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Date: August 30, 2018

From: Office of the Actuary

Subject: Proposed Safe Harbor Regulation

## Background

The proposed rule put forward by HHS would, for the Medicare Part D and Medicaid managed care programs, remove the safe harbor exemption for rebates applied after the point-of-sale and establish a new safe harbor that would enable a pharmaceutical manufacturer to offer reduced prices on a prescription pharmaceutical product (referred to as chargeback discounts) when they are applied at the point-of-sale. This rule would significantly alter payments across many stakeholders in the prescription drug market. In this memorandum, we summarize the estimated impacts of this proposal on both Medicare and Medicaid. Based on guidance from HHS, we understand that there would be no direct change to requirements in the private market, although we have modeled the indirect effects.

## Overview

The Office of the Actuary (OACT) considered impacts to Medicare Part D, Medicaid, Medicare Part B drugs, and the commercial private health insurance (PHI) market on a calendar-year cash basis. The impacts of the rule would be felt differently in each market, and some impacts could vary significantly based on how the regulation was interpreted and applied by agencies and stakeholders. Table 1 shows the change in spending by broad category of payer and in total to the national health expenditure (NHE) estimates.

**Table 1: Estimated Payer Costs (+) or Savings (−)**
**for Calendar Years 2020-2029 in Billions**

| Calendar Year | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2020-29 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Total Drug Spending (NHE)** | **$10.2** | **$10.3** | **$10.9** | **$11.2** | **$12.8** | **$13.9** | **$15.0** | **$16.1** | **$17.5** | **$19.0** | **$137.0** |
| **Household** | **−2.5** | **−2.9** | **−3.2** | **−3.6** | **−4.1** | **−4.4** | **−4.8** | **−5.4** | **−5.9** | **−6.4** | **−43.3** |
| Out-of-Pocket (OOP)[1] | −5.3 | −6.2 | −7.2 | −7.9 | −8.8 | −9.5 | −10.5 | −11.6 | −12.7 | −13.6 | −93.2 |
| Premium | 2.7 | 3.2 | 3.9 | 4.3 | 4.7 | 5.1 | 5.7 | 6.1 | 6.8 | 7.3 | 49.9 |
| **Federal Government** | **13.5** | **14.3** | **15.3** | **16.1** | **18.4** | **20.0** | **21.6** | **23.5** | **25.6** | **27.8** | **196.1** |
| **State Government** | **−0.1** | **−0.2** | **−0.2** | **−0.3** | **−0.4** | **−0.4** | **−0.5** | **−0.6** | **−0.6** | **−0.8** | **−4.0** |
| **Private Business** | **−0.7** | **−0.8** | **−0.9** | **−1.0** | **−1.2** | **−1.2** | **−1.3** | **−1.4** | **−1.5** | **−1.7** | **−11.8** |

[1] Includes spending paid directly by the consumer at the point-of-sale.
Note: Totals do not necessarily equal the sums of rounded components.

Over the 10-year period 2020-2029, overall drug spending net of rebates and the new chargeback discounts would increase by approximately $137 billion, and Federal spending would increase by $196 billion. Overall spending by households would decrease by $43 billion due to a $93-billion reduction in out-of-pocket (OOP) spending (defined as spending paid directly by the consumer at the point-of-sale), while premiums for households would increase by $50 billion—an expense that would be borne by Medicare Part D enrollees. Spending by States and private businesses would decrease by relatively small amounts. These results reflect the following assumptions: (i) that some of the current rebate under Medicare Part D, Medicare Part B drugs, and Medicaid would be retained by manufacturers; (ii) that drug list prices would decrease; and (iii) that price trends would be slightly lower.

Table 2 offers additional details of the drug market, by segment, under the proposed rule. As shown in the table, the Medicare program would experience the greatest impacts, with higher Federal spending and beneficiary premiums primarily due to lower average cost sharing. For Medicaid, there would be a small increase in costs for both States and the Federal Government. Spending for those with PHI coverage would decrease primarily as a result of the lower brand drug list prices.

**Table 2: Estimated Costs (+) or Savings (−) by Market for Calendar Years 2020-2029 in Billions**

| Calendar Year | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2020-29 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Total Drug Spending (NHE)** | **$10.2** | **$10.3** | **$10.9** | **$11.2** | **$12.8** | **$13.9** | **$15.0** | **$16.1** | **$17.5** | **$19.0** | **$137.0** |
| **Medicare Beneficiaries** | **12.0** | **12.5** | **13.3** | **14.0** | **16.1** | **17.4** | **18.8** | **20.3** | **22.1** | **24.3** | **170.9** |
| Beneficiary | −1.4 | −1.6 | −1.8 | −2.0 | −2.3 | −2.5 | −2.8 | −3.3 | −3.6 | −3.9 | −25.2 |
| Cost Sharing (OOP) | −4.6 | −5.4 | −6.3 | −7.0 | −7.8 | −8.5 | −9.4 | −10.4 | −11.4 | −12.3 | −83.2 |
| Premium | 3.2 | 3.8 | 4.5 | 5.0 | 5.5 | 6.0 | 6.6 | 7.1 | 7.8 | 8.4 | 58.0 |
| Federal Government | 13.4 | 14.1 | 15.1 | 16.0 | 18.4 | 20.0 | 21.6 | 23.6 | 25.7 | 28.1 | 196.1 |
| **Medicaid Beneficiaries** | **0.4** | **0.4** | **0.4** | **0.4** | **0.3** | **0.2** | **0.1** | **0.1** | **0.0** | **−0.2** | **2.0** |
| Beneficiary | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Cost Sharing (OOP) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Premium | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Federal Government | 0.3 | 0.3 | 0.3 | 0.3 | 0.2 | 0.2 | 0.1 | 0.1 | 0.1 | 0.0 | 1.7 |
| State Government | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.0 | 0.0 | 0.0 | −0.1 | −0.2 | 0.2 |
| **PHI Enrollees** | **−1.8** | **−2.0** | **−2.3** | **−2.5** | **−2.9** | **−3.0** | **−3.3** | **−3.6** | **−3.9** | **−4.2** | **−29.6** |
| Enrollee | −0.7 | −0.8 | −0.9 | −1.0 | −1.2 | −1.2 | −1.3 | −1.4 | −1.5 | −1.7 | −11.7 |
| Cost Sharing (OOP) | −0.2 | −0.3 | −0.3 | −0.3 | −0.4 | −0.4 | −0.4 | −0.4 | −0.5 | −0.5 | −3.7 |
| Premium | −0.5 | −0.6 | −0.6 | −0.7 | −0.8 | −0.8 | −0.9 | −1.0 | −1.1 | −1.1 | −8.0 |
| Federal Government | −0.1 | −0.1 | −0.1 | −0.2 | −0.2 | −0.2 | −0.2 | −0.2 | −0.2 | −0.3 | −1.8 |
| State Government | −0.3 | −0.3 | −0.3 | −0.4 | −0.4 | −0.4 | −0.5 | −0.5 | −0.6 | −0.6 | −4.3 |
| Private Business | −0.7 | −0.8 | −0.9 | −1.0 | −1.2 | −1.2 | −1.3 | −1.4 | −1.5 | −1.7 | −11.8 |
| **Other Government Programs and Those without Insurance** | **−0.5** | **−0.5** | **−0.5** | **−0.6** | **−0.6** | **−0.7** | **−0.7** | **−0.7** | **−0.8** | **−0.8** | **−6.3** |

Note: Totals do not necessarily equal the sums of rounded components.

*Key Assumptions*

As pharmaceutical manufacturers would have a unique opportunity to adjust their overall pricing and rebate strategy, we considered how much of the current Medicare Part D and Medicaid supplemental rebate they would repurpose to both the new chargeback system and lower list prices (for example, wholesale acquisition cost). These assumptions are shown in table 3.

**Table 3: Medicare Part D and Medicaid Supplemental Rebate Shift Assumptions**

| | Assumption Values |
|---|---|
| Rebates Retained by Manufacturers | 15% |
| Remaining Rebates Applied to Chargeback / List Prices | 75% / 25% |

After considering several issues, we established an assumption for the level of rebates that would be retained by manufacturers. First, because many of the current rebate arrangements are contingent on measures such as market share that would not be possible in the chargeback system, there is less assurance that the chargeback would provide the return on investment required by manufacturers. Secondly, as rebates have evolved over many years in the current system, manufacturers have increased rebate levels to compete for certain drugs that vary across payers. The change to the chargeback system would create an opportunity to lower the level of rebates currently provided. Lastly, given the relatively low recent price trend growth and policies that have required additional manufacturer concessions, this proposal would give manufacturers an opportunity to recapture some of these 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. Based on these factors, we assumed that 15 percent of the existing manufacturer rebates for Medicare Part D and Medicaid supplemental rebates would be retained by drug manufacturers.

Another key assumption is how much of the remaining rebates would be converted into the chargeback system versus used for lower list prices. Because manufacturers would still need negotiating power to determine formulary position among competitors, and because a chargeback would offer more flexibility to vary prices by market, we believe that the majority of rebates would be converted to a chargeback. Manufacturers would likely want to retain as much of this flexibility as possible while still being able to alleviate public pressure on high drug prices. We assumed that 75 percent of the remaining rebates would be applied to the chargeback system, with 25 percent applied to lower list prices. Table 4a shows the effects of these assumptions using an illustration for a hypothetical drug.

**Table 4a: Illustration of Assumption Effects for Hypothetical Brand Drug**

| | Current | Proposed | Explanation |
|---|---|---|---|
| Brand Drug List Price | $100.00 | $94.90 | List price is lowered by 25% of 85% of current $24 rebate |
| Rebate | $24.00 | $0.00 | Rebate no longer permitted |
| Chargeback | $0.00 | $15.30 | Chargeback is 75% of 85% of current $24 rebate |
| **Net Price** | **$76.00** | **$79.60** | |

Note: These are theoretical effects of preliminary assumptions applied entirely to Part D, not actual modeling results of the proposed rule. Actual results distribute impacts for Part D across other segments of the market.

To determine the proposed rule's net effects, which would not apply directly to the private sector, we considered the impact of Medicare changes on other markets. Because the list price of a brand drug would not vary between Medicare and the private sector, we applied the proportion of the Part D rebate that was assumed to lower list prices for all payers. This process resulted in a decrease of approximately 3.2 percent in brand drug list prices across the entire U.S. market. We assumed that some, but not all, of the price reductions would be reflected in reduced manufacturer rebates in the non-Part D markets. Although it is not a precise representation, the illustration in Table 4b roughly demonstrates the effect of the new policy on list and net prices, rebates, and chargebacks for a hypothetical branded drug in the Medicare Part D and non-Medicare Part D markets.

**Table 4b: Illustration of Assumption Effects for Hypothetical Brand Drug across Markets**

| | Medicare Part D | | Non-Medicare Part D | | Weighted-Average Effect[2] | |
|---|---|---|---|---|---|---|
| | Current | Proposed | Current | Proposed | Current | Proposed |
| Brand Drug List Price | $100.00 | $96.80 | $100.00 | $96.80 | $100.00 | $96.80 |
| Rebate[1] | $24.00 | $0.00 | $24.00 | $22.11 | $24.00 | $12.16 |
| Chargeback | $0.00 | $16.24 | $0.00 | $0.00 | $0.00 | $7.31 |
| Total Discounts | $24.00 | $16.24 | $24.00 | $22.11 | $24.00 | $19.47 |
| **Net Price** | **$76.00** | **$80.56** | **$76.00** | **$74.69** | **$76.00** | **$77.63** |

[1] For private health insurance, the rebate value used in this illustration reflects all types of private discounts, including rebates, coupons, and other discounts.

[2] The weighted-average effect represents an average effect if Medicare Part D accounted for 45 percent of brand drug gross spending and private health insurance accounted for the remaining 55 percent.

For purposes of this modeling, we assumed no changes in utilization. For private payers, we assumed that the net price reductions would be allocated proportionately between premiums and enrollee cost sharing.

Finally, we considered whether the proposed rule would have an impact on price trends prospectively. Because there are currently strong incentives in Medicare Part D to have high prices and high rebates that would be removed in the proposed rule, we assumed that prospective price trends would be reduced. The Fiscal Year (FY) 2019 Mid-Session Review (MSR) forecasts included assumptions that rebates would continue to grow at a faster rate than prices. When this disparity between price and rebate trends is eliminated and the forgone Medicare Part D rebate

growth concessions are applied to the reduction in price trends across the entire prescription drug market, the overall drug trend for the U.S. market is lowered by three basis points per year through 2024.

## Medicare Part D Impacts

*Results from 10-Year Impact Analysis*

Under the proposed rule, there would be a shift from rebates used to lower overall premiums to chargebacks and lower prices that would reduce beneficiary OOP spending. Table 5 shows the impacts for Medicare Part D under the proposed rule. Federal spending would increase by $196 billion over the 10-year period, while average beneficiary costs and manufacturer concessions would decrease. Though average beneficiary costs would decrease, the majority of beneficiaries would see an increase in their total OOP and premium costs. 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.

**Table 5: Estimated Federal and Beneficiary Costs (+) or Savings (−) for Medicare Part D in Calendar Years 2020-2029 in Billions**

| Calendar Year | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2020-29 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Beneficiary Costs** | **−$1.4** | **−$1.6** | **−$1.8** | **−$2.0** | **−$2.3** | **−$2.5** | **−$2.8** | **−$3.3** | **−$3.6** | **−$3.9** | **−$25.2** |
| Cost Sharing | −4.6 | −5.4 | −6.3 | −7.0 | −7.8 | −8.5 | −9.4 | −10.4 | −11.4 | −12.3 | −83.2 |
| Premium | 3.2 | 3.8 | 4.5 | 5.0 | 5.5 | 6.0 | 6.6 | 7.1 | 7.8 | 8.4 | 58.0 |
| **Government Costs** | **13.4** | **14.1** | **15.1** | **16.0** | **18.4** | **20.0** | **21.6** | **23.6** | **25.7** | **28.1** | **196.1** |
| Direct Subsidy | 20.1 | 20.5 | 20.0 | 21.8 | 23.8 | 25.7 | 28.0 | 30.4 | 33.0 | 35.5 | 258.7 |
| Reinsurance | −5.9 | −4.3 | −1.5 | −2.0 | −1.2 | −1.1 | −1.2 | −1.2 | −1.1 | −0.8 | −20.3 |
| Low-Income Cost-Sharing Subsidy | −1.8 | −3.1 | −4.6 | −5.1 | −5.6 | −6.2 | −6.8 | −7.5 | −8.3 | −8.8 | −57.7 |
| Low-Income Premium Subsidy | 0.9 | 1.0 | 1.2 | 1.3 | 1.5 | 1.6 | 1.7 | 1.9 | 2.1 | 2.3 | 15.4 |
| **Manufacturer Gap Discount** | **−2.5** | **−2.8** | **−3.1** | **−3.4** | **−3.7** | **−4.0** | **−4.4** | **−4.8** | **−5.3** | **−5.7** | **−39.8** |

Note: Totals do not necessarily equal the sums of rounded components.

*Methodology*

The impacts for Part D were calculated using the distribution of beneficiaries by gross drug spending for 2016 and the defined standard benefit design. The change in drug pricing would cause a change in the benefit parameter updates that would be fully reflected in 2022. We incorporated our most recent estimates, based on the FY 2019 MSR, of manufacturer rebates as a percent of gross drug costs.

We began by tabulating the beneficiaries by their year-end status in different phases of the defined standard benefit, separately for low-income and non-low-income beneficiaries. Next we calculated the modified distribution of beneficiaries, assuming that approximately 81 percent of the manufacturer rebates would be reflected in negotiated prices of brand drugs for each of the years 2020, 2021, and 2022. The 81-percent value is derived from the assumptions that (i) 15 percent of the Part D rebate, allocated across all segments of the market, would be retained by manufacturers; (ii) 25 percent of 85 percent of the Part D rebate would be used to reduce prices across the market; and (iii) 75 percent of 85 percent of the rebate would be reflected in

chargeback discounts for Part D. We also accounted for the changes in the beneficiary distribution due to the impacts of the proposed rule on the benefit parameter calculations.

*Assumptions*

- Based on the most recent Medicare Part D estimates, manufacturer rebates as a percentage of gross drug cost were assumed to be 24.4 percent in 2020, gradually increasing to 25.0 percent in 2024.
- Negotiated price decreases were assumed to be evenly distributed across all brand spending.
- Claims cost distributions were based on 2016 Prescription Drug Event data.
- The effects were modeled using the defined standard benefit.

## Medicaid Impacts

*Results from 10-Year Impact Analysis*

The proposed rule to eliminate the safe harbor for rebates between manufacturers and plans, and to thereby shift a portion of existing rebates to the point-of-sale, is anticipated to result in an effective average decrease of approximately 3.2 percent in the average brand price reported to the Medicaid drug program, as well as future drug price trend decreases. These decreases in drug prices would result in savings that would be offset by the reduction in price-based statutory rebates and lower drug price inflation penalties. In addition, for Medicaid managed care organizations (MCOs), the loss of rebate revenue would lead to higher spending for these contracts. For purposes of this modeling, we were directed that supplemental Medicaid drug rebates would still be allowed under the rule. Table 6 summarizes the estimated net Federal cost of $1.7 billion and the State cost of $0.2 billion for calendar years 2020-2029.

**Table 6: Estimated Federal and State Costs (+) or Savings (−) for Medicaid in Calendar Years 2020-2029 in Billions**

| Calendar Year | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2020-29 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Reduced Rebates | $1.6 | $1.7 | $1.7 | $1.8 | $1.8 | $1.9 | $1.9 | $2.0 | $2.0 | $2.1 | $18.5 |
| MCO Premiums | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 | 0.2 | 0.2 | 0.1 | 1.3 |
| Price reductions | −1.4 | −1.5 | −1.5 | −1.6 | −1.7 | −1.8 | −1.9 | −2.0 | −2.2 | −2.3 | −18.0 |
| **Net Federal Impact** | **0.3** | **0.3** | **0.3** | **0.3** | **0.2** | **0.2** | **0.1** | **0.1** | **0.1** | **0.0** | **1.7** |
| **State Impact** | **0.1** | **0.1** | **0.1** | **0.1** | **0.1** | **0.0** | **0.0** | **0.0** | **-0.1** | **-0.2** | **0.2** |

Note: Totals do not necessarily equal the sums of rounded components.

*Methodology*

Using the most recent available gross drug spending and rebate reporting from the CMS Medicaid Drug Repository and Medicaid Beneficiary Expenditure System, we projected gross drug spending and a break-out of the various Medicaid drug rebates according to the FY 2019 MSR projection. The results were adjusted to reflect a calendar-year basis.

On a national aggregated basis, we calculated the Federal rebate revenue lost and the reduced brand inflation rebate penalties due to the assumed reduction in average manufacturer prices

(AMPs) and termination of safe harbor for pharmacy benefit manager (PBM) negotiated rebates between MCOs and manufacturers.

We also calculated the additional cost of MCO premium increases that are assumed to occur as MCOs recover lost rebate revenue.

Finally, we projected the savings resulting from overall brand price reductions as an offset to the reduced collection of rebate revenue. Medicaid is projected to reduce rebate collections by more than the savings from lower prices, resulting in an overall cost.

*Assumptions*

- Federal statutory rebates based on AMP, as well as supplemental rebates under State sidebar agreements, would continue to be paid by the manufacturer.
- Eighty-five percent of additional Medicaid MCO rebates would no longer be negotiated between PBMs and manufacturers on behalf of Medicaid MCOs.
  - Half of the negotiated rebates retained would shift into additional State sidebar rebates.
  - Medicaid MCOs would raise their rates to reflect their own lost rebate revenue.
- There would be no change in drug utilization rates.

## Medicare Part B Impacts

*Results from 10-Year Impact Analysis*

Since the proposal does not apply to Part B drug rebates, we believe that the Part B impacts under the proposed rule would be confined to those drugs that are covered under both Part B and Part D and that have significant rebates under Part D. The results from shifting the rebates on these drugs to lower prices are shown in table 7.

**Table 7: Estimated Federal and Beneficiary Costs (+) or Savings (−) for Medicare Part B Drugs in Calendar Years 2020-2029 in Billions**

| Calendar Year | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2020-29 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Federal Impact | −$0.04 | −$0.04 | −$0.04 | −$0.05 | −$0.05 | −$0.05 | −$0.06 | −$0.06 | −$0.06 | −$0.07 | −$0.51 |
| Cost Sharing | −0.01 | −0.02 | −0.02 | −0.02 | −0.02 | −0.02 | −0.02 | −0.02 | −0.03 | −0.03 | −0.20 |
| Premium offset | −0.01 | −0.01 | −0.01 | −0.02 | −0.02 | −0.02 | −0.02 | −0.02 | −0.02 | −0.02 | −0.17 |
| Beneficiary Impact | −0.03 | −0.03 | −0.03 | −0.03 | −0.04 | −0.04 | −0.04 | −0.04 | −0.05 | −0.05 | −0.37 |

Note: Totals do not necessarily equal the sums of rounded components.

*Methodology and Assumptions*

Medicare pays average sales price (ASP) plus 6 percent for most Part B drugs. ASP is based on manufacturers' sales to all purchasers, net of manufacturer rebates, discounts, and price concessions. We determined which drugs are covered in both Part B and Part D, as well as their rebate levels in Part D. For those drugs with significant rebates in Part D, we assumed that the price effects from this proposal would slightly lower the ASP pricing and would generate a small savings of $0.5 billion over the 10-year period.

## Private Health Insurance Impacts

Since the proposed rule would not directly change private plan rebate structures, we assumed limited effects on the private health insurance (PHI) market. The assumed decrease in brand-name drug list prices and slightly lower price trends would reduce costs for the private sector. Slightly offsetting these reductions is an assumption that discounts in the private sector would be reduced as the effects of the rule were shared across the overall drug market. The results are shown in table 2, with savings of $30 billion for PHI enrollees over the 10-year period. Enrollees in private health insurance are estimated to experience a reduction in OOP spending of $4 billion and in premium costs of $8 billion. Other sponsors of private health insurance (private employers and Federal and State governments) are estimated to achieve savings of $18 billion over the 10-year period, and premiums are anticipated to be lower as well. Unlike the projected increase in Medicare Part D premium costs, PHI premiums are expected to be lower because reductions in discounts would be smaller than the assumed savings associated with the reduced brand-name list prices. The reduction in PHI premiums is anticipated to be shared across all of the major sponsors.

## Marketplace Impacts

To calculate the impact on Federal marketplace spending, we applied the private market assumptions regarding the impact of the proposed rule to the estimated spending for marketplace drugs. This calculation resulted in Federal savings of approximately $1 billion for calendar years 2020-2029. We estimate that the projected 2020 gross premium of $598 per month, would be reduced by $0.72. Our projected impacts on Federal spending by year are shown in table 8.

**Table 8: Estimated Federal Costs (+) or Savings (−) for Marketplace in Calendar Years 2020-2029 in Billions**

| Calendar Year | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2020-29 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Federal Impact | −$0.1 | −$0.1 | −$0.1 | −$0.1 | −$0.1 | −$0.1 | −$0.1 | −$0.1 | −$0.1 | −$0.2 | −$1.0 |

## Conclusion

The proposed rule would have impacts across all segments of the prescription drug market, with particularly large effects in Medicare Part D. While there would be benefits to reducing brand drug list prices for all payers and removing incentives for higher prices and higher rebates in the Part D program, the costs to the Federal Government would more than offset these savings, resulting in additional national spending for prescription drugs. The pharmaceutical manufacturers would benefit from the proposed rule overall, even as list prices were reduced.

There is a significant amount of uncertainty around this modeling, particularly for key assumptions such as the following:

- The percentage of rebates retained by manufacturers;
- The allocation of remaining rebates to chargeback and price reductions;

- The effect on drug price trends; and
- The implications for PHI markets.

These estimates are based on the proposed regulation draft with additional guidance from HHS, and results could change if the final regulation were to differ materially from the proposed rule.

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