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

February 5, 2019

On January 31, 2019, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) placed on public display a proposed rule: Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point of Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Services Fees. The proposed rule is scheduled to be published in the Federal Register on February 6, 2019.

The proposed rule would amend an existing safe harbor that protects from liability under the federal anti-kickback statute[1] certain reductions in price or other remuneration from a manufacturer of prescription pharmaceutical products to plan sponsors under Medicare Part D and Medicaid Managed Care Organizations (MCOs), or pharmacy benefit managers (PBMs) under contract with those programs. In addition, the rule would establish two new safe harbors. One would protect discounts between those entities if they are given at point of sale and meet certain other criteria. The second would protect flat fee service payments that manufacturers make to PBMs for specific activities.

Unless otherwise specified, the proposed changes would become effective on January 1, 2020. HHS seeks feedback from stakeholders on a large number of questions as summarized below. **Comments are due April 8th, 2019.**

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I. Purpose and Need for Regulatory Action

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

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

HHS also describes the background and need for its proposed changes. Since the passage of the anti-kickback statute, list prices of brand prescription drugs and "rebate" payments by manufacturers to PBMs have both grown substantially. But because of the increasing prominence and size of rebates, list prices have grown rapidly, while net prices have not grown as rapidly. This difference is called the "gross to net bubble."

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

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

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

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

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

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

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

Lack of Transparency. The terms of rebate agreements between manufacturers and PBMs is considered to be proprietary information and plan sponsors often have limited information about rebate contracts and amounts negotiated by their PBMs. HHS asserts that this lack of transparency impedes program integrity and the ability of parties to accurately account for rebates where required under program rules. **HHS seeks feedback on the impact that lack of transparency has on compliance particularly with respect to bundled rebates (agreements across multiple drug products) and price protection or rebate guarantees.**

HHS further presents its changed view that the statutory safe harbor exemption for discounts in the anti-kickback statute does not apply to most rebates paid by manufacturers to Part D plans or Medicaid MCOs as they are mostly paid to PBMs.[2]

II. Background

HHS describes the anti-kickback statute including the penalties and fines applicable to whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward the referral of business reimbursable under any of the federal health care programs. As the legislation was intentionally broad, Congress later directed HHS to promulgate regulations providing a safe-harbor for those innocuous commercial arrangements and business practices not subject to sanctions under the anti-kickback statute.[3] Later legislation provided criteria for those safe-harbors[4] and a series of regulations have established a number of them in various areas.

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

After the establishing the discount safe harbor, Congress enacted the Medicare Part D program and began requiring Medicaid rebates for prescription drugs offered through Medicaid MCOs.

[2] Section 1128B(b)(3)(A) excludes from the anti-kickback prohibition the following: A discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program.
[3] Section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987 (P.L. 100-93).
[4] Section 205 of the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191).

II. Provisions of the Proposed Rule

A. Amendment to the Discount Safe Harbor

The proposed rule would amend the discount safe harbor at 42 CFR 1001.952(h) by adding new (h)(5)(viii) to provide another explicit exception to the definition of "discount." This new exception would exclude from safe harbor protection certain price reductions on drugs from manufacturers to plan sponsors under Medicare Part D and Medicaid MCOs unless they are required by law (for example, Medicaid rebates required under federal law). It would add a new safe harbor to protect discounts between those entities if they are given at point of sale and meet certain other criteria. A second new safe harbor would protect certain fees that pharmaceutical manufacturers pay to PBMs for services rendered to the manufacturers that relate to PBMs' arrangements to provide pharmacy benefit management services to health plans.

HHS notes that the proposed rule would not directly affect Medicaid statutory drug rebates under section 1927 of the Social Security Act.

HHS seeks comment on how these proposals would work together or independently align or conflict with other program or legal requirements (e.g. antitrust laws) that apply to affected parties. **In addition, HHS seeks comment on whether the amendment to the discount safe harbor should be limited to prescription drug products payable by Medicare Part D and Medicaid MCOs, or whether it should also apply to prescription drugs payable under other HHS programs (e.g., Medicare Part B fee-for-service or a Medicaid managed care program operating under waiver authority).**

HHS would interpret the term "plan sponsor" under this amendment to include both prescription drug plan sponsors under Medicare Part D as well as Medicare Advantage (MA) organizations offering an MA prescription drug plan. **CMS solicits comment on whether it should adopt a broader definition of Part D plan sponsors, including for example, PACE organizations or cost plans offering qualified prescription drug coverage.**

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

HHS describes its intent for the discount safe harbor to continue to protect discounts offered to other entities including wholesalers, hospitals, physicians, pharmacies, and third-party taxpayers in other federal health care programs. **HHS seeks feedback on whether the proposed changes to the safe harbor would unintentionally impact other reductions in price not contemplated by the proposed amendment; whether any additional or different regulatory text is necessary to clarify that other types of discounts (e.g., volume or prompt payment**

discounts to wholesalers) that are currently protected would remain protected; and whether these proposed amendments would affect beneficiary access to prescription drugs either due to cost or formulary placement.

HHS raises concerns about whether the amendments would have unintended loopholes or would impact states' supplemental rebates under the Medicaid program. **It seeks comment on the extent to which Medicaid supplemental rebates could be impacted, whether there are other types of entities whose price reductions could be impacted, and whether there are safeguards that may already be in place or that could be included to protect beneficial price reductions.**

HHS does not intend for these amendments to impact value-based arrangements and asks for feedback on how they could affect existing or future arrangements.

HHS further requests feedback on whether the proposed effective date of January 1, 2020 gives entities sufficient time to enact the changes and restructure any impacted arrangements. Finally, it requests feedback on proposed definitions of terms as described below.

HHS proposes to include several new definitions in 1001.952(h):

- "Manufacturer" would be defined as under Medicaid (in section 1927(k)(5));
- "Wholesaler" and "distributor," which are used interchangeably, would be defined as "wholesaler" is defined under Medicaid (in section 1927(k)(11));
- "Pharmacy benefit manager" would be defined as an entity that provides pharmacy benefits management on behalf of health benefits plans that manage prescription drug coverage;
- "Prescription pharmaceutical product" would be either a drug or biological as those terms are defined under Medicaid (in section 1927(k)(2)(A), (B) and (C))
- "Medicaid Managed Care Organization" would have the same meaning as under Medicaid (section 1903(m)).

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

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

HHS would establish a new safe harbor, effective 60 days after publication of the final rule, to protect point of sale price reductions offered by manufacturers for certain Medicare or Medicaid drugs. HHS states that it intends for this safe harbor to apply to Medicare Part D drugs throughout all phases of the benefit and **solicits comment on how it can clarify that this safe harbor applies during periods of 100 percent beneficiary cost sharing**.

HHS also seeks comment on the extent to which this safe harbor would incentivize point of sale discounts and notes that it is considering additional policies to encourage such point of sale price reductions.

The conditions for this proposed safe harbor to apply would be as follows:

(1) The price reduction would need to be set in advance, fixed, and disclosed in writing to the plan sponsor by the time of initial purchase. By "initial purchase," HHS means the first purchase of the product at the reduced price by the Part D plan or Medicaid MCO.

As under existing rules, this safe harbor would not protect those price reductions offered to a payer but not to Medicare or Medicaid to avoid protecting arrangements where such discounts serve as inducements for the purchase of federally reimbursable products as described above. HHS solicits feedback on whether this intent is captured in the proposed regulatory text.

(2) The price reduction cannot be a rebate unless its full value is provided at the point of sale to the dispensing pharmacy through a "chargeback" which HHS would define as "payment made directly or indirectly by a manufacturer to a dispensing pharmacy so that the total payment to the pharmacy for the prescription pharmaceutical product is at least equal to the price agreed upon in writing between the Plan Sponsor under Part D, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product." The current rebate framework where rebates are paid indirectly via PBMs would not meet this criterion.

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

HHS solicits comments on any potential issues that ownership interests might create, whether these policies would create the potential for a pharmacy to use data to uncover the PBM's discount structure and any impacts on competition would arise as a result.

C. New Safe Harbor for Certain PBM Service Fees

HHS' second proposed new safe harbor would protect fixed fees that manufacturers pay to PBMs for services rendered to the manufacturers. This safe harbor would be specific to PBMs and would protect fees for services such as those that depend on the data gathered by PBMs, for example, to prevent duplicate discounts on 340B claims, and other "pharmacy benefit management services" that relate to the PBM's arrangements to provide pharmacy benefit management services to health plans, including contracting with a network of pharmacies; establishing payment levels for network pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; performing drug utilization review; and operating disease management programs.

HHS declines to propose a definition for "pharmacy benefit management services" as these services could evolve over time but solicits comment on this approach; on whether other

services should be considered "pharmacy benefit management services" for purposes of this safe harbor; and on its 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.

In order for this safe harbor to apply, several conditions would need to be met:

(1) The PBM and the manufacturer would need to have a written agreement that covers all of the services that the PBM provides; and specifies each of those services as well as the fees associated with each. **HHS requests feedback on whether the format of this agreement should be specified.**

(2) Compensation to the PBM for those services must be consistent with fair market value; be a fixed payment that is not based on a percentage of sales; and not be set in a way that takes volume, value of referrals, business generated between the parties or the manufacturer and the PBM's health plans into account. **HHS requests feedback on how to avoid gaming with respect to these conditions, on any arrangements between manufacturers and PBMs that take into account volume or value of referrals or business otherwise generated between the parties or plans, but otherwise would be low risk or appropriate.**

(3) The PBM would be required to disclose in writing to each health plan with which it contracts at least annually, and to the Secretary on request, the services rendered to each manufacturer that are related to the PBM's arrangements with that health plan and the associated costs for the service. **HHS seeks comments on potential additional disclosures that it is considering: requiring PBMs to disclose the fee arrangements to the health plans; requiring PBMs to disclose additional information to HHS such as 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. HHS asks for feedback on PBM arrangements with manufacturers and whether such arrangements can be attributed to services provided to particular plans as well as any competitive concerns that these disclosures would raise.**

IV. Regulatory Impact Statement

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

The Unfunded Mandates Reform Act of 1995 requires that agencies assess any anticipated costs to states if requiring spending in any one year of $100 million in 1995 dollars, updated annually for inflation. That amount would be $150 million for 2018. HHS discusses the potential impact on states. Even though the rule does not directly alter any Medicaid drug rebate or best price

statutory provisions, it may have an impact on Average Manufacturer Prices (AMP). To the extent that discounts are shifted from rebates to point of sale, AMP could be lowered, which would have the secondary effect of lowering Medicaid drug rebates calculated based on AMP.

In one of the analyses that HHS arranged for, a contractor estimates that the loss of rebates could exceed savings from lowering list prices.[5] HHS actuaries, however, estimate that states' Medicaid costs would rise by $0.2 billion over the 2020 – 2029 period but costs for state employees would decline by $4.3 billion over the period. On net, according to the HHS actuaries, states are estimated to save $4 billion over 10 years.[6] In addition, the actuaries estimate that federal Medicaid costs would rise by $1.7 billion. Some federal savings may arise through Veteran's Health Programs and other federal programs that purchase drugs, but they are not estimated.

Affected Entities

HHS estimates that manufacturers, PBMs, plan sponsors, and Medicaid agencies would need two hours each to review the rule. The costs of that review, the hours for which are assumed to be divided evenly between managers and lawyers, is expected to total $5.3 million in the first year. If finalized, many of those entities would need to make changes to policies and pricing models, and engage in negotiations with other entities, or restructure contractual arrangements. HHS estimates costs of $53.5 million in the first year, and $24.5 million in years two through five to make those changes. An additional $5.45 million in the first year is estimated for updating contracts. Documentation and reporting requirements of PBMs would increase their costs by an estimated $1.28 million in each year. Finally, stakeholders such as PBMs and pharmacies may need to make updates to their information technology and claims processing systems in accordance with the new arrangements. HHS estimates a cost of $10.8 million in each of the first 5 years after publication for these changes.

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

Benefits

HHS identifies and provides a qualitative description of potential benefits of the proposed changes. **HHS requests comment on methodologies and data sources that could be used to quantify these benefits.**

- Improved transparency of premiums and out-of-pocket costs and improved formulary designs could lead to beneficiaries making more actuarially favorable decisions.
- Lowered out-of-pocket costs could improve adherence and lower total costs of care.

[5] 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.
[6] 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.

- Reduced costs for pharmacies to store and track abandoned prescriptions because lower beneficiary copayments will result in fewer beneficiaries abandoning their prescriptions.

CMS requests comments on other possible benefits of the rule.

Transfers

HHS points out that accounting for the impact on manufacturers' list prices is unpredictable, as is predicting Part D plans' reactions to the changing practices. **HHS requests feedback from stakeholders about the impact that the regulation would have on list and net prices.**

Analyses of the Impact

HHS commissioned multiple analyses of the impact of this proposal which varied by the amount of rebates converted to discounts at point of sale and by other behavioral effects of plans, manufacturers, and beneficiaries.

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

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

The results of most of those analyses on the impact of the policy on costs to beneficiaries and to the federal government are summarized in Table 1. below.

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

Table 1. Estimated Impacts on Beneficiaries and the Federal Government

	OACT	Milliman, Scenario 1	Milliman, Scenario 2	Milliman, Scenario 3	Milliman, Scenario 4	Wakely
Modeled Assumptions	• 15% of current Part D rebates retained by manufacturer • 75% of remaining amount applied to per-sponsor/PBM negotiated discounts • 25% of remainder applied as reduction to list price • No beneficiary or plan behavioral changes are assumed	• 100% of current Part D rebates are converted into list price concessions (agnostic on list price reductions versus up front discounts)	• 100% of current rebates are converted into list price concessions • Part D plans exert greater formulary control	• More than 100% of rebates are converted into list price concessions (same agnosticism on how applied) • Part D plans exert greater formulary control	• 20% of current Part D rebates are retained by manufacturers (same agnosticism on how applied) • 80% of current Part D rebates are converted to price concessions (list price or discounts)	• 100% of current manufacturer rebates are converted into reductions in drug costs at the point of sale • No beneficiary or plan behavioral changes are assumed
Beneficiary Impacts, Per Member Per Month, Non-Low Income Subsidy Enrollees, CY 2020						
Impact on Beneficiary Premium	+$5.64 (+19%)	+$3.15 (+14%)	+$2.70 (+12%)	+$2.77 (+12%)	+$5.11 (+22%)	+$3.73 (+8%)
Impact on Beneficiary Cost Sharing	-$8.01 (-14%)	-$4.85 (-11%)	-$5.44 (-13%)	-$5.22 (-12%)	-$3.86 (-9%)	-$5.75 (-10%)
Total	**-$2.37 (-3%)**	**-$1.70 (-3%)**	**-$2.74 (-4%)**	**-$2.44 (-4%)**	**+$1.25 (+2%)**	**-$2.02 (-2%)**
Beneficiary Impacts, Per Member Per Month, Non-Low Income Subsidy Enrollees, CY 2020- CY 2029						
Premium	+25%	+$4.03 (+13%)	+$1.27 (+4%)	+$0.61 (+2%)	+$6.84 (+21%)	N/A
Cost Sharing	-18%	-$6.23 (-12%)	-$9.85 (-19%)	-$9.68 (-19%)	-$4.97 (-10%)	N/A
Total	**-4%**	**-3%**	**-18%**	**-11%**	**+2%**	**N/A**

	OACT	Milliman, Scenario 1	Milliman, Scenario 2	Milliman, Scenario 3	Milliman, Scenario 4	Wakely
Government Spending Impact, CY 2020 ($ in billions)						
Direct Subsidy	+$20.1 (+128%)	+$15.1 (+149%)	+$0.7 (+12%)	+$14.8 (+146%)	+$15.6 (+154%)	Not avail. (+146%)
Low-Income Premium Subsidy	+$0.9 (+20%)	+$0.8 (+14%)	-$6.2 (-20%)	+$0.7 (12%)	+$0.7 (12%)	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. (-12%)
Total	**+$13.4 (+14%)**	**+$2.8 (+3%)**	**+$1.1 (+1%)**	**+$1.5 (+1%)**	**+$9.5 (+10%)**	**Not avail. (+3%)**
Government Spending Impact, CY 2020 – 2029 ($ in billions)						
Direct Subsidy	+$258.7 (+119%)	+$215.4 (+193%)	+$174.7 (+157%)	+$180.3 (+162%)	+$221.1 (+199%)	Not avail.
Low-Income Premium Subsidy	+$15.4 (+24%)	+$12.0 (+13%)	+$3.8 (+4%	+$1.9 (+2%)	+$20.5 (+21%)	
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%)**	**Not avail.**

Source: HPA excerpted from Tables 2.A, 2.B., 4.A and 4.B. on pages 91-93 and 101 – 103 of the version of the proposed rule placed on public display.

Accounting Statement

HHS provides the following accounting statement with its estimate of the costs, benefits and transfers of the proposed rule that takes into account the estimates of the scenarios by the HHS Actuaries and contractors.

Category		Benefits
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
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

Source: HPA from Tables on pages 111-112 of Public Display Copy.