IT) staff throughout this analysis. To value the time of Medicare prescription drug benefit enrollees, we take the average wage across all occupations in the U.S. We assume that the total dollar value of labor, which includes wages, benefits, and overhead, is equal to 200 percent of the wage rate. Estimated hourly rates for all relevant categories are included below.

Table 1. Hourly Wages⁷⁷

Medical and Health Services Managers	\$52.58
Lawyers	\$67.25
Network and Computer Systems Administrators	\$40.63
Medicare Prescription Drug Benefit Enrollees	\$23.86

D. Costs

Comment: We received a number of comments on our assumptions associated with the costs of the Proposed Rule. Various commenters suggested the Department underestimated

⁷⁶ https://www.bls.gov/oes/2016/may/oes_nat.htm.

⁷⁷ https://www.bls.gov/oes/2016/may/oes_nat.htm

administrative burden generated by the Proposed Rule, and two commenters provided quantitative feedback on the burden estimates. In addition, a report discussing the Proposed Rule provides additional quantitative feedback on the cost estimates.⁷⁸ Another commenter suggested information technology improvements would require thousands of hours of effort.

Response: The Department has substantially revised estimates of administrative burden in response to public comments. These changes take a number of pieces of information into consideration. First, a single commenter provided the most substantial quantitative feedback on the cost estimates in the Proposed Rule, with alternative estimates greatly exceeding those in the Proposed Rule. The commenter also sponsored the report discussed above; the comment and the report both suggest much more moderate changes to the cost analysis. This suggests a range of reasonable estimates. Second, this commenter represents a subset of entities affected by the rule. Other categories of entities expressed confidence that the rule can be implemented quickly, suggesting the rule is less burdensome for some entities than described in the most comprehensive quantitative comments, and reflecting the fact that the implementation may be more resource intensive for some entities than others. In addition to adjusting estimates in response to this feedback, we have provided ranges of impacts to reflect uncertainty regarding the rule's effects on administrative

⁷⁸ See <http://getmga.com/wp-content/uploads/2019/04/MGA-Report-on-Proposed-Rebate-Restriction-3.pdf>.

burden. Finally, we received feedback on the timing of impacts for Medicare enrollees who learn of and respond to the changes generated by this rule. However, the commenter did not provide any rationale to support this feedback, and as a result these estimates were not changed. More detail on specific changes can be found in the sections on affected entities above and the cost estimates below.

In order to comply with the regulatory changes in this rule, affected businesses would first need to review the rule. The Department estimates that this would require an average of 5 to 15 hours, with a primary estimate of 10 hours, for affected businesses to review, divided evenly between managers and lawyers, in the first year following publication of the final rule. As a result, using wage information provided in Table 1, this implies costs of \$13.4 to \$40.2 million, with a primary estimate of \$26.8 million, in the first year following publication of a final rule after adjusting for overhead and benefits.

After reviewing the rule, businesses would need to review their policies in the context of these new requirements and determine how to respond. For some affected businesses, this may mean substantially changing their pricing models, and engaging in lengthy negotiations with other businesses. For others, much more modest changes are likely needed. The Department estimates that this would result in affected businesses spending an average of 50 to 150 hours, with a

primary estimate of 100 hours, reviewing their policies and determining how to respond, divided evenly between lawyers and managers, in the first year following publication of the final rule. In years two through five, the Department estimates this would result in affected businesses spending an average of 5-15 hours, with a primary estimate of 10 hours, implementing policy changes, with 20 percent of time spent by lawyers and 80 percent of time spent by managers. As a result, using wage information provided in Table 1, the Department estimates costs of \$133.9 to \$401.7 million, with a primary estimate of \$267.8 million, in the first year and \$12.4 to \$37.2 million, with a primary estimate of \$24.8 million, in years two through five following publication of the final rule after adjusting for overhead and benefits.

This rule imposes documentation and reporting requirements on PBMs for parties choosing to use the PBM services fee safe harbor. In particular, PBMs and pharmaceutical manufacturers must have a written agreement signed by the parties 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 associated with such services. In addition, PBMs must disclose to the health plan and to the Secretary (upon request) their services rendered to each pharmaceutical manufacturer related to the PBM's arrangements to furnish pharmacy benefit management services to

the health plan. In addition, PBMs also must disclose to the Secretary upon request the fees paid for such services. We believe that these written agreements already exist as a matter of standard business practice, as they need to be in place in order to enforce contractual arrangements between these entities. As a result, we believe that the documentation requirement merely codifies standard practice, and therefore imposes no marginal costs on affected entities. We believe that the disclosure requirements will not require PBMs to generate new information or retain additional records related to their interactions with pharmaceutical manufacturers or health plans. However, we believe that the disclosure requirements will result in additional disclosure to health plans and potentially the Secretary. We estimate that each PBM will provide this information an additional 25 to 75 times per year, with a primary estimate of 50 times each year. We estimate that these disclosures will require an average of 4 hours, with 50 percent of time spent by managers, 25 percent of time spent by attorneys, and 25 percent of time spent by IT staff. As a result, using wage information provided in Table 1, the Department estimates costs of \$0.7 to \$2.1 million, with a primary estimate of \$1.4 million, in each year following publication of the final rule after adjusting for overhead and benefits.

We expect that this rule will also lead businesses affected by the rule to update their IT systems for processing claims and

payments. For these entities, the Department estimates that this will require an average of 40 to 120 hours, with a primary estimate of 80 hours, in the first year following publication of the final rule to make these changes. In years two through five, the Department estimates this this will require an average of 10 to 30 hours, with an average of 20 hours, in each of these years. We note that these estimates are in line with a comment suggesting thousands of hours are required for covered entities to make IT changes in response to this rule. Using wage information provided in Table 1, we estimate this will generate costs of \$66.7 to \$200.1 million, with a primary estimate of \$133.4 million, in the first year following publication of the final rule, and \$16.7 to \$50.0 million, with a primary estimate of \$33.3 million, per year in years two through five following publication of the final rule after adjusting for overhead and benefits.

Medicare prescription drug benefit enrollees will also spend time responding to the rule. In particular, the Department believes that this rule will result in changes to the characteristics of Medicare prescription drug plans. Once enrollees become aware that changes have been made, we believe they will review available plans to determine the plan which best suits their needs. The Department expects that Medicare enrollees will become aware of these changes gradually over time. In particular, the Department expects that 20 percent of enrollees will become aware of these changes in each of the five

years following publication of the final rule, and that responding to these changes will require an average of thirty minutes per enrollee. As a result, using wage information provided in Table 1, we estimate costs of \$209 million in each of the first five years following publication of a final rule after adjusting for overhead and benefits.

This rule may lead to shifts in the composition of affected industries by affecting the extent to which entities vertically integrate, and the rate at which entities of various sizes (particularly small entities) enter and exit the market. Vertical integration is a strategy where a firm acquires business operations in a different sector of the supply chain and reimbursement system. Entities are affected by this rule to the extent that their business models depend on using rebates, and rebates are streamlined regardless of where they are paid if a company is vertically integrated. As a result, this rule may affect incentives for vertical integration for affected entities. For example, PBMs, plan sponsors, and pharmacies may want to vertically integrate as a result of this rule. At the same time, the potential loss of retained rebate revenue by PBMs may cause existing vertically integrated businesses to consider new organizational structures. These changes, in turn, may generate costs and benefits.

E. Benefits

Comment: A commenter suggested that the Proposed Rule does not clearly articulate the benefits of replacing rebates with up

front price reductions, noting that it only qualitatively describes two possible benefits: transparency, which the commenter did not find compelling, and adherence and outcomes, which the commenter suggested is not adequately explored. Multiple commenters suggested that the estimates do not account for Part D plan behavioral changes and do not account for offsetting savings in Medicare Parts A and B.

Response: We have updated the analysis to reflect evidence on the rule's effects on behavioral changes and note that these estimates suggest the rule generates substantial benefits to the public.

It is difficult to accurately quantify the benefits of this rule due to the complexity and uncertainty of stakeholder response. As such, the Department relied on qualitatively describing two potential benefits in the Proposed Rule.

First the Department anticipates the enhanced transparency of premiums, out-of-pocket costs, and improved formulary designs will help beneficiaries make more actuarially favorable decisions, because the new point-of-sale price reductions negotiated by PBMs would be reflected in the price paid by beneficiaries at the point of sale for those enrolled in health plans electing to use the new safe harbor protecting certain point-of-sale reductions in price on prescription pharmaceutical products.

Second, with reduced out-of-pocket payments, patient adherence and persistence with prescription drug regimens may

improve. Patients abandoned 21 percent of all prescriptions for branded drugs processed by pharmacies in the United States in the fourth quarter of 2017,⁷⁹ and copayment or coinsurance amounts can be a predictor of abandonment.⁸⁰ While there may be a variety of reasons patients may not pick up a medication, one factor that may impact patient decision-making is the out-of-pocket cost of a prescription. One study suggested that for chronic myeloid leukemia, patients using tyrosine kinase inhibitors were 42 percent more likely to be non-adherent (which may include delaying the purchase of, never purchasing, or switching their prescription to a less optimal choice) if they were in the higher copayment group compared to the lower copayment group.⁸¹ The intent of this rule is to lower the out-of-pocket costs for prescription drugs for some Medicare prescription drug enrollees. The pricing decisions of drug companies, and negotiations between manufacturers and PBMs, will determine how plan sponsors make formulary decisions that determine whether beneficiaries pay more or less in out-of-pocket costs.

Furthermore, lower out-of-pocket costs may lead to fewer enrollees abandoning prescription drugs. This could result in beneficiaries filling more prescriptions, thus increasing spending, as prescriptions that were once unaffordable are now

⁷⁹ IQVIA Institute for Human Data Science, *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*, April 2018, p. 31.

⁸⁰ William H. Shrank, et al., *The Epidemiology of Prescriptions Abandoned at the Pharmacy*, 153 *Annals Internal Med.* 633 (2010).

⁸¹ Stacie B. Dusetzina, et al. "Cost Sharing and Adherence to Tyrosine Kinase Inhibitors for Patients with Chronic Myeloid Leukemia." 32:4 *Journal of Clinical Oncology*. Feb. 2014.

attainable. It could also lead to lower total costs-of-care, if increased adherence led to improved health outcomes. The Department is unable to estimate the extent to which this rule would reduce abandonment across all drug markets or the resulting health benefits of higher adherence of prescription drugs.⁸²

In addition, the reduction in abandonment could benefit pharmacies by reducing costs related to storage and tracking of abandoned prescriptions.

F. Transfers

The provisions of this rule are specifically aimed at incentives related to pharmaceutical list prices as set by manufacturers, increases in these prices by manufacturers, rebates paid by manufacturers to PBMs acting on behalf of Part D plan sponsors, and the misalignment of incentives caused by concurrently increasing list prices and rebates. A significant, though difficult to quantify, potential transfer resulting from this rule would be the reduction of list prices and/or a reduction in the annualized increases thereof. Retrospective

⁸² Given data available at this time, it is not possible to calculate any particular impact from the COVID-19 public health emergency on these effects. However we note that the Medicare Current Beneficiary Survey (MCBS) COVID-19 Summer 2020 Supplement and preliminary 2019 MCBS data", available at <https://www.cms.gov/files/document/medicare-current-beneficiary-survey-covid-19-data-snapshot.pdf>, indicates that only 8% of Medicare beneficiaries surveyed between June 10, 2020 and July 15, 2020 had forgone prescription drugs or medications during the COVID-19 public health emergency. We would expect such a figure to decrease by the time this rule is implemented in 2022. These points, considered alongside the expected increase in prescriptions from plans' relaxation of 'refill too soon' edits, suggest there is no particular reason to believe the effects of this rule will be materially different as a result of the COVID-19 public health emergency.

rebate-based contractual arrangements between manufacturers and PBMs and health insurers may be renegotiated to match these regulations' new conditions. Manufacturers may reset their pricing strategies to better match net pricing trends and strategies. Changes in list prices could flow throughout the entire pharmaceutical supply chain and reimbursement system.

Medicare Part D

If manufacturers reduced their current list prices to an amount equal or similar to their current net prices, there would be less impact on premiums and a decline in net prices could result in a decrease in premiums. If manufacturers did not reduce their list prices, beneficiary and Federal spending on premiums might increase and beneficiary cost-sharing might not decrease.

If Part D plans changed their benefit structures (e.g., increased formulary controls, greater use of generic drugs), and sought to prevent or ameliorate premium increases, they may be able to obtain additional price concessions from manufacturers. If list price reductions and increased price concessions led to lower net prices and gross drug costs in Part D plans, beneficiary and Federal spending on premiums and cost-sharing could decrease. If Part D plans were unable to achieve additional price concessions, and net prices increased, beneficiary and Federal spending on premiums and cost-sharing could increase.

Under the Part D program, plan sponsors pay network pharmacies a negotiated rate for a covered Part D drug that is intended to cover a pharmacy's acquisition cost (termed the negotiated price at section 1860D-2(d) of the Act), plus a dispensing fee. Currently, pharmacies are not a part of the financial flow related to rebates that are paid after the point of sale, nor do beneficiaries receive any out-of-pocket benefit from these rebates. This means that beneficiaries, whose cost-sharing for Part D covered drugs is calculated as coinsurance, or a percentage of the price of the drug dispensed, are charged a percentage of the price paid to pharmacies (or the full price prior to meeting their deductible), which almost always does not include the rebates plans receive through PBMs from manufacturers. Removing the existing safe harbor protection for retrospectively paid rebates that are not reflected in the prices paid at the point of sale may reduce beneficiary out-of-pocket spending for Part D covered drugs. If list prices did not decrease or point-of-sale chargebacks were not reflected in the prices paid at the point of sale, beneficiaries could see an increase in premiums without the benefit of decreased cost-sharing.

Below, this section discusses the potential specific effects within Part D on premiums, benefit design thresholds, and Federal outlays for the portions of the benefit subsidized by the Medicare Part D program.

The Department's Medicare Part D analysis is based on OACT's work commissioned specifically for this rulemaking⁸³ and two commissioned actuarial analyses independent of OACT.⁸⁴ OACT "directs the actuarial program for CMS and directs the development of and methodologies for macroeconomic analysis of health care financing issues." The two external actuarial firms were chosen based on their commercial experience assisting plan sponsors with their plan bids. We have not asked these organizations to revise the estimates they prepared before release of the Proposed Rule.

There are significant differences in the assumptions the respective actuaries used to estimate stakeholder behavior. OACT predicts that while some current rebates will be retained by manufacturers, future price increases will be smaller and fewer. Per OACT's assumption, rather than reducing list prices and offering discounts to achieve current net prices, the expected behavior is to reduce future price increases so that post-rule net prices converge over time to meet the trend on pre-rule net price forecasts. As such, OACT predicts that the Federal government would increase spending on premium subsidies

⁸³ CMS Office of the Actuary, Proposed Safe Harbor Regulation (Aug. 30, 2018). The OACT analysis is posted as supplementary material in the docket for this rule at [regulations.gov](https://www.regulations.gov).

⁸⁴ Wakely Consulting Group, 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 (Aug. 30, 2018); Milliman, Inc., "Impact of Potential Changes to the Treatment of Manufacturer Rebates" (Jan. 31, 2019). The Wakely and Milliman analyses were posted as supplementary material in the docket for this rule at [regulations.gov](https://www.regulations.gov). Certain discussions of the Milliman analysis, including some citations and figures, in the Proposed Rule contained unintentional errors that we have corrected throughout this section of the final rule. These corrections do not materially change the RIA.

for Medicare beneficiaries, and that consumers and private businesses would experience decreased overall spending.

Because drug manufacturers pay a portion of the drug costs incurred by beneficiaries in the Part D coverage gap, their expenses would be reduced in relation to the reduction of beneficiary spending in the coverage gap. The Milliman non-behavioral analysis estimates gross drug costs would decrease by \$679.7 billion and coverage gap discount payments would decrease by \$20.6 billion over the same period.⁸⁵ Federal spending would increase by \$34.8 billion, and beneficiary spending would decrease by \$14.5 billion.⁸⁶

In addition to the actuarial analysis described above, the economic analysis of this rule is also informed by stakeholder comments and meetings in response to the drug pricing blueprint.⁸⁷

All three of these analyses contemplate and quantify the behavioral changes by plans in the form of changes to benefit offerings, or by manufacturers in the form of changes to pricing processes but differed in their assumptions. All three assessed pharmaceutical manufacturers' unique opportunity to adjust their overall pricing and rebate strategy but differed in the assumed amount of rebates that would be retained by manufacturers, if any, and the effect on list and net prices.

⁸⁶ Milliman, Inc., Impact of Potential Changes to the Treatment of Manufacturer Rebates (Jan. 31, 2019). See Appendix A1, Scenario 1A, page 1.

⁸⁷ Comments are available for viewing at <https://www.regulations.gov/document?D=CMS-2018-0075-0001>.

The OACT analysis assumed manufacturers would retain 15 percent of the existing Medicare Part D rebates, that 75 percent of the remaining rebates would be applied as discounts to beneficiaries, and that manufacturers would apply the remaining 25 percent to lower list prices. OACT based this assumption on the belief that consumer discounts provide less return on investment to drug manufacturers than rebates and that resetting the rebate system would allow manufacturers to recapture forgone revenue streams such as those that occurred from the changes in the Coverage Gap Discount Program included in the Bipartisan Budget Act of 2018. OACT's assumption would lead to higher net prices in Medicare Part D at the beginning of time period analyzed, while the reduced-price increase trend would lead to post-rule net prices eventually converging to pre-rule net price forecasts. Each of the analyses took varying approaches to the treatment of discounts and acknowledge uncertainty around this assumption. The Milliman and Wakely analyses assumed that all existing manufacturer rebates would be passed along as either list price reductions or discounted prices at the point of sale.

Milliman provided six additional scenarios based on a range of strategic behavior changes by stakeholders, including increased formulary controls, increased price concessions, reduced price concessions in Part D to offset list price decreases in other markets, decreased brand unit cost trend, and increased utilization and decreased brand unit cost trend. These scenarios are intended to bookend the baseline analysis by

showing a range of possible scenarios, given the uncertainty inherent in such a policy change. Tables 2 and 4 later in this section present the main assumptions and findings of the analyses we discuss.

Only one analysis contemplated, but did not seek to quantify, the behavioral change of beneficiaries choosing lower-cost plans, switching from PDPs to MA-PDs, or in the form of increased persistence and adherence caused by induced demand due to decreased out-of-pocket costs.

We note that all the actuaries who submitted analyses developed different results based on differing, yet plausible, assumptions. The sheer size of the Medicare Part D program makes these results sensitive to small differences in assumptions, particularly over a ten-year period. As such, there are often good reasons for small differences in assumptions that are neither right nor wrong but may be reasonable within a plausible range of outcomes. The different assumptions made include the initial values used for the direct subsidy and base beneficiary premium, the pattern of future costs, the granularity with which growth rates or future effects are applied uniformly or based on product type. The actuarial analyses used to prepare this impact analysis are posted as supplementary material in the docket for this rule at [regulations.gov](https://www.regulations.gov).

Effect on Beneficiary Spending

This rule will likely impact beneficiary spending on the Part D program. As noted above, the Department is presenting three actuarial analyses (six total scenarios) conducted under various behavioral assumptions.

The projected decrease in beneficiary spending on premiums and cost-sharing that would have occurred in 2020 was \$1.0 to \$1.6 billion. The projected decrease in beneficiary spending on premiums and cost sharing that would have occurred from 2020 to 2029 ranges from a decrease of \$59.5 billion to an increase of \$12.3 billion. Individuals who qualify for the LIS pay low or no premiums to enroll in the Part D benefit and have their cost-sharing obligations under each benefit phase reduced significantly (called the Low Income Cost Sharing Subsidy or LICS). We expect a smaller effect among these enrollees (about 30 percent of total Part D enrollees) than among those not receiving the LIS and LICS.

All three actuarial reports support the conclusion that non-LIS Medicare beneficiaries enrolled in, and actively utilizing, plans with coinsurance-based cost-sharing structures for covered outpatient drugs for which their respective plan has negotiated a rebate, will likely see lower out-of-pocket cost-sharing at the pharmacy counter as a result of this regulatory change.

OACT, Wakely and five of the six Milliman scenarios considered by the Department suggest total beneficiary cost-sharing would decrease and that the decrease in total

beneficiary cost-sharing would offset any increase in premiums across all beneficiaries, regardless of assumptions regarding whether or not manufacturers retained rebates or applied a percentage of them as list price reductions, or PBMs and plan sponsors changed formularies or obtained additional price concessions. However, the analyses that estimated higher premiums found that more beneficiaries would pay more for premiums than they would save in cost-sharing, suggesting that out-of-pocket impacts are likely to vary by individual and the greatest benefit of these transfers accrues to sicker beneficiaries (e.g., those with more drug spending and/or those using high-cost drugs).

However, it is important to note that the effect of this rule on individual beneficiaries depends on whether they use medications, what behavioral responses manufacturers and plans adopt in response to the rule, and whether the manufacturers of the drugs in their regimen are paying rebates.

Analyses that contemplated increased price concessions or benefit design changes predicted beneficiaries having lower premiums and out of pocket costs overall. Table 2 describes the net beneficiary impact predicted by each analysis and assumption. (Scenarios 5, 6, and 7 in the Milliman analysis are available online rather than reproduced here, since they are not referenced further in our write-up.)

TABLE 2 - BENEFICIARY IMPACTS, PER BENEFICIARY PER MONTH, ESTIMATED FOR CY 2020 TO CY 2029

	OACT	Milliman, Scenario 1	Milliman, Scenario 2	Milliman, Scenario 3	Milliman, Scenario 4	Wakely
Modeled Assumptions	<ul style="list-style-type: none"> 15 percent of current Part D rebates retained by manufacturer 75 percent of remaining amount applied to per-sponsor/PBM negotiated discounts 25 percent of remainder applied as reduction to list price No beneficiary or plan behavioral changes are assumed 	<ul style="list-style-type: none"> 100 percent of current Part D rebates are converted into list price concessions (agnostic on list price reductions versus up front discounts) 	<ul style="list-style-type: none"> 100 percent of current rebates are converted into list price concessions Part D plans exert greater formulary control 	<ul style="list-style-type: none"> More than 100 percent of rebates are converted into list price concessions (same agnosticism on how applied) Part D plans exert greater formulary control 	<ul style="list-style-type: none"> 20 percent of current Part D rebates are retained by manufacturers (same agnosticism on how applied) 80 percent of current Part D rebates are converted to price concessions (list price or discounts) 	<ul style="list-style-type: none"> 100 percent of current manufacturer rebates are converted into reductions in drug costs at the point of sale No beneficiary or plan behavioral changes are assumed
Premium ⁸⁸	+25%	+\$4.03 +13%	+\$1.27 +4%	+\$0.61 +2%	+\$6.84 +21%	N/A
Cost-sharing	-18%	-\$6.23	-\$9.85	-\$9.68	-\$4.97	N/A

⁸⁸ Since 2010, Medicare has published guidance defining de minimis variation in Medicare Part D plan bids. The de minimis amount was \$2 for the 2020 plan year. Milliman scenarios 2 and 3 estimate a de minimis level of variation from existing premium estimates.

		-12%	-19%	-19%	-10%	
Total	-4%	-3%	-10%⁸⁹	-11%	+2%	N/A

⁸⁹ Corrected from the Proposed Rule.

Premiums

As explained in the Proposed Rule, all analyses that assumed no behavioral changes that would reduce net prices below current net prices would have seen Part D premiums increase in 2020 and beyond. The estimated increase in 2020 Part D premiums ranged from \$3.20 per beneficiary per month to \$5.64 per beneficiary per month (PBPM).

The Milliman analyses that contemplated behavioral changes that increased price concessions beyond current levels and/or greater formulary controls predicted a significant decrease in premiums compared to the baseline scenarios presented in Table 3 of the Milliman analysis. (That is, premiums would increase 2 percent to 4 percent over the ten-year period, a *de minimis* level of variation, rather than 6 percent to 21 percent without such assumptions.)

Out-of-Pocket Spending

Absent behavioral changes leading to lower list and net prices, two groups of beneficiaries would benefit most from this rule: (1) beneficiaries that are prescribed and dispensed high cost drugs and (2) beneficiaries with total drug spending into the coverage gap. The range of total decreased beneficiary cost-sharing that would have occurred in 2020 was estimated to be -\$8.01 PBPM to -\$4.85 PBPM.

However, reductions in cost-sharing would only accrue to beneficiaries using drugs for which manufacturers are currently paying rebates. For example, a beneficiary taking a brand-name

drug in a competitive class may see his or her coinsurance-based cost-sharing for the drug reduced significantly, if behavioral changes in response to this policy result in rebates largely being converted to point-of-sale reductions in price. By contrast, a beneficiary using high-cost drugs in protected classes is less likely to benefit from a reduced pharmacy purchase price, because manufacturers generally offer low or no rebates to plans for these drugs, since drugs in protected classes must be included on Part D plan formularies.

The analysis by OACT estimated the annual changes in benefit parameters as a result of the proposed rule; this analysis has not been updated to reflect the change in effective date for reasons discussed above. See Table 3 below.

TABLE 3: PART D STANDARD BENEFIT DESIGN PARAMETERS WITH AND WITHOUT THIS RULEMAKING

Year	2020	2021	2022	2023	///	2029
Baseline:					///	
Deductible	\$435	\$460	\$490	\$520	///	\$725
Initial Coverage Limit	\$4,010	\$4,250	\$4,520	\$4,800		\$6,690
Catastrophic Limit	\$6,350	\$6,750	\$7,150	\$7,600		\$10,600
Total Drug Costs at TrOOP Limit ⁹⁰	\$9,296	\$9,874	\$10,470	\$11,126		\$15,515
Under Rule:						
Deductible	\$435	\$405	\$395	\$420		\$580
Initial Coverage Limit	\$4,010	\$3,740	\$3,630	\$3,840		\$5,310
Catastrophic Limit	\$6,350	\$5,950	\$5,750	\$6,100		\$8,400
Total Drug Costs at TrOOP Limit	\$9,296	\$8,699	\$8,416	\$8,919		\$12,297
Difference (Percent):						
Deductible	0%	-12.0%	-19.4%	-19.2%		-20.0%
Initial Coverage Limit	0%	-12.0%	-19.7%	-20.0%		-20.6%
Catastrophic Limit	0%	-11.9%	-19.6%	-19.7%		-20.8%
Total Drug Costs at TrOOP Limit	0%	-11.9%	-19.6%	-19.8%		-20.7%

⁹⁰ This limit varies by beneficiary, according to the mix of brand and generic drugs taken. As presented here, this figure is calculated assuming that only brand-name drugs are dispensed, which represents the lowest possible estimate for this threshold.

Under OACT's analysis, the majority of beneficiaries would see an increase in their total out-of-pocket payments and premium costs; reductions in total cost-sharing will exceed total premium increases. The minority of beneficiaries who utilized drugs with significant manufacturer rebates would experience a substantial decrease in costs, causing average beneficiary cost across the program to decline.

Medicare beneficiaries with lower levels of drug spending were expected to benefit by way of a lowered deductible. Following the first year of this new environment, and into the second year as well, the Part D benefit design thresholds are projected to change to the benefit of lower-cost beneficiaries, providing lower out-of-pocket payments for these beneficiaries. Because the Part D benefit design's parameters are calculated annually to account for aggregate growth in Part D spending, and because the estimated potential effects of this regulation would be to reduce aggregate spending levels to more closely match net spending trends, the applicable deductible would decrease for plan year 2021. Beneficiaries whose spending is above the current deductible amount but lower than the coverage gap would benefit from a reduced deductible.

OACT also found that while the deductible and initial coverage limit would decrease, the patient out-of-pocket spending threshold to enter catastrophic coverage would increase significantly in the second year as the full effects of reduced purchase prices are incorporated. The out-of-pocket threshold

is set in statute and updated annually by aggregate Part D program growth. Because overall beneficiary spending levels would now match the net price of drugs rather than their list prices, progress toward the out-of-pocket limit would be slowed, though total dollars paid by beneficiaries would not change aside from statutory and annual updates.

Milliman's analysis did not incorporate changes to the Part D benefit thresholds, and these actuaries based their break-even analyses on the 2019 threshold amounts. Their analysis projects that the distribution of changes is far from uniform, and that the impact of the change is concentrated around the non-LIS beneficiaries who account for about 70 percent of the benefit. The break-even point would be \$3.20 per beneficiary per month in cost-sharing reductions. Beneficiaries with cost-sharing reductions above that point would save money, and those with cost-sharing reductions below that figure would spend more on premiums than they saved in cost-sharing. Their analysis also projects about 7 percent of non-LIS beneficiaries do not use any medication, and therefore would see premium costs exceeding reductions in cost-sharing (\$0 reductions in cost-sharing). Up to 30 percent of non-LIS beneficiaries have drug costs such that they could directly benefit from the changes in the point-of-sale costs by enough to make up for the average increase in premium. The remaining 63 percent of beneficiaries may or may not have their out-of-pocket costs reduced enough to offset any potential premium increase, depending on the mix of brand and

generic drugs used. All else constant, these members generally do not have enough cost-sharing savings to fully offset the increase in premium. However, they may benefit from changes to copayments made by plan sponsors to maintain the minimum required actuarial value of 25 percent.

Taken together, the actuarial analyses project reductions in total cost-sharing would exceed total premium increases; however, impact on beneficiaries will vary greatly with some beneficiaries seeing savings while others experience increases in out-of-pocket spending.

Effect on Federal Government Spending

This rule will impact Federal spending on Part D direct premium subsidies, reinsurance, low income cost-sharing subsidies, and low income premium subsidies.

If there were no behavioral changes by manufacturers and Part D plans (e.g., drug prices and benefit designs were held constant), all three actuarial analyses previously described predicted increased Federal spending. As explained in the Proposed Rule, the projected increase in 2020 Federal spending ranged from \$2.8 billion to \$13.5 billion. The projected increase in Federal spending from 2020 to 2029 ranged from \$34.8 billion to \$196.1 billion.

The Milliman analyses that contemplated behavior changes that would lower net prices from current levels predicted Federal spending from 2020 to 2029 could decrease by \$78.9 billion if Part D plan sponsors increased formulary controls,

decrease by \$99.6 billion if Part D plan sponsors increased formulary controls and obtained additional price concessions, but increase by \$139.9 billion if manufacturers reduced price concessions in Part D to offset list price decreases in other markets.

Table 4 describes the impacts on Federal spending predicted by each analysis and assumption at the proposed rule stage.

TABLE 4 - GOVERNMENT SPENDING IMPACTS, AS ESTIMATED FOR CY 2020 THROUGH 2029 (\$BILLIONS)

	OACT	Milliman, Scenario 1	Milliman, Scenario 2	Milliman, Scenario 3	Milliman, Scenario 4	Wakely
Modeled Assumptions	<ul style="list-style-type: none"> • 15 percent of current Part D rebates retained by manufacturer • 75 percent of remaining amount applied to per-sponsor/PBM negotiated discounts • 25 percent of remainder applied as reduction to list price • No beneficiary or plan behavioral changes are assumed 	<ul style="list-style-type: none"> • 100 percent of current Part D rebates are converted into list price concessions (agnostic on list price reductions versus up front discounts) 	<ul style="list-style-type: none"> • 100 percent of current rebates are converted into list price concessions • Part D plans exert greater formulary control 	<ul style="list-style-type: none"> • More than 100 percent of rebates are converted into list price concessions (same agnosticism on how applied) • Part D plans exert greater formulary control 	<ul style="list-style-type: none"> • 20 percent of current Part D rebates are retained by manufacturers (same agnosticism on how applied) • 80 percent of current Part D rebates are converted to price concessions (list price or discounts) 	<ul style="list-style-type: none"> • 100 percent of current Part D rebates converted to up front discounts • No beneficiary or plan behavioral changes are assumed
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%)	
Low income cost-sharing subsidy	-\$57.7 (-15%)	-\$89.5 (-20%)	-\$118.3 (-26%)	-\$118.5 (-26%)	-\$71.4 (-16%)	
Reinsurance	-\$20.3 (-3%)	-\$103.1	-\$139.1	-\$163.2	-\$30.2	

		(-13%)	(-18%)	(-18%)	(-4%)	
Total	+\$196.1 (+14%)	+\$34.8 (+2%)	-78.8 (-5%)	-\$99.6 (-7%)	+\$139.9 (+10%)	N/A

Direct Premium Subsidy Spending

The Medicare program provides a direct subsidy to Part D plans of 74.5 percent of expected costs. Medicare program payments for direct subsidies would have increased by an estimated \$14.5 to \$20.1 billion (128 percent to 154 percent) in 2020 and \$174.7 to \$258.7 billion (119 percent to 199 percent) from 2020 to 2029. The increase in program payments would require plans to smooth the effects of negotiated discounts across the entire benefit, rather than concentrate them on the initial coverage limit as is current practice. As noted above, premiums paid by beneficiaries are predicted to increase overall in analyses without behavioral changes that would reduce net prices below current levels.

In the Milliman analysis, the two scenarios that contemplated behavior changes that would reduce net prices compared to current levels predicted that Federal spending on direct premium subsidies from 2020 to 2029 could have increased less compared to a scenario with no behavior change. In these scenarios, Part D plan sponsors increased formulary controls and/or obtained additional price concessions. Payments for direct premium subsidies would be higher than under the scenario with no behavior change, if manufacturers reduced price concessions in Part D to offset list price decreases in other markets (as described in the OACT analysis and Milliman scenario 4). See Table 4 for magnitude and percent changes.

Reinsurance Spending

Transforming rebates into upfront reductions in price may result in fewer beneficiaries reaching catastrophic coverage. This would benefit the government because the government bears the majority of the cost (80 percent) for beneficiaries who reach catastrophic levels of drug spending. As such, all analyses suggested Medicare payments for reinsurance would have decreased by an estimated \$3.0 to \$7.9 billion (6 percent to 17 percent) in 2020 and 3 percent to 18 percent from 2020 to 2029. In the catastrophic coverage phase, Medicare makes payments to Part D plans for 80 percent of gross drug costs incurred once the beneficiary reaches the out-of-pocket threshold. As discussed above, the effect of this rule would be to reduce the effective purchase price of drugs, which in turn would require more prescriptions before a beneficiary would enter the catastrophic phase. If fewer beneficiaries enter this benefit phase, and the prices of the drugs they receive in this benefit phase are reduced, the Medicare Program would experience lower reinsurance payments to Part D plans.

Milliman's scenarios that contemplated behavior changes predicted Federal spending on reinsurance from 2020 to 2029 could have decreased by \$139.1 billion if Part D plan sponsors increased formulary controls, decreased by \$163.2 billion if Part D plan sponsors increased formulary controls and obtained additional price concessions, and decreased by only \$30.2 billion if manufacturers reduced price concessions in Part D to offset list price decreases in other markets.

Low Income Subsidy Spending

Medicare payments for LIS enrollees would on net have decreased by an estimated \$0.9 to \$5.5 billion in 2020 and \$42.3 to \$116.6 billion from 2020 to 2029. Generally, LIS enrollees will not see the same out-of-pocket savings that non-LIS enrollees will, because they are assessed cost-sharing based almost exclusively on copayments. However, payments for the LICS will decrease for the same reasons that Medicare payments for reinsurance will decrease. Under the provisions of LICS, the Medicare program makes payments to plans to cover the difference between the LIS enrollee's copayment and the otherwise applicable coinsurance. As prices are reduced to account for discounts rather than applied to the plan liability exclusively, Medicare payments for these amounts will decrease. These savings were estimated to be \$57.7 to \$118.5 billion over ten years.

Analyses that contemplated behavior changes predicted Federal spending on low income cost-sharing subsidies from 2020 to 2029 could have decreased by \$118 billion if Part D plan sponsors increased formulary controls, decreased by \$119 billion if Part D plan sponsors increased formulary controls and obtained additional price concessions, and decreased by \$71 billion if manufacturers reduced price concessions in Part D to offset list price decreases in other markets.

Other Stakeholder Impacts

Based on the provisions of this rulemaking, the actuarial estimates we received estimated that drug manufacturers would have seen revenues, as measured by changes in gross drug costs and Coverage Gap Discount Program payments, decrease beginning in CY2020 and each year thereafter. However, when drug costs net of all discounts and rebates are considered, the actuarial analyses results converged in finding net increases in total drug spending. Milliman's Scenario 1 analysis also estimated an increase in government costs of \$34.8 billion over ten years, with beneficiary costs decreasing by \$14.5 billion.⁹¹ These changes in revenue will predominantly affect brand-name drugs more so than generic drugs. Since 2011, brand-name drug manufacturers have been required to provide a discount applied at the point of sale to beneficiaries whose claims occur during the coverage gap. Since the intent of this rulemaking is to reduce the negotiated prices paid by plans to pharmacies by incorporating up front discounts into them, both the frequency of beneficiaries entering the coverage gap, and the length of the coverage gap itself, are potentially reduced by the rule's effects.

Comment: A commenter suggested that the Proposed Rule did not adequately account for entities in the pharmaceutical supply chain, Federal purchases, the 340B program, or the uninsured. The commenter also suggested that the Proposed Rule did not

⁹¹ Milliman, Inc., Impact of Potential Changes to the Treatment of Manufacturer Rebates, (Jan. 31, 2019). Appendix A1, Scenario 1A, page 1.

account for existing discount programs such as GoodRx when estimating savings for the uninsured.

Response: The impact on the uninsured is implicitly included in our Household estimates. We did not explicitly model the effects for those in the pharmaceutical supply chain, Federal direct purchases, or the 340B program.

Likewise, this rule will affect the way pharmacies are reimbursed. If list prices come down, pharmacies will experience lower acquisition costs, and their combined reimbursement from plan sponsors and beneficiaries will be reduced by the amount of discount provided by manufacturers to beneficiaries of each plan sponsor. The use of chargebacks to make pharmacies whole for the difference between acquisition cost, plan payment, and beneficiary out-of-pocket payment is described earlier in this rule. The actuarial analyses we commissioned were not designed to evaluate the effects on the pharmacy supply chain by moving from a system where reimbursement rates were divorced from actual negotiated prices after accounting for rebates.

Summary of Part D Impacts

This rule will significantly redirect the dollars flowing through the Part D program. Several of the positive and negative transfers are imperfect offsets of one another. For example, the analyses commissioned for this rule estimated that the amount saved by reducing cost-sharing exceeds the cost of any increase in premiums for beneficiaries overall. However,

more beneficiaries would pay more for premiums, if premiums rise, than they would save in cost-sharing, suggesting that out-of-pocket impacts are likely to vary by individual and the greatest benefit of these transfers accrues to sicker beneficiaries (e.g., those with more drug spending and/or those using high cost drugs).

It is difficult to predict the full extent of the transfers created by this rule in the absence of information about strategic behavior changes by manufacturers and Part D plan sponsors in response to this rule. In scenarios without behavioral changes, enrolled beneficiaries might have seen premiums increase in 2020 (had the rule become effective then) by \$3.15 PBPM to \$5.64 PBPM (8 percent to 19 percent) but average cost-sharing under their benefits would have declined by \$4.85 PBPM to \$8.01 PBPM (10 percent to 14 percent).⁹² However, the revised effective date of January 1, 2022 for the amendment to § 1001.952(h)(5) of the discount safe harbor will provide manufacturers and plans with additional time to conduct negotiations and adjust any business practices as necessary based on the amended safe harbor. Premium and cost-sharing estimates were calculated on a different basis by each firm. OACT estimated actual beneficiary paid amounts for all enrollees on average. Milliman estimated beneficiary payments based upon

⁹² Wakely Consulting Group, *Estimate 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* (Aug. 30, 2018); Milliman, Inc., *Impact of Potential Changes to the Treatment of Manufacturer Rebates* (Jan. 31, 2019) Scenario 1.

the basic benchmark amounts. We present the range across these calculation types.

In the absence of the stakeholder behavior changes described often in this section, government payments to plans for direct subsidies, subsidies for low income enrollees' premiums and cost sharing will likely increase and be partially offset by reduced payments to plans for reinsurance, increasing overall by 3 percent to 14 percent in the 2020 estimates.

If manufacturer and plan behavior caused net prices to decrease in response to this rule, enrolled beneficiaries might have seen premiums increase 12 percent (\$2.70 to \$2.77 PBPM) in the first year with a very accelerated implementation timeline, and average cost sharing under their benefits may have declined by 12 percent to 13 percent (\$5.22 to \$5.44 PBPM) in 2020. Total government payments to plans would have increased 1 percent to 3 percent, as the net result of increased payments for direct subsidies (144 percent to 149 percent) and low-income premium subsidies (12 percent to 14 percent) and decreased payments for low income cost-sharing (-18 percent to -20 percent) and reinsurance (-16 percent to -17 percent).

If manufacturer and plan behavior caused Part D net prices to increase in response to this rule, enrolled beneficiaries would have seen published premiums increase 22 percent (\$5.11) and average cost-sharing under their benefits might have declined by 9 percent to 14 percent (-\$5.22 to -\$8.01). Government payments to plans for direct subsidies and subsidies

for low income enrollees' premiums and cost-sharing would have increased and reinsurance payments would have decreased.

Medicaid and State Impacts

OACT estimated that the rule would result in estimated aggregate savings of \$4.0 billion for states over ten years, as follows.⁹³ The impact of the rule on Medicaid prescription drug rebates, MCO premiums, and prescription drug prices could have resulted in net Federal Medicaid costs of \$1.7 billion between 2020 and 2029, and net state Medicaid costs of \$0.2 billion over the same period. OACT also estimated that state governments would have saved \$4.3 billion between 2020 and 2029 through lower prescription drug prices for state employees. These estimates are at the national level; Medicaid costs, state employee savings, and the net of the two may vary among states.

G. Accounting Statement

	Present Value over 5 Years by Discount Rate (Millions of 2016 Dollars)		Annualized Value over 5 Years by Discount Rate (Millions of 2016 Dollars)	
BENEFITS	3 Percent	7 Percent	3 Percent	7 Percent
Non-quantified Benefits				
Improved information for consumers regarding the characteristics of their health insurance plans				
COSTS	3 Percent	7 Percent	3 Percent	7 Percent
Quantified Costs	1,591	1,448	347	353

Category	Transfers (\$Billions) 10 years (as estimated for CY 2020-2029)
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⁹³ CMS Office of the Actuary. "Proposed Safe Harbor Regulation." August 30, 2018. The OACT analysis was posted as supplementary material in the docket for this rule at regulations.gov in February 2019. The estimated impacts on MCO premiums in the OACT analysis do not apply to the Final Rule because we are not finalizing the proposal to remove the existing safe harbor for Medicaid MCOs. Most of the estimated Medicaid costs in the OACT analysis, however, are associated with the impacts on rebates and drug prices rather than the impacts on MCO premiums from the removal of MCO from the existing safe harbor.

Decreased Medicare beneficiary spending	-25.2 to -59.5
Decreased employee premium and OOP spending	-11.7
Decreased beneficiary premium and cost-sharing spending	-14.5 to - 25.2
Changes in Federal spending	-99.6 to 196.1
Decreased State spending (OACT only)	-4.0
Decreased manufacturer coverage gap discount payments	17 to 39.8

H. Regulatory Alternatives

One option is no action. This means that there would be no change in the safe harbor regulations. None of the costs or benefits of the rule would be realized and Medicare drug plan enrollees will continue to pay deductibles and coinsurance based on the list prices for prescription drugs.

This final rule adopts a delayed effective date for the amendments to § 1001.952(h)(5) of the discount safe harbor consistent with an alternate described in the proposed rule.

Another option contemplated by the Department, unrelated to safe harbor rulemaking, would require sponsors to incorporate into the point-of-sale price for a covered drug a specified minimum percentage of the average rebates expected to be received for the therapeutic class of drugs to which that covered drug belongs. This option, described in an RFI contained in the proposed rule proposing Contract Year 2019 Part C & D policy and technical changes,⁹⁴ would require sponsors to report the point-of-sale price for a covered drug as the lowest possible reimbursement that a network pharmacy could receive for that drug, inclusive of all pharmacy price rebates and concessions.

I. Regulatory Flexibility Analysis

⁹⁴ 82 FR 56336, 56419-28 (Nov. 28, 2017).

As discussed above, the RFA requires agencies that issue a regulation to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. HHS considers a rule to have a significant economic impact on a substantial number of small entities if at least 5 percent of small entities experience an impact of more than 3 percent of revenue. At the proposed rule stage, the Department calculated the costs of the changes per affected business between 2020 and 2024. The estimated average costs of the rule per business according to this estimate peaked in 2020 at approximately \$18,900 and are approximately \$2,800 in subsequent years. The Department notes that relatively large entities are likely to experience proportionally higher costs and that costs will occur at a later point in time than if the rule had been finalized with a 2020 effective date. The U.S. Small Business Administration establishes size standards that define a small entity. For entities with standards based on revenue, they ranged from \$17.5 million to \$38.5 million in 2017. Since the estimated average costs of the rule are a small fraction of these thresholds, the Department anticipates that the rule would not have a significant economic impact on a substantial number of small entities.

VI. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, we are required to solicit public comments, and receive final OMB approval, on any information collection requirements set forth

in rulemaking. This rule imposes documentation and disclosure requirements on PBMs. Specifically, for one of the new safe harbors, PBMs and pharmaceutical manufacturers must have a written agreement that specifies their contractual arrangements and interactions with health plans, and PBMs must disclose their services rendered and compensation associated with transactions with pharmaceutical manufacturers related to interactions between the PBM and the health plan. In addition, PBMs may be required to disclose this information to the Secretary upon request.

We believe that the documentation requirements necessary to enjoy safe harbor protection do not qualify as an added paperwork burden, because the requirements deviate minimally, if at all, from the information PBMs and manufacturers would routinely collect in their normal course of business. We believe it is usual and customary for PBMs and manufacturers to memorialize contracts and other similar agreements in writing. Ensuring that such writings are comprehensive and that the actual business activities are accurately reflected by documentation are standard prudent business practices. However, we recognize that the disclosure of this information to plans, and potentially to the Secretary, is not a routine business practice.

List of Subjects in 42 CFR Part 1001

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare, Social Security.

Accordingly, 42 CFR part 1001 is amended as set forth below:

PART 1001—PROGRAM INTEGRITY—MEDICARE AND STATE HEALTH CARE PROGRAMS

1. The authority citation for part 1001 continues to read as follows:

AUTHORITY: 42 U.S.C. 1302; 1320a-7; 1320a-7b; 1395u(j); 1395u(k); 1395w-104(e)(6), 1395y(d); 1395y(e); 1395cc(b)(2)(D), (E), and (F); 1395hh; 1842(j)(1)(D)(iv), 1842(k)(1), and sec. 2455, Pub. L. 103-355, 108 Stat. 3327 (31 U.S.C. 6101 note).

2. Section 1001.952 is amended:

a. Effective January 1, 2022, by revising paragraphs (h)(5)(vi) and (vii) and adding paragraph (h)(5)(viii); and

b. Effective [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER], by adding paragraphs (h)(6) through (9), (cc), and (dd).

The revisions and additions read as follows:

§ 1001.952 Exceptions.

* * * * *

(h) * * *

(5) * * *

(vi) Services provided in accordance with a personal or management services contract;

(vii) Other remuneration, in cash or in kind, not explicitly described in this paragraph (h) (5); or

(viii) A reduction in price or other remuneration in connection with the sale or purchase of a prescription pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D either directly to the plan sponsor under Medicare Part D, or indirectly through a pharmacy benefit manager acting under contract with a plan sponsor under Medicare Part D, unless it is a price reduction or rebate that is required by law.

(6) For purposes of this paragraph (h), the term manufacturer carries the meaning ascribed to it in Social Security Act section 1927(k) (5).

(7) For purposes of this paragraph (h), the terms wholesaler and distributor are used interchangeably and carry the same meaning as the term "wholesaler" defined in Social Security Act section 1927(k) (11).

(8) For purposes of this paragraph (h), the term pharmacy benefit manager or PBM means any entity that provides pharmacy benefit management on behalf of a health plan that manages prescription drug coverage.

(9) For purposes of this paragraph (h), a prescription pharmaceutical product means either a drug or biological product as those terms are described in Social Security Act section 1927(k)(2)(A), (B), and (C).

* * * * *

(cc) *Point-of-sale reductions in price for prescription pharmaceutical products.* (1) As used in section 1128B of the Act, "remuneration" does not include a reduction in price from a manufacturer to a plan sponsor under Medicare Part D or a Medicaid Managed Care Organization for a prescription pharmaceutical product that is payable, in whole or in part, by a plan sponsor under Medicare Part D or a Medicaid Managed Care Organization, provided the following conditions are met with regard to that reduction in price:

(i) The manufacturer and the plan sponsor under Medicare Part D, a Medicaid MCO, or the PBM acting under contract with either, set the reduction in price in advance, in writing, by the time of the first purchase of the product at that reduced price by the plan sponsor or Medicaid MCO on behalf of an enrollee;

(ii) 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

(iii) 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.

(2) (i) For purposes of this paragraph (cc), the terms manufacturer, pharmacy benefit manager or PBM, prescription pharmaceutical product, and rebate have the meanings ascribed to them in paragraph (h) of this section.

(ii) For purposes of this paragraph (cc), a point-of-sale chargeback is a payment by a manufacturer made directly or indirectly (through a PBM or other entity) to a dispensing pharmacy equal to the reduction in 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.

(iii) For purposes of this paragraph (cc), the term Medicaid Managed Care Organization or Medicaid MCO carries the meaning ascribed to it in section 1903(m) of the Social Security Act.

(dd) *PBM service fees.* (1) As used in section 1128B of the Act, ``remuneration`` does not include any payment by a pharmaceutical manufacturer to a pharmacy benefit manager (PBM) for services the PBM provides to the pharmaceutical manufacturer related to the pharmacy benefit management services that the PBM furnishes to one or more health plans as long as the following conditions are met:

(i) The PBM has a written agreement with the pharmaceutical manufacturer, signed by the parties, 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 associated with such services.

(ii) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(iii) The compensation paid to the PBM is:

(A) Is consistent with fair market value in an arm's-length transaction;

(B) Is a fixed payment, not based on a percentage of sales; and

(C) Is not 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.

(iv) The PBM discloses in writing to each health plan with which it contracts at least annually the services rendered to each pharmaceutical manufacturer related to the PBM's arrangements to furnish pharmacy benefit management services to the health plan, and to the Secretary upon request, the services

rendered to each pharmaceutical manufacturer related to the PBM's arrangements to furnish pharmacy benefit management services to the health plan and the fees paid for such services.

(2) For purposes of safe harbor in this paragraph (dd), the terms manufacturer, pharmacy benefit manager or PBM, and prescription pharmaceutical product have the meanings ascribed to them in paragraph (h) of this section, and health plan has the meaning ascribed to it in paragraph (l) of this section.

DATED: November 16, 2020.

Christi A. Grimm
Principal Deputy Inspector General

DATED: November 17, 2020.

Alex M. Azar II
Secretary

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