

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Office of Inspector General****42 CFR Part 1001**

RIN 0936-AA08

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

ACTION: Proposed rule.

SUMMARY: In this proposed rule, the Department of Health and Human Services (Department or HHS) proposes to amend the safe harbor regulation concerning discounts, which are defined as certain conduct that is protected from liability under the Federal anti-kickback statute, section 1128B(b) of the Social Security Act (the Act). The amendment would revise the discount safe harbor to explicitly exclude 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, Medicaid managed care organizations as defined under section 1903(m) of the Act (Medicaid MCOs), or pharmacy benefit managers (PBMs) under contract with them. In addition, the Department is proposing two new safe harbors. The first would protect certain point-of-sale reductions in price on prescription pharmaceutical products, and the second would protect certain PBM service fees.

DATES: To ensure consideration, comments must be delivered to the address provided below by 5 p.m. Eastern Standard Time on April 8, 2019.

ADDRESSES: In commenting, please reference file code OIG-0936-P. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission. However, you may submit comments using one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronically through the Federal eRulemaking Portal at <http://www.regulations.gov>. (Attachments should be in Microsoft Word, if possible.)

2. *By regular, express, or overnight mail.* You may mail your printed or written submissions to the following address: Aaron Zajic, Office of Inspector General, Department of Health and Human Services, Attention: OIG-0936-P, Room 5527, Cohen Building, 330 Independence Avenue SW, Washington, DC 20201.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* You may deliver, by hand or courier, before the close of the comment period, your printed or written comments to: Aaron Zajic, Office of Inspector General, Department of Health and Human Services, Cohen Building, Room 5527, 330 Independence Avenue SW, Washington, DC 20201.

Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 619-0335.

Inspection of Public Comments: All comments received before the end of the comment period will be posted on <http://www.regulations.gov> for public viewing. Hard copies will also be available for public inspection at the Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW, Washington, DC 20201, Monday through Friday from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (202) 619-0335.

FOR FURTHER INFORMATION CONTACT:
Aaron Zajic, (202) 619-0335.

SUPPLEMENTARY INFORMATION:

Social Security Act citation	United States Code citation
1128B	42 U.S.C. 1320a-7b.
1128D	42 U.S.C. 1320a-7d.
1102	42 U.S.C. 1302.

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

Pursuant to section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987 and its legislative history, Congress required the Secretary of Health and Human Services (the Secretary) to promulgate regulations setting forth various “safe harbors” to the anti-kickback statute, which would be evolving rules that would be periodically updated to reflect changing business practices and technologies in the health care industry. In accordance with this authority, OIG published a

safe harbor to protect certain discounts and reductions in price.¹ The purpose of this proposed rule is to update the discount safe harbor to address the modern prescription drug distribution model and ensure safe harbor protections extend only to arrangements that present a low risk of harm to the Federal health care programs and beneficiaries.

A. Rebates to Medicare Part D and Medicaid Managed Care Plans

Since 2010, the prices of existing drugs have been rising in the United States much more rapidly than warranted either by inflation or costs.² Since 2016, the prescription drug component of the consumer price index grew 2 percent less than inflation, and one official measure of drug price inflation was actually negative in 2018, for the first time in almost 50 years. Nevertheless, this January, drug companies once again announced large price increases—by one analysis averaging around 6 percent per drug. The Department’s research shows that these price increases are largely unsupported by objective economic criteria (e.g., inflation, increased costs of goods sold, increased demand) and reflect significant distortions in the distribution chain.³

Prescription drug manufacturers prospectively set the list price (*i.e.*, wholesale acquisition cost) of the drugs they sell to wholesalers and other large purchasers. Manufacturers also retrospectively pay PBMs or other entities in the drug supply chain, under rebate arrangements, that meet certain volume-based or market-share criteria. Industry parlance refers to the “net price” of a drug as the drug’s list price absent the rebate amount. Since the passage of the anti-kickback statute and

¹ Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR 35952 (July 29, 1991). We note that to qualify as a “discount,” the remuneration must involve a reduction in price to a buyer. The safe harbor acknowledges that a “rebate” may qualify as a discount. However, some payments, while labeled as “rebates,” may not have the effect of reducing the price of an item or service to a buyer.

The determination of whether a particular payment is a protected discount depends on the circumstances. Rebates paid by drug manufacturers to or through PBMs to buy formulary position are not reductions in price. In the Secretary’s view, such a payment would not qualify as “a discount or other reduction in price.” 42 U.S.C. 1320a-7b(b)(3)(A).

² Schondelmeyer SW, Purvis L. Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans: 2006 to 2015. AARP Public Policy Institute. December 2017.

³ Observations on Trends in Prescription Drug Spending. U.S. Department of Health and Human Services. Assistant Secretary for Planning and Evaluation. March 8, 2016.

the establishment of the various safe harbors, the list prices of branded prescription drugs, and the “rebate” payments by manufacturers to PBMs, have grown substantially.⁴ The phenomenon of list prices rising faster than “net prices” is referred to as the “gross to net bubble.”⁵

The prominence of rebate arrangements in the prescription drug supply chain has been cited as a potential barrier to lowering drug costs.⁶ For instance, the system may create incentives for manufacturers to raise list prices and discourage manufacturers from reducing their list prices or, in some cases, penalize them if they do.⁷ Often, a portion of PBM compensation is derived from the savings they create, or the gap between the list price and “net price.” This compensation may be derived from retaining a portion of the rebate, as well as receiving “price protection” payments from manufacturers.⁸ Rebates and price protection payments increase when list prices increase.⁹ Thus, there may be a greater incentive for a PBM to encourage the use of drugs with higher list prices, typically via preferred formulary placement, than the use of lower price drugs that would generate lower rebates or price protection payments. A manufacturer choosing to lower the list price of a drug would be reducing the gap between list price and “net” price,

which would reduce either the size of the rebate or price protection guarantee. This could result in a drug being removed from the formulary or being placed in a less-preferred formulary tier. As a result, the current system works to the disadvantage of beneficiaries, and the Federal health care programs.

1. The Rebate-Based System Harms Beneficiaries

There are significant concerns about the ways in which the current rebate framework may be increasing financial burdens for beneficiaries. Many rebates do not flow through to consumers at the pharmacy counter as reductions in price. In these instances, beneficiaries 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.¹⁰ More often, they are applied to reduce premiums for all enrollees. However, beneficiaries may not be fully benefitting from these premium reductions. Part D plan sponsors include estimates of the amount of rebates they expect to receive in their bids, which in turn drive premiums. A 2011 OIG study found that Part D plan sponsors commonly underestimated rebates in their bids. When this occurs, “beneficiary premiums are higher than they otherwise would be.”¹¹

In addition, OIG work shows that the increases in costs for Part D brand-name drugs have led to higher out-of-pocket spending for some beneficiaries. OIG found that beneficiaries’ out-of-pocket costs for drugs with an average price of more than \$1,000 per month in catastrophic coverage increased by 47 percent from 2010 to 2015. While beneficiaries paid an average of \$175 per month in 2010 for each high-priced drug in catastrophic coverage, this amount increased to \$257 per month in 2015.¹² OIG also found that “the

percentage of beneficiaries who were responsible for out-of-pocket costs of at least \$2,000 per year for brand-name drugs nearly doubled [between 2011 and 2015],”¹³ some of which is potentially driven by changing drug mix and some by increases in list prices.

The following is one example in the context of a branded prescription drug dispensed at a retail pharmacy. In this example, a drug has a Wholesale Acquisition Cost (WAC)/list price of \$100. A manufacturer sells the drug to a wholesaler at a 2 percent discount off of 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, $1.20 \times \text{WAC}/\text{list price} - 15\%$ 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. Thus, in this example, the plan receives back \$30 in rebates, reducing its net cost for the drug to \$74 (*i.e.*, \$104–\$30). 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).

⁴ See, e.g., Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 82 FR 56336, 56419 (Nov. 28, 2017); MedPAC, Status Report on the Medicare Prescription Drug Program 403 (Mar. 2017); CMS, Medicare Part D—Direct and Indirect Remuneration (DIR) (2017), <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>; Nicole M. Gastala et al., Medicare Part D: Patients Bear the Cost of ‘Me Too’ Brand-Name Drugs, 35 Health Affairs (2016).

⁵ OIG, Concerns with Rebates in the Medicare Part D Program (2011).

⁶ OIG, High-Price Drugs Are Increasing Federal Payments for Medicare Part D Catastrophic Coverage, *supra* note 24, at 10.

⁷ OIG, Increases in Reimbursement for Brand-Name Drugs in Part D, *supra* note 16, at 9.

⁸ 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds 143 (2018); see also Jared S. Hopkins, *Drugmakers Raise Prices on Hundreds of Medicines*, Wall St. J. (Jan. 1, 2019).

⁹ New Data Show the Gross-to-Net Rebate Bubble Growing Even Bigger. Drug Channels Institute. June 14, 2017.

¹⁰ E.g., *A perspective from our CEO: Gilead Subsidiary to Launch Authorized Generics to Treat HCV*. Gilead Pharmaceuticals. <https://www.gilead.com/news-and-press/company-statements/authorized-generics-for-hcv>.

¹¹ Letter from David A. Balto on Behalf of Consumer Action to Federal Trade Commission (Dec. 6, 2017). https://www.ftc.gov/system/files/documents/public_comments/2017/12/00303-142565.pdf.

¹² Price protection provisions in PBM contracts provide a cost or growth-rate threshold above which a manufacturer provides an additional payment to the PBM. If a manufacturer increases its price beyond the cost or rate specified, the PBM is held harmless for some or all of the increase. These payments may be for multiple years, and may or may not be described as rebates in PBM contracts with plan sponsors.

¹³ “Under this proposed structure, the PDP sponsor achieves cost control with less earnings volatility while the manufacturer achieves increased volume and regular revenue increases.” Pharmacy manufacturer rebate negotiation strategies: A common ground for a common purpose. Milliman. November 17, 2015.

Transaction	Brand	Notes
List Price	\$100	(A).
Pharmacy Reimbursement	\$104	(P).
Rebates to Health Insurer	(\$30)	(B) = 30% Rebate from Manufacturer * (A).
Net Drug Cost	\$74	(C) = (P) – (B).*
Patient Coinsurance	(\$26)	(D) = 25% * (P).
Net Cost to Health Insurer	\$48	(E) = (C) – (D).
Patient Coinsurance	\$26	(D)
Gross Drug Cost	\$104	(P).
Net Drug Cost	\$74	(C).
Share of Gross Cost	25%	(H) = (P)/(A).
Share of Net Cost	35%	(I) = (D)/(C).

* 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>.

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.¹⁴ 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 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.

Beyond the effects of rebates on beneficiary cost-sharing, the rebate system could be skewing decisions on which drugs appear on a beneficiary's drug formulary, and a drug's placement on the formulary. It may also have a paradoxical effect on competition, which would normally be expected to decrease prices among competitors. The use of rebates creates a financial incentive to make formulary decisions

based on rebate potential, not the quality or effectiveness of a drug.¹⁵ Research suggests that in many therapeutic classes, the approval of a new drug leads to higher list prices not just for the new drug, but for the existing drugs as well.^{16 17 18} Comments submitted in response to a Request for Information¹⁹ from the Department reiterate these concerns, suggest that PBMs may favor drugs with higher rebates over drugs with lower costs, and raise new concerns about "bundled" rebates²⁰ discouraging the adoption of new, lower-cost brand drugs and biosimilars.

2. High List Prices Harm Federal Health Care Programs

The current rebate framework for prescription pharmaceutical products does not appear to translate into lower Medicare and Medicaid per beneficiary spending on prescription drugs, when age and inflation are accounted for, and, to the extent that the rebate structure fuels high list prices, may in fact increase Medicare and Medicaid costs, which is antithetical to the purposes of both the discount exception and the discount safe harbor. This issue is particularly salient for the Centers for Medicare & Medicaid Services (CMS),

¹⁵ Shire, Pfizer antitrust lawsuits could rewrite the rules for formulary contracts: report. Arlene Weintraub. Fierce Pharma. October 10, 2017.

¹⁶ 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.

¹⁷ https://www.achp.org/wp-content/uploads/Rheumatoid-Arthritis_Final.pdf.

¹⁸ https://www.achp.org/wp-content/uploads/Diabetes_FINAL_Revised-12.7.15.pdf.

¹⁹ <https://www.federalregister.gov/documents/2018/05/16/2018-10435/hhs-blueprint-to-lower-drug-prices-and-reduce-out-of-pocket-costs>.

²⁰ Some manufacturer-PBM contracts tie the rebates or formulary position of one product, to the rebate or formulary position of other products made by the same manufacturer. These agreements may discourage PBM adoption of a lower-cost competitor in one therapeutic class because they would forgo manufacturer payments for the other drugs.

the single largest payor of prescription drugs in the nation.

The Medicare Part D and Medicaid programs, as purchasers of health care items and services, stand to benefit from robust competition on both the cost and quality of the products they cover. The cost to the Medicare Part D program and the Medicaid program for certain brand and specialty prescription pharmaceutical products has been rising at a rate far greater than the rate of general inflation.^{21 22}

In 2016, gross drug spending in Medicare Part D was \$146 billion, of which Part D plans paid \$90 billion and beneficiaries paid \$49.7 billion (excluding the coverage gap discount program).²³ OIG recently released a report finding that from 2011 to 2015, reimbursement for Part D brand drugs increased by 77 percent, despite a 17 percent decrease in the number of prescriptions for these drugs.²⁴ In another recent report, OIG found that Federal payments for catastrophic coverage under Part D more than tripled from 2010 to 2015, growing from \$10.8 billion to \$33.2 billion.²⁵ With respect to catastrophic coverage in particular, OIG found that spending for high-priced drugs, those with average prices of more than \$1,000 per month, contributed

²¹ See, e.g., OIG, INCREASES IN REIMBURSEMENT FOR BRAND-NAME DRUGS IN PART D 5 (2018); MEDICAID AND CHIP PAYMENT AND ACCESS COMMISSION, MEDICAID PAYMENT FOR OUTPATIENT PRESCRIPTION DRUGS (2018), <https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf>.

²² Generic drugs prices have generally decreased over the last decade, save for a period of price increases in 2013–2014. See Schondelmeyer SW. Purvis L. Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans: 2006 to 2015. AARP Public Policy Institute. December 2017.

²³ Analysis by the CMS Office of the Actuary.

²⁴ OIG, Increases in Reimbursement for Brand-Name Drugs in Part D 5 (2018).

²⁵ OIG, High-Price Drugs Are Increasing Federal Payments for Medicare Part D Catastrophic Coverage 6 (2017).

¹⁴ Perverse Market Incentives Encourage High Prescription Drug Prices. Garthwaite and Scott Morton. Pro-Market: The blog of the Stigler Center at the University of Chicago Booth School of Business. November 1, 2017.

significantly to the growth in payments during this phase of coverage.²⁶

Although the introduction and changing utilization patterns of new drugs and biologicals can contribute to a rise in Part D spending, increasing prices of existing drugs and biologicals also play a critical role. For example, of the 10 high-priced drugs responsible for nearly one-third of all spending in Part D catastrophic coverage in 2015, OIG found that 6 were not new to the market but had large increases in their average price per month, ranging from 29 percent to 145 percent.²⁷ The remaining four were new to the market.²⁸ OIG has also recently found that of the brand-name drugs reimbursed by Part D in every year from 2011 to 2015, 89 percent had some unit cost increase (on average 29 percent), and nearly half had an increase in unit cost of at least 50 percent (significantly greater than general inflation over this same time period).²⁹³⁰

Although the precise amounts are difficult to isolate, the Medicare program also incurs costs for drugs furnished under prospective payment (e.g., the inpatient prospective payment system) and those covered by Medicare Advantage plans under Part C. In 2016, gross spending on prescription drugs in retail and non-retail settings by CMS and its beneficiaries exceeded \$235 billion, more than half of total United States gross expenditures on prescription drugs of approximately \$450 billion.³¹³²

In 2016, CMS and State Medicaid programs spent \$64 billion (\$29.1 billion net rebates) on drugs covered under Medicaid. For brand-name drugs, manufacturers must pay rebates to Medicaid equal to 23.1 percent of the average manufacturer price (AMP) or the AMP minus the “best price” provided to most other purchasers, whichever is greater. Manufacturers must also pay additional rebates to Medicaid if drug prices rise higher than general inflation. However, rebates, discounts, or other financial transactions paid by manufacturers to PBMs are excluded from AMP and best price, and the maximum rebate

(including the inflation penalty) is capped at 100 percent of the average manufacturer price. As a result, Medicaid is deprived of the lower costs or higher mandatory rebates that could result if rebates paid to PBMs were included in AMP or best price, and the inflation penalty no longer serves as an effective brake on list price increases for drugs already exceeding the 100 percent AMP cap.³³³⁴ Because Medicaid is a much smaller drug market than Medicare Part D and commercial insurance coverage, it may be advantageous for manufacturers to increase list prices and pay rebates to PBMs in these markets.

Though proponents of the current system describe rebates as discounts that lower drug costs, HHS believes that rebates have proven to be ineffective at and counterproductive to putting downward pressure on drug prices. Indeed, rebates may be harming Federal health care programs by increasing list prices, preventing competition to lower drug prices, discouraging the use of lower-cost brand or generic drugs, and skewing the formulas used to determine pharmacy reimbursement or Medicaid rebates.

3. The Rebate System Is Not Transparent

In some or many instances, plan sponsors under Medicare Part D and Medicaid MCOs have limited information about the percentage of rebates passed on to them and the percentage retained by their PBMs. The terms of rebate agreements manufacturers negotiate with PBMs may be treated as highly proprietary and, in many instances, may be unavailable to the plans. For example, in a 2011 evaluation, OIG learned that some Part D plan sponsors had limited information about rebate contracts and rebated amounts negotiated by their PBMs.³⁵ To the extent still true, this lack of transparency could potentially impede the ability of parties to disclose, report, and otherwise account accurately for rebates where required by program rules (and potentially, under the discount safe harbor). This, in turn, creates a potential program integrity vulnerability because compliance with program rules may be more difficult to verify. We are interested in stakeholder

feedback on the issue of transparency and compliance with program rules, particularly as it relates to bundled rebates, price protection or rebate guarantees, and other information not readily apparent when rebates are reported.

4. Changing the Rebate Framework

Based on the problems described above, the Secretary is concerned that rebate arrangements are neither beneficial to health care programs and beneficiaries, nor are they innocuous. In the Secretary’s view, moreover, the statutory exemption for discounts (42 U.S.C. 1320a-7b(b)(3)(A)) does not apply to most rebates paid by drug manufacturers to part D plans or to Medicaid managed care plans. To the extent those rebates are paid to or through PBMs to buy formulary position, such payments would not be protected by the discount statutory exemption. In accordance with the authority described above, this rule proposes to update the regulatory discount safe harbor at 42 CFR 1001.952(h) to exclude from the discount safe harbor certain types of remuneration offered by drug manufacturers to Part D plan sponsors and Medicaid MCOs that may pose a risk to certain Federal health care programs and beneficiaries.³⁶ At the same time, this rule proposes a new safe harbor that would protect discount arrangements that the Department has determined would be beneficial and present a low risk of fraud and abuse if structured in accordance with the safe harbor’s conditions. This new safe harbor (which is one of two new safe harbors proposed in this rule) would protect certain price reductions offered by manufacturers to Part D plans and Medicaid managed care organizations that are reflected at the point of sale to the beneficiary.

By excluding rebates paid by manufacturers to plan sponsors under Medicare Part D and Medicaid MCOs from the discount safe harbor and creating a new safe harbor for point of sale price reductions, the Department believes that there may be an improved

²⁶ *Id.* at 7.

²⁷ *Id.* at 10.

²⁸ *Id.* at 9.

²⁹ OIG, Increases in Reimbursement for Brand-Name Drugs in Part D, *supra* note 16, at 6.

³⁰ MEDPAC, The Medicare Prescription Drug Program (Part D): Status report. Report to the Congress: Medicare Payment Policy, (Mar. 2018).

³¹ CMS’ spending estimate is the sum of Part D gross drug costs, Part B spending on outpatient drugs, and Medicaid gross drug costs.

³² IQVIA Institute for Human Data Science, Medicine Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021, May 2017.

³³ Horn and Dickson. Modernizing and Strengthening Existing Laws to Control Drug Costs. Health Affairs Blog. March 31, 2017. <https://www.healthaffairs.org/do/10.1377/hblog20170331.059428/full/>.

³⁴ Comments to the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. Georgetown Health Policy Institute Center for Children and Families. June 29, 2018.

³⁵ OIG, Concerns with Rebates in the Medicare Part D Program, *supra* note 32, at 17.

³⁶ We recognize that the payments manufacturers retrospectively make to PBMs under rebate agreements would not constitute discounts or other reductions in price to the extent such payments are retained by the PBM and not passed through to any buyer. We do not intend to imply through the issuance of this proposed rule that such payments qualify for safe harbor protection under 42 CFR 1001.952(h). Notwithstanding, out of an abundance of caution and desire to offer bright line guidance regarding the treatment of retrospective payments to PBMs that they retain, we are proposing to specify that such payments (including payments that may be labeled as “rebates”) are not protected by the discount safe harbor.

alignment of incentives among these parties that may curb list price increases, reduce financial burdens on beneficiaries, lower or increase Federal expenditures, improve transparency, and reduce the likelihood that rebates would serve to inappropriately induce business payable by Medicare Part D and Medicaid MCOs. The Department is soliciting comment on whether this action would advance those goals. Specifically, the Department is interested in comments on the effect that the proposed revision to the discount safe harbor and the proposed establishment of a new safe harbor that would protect only point-of-sale reductions in price may have on (i) beneficiary out-of-pocket spending for existing prescription pharmaceutical products, (ii) manufacturers' setting of list prices for newly launched products, (iii) the Federal Government, and (iv) commercial markets.

Additionally, the current rebate framework may deter plans or their PBMs from placing lower cost, therapeutically equivalent drugs on their formularies or may incentivize these entities to give preferred formulary placement to a higher-cost drug that carries a higher associated rebate.³⁷ Therefore, the Department is soliciting comments on (i) the extent to which rebates deter plans or their PBMs from placing lower cost, therapeutically equivalent drugs on their formularies or incentivizes plans or their PBMs to give preferred formulary placement to a higher-cost drug that carries a higher associated rebate, and (ii) how these practices might change if the Department were to eliminate safe harbor protection for rebates and protect only point-of-sale discounts for prescription pharmaceutical products.

The goal is to better align protected discount arrangements with evolving understandings of beneficial industry practices. However, we understand that PBMs still would be in competition with other PBMs; likewise, manufacturers still would be in competition with other manufacturers. We seek comments on possible negative or positive effects on pricing or competition that could result from an increase in transparency under the proposed point-of-sale discount safe harbor.

³⁷ "Meet the Rebate, the New Villain of High Drug Prices." New York Times. July 27, 2018. "The size of the rebate depends on a range of factors, including how many drugs are used by the insurers' members, and how generously the product will be covered on a formulary, or list of covered medicines. Companies that offer bigger rebates are often rewarded with better access like smaller copayments."

The Department recognizes that modifications to the discount safe harbor will affect beneficiary and government spending on Part D plan premiums and cost sharing. However, it is difficult to predict manufacturer and Part D plan behavior in response to this regulation. Because their responses to the regulation will directly affect benefit design, plan bids and, ultimately, beneficiary and government spending on Part D plan premiums and cost sharing, the Department engaged CMS's Office of the Actuary (OACT) and two independent actuarial firms with experience working with Part D plan bid preparation to assess the potential effects on both premiums and out-of-pocket expenses under various assumptions.³⁸ These analyses are discussed in greater detail in the Regulatory Impact Analysis, and we seek feedback on the various approaches to estimating the potential costs and benefits of this regulation.

B. Payments to PBMs

When PBMs contract to administer the pharmacy benefit for health plans, the PBMs are the health plans' agents. However, the contracting health plans may not always know the services their PBMs are providing to pharmaceutical manufacturers. Manufacturers often pay PBMs fees for certain services (*e.g.*, utilization management, medical education, medication monitoring, data management, etc.), and these fees may be calculated as a percentage of the list price of a particular drug product. If service fees paid by manufacturers are tied to the list price of the prescription pharmaceutical product, based on sales volume, or far exceed the fair market value of the services performed, these fees could function as a disguised kickback. This proposed rule would create a new safe harbor that would provide a pathway, specific to PBMs, to protect remuneration in the form of flat fee service fees that would be protected if they meet specified criteria.

The Department believes the terms of the PBMs' agreements with the pharmaceutical manufacturers should be transparent to the health plans. Health plans may be better able to identify and protect themselves from conflicts of interest if they know with some specificity the fees manufacturers are paying PBMs and the services PBMs are rendering to the manufacturers. We solicit comments on any anticompetitive or other issues that may arise from providing health plans with

³⁸ These analyses were conducted by Milliman and Wakely Consulting Group. We will refer to them by firm name in later sections for clarity.

transparency into interactions between pharmaceutical manufacturers and PBMs.

II. Summary of the Major Provisions

This proposed rule would amend the discount safe harbor at 42 CFR 1001.952(h) by adding an explicit exception to the definition of "discount" such that certain price reductions on prescription pharmaceutical products from manufacturers to plan sponsors under Medicare Part D, and Medicaid MCOs would not be protected under the safe harbor. In addition, the proposed rule would add one new safe harbor to protect discounts between those same entities if such discounts are given at the point of sale and meet certain other criteria. Finally, this proposed rule would add a second new safe harbor specifically designed to protect certain 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.

The proposed rule would not alter obligations under the statutory provisions for Medicaid prescription drug rebates under Section 1927 of the Social Security Act, including without limitation the provisions related to best price, the additional rebate amounts for certain drugs if 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. Nor would this proposed rule alter the regulations and guidance to implement Section 1927 provisions, although the Department may issue separate guidance if this proposal is finalized to clarify the treatment of pharmacy chargebacks in calculation of AMP and Best Price. This proposed rule recognizes that rebates paid by manufacturers to Medicaid MCOs should be treated differently than supplemental rebates paid by manufacturers to states because of the differing risk posed under the Federal anti-kickback statute.

III. Background

A. 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. 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.³⁹ 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 inducing 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

³⁹ See, e.g., Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR 35952 (July 29, 1991).

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;
- 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.⁴⁰

Since July 29, 1991, there have been a series of final regulations published in the **Federal Register** establishing safe harbors in various areas.⁴¹ These safe

⁴⁰ 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).

⁴¹ 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 Anti-Kickback Statute, 64 FR 63518 (Nov. 19, 1999); 64 FR 63504 (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

harbor provisions have been developed "to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements."⁴²

Health care 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 health care industry.

B. The Discount Safe Harbor

1. Discount Safe Harbor

The discount safe harbor was created to align with the statutory exception's intent to encourage price competition that benefits the Medicare and Medicaid programs.⁴³

Section 1128B(b)(3)(E) of the Act protects from the anti-kickback statute "any payment practice specified by the Secretary in regulations promulgated pursuant to section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987." Using the authority granted under section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, in the January 23, 1989, **Federal Register**, OIG published a notice of proposed rulemaking that proposed various safe harbors, including a safe harbor for discounts that would apply "to individuals and entities, including providers, who solicit or receive price reductions, and to individuals and entities who offer or pay them."⁴⁴ Subject to certain modifications, OIG finalized the discount safe harbor, among others, in a final rule published on July 29, 1991.⁴⁵ This regulatory discount safe harbor was designed to

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).

⁴² Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR at 35958.

⁴³ Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 FR at 3092.

⁴⁴ Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 FR 3088 (Jan. 23, 1989).

⁴⁵ Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR 35952 (July 29, 1991).

protect all discounts or reductions in price protected by Congress in the statutory exception, as well as additional discounting practices not included in the statutory exception that are not abusive.⁴⁶

In response to requests from stakeholders, in the July 21, 1994, **Federal Register**, OIG proposed a number of clarifications to the discount safe harbor. For instance, OIG proposed to divide the relevant parties into three groups (buyers, sellers, and offerors) in order to delineate the different obligations individuals or entities must meet to receive protection under the discount safe harbor.⁴⁷

OIG modified the proposed regulations in response to comments received and finalized the clarifications to the discount safe harbor, among others, in the final rule published in the November 19, 1999, **Federal Register**.⁴⁸ Specifically, OIG defined “rebate” to include “any discount the terms of which are fixed at the time of the sale of the good or service and disclosed to the buyer, but which is not received at the time of the sale of the good or service.” OIG recognized that a manufacturer may offer a discount in the form of a rebate to a buyer. In addition, OIG stated that the regulatory safe harbor both incorporates and enlarges upon the statutory exception.⁴⁹

Finally, in the October 20, 2000, **Federal Register**, OIG proposed several technical revisions to the discount safe harbor, including a revision that would expand the safe harbor to cover discounts for items or services for which payment may be made, in whole or in part, under Medicare, Medicaid, or other Federal health care programs.⁵⁰ OIG finalized this expanded scope of the discount safe harbor in the **Federal Register** published on March 18, 2002.⁵¹

Subsequent OIG guidance has emphasized that, “to qualify for the

⁴⁶ 64 FR 63518, 63528 (Nov. 19, 1999).

⁴⁷ Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the OIG Safe Harbor Anti-Kickback Provisions, 59 FR 37202 (July 21, 1994).

⁴⁸ 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 Anti-Kickback Statute, 64 FR 63518 (Nov. 19, 1999). That final rule also confirmed that “the regulatory safe harbor expands upon the statutory [exception] by defining additional discounting practices not included in the statutory exception that are not abusive” *Id.* at 63528.

⁴⁹ 64 FR 63518, 63528 (Nov. 19, 1999).

⁵⁰ Medicare and State Health Care Programs: Fraud and Abuse; Revisions and Technical Corrections, 65 FR 63035, 63041 (Oct. 20, 2000).

⁵¹ Medicare and Federal Health Care Programs: Fraud and Abuse; Revisions and Technical Corrections, 67 FR 11928, 11934 (Mar. 18, 2002).

discount exception, the discount must be in the form of a *reduction in the price* of the good or service based on an arms-length transaction.”⁵²

2. Treatment of “Rebates” Under the Discount Safe Harbor

Section 1128B of the statute explicitly identifies rebates, along with kickbacks and bribes, as remuneration. When OIG first proposed a regulation implementing the discount exemption, it closely followed the statutory language, limiting its application to reductions in the amount a seller charges in a specific transaction for a good or service to a buyer.⁵³ It specifically did not apply to remuneration in the form of things of value, such as rebates of cash, other free goods or services, redeemable coupons, or credit towards the future purchases of other goods or services.⁵⁴ At the time, OIG recognized that these forms of remuneration may not be legitimate “discounts” and could be subject to abuse.⁵⁵ In the July 29, 1991 final rule, OIG recognized that rebates can function like legitimate reductions in price, and defined discount to include protection for rebate checks, subject to the limitation that they only be applied to the same good or service that was purchased or provided, and must be fully and accurately reported.⁵⁶ In the July 21, 1994, **Federal Register**, OIG proposed to clarify the definition of the term “rebate” for purposes of the safe harbor.⁵⁷ OIG modified the proposed regulations in response to comments received and finalized the clarifications to the discount safe harbor, among others, in the final rule published in the November 19, 1999, **Federal Register**.⁵⁸ Specifically, OIG defined “rebate” to include “any discount the terms of which are fixed at the time of the sale

⁵² 2003 Compliance Program Guidance for Pharmaceutical Manufacturers, 68 FR 23731, 23735 (May 5, 2003) (emphasis in the original).

⁵³ Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 FR at 3092.

⁵⁴ *Id.*

⁵⁵ Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR at 35978–35979.

⁵⁶ Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the OIG Safe Harbor Anti-Kickback Provisions, 59 FR 37202 (July 21, 1994).

⁵⁷ 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 Anti-Kickback Statute, 64 FR 63518 (Nov. 19, 1999). That final rule also confirmed that “the regulatory safe harbor expands upon the statutory [exception] by defining additional discounting practices not included in the statutory exception that are not abusive” *Id.* at 63528.

of the good or service and disclosed to the buyer, but which is not received at the time of the sale of the good or service.”⁵⁹ OIG recognized that a manufacturer may offer a discount in the form of a rebate to a buyer.⁶⁰

3. Further Developments: Establishment of the Medicare Prescription Drug Benefit and Drug Rebates to Medicaid Managed Care Organizations

Long after Congress passed the legislation creating the modern anti-kickback statute and discount exception, and OIG issued the discount safe harbor regulation, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, establishing a prescription drug benefit for Medicare Beneficiaries (Medicare Part D).

The standard Part D benefit structure established by the Medicare Modernization Act required beneficiaries to pay a monthly premium, annual deductible, and copayments or coinsurance for drugs purchased at pharmacies. The standard benefit also included a coverage gap (also known as the doughnut hole) during which beneficiaries were required to pay 100 percent of their drug costs until their out-of-pocket spending reached the catastrophic threshold. The Part D benefit has been modified by a number of statutory changes, including the Patient Protection and Affordable Care Act of 2010 and the Bipartisan Budget Act of 2018.

In 2019, applicable beneficiaries enrolled in standard coverage would pay a \$415 deductible, 25 percent of their gross drug costs up to the initial coverage limit of \$3,820 (an additional \$851.25), and 25 percent of their brand drug costs and 37 percent of generic drug costs until reaching the out-of-pocket threshold of \$5,100 (an estimated \$8,139.54 of total covered Part D spending). These thresholds, and the actuarial equivalence of alternative benefits designs, are determined annually based on gross Part D drug costs.

Applicable beneficiaries, defined as those enrollees of prescription drug plans who do not receive the Low-Income Subsidy, pay 5 percent of their gross drug costs after reaching the out-of-pocket limit and entering catastrophic coverage. Part D plan sponsors are responsible for 75 percent of the gross covered drug costs between the deductible and the initial coverage limit, 5 percent and 63 percent of gross brand and generic drug costs,

⁵⁹ *Id.* at 63527.

⁶⁰ *Id.* at 63528.

respectively, in the coverage gap, and 15 percent of the gross drug costs in the catastrophic phase of the benefit. The Federal Government pays 74.5 percent of the plan benefit costs,⁶¹ and 80 percent of the gross drug costs during catastrophic coverage. The government also provides premium subsidies and cost-sharing subsidies for low-income beneficiaries.

Part D plan sponsors are permitted to offer plans with alternative benefit designs that are actuarially equivalent to standard Part D coverage, but have different deductibles and cost-sharing requirements. In 2019, many Part D plan sponsors will offer an alternative benefit design. The weighted average total premium for all Part D plans is \$43.50 per month. Part D beneficiaries enrolled in the 10 largest Part D plans will have formularies with 5 tiers of cost-sharing, and pay between \$0 to \$5 copayments for preferred generic drugs, \$1 to \$13 copayments for generic drugs, \$25 to \$47 copayments for preferred brands, 32 percent to 50 percent coinsurance for non-preferred drugs, and 25 percent to 33 percent coinsurance for specialty drugs.

Like the statutory exception, the discount safe harbor and all revisions to such safe harbor were promulgated prior to the enactment of the Medicare prescription drug benefit and prior to the promulgation of comprehensive regulations governing Medicaid managed care delivery systems. Moreover, after the current version of the discount safe harbor was finalized, there were two statutory changes involving the intersection of drug pricing under the Medicaid Drug Rebate Program and Medicaid MCOs (including the availability of mandatory Medicaid rebates for drugs dispensed to individuals enrolled with a Medicaid MCO if the MCO is responsible for covering those drugs),⁶² and the Department recently finalized regulations to modernize the Medicaid managed care regulatory structure.⁶³

III. Provisions of the Proposed Rule

To address the Department's concerns with the current rebate system, the

⁶¹ On average, beneficiary premiums are 25.5 percent of the benefit costs, or the cost of a standard Part D plan, as determined by annual bids submitted by Part D plan sponsors.

⁶² Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, sec. 1002; Patient Protection and Affordable Care Act, Public Law 111–148, as amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, sec. 2501(c).

⁶³ Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions to Third Party Liability, 81 FR 27498 (May 6, 2016).

Department proposes to eliminate safe harbor protection for manufacturer reductions in price on prescription pharmaceutical products to Medicare Part D plans operating under section 1860D–1 *et seq.* of the Act, and Medicaid MCOs, as defined under section 1903(m) of the Act. In conjunction with this amendment, the Department is proposing a new safe harbor that would protect manufacturer point-of-sale reductions in price on prescription pharmaceutical products to a plan sponsor under Medicare Part D, a Medicaid MCO, or a PBM acting under contract with either, that would be applied at the point of sale to benefit the beneficiary, the plan, and, by extension, the Government. Finally, the Department is proposing a new safe harbor to protect certain fixed service fees that pharmaceutical manufacturers pay to PBMs. We are interested in and solicit comments on how these proposals, individually and/or collectively, would align or conflict with program requirements and any legal requirements (*e.g.*, antitrust laws) that may apply to affected parties.

A. Amendment to the Discount Safe Harbor

The Department proposes to amend the existing discount safe harbor so that it would no longer protect price reductions from manufacturers to plan sponsors under Medicare Part D or Medicaid MCOs, either directly or through PBMs acting under contract with plan sponsors under Medicare Part D or Medicaid MCOs, in connection with the sale or purchase of prescription pharmaceutical products, unless the reduction in price is required by law. Given that the discount safe harbor applies to items payable under Medicare, Medicaid, or other Federal health care programs, we solicit comments on whether this amendment should be limited to prescription pharmaceutical products payable by Medicare Part D and Medicaid MCOs, or whether the amendment also should apply to prescription pharmaceutical products payable under other HHS programs (*e.g.*, Medicare Part B fee-for-service, a Medicaid managed care program operated using waiver authority under section 1915(b) of the Act).

For purposes of this amendment as well as the proposed new safe harbor, we propose to interpret the term "plan sponsor under Medicare Part D" to include the sponsor of a prescription drug plan (PDP) as well as a Medicare Advantage organization offering a Medicare Advantage prescription drug plan. These two categories of plans are

the predominant types of plans through which beneficiaries receive prescription drug coverage under Part D. We solicit comments on this definition and also whether we should adopt a broader definition that would include all entities considered to be "Part D plan sponsors" under 42 CFR 423.4 (*i.e.*, expand to also include PACE organizations offering a PACE plan including qualified prescription drug coverage and cost plans offering qualified prescription drug coverage).

We also note that nothing in this proposed rule changes the discount safe harbor's provision that excludes from protection price reductions offered to one payor but not to Medicare or Medicaid, particularly when such discounts serve as inducements for the purchase of federally reimbursable products. OIG has a long-standing concern about arrangements under which parties "carve out" referrals of Federal health care program beneficiaries or business generated by Federal health care programs from otherwise questionable financial arrangements. Such arrangements implicate, and may violate, the anti-kickback statute by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business. This concern would extend to certain pharmaceutical rebate arrangements. For example, if a manufacturer offered a rebate on a product to an insurer for its private pay plans conditioned (explicitly or implicitly) on the product's favorable formulary placement across all plans (including Part D plans), such a rebate could be remuneration that would implicate the anti-kickback statute and would not be protected by the current discount safe harbor or by the provisions of this proposed rulemaking.

While this amendment would exclude from protection 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 required by law (*e.g.*, rebates under the Medicaid Drug Rebate Program), the Department is proposing a new safe harbor, with different criteria, that would protect certain point-of-sale discounts that the proposed amendment would carve out from the current discount safe harbor. For the policy and program integrity reasons articulated above, the changes reflected in this proposed rulemaking

are 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 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. We solicit comments regarding whether the proposed regulatory text amending the discount safe harbor (when read in conjunction with the proposed new safe harbor at 42 CFR 1001.952(cc)) excludes reductions in price not contemplated by the proposed amendment. In addition, we solicit comments on any additional or different regulatory text necessary to clarify that other types of discounts (e.g., volume or prompt payment discounts to wholesalers) that currently are protected by the discount safe harbor would remain protected if all safe harbor conditions are met. We also solicit comments regarding whether declining to protect rebates to plan sponsors under Medicare Part D and Medicaid MCOs under a safe harbor might affect beneficiary access to prescription pharmaceutical products either due to cost or formulary placement.

While the Department intends 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, and Medicaid MCOs, the Department is concerned about the potential for unintended loopholes. For example, we are concerned that in some circumstances, such price reductions could be used to funnel remuneration to parties that otherwise would have been in the form of rebates where such rebates, under this proposed rule, would no longer qualify for safe harbor protection.

We also are aware that many states have negotiated supplemental rebate agreements with drug manufacturers, which the Department does not presently believe should be affected by this proposal. We are considering and solicit comments on the extent, if any, to which these supplemental rebates would be affected by this proposal. In addition, we solicit comments on other types of entities who receive price reductions from manufacturers for the same types of prescription pharmaceutical products that are also sold to or purchased by plan sponsors

under Medicare Part D, Medicaid MCOs, or pharmacy benefit managers acting under contract with either and whether price reduction arrangements with those entities may pose similar risks. We are considering and seek comments on safeguards that already may be in place or could be included in the discount safe harbor to protect beneficial price reductions (*i.e.*, that benefit programs or beneficiaries) while at the same time preventing the potential abuses described above.

As part of this proposal, the Department is soliciting comments on a definition for “in connection with” in the discount safe harbor; such a definition would clarify the scope of those price reductions that would no longer be protected under the discount safe harbor because they relate to the purchase of pharmaceutical products ultimately sold to or purchased by a plan sponsor under Medicare Part D, a Medicaid MCO, or a pharmacy benefit manager acting under contract with either. As stated above, we are considering and also soliciting comments on whether additional or different regulatory text would be necessary to clarify that other types of discounts (e.g., volume or prompt payment discounts to wholesalers) that currently are protected by the discount safe harbor would remain protected if all safe harbor conditions are met.

The Department is exploring value-based arrangements and their use in the sale of prescription pharmaceutical products. The Department does not intend for this proposal to have any effect on existing protections for value-based arrangements between manufacturers and plan sponsors under Medicare Part D and Medicaid MCOs. We are interested in hearing from stakeholders about, and are soliciting comments on, the extent to which the proposed amendment and accompanying proposed safe harbor may affect any existing or future value-based arrangements. We request that any such comments specify how any currently protected arrangements or arrangements that might be protected under the proposed safe harbor are “value based.”

We are proposing that this amendment, if finalized, be effective on January 1, 2020. We are mindful that many entities may be using the current discount safe harbor to protect financial arrangements that no longer would meet the definition of “discount” under this proposed change. We are soliciting comments on whether the proposed effective date gives affected entities a sufficient transition period to restructure any arrangements that could

implicate the anti-kickback statute and no longer would be protected by a safe harbor.

Finally, we solicit comments on proposed definitions for the terms “manufacturer,” “wholesaler,” “distributor,” “pharmacy benefit manager” or “PBM,” and “prescription pharmaceutical product” for purposes of 42 CFR 1001.952(h). We solicit comments on the sufficiency of the proposed definitions to accurately describe these terms for use in this proposed rule.

B. New Safe Harbor for Certain Price Reductions on Prescription Pharmaceutical Products

The Department is proposing a new safe harbor (Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products) that would protect point-of-sale price reductions offered by manufacturers on certain prescription pharmaceutical products that are payable under Medicare Part D or by Medicaid MCOs that meet certain criteria. The proposed effective date for the new safe harbor would be 60 days after publication of the final rule. The Department intends for this new safe harbor to protect reductions in price for prescription pharmaceutical products without regard to what phase of the benefit the beneficiary is in. We solicit comment on potential revisions to clarify how the safe harbor would apply during periods of 100 percent beneficiary cost sharing.

As we describe throughout this preamble, point-of-sale reductions in price pose less risk to Medicare Part D, Medicaid MCOs, and beneficiaries than the current rebate system for prescription pharmaceutical products. In that regard, we are soliciting comments on the extent to which the safe harbor, if finalized, would incentivize manufacturers to provide point-of-sale discounts. We are considering whether and, if so, how the proposed safe harbor conditions should be modified to encourage these point-of-sale price reductions without posing any undue risk to programs or patients. We will consider alternative suggestions as well.

We continue to believe that “discounts are distinct from across-the-board price reductions offered to all buyers where the inducement that is made is so diffuse that it does not appear intended to encourage a particular buyer to purchase or order a particular good or service payable under

Medicare or Medicaid.”⁶⁴ For example, if a manufacturer were to implement an across-the-board reduction in price for a prescription pharmaceutical product (*e.g.*, a reduction in WAC), such a reduction in price would not need the protection of the discount safe harbor or the safe harbor proposed in this rulemaking.

Under the proposed new safe harbor, a manufacturer could offer a reduction in price on a particular prescription pharmaceutical product to a plan sponsor under Medicare Part D, to a Medicaid MCO, or through a PBM acting under contract with either if certain conditions are met. First, the reduction in price would have to be set in advance with the plan sponsor under Medicare Part D, a Medicaid MCO, or a PBM. We propose that “set in advance” would mean that the terms of the reduction in price would be fixed and disclosed in writing to the plan sponsor under Medicare Part D or the Medicaid MCO by the time of the initial purchase. We propose to interpret “the initial purchase” to mean the first purchase of the product at that reduced price by the plan sponsor or Medicaid MCO on behalf of an enrollee. Like the current discount safe harbor, we propose that this new safe harbor would exclude from protection price reductions offered to one payor but not to Medicare or Medicaid and solicit comments on whether the regulation captures this intent.

Second, the reduction in price could not involve a rebate, as defined in 42 CFR 1001.952(h), unless the full value of the reduction in price is provided to the dispensing pharmacy through a chargeback or a series of chargebacks, or the rebate is required by law. We propose to define a “chargeback” as a payment made directly or indirectly by a manufacturer to a dispensing pharmacy so that the total payment to the pharmacy for the prescription pharmaceutical product is at least equal to the price agreed upon in writing between the Plan Sponsor under Part D, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product. For example, when a pharmacy dispenses a drug to a beneficiary that is reimbursed by a particular Part D plan or Medicaid MCO, the total payment to the pharmacy (*i.e.*, cost-sharing from the beneficiary, payment from the Part D plan or Medicaid MCO, and any chargeback) will be at least equal to the

price agreed upon between the manufacturer of that drug and the Part D Plan or Medicaid MCO, or a PBM acting under contract with either. We solicit comments on this definition. Notably, the current rebate frameworks under which a manufacturer pays the plan sponsor under Medicare Part D or Medicaid MCO directly or through a PBM would not meet this criterion absent those chargebacks resulting in the dispensing pharmacy receiving the full value of the reduction in price.

Third, the reduction in price must be completely reflected in the price the pharmacy charges to the beneficiary at the point of sale. For example, if the discounted rate is set in advance, at the time of dispensing the pharmacy would have the necessary information to appropriately charge a beneficiary who owes coinsurance, even if the manufacturer ultimately tenders the dispensing pharmacy a payment through a chargeback to reflect this negotiated price with the payor.

The proposed safe harbor’s requirements are intended to exclude from its protection conduct that mimics rebates but are referenced in other ways in the contracts between a manufacturer and a PBM, a plan sponsor under Medicare Part D, or a Medicaid MCO. For example, fees that are based on a percentage of a prescription pharmaceutical product’s list price could be a disguised kickback and would not be protected by this proposed safe harbor unless the requirements created by this rule are met. We are soliciting comments on this approach and whether, and if so, how the regulatory text should be modified to best reflect this intent.

We recognize that some pharmacies and PBMs are related through ownership, and we solicit comments on any potential issues such ownership interests might create under this proposed safe harbor and how best to address them. We also recognize that some PBMs may argue that allowing the reduction in price to be processed at the point of sale may provide pharmacies sufficient data to reverse engineer the manufacturer’s or the PBM’s discount structure. We solicit comments on whether this is likely, and if so, how it might transpire, what impact it might have on competition, and how, if at all, this should be addressed in the proposed safe harbor.

For purposes of proposed 42 CFR 1001.952(cc) we propose to incorporate the definitions of the terms “manufacturer,” “pharmacy benefit manager” or “PBM,” “prescription pharmaceutical product,” “rebate,” and “Medicaid managed care organization”

or “Medicaid MCO” as they would be set forth in the proposed amendment to 42 CFR 1001.952(h). We also propose a definition of “chargeback.” We solicit comments on the sufficiency of the proposed definitions to accurately describe these terms for use in this proposed rule.

C. New Safe Harbor for Certain PBM Service Fees

The Department is proposing a new safe harbor (PBM Service Fees) that would protect fixed fees that manufacturers pay to PBMs for services rendered to the manufacturers that meet specified criteria. In some circumstances, services that PBMs provide to health plans and pharmaceutical manufacturers put PBMs in a position to recommend or arrange for the purchase of pharmaceutical manufacturers’ products. The Department recognizes the possibility that certain types of remuneration that manufacturers might pay to PBMs either would not implicate the anti-kickback statute or could be protected under another existing safe harbor. However, this proposed new safe harbor would provide a pathway, specific to PBMs, to protect remuneration in the form of flat fee service fees that would be low risk if they meet specified criteria.

This proposed safe harbor would protect payments pharmaceutical 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. With respect to services that relate in some way to the PBM’s arrangements with health plans, we have in mind, by way of example, services rendered to manufacturers that depend on or use data gathered by PBMs from their health plan customers (whether claims or other types of data). For example, PBMs might provide services for pharmaceutical manufacturers to prevent duplicate discounts on 340B claims.⁶⁵ Such a service is for the benefit of the manufacturer but relies on certain

⁶⁴ Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR 35952, 35977 (July 29, 1991).

⁶⁵ Section 256b(a)(5)(A)(i) of Title 42 provides that manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug.

information the PBM would have from its contracted health plans. We note, however, that nothing in this proposed safe harbor would preempt any contractual terms that a PBM has with a health plan that limits or delineates the PBM's use of the health plan's data.

We consider "pharmacy benefit management services" to be services 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. We do not propose to create a definition for "pharmacy benefit management services" as these services could evolve over time. We solicit comments on this approach and whether other services should be considered "pharmacy benefit management services" for purposes of this safe harbor. We also solicit comments on our proposal to limit this safe harbor to the fees that pharmaceutical manufacturers pay to PBMs that relate to the PBM's arrangements to provide pharmacy benefit management services to health plans.

The first proposed condition of the safe harbor would require the PBM and the pharmaceutical manufacturer to have a written agreement that: (i) 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 (ii) specifies each of the services to be provided by the PBM and the compensation for such services. Compliance with this first condition is necessary to demonstrate compliance with the second proposed condition. We solicit comments regarding whether the safe harbor 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).

The second proposed condition would specify that compensation paid to the PBM must: (i) Be consistent with fair market value in an arm's-length transaction; (ii) be a fixed payment, not based on a percentage of sales; and (iii) 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 first sub-condition requires that the remuneration be consistent with fair market value in an arm's length transaction and we welcome comments on the requirement, including comments on avoiding any risks of gaming with respect to valuation or other conditions in this proposed safe harbor. The second sub-condition would permit flat fees, but not percentage-based fees, including fees based on a percentage of sales. Flat fees pose lower risk of abuse and conflicts of interest. For example, if a pharmaceutical manufacturer were to offer compensation to a PBM for its services based on a percentage of the price of the manufacturer's product, the PBM could be influenced to include higher-priced alternatives in favorable tiers on its formulary, which would increase the PBM's own profits but be less beneficial for the health plans for which the PBM is supposed to be acting as an agent. (We note that the current rebate framework, where we understand that PBMs generally seek payments (which the parties refer to as "rebates") from manufacturers in exchange for a favorable formulary placement, may be instructive with respect to the relative risks of payments based on sales versus fixed fees.) Therefore, we are proposing that the protected payments must be fixed fees, rather than fees that are based on a percentage of sales or other variable. We solicit comments on this approach and these concerns.

The third sub-condition would require that the fees not be determined in a manner that takes into account the volume or value of any referrals or other business generated. We solicit comments regarding this volume or value criterion. In particular, we solicit comments on any services arrangements between pharmaceutical manufacturers and PBMs that take into account the volume or value of referrals or business otherwise generated between the parties, or the manufacturer and the PBM's health plans, but otherwise would be low risk or appropriate. We are considering whether, and if so how, we could include criteria that would allow us to deem certain arrangements not to take into account the volume or value of any referrals or business otherwise generated between the parties so that they may be protected under this safe harbor if all other criteria are met.

Finally, the Department proposes that the PBM disclose in writing to each health plan with which it contracts at least annually, and to the Secretary upon request, the services it rendered to

each pharmaceutical manufacturer that are related to the PBM's arrangements with that health plan and the associated costs for such services. We are also considering, and solicit comments on, whether, and if so under what conditions, PBMs should also be required as an additional condition of safe harbor compliance to disclose the fee arrangements to the health plans. We propose that the PBMs be required to disclose the fee arrangements to the Secretary upon request. To promote transparency and minimize risks of fraud or abuse, we are also considering, and solicit comments on, requiring PBMs to disclose, in order to use the safe harbor, additional information about the fee arrangements to the Secretary upon request, including information about some or all of the following: Information about valuation and valuation methodology; information demonstrating that fee arrangements are not duplicative of other arrangements for which the PBM might receive duplicative payments ("double-dipping"); and information demonstrating that fee arrangements meet the "volume or value" criterion. The Department believes that PBMs are agents of the health plans with which they contract and that this transparency requirement is important to ensure that the 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 solicit comments on this transparency requirement. For example, we solicit comments on whether arrangements that PBMs have, or would seek to have, with pharmaceutical manufacturers could be attributed to services provided to particular health plans. We are also soliciting comments on any competitive concerns this transparency condition would raise and how we might address them in this rulemaking. Nothing in this proposal would affect the ability of the health plan and PBMs to negotiate different disclosure provisions in their contracts; however, safe harbor protection would only apply if the conditions of the safe harbor are fully met.

IV. 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

(RIA) 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 proposed 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 \$56.2 million in annualized costs at a 7% discount rate, discounted relative to 2016, over a perpetual time horizon.

The Regulatory Flexibility Act 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 proposed 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 2018, that threshold is approximately \$150 million. The proposed rule may have effects on states through its effects on the Medicaid Drug Rebate Program, under which rebates are shared between the Federal Government and the states based on the Federal Medical Assistance Percentage (FMAP) for each state, and through its effects on Medicaid managed care. We invite comments on these or other potential impacts.

The rule does not alter the statutory provisions for Medicaid prescription

drug rebates under Section 1927 of the Social Security 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.

To the extent that the rule reduces Average Manufacturer Price (AMP), however, 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.⁶⁶

The proposed rule would also change the safe harbor provision that currently protects rebates that PBMs negotiate on behalf of Medicaid MCOs while establishing a new safe harbor that allows point-of-sale price reductions under certain conditions. Finally, we seek comment regarding how these changes would influence bids submitted by Medicaid MCOs, including whether or not reducing rebate revenue for Medicaid managed care plans could result in states receiving bids with increased costs for Medicaid MCO contracts.

The Office of the Actuary estimates that the rule will result in estimated aggregate savings of \$4.0 billion for states over ten years, as follows.⁶⁷ The impact of the rule on Medicaid prescription drug rebates, MCO premiums, and prescription drug prices could result 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.⁶⁸ The Office of the Actuary also estimates that state governments will save \$4.3 billion between 2020 and 2029 through lower prescription drug prices for state

⁶⁶ Milliman. “Impact of Potential Changes to the Treatment of Manufacturer and Pharmacy Rebates.” September 2018. The Milliman analysis is posted as supplementary material in the docket for this rule at *regulations.gov*.

⁶⁷ CMS Office of the Actuary. “Proposed Safe Harbor Regulation.” August 2018. The OACT analysis is posted as supplementary material in the docket for this rule at *regulations.gov*.

⁶⁸ CMS Office of the Actuary. “Proposed Safe Harbor Regulation.” August 2018. The OACT analysis is posted as supplementary material in the docket for this rule at *regulations.gov*.

employees.⁶⁹ These estimates are at the national level; Medicaid costs, state employee savings, and the net of the two may vary among states.

We further note that the Veterans Health Administration, the Indian Health Service, tribes administering health programs under tribal self-governance, and other entities are eligible to purchase prescription drugs under the Federal Supply Schedule (FSS). FSS pricing is negotiated based on a unique commercial sales practices format, using commercial list pricing and most favored customer pricing as a base for negotiating, in most cases, up front discounts. In addition, the Veterans Health Administration, 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 Federal Ceiling Price is calculated as a percentage of non-Federal average manufacturer pricing (non-FAMP). Eligible programs can purchase drugs using the lesser of the 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 VA may realize some additional savings. We solicit comment on effects on these stakeholders.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed 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.

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

⁶⁹ CMS Office of the Actuary. “Proposed Safe Harbor Regulation.” August 2018. The OACT analysis is posted as supplementary material in the docket for this rule at *regulations.gov*.

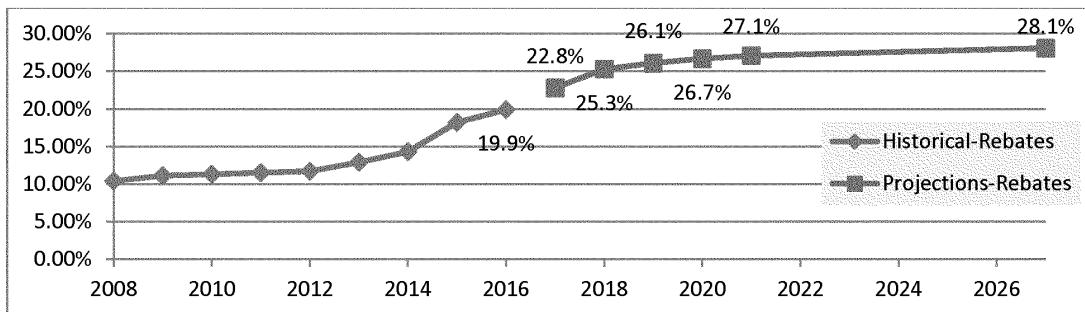
for consumers, because their out-of-pocket costs during the deductible, coinsurance, and coverage gap phases of their benefits are based on the list price. Rebates may also increase costs for the government, which pays a portion of the premium, cost-sharing, and reinsurance payments associated with the 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).⁷⁰ According to the IQVIA Institute for

Human Data 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 US invoice spending (the amount paid by distributors) and net spending (which accounts for all price concessions) across all distribution channels has increased from approximately \$74 billion in 2013 to \$130 billion 2017 for retail drugs. The IQVIA Institute found a similar growth in the difference between invoice and net spending for the total US retail market.⁷¹

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,
2008–2027 (Projected)



Source: 2018 Medicare Trustees Report, Table IV.B8

B. Background on Costs, Benefits, and Transfers

This proposed rule seeks to eliminate rebates so that manufacturers will have an incentive to lower list prices and PBMs will have more incentive to negotiate greater discounts from manufacturers. The goal of this policy is to lower out-of-pocket costs for consumers and reduce government drug spending in Federal health care programs.

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 proposal to result in manufacturers lowering their list prices, and replacing rebates with discounts. One way to

quantify this impact is to simply replace all manufacturer rebates paid to PBMs with discounts paid to consumers, and estimate the effect of this transfer on stakeholders. However, this approach does not consider the range of strategic behavior 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.

Today, prescription drug manufacturers prospectively set the Wholesale Acquisition Cost, or list

price, of the drugs they sell to wholesalers and other large purchasers. Manufacturers also retrospectively make payments to pharmacy benefit managers (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 pharmacy benefit managers, 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. PBMs may favor drugs with higher rebates over drugs with lower costs, or otherwise discourage the

⁷⁰“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.

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 (who 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 proposed rule would remove safe harbor protection for rebates received by PBMs from manufacturers in connection with Medicare Part D and Medicaid MCOs, and create two new safe harbors protecting certain discounts by manufacturers and protecting certain flat fees paid by manufacturers to a PBM for services the PBM renders to the manufacturer. To the extent that this rule would result in manufacturers reducing the list price of drugs, this rule would impact all cash flows throughout the system.

The intent of this rule is to eliminate rebates from manufacturers to PBMs, and replace them with discounts provided to beneficiaries at the point of sale. This change would also 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.⁷² For most health care services, consumer deductibles and coinsurance are based on the prices 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 consumers' deductible and coinsurance payments are based on the list price.

With a reduced price charged by the pharmacy, patients with coinsurance or deductible plans will likely experience reductions in cost-sharing for rebated brand-name at the point of sale. Patients with fixed co-payments may not 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, the benefit of lower premiums and out-of-pocket costs could 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, coverage, and in-network providers. Research shows that consumers often do not understand their health insurance plans and would better understand a simpler plan.⁷³ Research specific to Medicare Part D suggests beneficiaries place a greater weight on premium than out-of-pocket cost, are most likely to choose the plan with the lowest premium.⁷⁴ Oftentimes they select the plan with the lowest premiums when plans with higher premiums and more comprehensive coverage were actuarially favorable.⁷⁵ 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% coinsurance on a drug with a \$100 WAC and 30% rebate effectively pays 28% 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 cost sharing of beneficiaries eligible for the Part D low-income subsidy. If this rule increases premiums, Federal spending on premium subsidies will also increase, potentially outweighing estimated Federal savings associated with this proposal. These potential effects are described in the transfers section of this regulatory impact analysis.

Lastly, 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. We seek comment on the impacts identified and any other impacts.

C. Affected Entities

This proposed rule would affect the operations of entities that are involved in the distribution and reimbursement of prescription drugs to Medicaid beneficiaries and Medicare Part D prescription drug benefit enrollees. According to the US Census⁷⁶ and other sources,⁷⁷ 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 US in 2015. In 2018, there are 44 Pharmacy Benefit Managers (PBMs) listed in the Pharmacy Benefit Management

⁷² Loewenstein G et al. Consumers' misunderstanding of health insurance. *Journal of Health Economics*. 32(2013) 850–862.

⁷⁴ Abaluck and Gruber. Evolving Choice Inconsistencies in Choice of Prescription Drug Insurance. *Am Econ Rev*. 2016 Aug; 106(8): 2145–2184.

⁷⁵ Heiss, Leive, McFadden and Winter. Plan Selection in Medicare Part D: Evidence From Administrative Data. *J Health Econ*. 2013 Dec; 32(6): 1325–1344.

⁷⁶ <https://www.census.gov/data/tables/2015/econ/susb/2015-susb-annual.html>.

⁷⁷ Qato, Zenk, Wilder, et al. *PLoS One*. 2017 Aug 16;12(8).

⁷² Consumer Affordability Part One: The Implication of Changing Benefit-Designs and High Cost sharing.

Institute⁷⁸ directory. 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.

This rule also affects the operation of 56 Medicaid agencies, including all states, the District of Columbia, American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the US Virgin Islands.

Finally, the proposed rule if finalized would affect Medicare prescription drug enrollees. CMS reports there were 44,491,003 Medicare prescription drug enrollees in December 2018.⁷⁹ 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. Throughout, we use these numbers as estimates of affected entities in relevant categories, and we request comments on these assumptions.

The Department estimates the hourly wages of individuals affected by this proposed rule using the May 2016 National Occupational Employment and Wage Estimates provided by the US Bureau of Labor Statistics.⁸⁰ 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 US. 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. We seek public comment on these assumptions.

TABLE 1—HOURLY WAGES⁸¹

Medical and Health Services Managers	\$52.58
Lawyers	67.25

⁷⁸ https://www.pbmi.com/PBMI/Directory/Pharmacy_Benefit_Manager_Directory.aspx, accessed 7/13/2018.

⁷⁹ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/Medicare-Enrollment/Enrollment%20Dashboard.html>.

⁸⁰ https://www.bls.gov/oes/2016/may/oes_nat.htm.

TABLE 1—HOURLY WAGES⁸¹—Continued

Network and Computer Systems Administrators	40.63
Medicare Prescription Drug Benefit Enrollees	23.86

D. Costs

In order to comply with the regulatory changes proposed in this proposed rule, affected businesses and Medicaid agencies would first need to review the rule. The Department estimates that this would require an average of 2 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 \$5.3 million in the first year following publication of a final rule after adjusting for overhead and benefits. We seek public comment on these assumptions.

After reviewing the rule, businesses and Medicaid agencies 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 20 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 subsequent years, the Department estimates this would result in affected businesses spending an average of 10 hours implementing policy changes, with 20% of time spent by lawyers and 80% of time spent by managers. As a result, using wage information provided in Table 1, the Department estimates costs of \$53.5 million in the first year and \$24.8 million in years two through five following publication of the final rule after adjusting for overhead and benefits. We seek public comment on these assumptions.

The Department is proposing that this amendment, if finalized, be effective on January 1, 2020, and is soliciting comments on whether the proposed effective date gives affected entities a sufficient transition period for any necessary restructuring of arrangements. Plan sponsor and manufacturer negotiations for the 2020 benefit year could be influenced by the release of

this proposal, and bids could be submitted without knowledge of whether or not the proposal will be finalized with a January 1, 2020 effective date. Parties who wish to enjoy protection under a new safe harbor may need to restructure their contractual arrangements, and the change in law itself would trigger contractual obligations to terminate or amend existing contracts. These changes could affect the assumptions underlying plan sponsors' bids. As a result, we estimate the cost of 218 Part D parent organizations of Part D plan sponsors updating their bids with new information to be \$5.45 million in the first year this rule is finalized.

This rule imposes documentation and reporting requirements on PBMs. In particular, PBMs and pharmaceutical manufacturer 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 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 50 times each year. We estimate that these disclosures will require an average of 4 hours, with 50% of time spent by managers, 25% of time spent by attorneys, and 25% of time spent by IT staff. As a result, using wage information provided in Table 1, the Department estimates costs of \$1.28 million in each year following publication of the final rule after adjusting for overhead and benefits. We request comments on these assumptions.

We expect that this rule will also lead PBMs, pharmacies, and health insurance providers to update their IT

⁸¹ https://www.bls.gov/oes/2016/may/oes_nat.htm.

systems for processing claims and payments. For these entities, the Department estimates that this will require an average of five hours per year over the first five years following publication of the final rule to make these changes. Using wage information provided in Table 1, we estimate this will cost \$10.8 million in each of the first five years following publication of a final rule after adjusting for overhead and benefits. We seek public comment on these assumptions.

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% 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. We seek public comment on these assumptions.

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

It is difficult to accurately quantify the benefits of this proposed rule due to the complexity and uncertainty of stakeholder response. As such, the Department has qualitatively described two potential benefits of the proposed rule, and we request comment on the methodology and data sources that could be used to quantify these benefits.

First, if this rule is finalized, 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 discounts negotiated by PBMs would be passed on to beneficiaries at the point of sale for those enrolled in health plans electing to use the proposed 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 2017,⁸² and copayment or coinsurance amounts can be a predictor of abandonment.⁸³ 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% 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.⁸⁴ The intent of this proposal 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 or not beneficiaries pay more or less in out-of-pocket costs.

⁸² 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.

⁸³ William H. Shrank et al., *The Epidemiology of Prescriptions Abandoned at the Pharmacy* 153 Annals Internal Med. 633 (2010).

⁸⁴ 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. February 2014.

Furthermore, lower out-of-pocket costs may lead to fewer enrollees abandoning prescription drugs. This could result in beneficiaries filling more prescriptions, and thus increasing spending, as prescriptions that were once unaffordable are now 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 proposal would reduce abandonment across all drug markets or the resulting health benefits of higher adherence of prescription drugs. We request comment on the methodology and data sources that could be used to estimate such impacts.

In addition, the reduction in abandonment could benefit pharmacies by reducing costs related to storage and tracking of abandoned prescriptions. We request comment on the methodology or data sources that could be used to estimate such impacts. Further, we request comment on any other benefits of this rule and the data sources that could be used to estimate such benefits.

F. Transfers

The provisions of this proposed 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 Medicaid MCOs, 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 if finalized would be the reduction of list prices and/or a reduction in the annualized increases thereof. Retrospective 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.

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. If manufacturers did not reduce their list price, or adopted pricing processes that led to higher net prices, beneficiary and Federal spending on premiums and cost sharing could increase beyond the increase attributable to simply eliminating rebates. We seek feedback from stakeholders about the impact of

this regulation on list and net prices, and the magnitude of these changes.

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. We seek feedback from Part D plans and others about the impact of this regulation on list and net prices, and the magnitude of these changes.

Under the Part D program, plan sponsors pay network pharmacies a negotiated price 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 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, if the proposal is finalized and if list prices decrease as a result, reduce beneficiary out-of-pocket spending for Part D covered drugs. If the proposal is finalized but list prices do not decrease, 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 the CMS Office of the Actuary's work commissioned specifically for this rulemaking⁸⁵ and

two commissioned actuarial analyses independent of the CMS Office of the Actuary.⁸⁶ The Office of the Actuary '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.

There are significant differences in the assumptions the respective actuaries used to estimate stakeholder behavior. The Office of the Actuary predicts that while some current rebates will be retained by manufacturers, future price increases will be smaller and fewer. Per the Office of the Actuary'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, the Office of the Actuary predicts that the Federal Government would increase spending on premium subsidies 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, representing a \$659.1 billion decrease in gross manufacturer revenue. The same analysis also shows that drug spending net of all discounts and rebates would increase more than \$20 billion over 10 years; Federal spending would increase by \$34.8 billion, and beneficiary spending would decrease by \$14.5 billion.⁸⁷ We seek feedback on these

analysis is posted as supplementary material in the docket for this rule at regulations.gov.

⁸⁶ Wakely Consulting Group. "Estimate of the Impact of Eliminating Rebates for Reduced List Prices at Point-of-Sale on Beneficiaries." August 2018. The Wakely analysis is posted as supplementary material in the docket for this rule at regulations.gov.

⁸⁷ Available at XXX. And Milliman. "Impact of Potential Changes to the Treatment of Manufacturer and Pharmacy Rebates." September 2018. The Milliman analysis is posted as supplementary material in the docket for this rule at regulations.gov.

⁸⁸ Milliman. "Impact of Potential Changes to the Treatment of Manufacturer and Pharmacy Rebates." September 2018. The Milliman analysis is posted as supplementary material in the docket for this rule

estimates, and are interested in assessing the full economic effects of this proposed rulemaking. We invite comment on the structure of and sources for such an analysis.

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.⁸⁸ We invite comment on additional sources the Department could consider related to the economic impacts on the Part D program, and stakeholders to specifically comment on the most likely strategic behavior changes in response to this rule.

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.

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. Wakely's analysis assumed that all existing manufacturer rebates would be passed along as either list price reductions or discounted prices at the point of sale. The Milliman baseline assumption was that manufacturers

at regulations.gov. Appendix A1, Scenario 1A, page 1.

⁸⁸ Comments are available for viewing at <https://www.regulations.gov/document?D=CMS-2018-0075-0001>.

⁸⁵ CMS Office of the Actuary. "Proposed Safe Harbor Regulation." August 2018. The OACT

would reduce list prices to their current net prices, which would lead to no changes in net prices.

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 2A, 2B, 4A, and 4B 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 invite comment on sources the Department could consider to more fully illustrate the effects of reduced purchase prices for drugs.

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 proposal at regulations.gov.

Given that all stakeholders involved in the manufacture, sale, dispensing and coverage of prescription drugs have their own actuarial models and financial estimates, we invite comment on additional sources the Department could consider related to the economic impacts on the Part D program, and encourage stakeholders to specifically comment on the most likely strategic behavior changes in response to this rule.

Effect on Beneficiary Spending

This rule will likely impact beneficiary spending on Part D premium subsidies, low-income cost-sharing, and reinsurance. It is difficult to quantify the impact on beneficiary spending without knowing manufacturer and Part D plan behavior in response to this regulation. 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 in 2020 is \$1.0 to 1.4 billion. The projected decrease in beneficiary spending on premiums and cost-sharing from 2020–2029 is \$14.5 billion to \$25.2 billion. Individuals who qualify for the Low Income Subsidy (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% 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.

The Office of the Actuary, Wakely and five of the six Milliman scenarios considered by the Department suggest total beneficiary cost sharing would decrease and premiums would increase, and that the decrease in total beneficiary cost-sharing would offset the total 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 reduction, or PBMs and plan sponsors changed formularies or obtained additional price concessions. However, 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, 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. Tables 2A and 2B describe 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.) We seek feedback on these estimates and the assumptions.

TABLE 2.A.—BENEFICIARY IMPACTS, PER MEMBER PER MONTH, NON-LOW INCOME SUBSIDY ENROLLEES, CY 2020

	OACT	Milliman, Scenario 1	Milliman, Scenario 2	Milliman, Scenario 3	Milliman, Scenario 4	Wakely
Modeled Assumptions	<ul style="list-style-type: none"> • 15% of current Part D rebates retained by manufacturer. • 75% of remaining amount applied to per-sponsor/PBM negotiated discounts. • 25% of remainder applied as reduction to list price. • No beneficiary or plan behavioral changes are assumed. 	<ul style="list-style-type: none"> • 100% 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% 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% 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% of current Part D rebates are retained by manufacturers (same agnosticism on how applied). • 80% of current Part D rebates are converted to price concessions (list price or discounts). 	<ul style="list-style-type: none"> • 100% of current manufacturer rebates are converted into reductions in drug costs at the point of sale. • No beneficiary or plan behavioral changes are assumed.

TABLE 2.A.—BENEFICIARY IMPACTS, PER MEMBER PER MONTH, NON-LOW INCOME SUBSIDY ENROLLEES, CY 2020—Continued

	OACT	Milliman, Scenario 1	Milliman, Scenario 2	Milliman, Scenario 3	Milliman, Scenario 4	Wakely
Impact on Beneficiary Premium.	+\$5.64, (+19%) ⁸⁹	+\$3.15, (+14%) ⁹⁰	+\$2.70, (+12%) -\$5.44, (-13%)	+\$2.77, (+12%) -\$5.22, (-12%)	+\$5.11, (+22%) -\$3.86, (-9%)	+\$3.73, (+8%) ⁹¹ -\$5.75, (-10%).
Impact on Beneficiary Cost sharing.	-\$8.01, (-14%)	-\$4.85, (-11%)				
Total	-\$2.37, (-3%)	-\$1.70, (-3%)	-\$2.74, (-4%)	-\$2.44, (-4%)	+\$1.25, (+2%)	-\$2.02, (-2%).

TABLE 2.B.—BENEFICIARY IMPACTS, PER MEMBER PER MONTH, NON-LOW INCOME SUBSIDY ENROLLEES, CY 2020—CY 2029

	OACT	Milliman, Scenario 1	Milliman, Scenario 2	Milliman, Scenario 3	Milliman, Scenario 4	Wakely
Premium ⁹²	+25%	+\$4.03, +13%	+\$1.27, +4%	+\$0.61, +2%	+\$6.84, +21%	N/A.
Cost sharing	-18%	-\$6.23, -12%	-\$9.85, -19%	-\$9.68, -19%	-\$4.97, -10%	N/A.
Total	-4%	-3%	-18%	-11%	+2%	N/A.

Premiums

All analyses that assumed no behavioral changes that would reduce net prices below current net prices saw Part D premiums increase in 2020 and beyond. The 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 to 8% by 2029 rather than 13 to 25% without such

assumptions.) We seek feedback on these estimates and the 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 in 2020 was -\$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 discounts. 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 the Office of the Actuary estimated the annual changes in benefit parameters as a result of this rule. See Table 3 below.

TABLE 3—PART D STANDARD BENEFIT DESIGN PARAMETERS WITH AND WITHOUT THIS PROPOSED 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 ⁹³	9,296	9,874	10,470	11,126	15,515
Under Proposed 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%

⁸⁹ Calculated against actual paid premium, not basic premium, calculated as \$29.22 for non-LIS enrollees absent this proposal.

⁹⁰ For this and the next two columns, calculated against actual paid premium.

⁹¹ Calculated against basic premium, calculated as \$47.02 for 2020 absent this proposal.

⁹² See footnotes above regarding actual paid versus basic premium.

⁹³ 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 the CMS Actuary'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 are 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 spend levels to more closely match net spending level 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.

The CMS Actuary also finds 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 year 2 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% of the benefit. The break-even point would be \$3.20 per-member 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% 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% 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% 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%.

Taken together, the actuarial analyses project reductions in total cost sharing

will 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. We invite comment on the impact of the changes in premiums and cost sharing on beneficiaries with different levels of drug 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. The projected increase in 2020 Federal spending ranged from \$2.8 billion to \$13.5 billion. The projected increase in Federal spending from 2020–2029 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 2020–2029 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.

Tables 4A and 4B describe the impact on Federal spending predicted by each analysis and assumption. We seek feedback on these estimates and the assumptions.

TABLE 4.A.—GOVERNMENT SPENDING IMPACTS, CY 2020
[\$billions]

	OAFT	Milliman, Scenario 1	Milliman, Scenario 2	Milliman, Scenario 3	Milliman, Scenario 4	Wakely
Modeled Assumptions	<ul style="list-style-type: none"> • 15% of current Part D rebates retained by manufacturer. • 75% of remaining amount applied to per-sponsor/PBM negotiated discounts. • 25% of remainder applied as reduction to list price. • No beneficiary or plan behavioral changes are assumed. <ul style="list-style-type: none"> • 100% 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% 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% of current 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"> • More than 100% 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% of current Part D rebates are retained by manufacturers (same agnosticism on how applied). • 80% of current Part D rebates are converted to price concessions (list price or discounts). 	<ul style="list-style-type: none"> • 100% of current Part D rebates converted to up front discounts • No beneficiary or plan behavioral changes are assumed.

TABLE 4.A.—GOVERNMENT SPENDING IMPACTS, CY 2020—Continued
[\$billions]

	OACT	Milliman, Scenario 1	Milliman, Scenario 2	Milliman, Scenario 3	Milliman, Scenario 4	Wakely
Direct subsidy	+\$20.1, (+128%)	+\$15.1, (+149%)	+\$14.5, (+144%)	+\$14.8, (+146%)	+\$15.6, (+154%)	Not avail., (+146% ⁹⁴). Not avail., (+8%).
Low income premium subsidy.	+\$0.9, (+20%)	+\$0.8, (+14%)	+\$0.7, (+12%)	+\$0.7, (12%)	+\$1.4, (+22%)	Not avail., (+8%).
Low income cost sharing subsidy.	-\$1.8, (-6%)	-\$5.8, (-18%)	-\$6.2, (-20%)	-\$6.1, (-20%)	-\$4.4, (-14%)	Not avail., (-12%).
Reinsurance	-\$5.9, (-12%)	-\$7.3, (-16%)	-\$7.9, (-17%)	-\$8.0, (-17%)	-\$3.0, (-6%)	Not avail., (-14%).
Total	+\$13.4, (+14%)	+\$2.8, (+3%)	+\$1.1, (+1%)	+\$1.5, (+1%)	+\$9.5, (+10%)	Not avail., +3%.

TABLE 4.B.—GOVERNMENT SPENDING IMPACTS, CY 2020 THROUGH 2029
[\$billions]

	OACT	Milliman, Scenario 1	Milliman, Scenario 2	Milliman, Scenario 3	Milliman, Scenario 4	Wakely
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, (-13%)	-\$139.1, (-18%)	-\$163.2, (-18%)	-\$30.2, (-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% of expected costs. Medicare program payments for direct subsidies will increase by an estimated \$14.1 to \$20.1 billion (128% to 154%) in 2020 and \$174.7 to \$258.7 billion (119% to 199%) from 2020–2029. The proposed change 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 2020–2029 could increase 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 4B for magnitude and percent changes.

⁹⁴Calculated as percent change in per member per month payments for each category.

Reinsurance Spending

Transforming rebates into upfront discounts may result in fewer beneficiaries reaching catastrophic coverage. This benefits the government because the government bears the majority of the cost (80%) for beneficiaries who reach catastrophic levels of drug spending. As such, all analyses suggest Medicare payments for reinsurance will decrease by an estimated \$3.0 to \$7.9 billion (6 to 17%) in 2020 and 3 to 18% from 2020–2029. In the catastrophic coverage phase, Medicare makes reconciliation payments to Part D plans for 80% of gross drug costs incurred once the beneficiary reaches the out-of-pocket threshold. As discussed above, the effect of this proposed 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 2020–2029 could decrease by \$139.1 billion if Part D plan sponsors increased formulary controls, decrease by \$163.2 billion if Part D plan sponsors increased formulary controls and obtained additional price concessions, and decrease by only \$30.2 billion if manufacturers reduced price concessions in Part D to offset list price decreases in other markets.

concessions in Part D to offset list price decreases in other markets.

Low Income Subsidy Spending

Medicare payments for Low Income Subsidy enrollees will on net decrease by an estimated \$0.9 to \$5.5 billion in 2020 and \$42.3 to \$114.5 billion from 2020–2029. 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 Low Income Cost Sharing Subsidy (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 are estimated to be \$57.5 to \$118.3 billion over ten years.

Analyses that contemplated behavior changes predicted Federal spending on low-income cost sharing subsidies from 2020–2029 could decrease by \$118 billion if Part D plan sponsors increased formulary controls, decrease by \$119 billion if Part D plan sponsors increased formulary controls and obtained additional price concessions, and decrease 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 proposed rulemaking, the actuarial estimates we received estimated that drug manufacturers will see 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. In terms of dollar effects, Milliman's analysis identifies a reduction in gross revenues of \$38 billion in CY2020 and \$588 billion through the ten year budget window. However, Milliman's analysis also estimated an increase in government costs of \$34.8 billion over ten years, with beneficiary costs decreasing by \$14.5 billion, resulting in an increase in Part D drug spending net of all discounts and rebates of more than \$20 billion over 10 years.⁹⁵ 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 proposed 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. We seek feedback on this analysis and potential impacts.

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 particular 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. We invite comments on how we might structure such an analysis, along with the effects on these and other stakeholders. We also seek comment on the ability of wholesalers to facilitate chargebacks to pharmacies in a timely fashion, replacing PBMs rebates with manufacturer discounts routed through wholesalers, and other concerns related to disrupting the relationship between pharmacies and PBMs.

Summary of Part D Impacts

This proposed rule, if finalized, would 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 proposed rule estimated that the amount saved by reducing cost-sharing exceeds the cost of increasing premiums for beneficiaries overall. However, 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).

It is difficult to predict the full extent of the transfers created by this proposed rule in the absence of information about strategic behavior changes by manufacturers and Part D plan sponsors in response to this rule. Without behavioral changes, enrolled beneficiaries may see premiums increase in 2020 by \$3.15 PBPM to \$3.73 PBPM (14 to 19%) but average cost-sharing under their benefits will decline by -\$8.01 PBPM to -\$5.75 PBPM (11 to 14%).⁹⁶ Premium and cost-sharing estimates were calculated on a different basis by each firm. The Office of the Actuary estimated actual

beneficiary paid amounts for all enrollees on average. Milliman estimated beneficiary payments based upon 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 2 to 14% in the absence of behavior change.

If manufacturer and plan behavior caused net prices to decrease in response to this rule, enrolled beneficiaries may see premiums increase 12% (\$3.15 PBPM) and average cost-sharing under their benefits may decline by 13% (-\$4.85 PBPM) in 2020. Total government payments to plans would increase 1–3%, as the net result of increased payments for direct subsidies (144–149%) and low income premium subsidies (12–14%) and decreased payments for low income cost sharing (-18 to -20%) and reinsurance (-16 to -17%).

If manufacturer and plan behavior caused Part D net prices to increase in response to this rule, enrolled beneficiaries will see published premiums increase 8 to 22% (\$5.11 to \$5.64) and average cost-sharing under their benefits will decline by 9 to 14% (-\$5.22 to -\$8.01). Government payments to plans for direct subsidies and subsidies for low income enrollees' premiums and cost sharing will increase and reinsurance payments will also decrease.

The goal of this policy is to lower out-of-pocket costs for consumers and reduce government drug spending in Federal health care programs. We seek feedback from stakeholders about the impact of this regulation on list and net prices, the magnitude of these changes, and the ability of this regulation to meet these goals.

G. Accounting Statement

Category	Benefits (\$Millions)
Improved information for consumers regarding the characteristics of their health insurance plans supporting more actuarially favorable plan choices.	Not Quantified.
Lower prescription abandonment rates leading to better medication adherence	Not Quantified.

⁹⁵ Milliman, "Impact of Potential Changes to the Treatment of Manufacturer and Pharmacy Rebates," Appendix A1, Scenario 1A, page 1. September 2018. The Milliman analysis is posted as supplementary material in the docket for this rule at regulations.gov.

⁹⁶ Wakely Consulting Group, "Estimate of the Impact of Eliminating Rebates for Reduced List Prices at Point-of Sale on Beneficiaries," August 2018. The Wakely analysis is posted as supplementary material in the docket for this rule at regulations.gov.

And Milliman, "Impact of Potential Changes to the Treatment of Manufacturer and Pharmacy Rebates," Scenario 1. September 2018. The Milliman analysis is posted as supplementary material in the docket for this rule at regulations.gov.

Category	Benefits (\$Millions)	
Lower prescription abandonment rates leading to decreased storage and restocking costs for pharmacies	Not Quantified.	
Category	Costs (\$Millions)	Timeframe
Manufacturers, PBMs, and plan sponsors reading and understanding the rule	5.3	First year.
Changes to business practices for manufacturers, PBMs, and plan sponsors	53.5; 24.8	First year; years two through five.
Cost of plan sponsors updating contracts and bids	5.45	First year.
Cost of annual disclosures from PBMs to health plans	1.28	Each year.
Costs to PBMs, pharmacies, and health insurance providers to update their IT systems for claims processing and payments.	10.8	In each of the first five years.
Beneficiaries comparing new Part D plan features and benefits	209	In each of the first five years.
Category	Transfers (\$Billions) CY 2020–2029	
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

The first 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.

As a second option, the compliance date could be delayed by one year from January 1, 2020 to January 1, 2021. This would lower transition costs by giving affected entities additional time to respond to the rule and institute necessary changes into contracts and claim software updates, and to integrate these changes into their scheduled updates. However, this also means that benefits and costs would be delayed by a year.

A third 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 2019 Part C & D policy and technical NPRM, 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

As discussed above, the RFA requires agencies that issue a regulation to analyze options for regulatory relief of small entities if a proposed 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. The Department calculates the costs of the proposed changes per affected business over 2020–2024. The estimated average costs of the rule per business peak in 2020 at approximately \$3,200, and are approximately \$1,600 in subsequent years. The Department notes that relatively large entities are likely to experience proportionally higher costs. The U.S. Small Business Administration establishes size standards that define a small entity. For entities with standards based on revenue, they range from \$17.5 million to \$38.5 million in 2017. Since the estimated average costs of the proposed rule are a small fraction of these thresholds, the Department anticipates that the proposed rule would not have a significant economic impact on a substantial number of small entities. We seek public comment on this determination, and the rule's impact on small entities.

V. 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 manufacturer 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. We have included estimates of disclosure related burden in the Regulatory Impact Statement and seek feedback on these

estimates. We request comments on this proposed collection of information in accordance with the Paperwork Reduction Act.

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.

For the reasons set forth in the preamble, the Office of the Inspector General, Department of Health and Human Services proposes to amend 42 CFR part 1001 as set forth below:

PART 1001—[AMENDED]

■ 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 by revising paragraphs (h)(5)(vi) and (vii) and adding paragraphs (h)(5)(viii), (h)(6) through (10), (cc), and (dd) to 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 from a manufacturer in connection with the sale or purchase of a prescription pharmaceutical product to a plan sponsor under Medicare Part D, a Medicaid Managed Care Organization as defined in section 1903(m) of the Act, or to a pharmacy benefit manager acting under contract with a plan sponsor under Medicare Part D, or Medicaid Managed Care Organization, 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 benefits management on behalf of a health benefits plan that manages prescription drug coverage.

(9) For purposes of this paragraph (h), a *prescription pharmaceutical product* is either a drug or a biological as those terms are defined in Social Security Act section 1927(k)(2)(A), (B), and (C).

(10) For purposes of this paragraph (h), the term *Medicaid Managed Care Organization* or *Medicaid MCO* carries the meaning ascribed to it in section 1903(m) of the Social Security Act.

* * * * *

(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 the price charged 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, provided the manufacturer meets the following conditions with regard to that reduction in price:

(i) The reduced price must be set in advance with a plan sponsor under Medicare Part D, a Medicaid MCO, or the PBM acting under contract with either;

(ii) The sale does not involve a rebate unless the full value of the reduction in price is provided to the dispensing pharmacy through a chargeback or series of chargebacks, or is required by law; and

(iii) 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.

(2)(i) For purposes of this paragraph (cc), the terms *manufacturer*, *pharmacy benefit manager* or *PBM*, *prescription pharmaceutical product*, *rebate*, and *Medicaid managed care organization* or *Medicaid MCO* have the meanings ascribed to them in paragraph (h) of this section.

(ii) For purposes of this paragraph (cc), a *chargeback* is a payment made directly or indirectly by a manufacturer to a dispensing pharmacy so that the total payment to the pharmacy for the prescription pharmaceutical product is at least equal to the price agreed upon in writing between the Plan Sponsor under Part D, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product.

(dd) *PBM service fees.* 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:

(1) The PBM must have a written agreement with the pharmaceutical manufacturer 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.

(2) The compensation paid to the PBM must:

(i) Be consistent with fair market value in an arm’s-length transaction;

(ii) Be a fixed payment, not based on a percentage of sales; and

(iii) 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.

(3) The PBM must disclose in writing to each health plan with which it contracts at least annually, 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.

(4) 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: January 25, 2019.

Alex M. Azar II,
Secretary.

Dated: January 18, 2019.

Daniel R. Levinson,
Inspector General.

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