DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N3-01-21
Baltimore, Maryland 21207-0512

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From: Office of the Actuary

Subject: Updated Financial Impacts of Titles I and II of H.R. 3, "Lower Drug Costs Now Act of 2019"

On October 11, 2019, the CMS Office of the Actuary released a previous version of this memorandum, which considered provisions of the inflation rebate that were not reflected in the draft of the bill that was introduced. This new version provides estimates of Titles I and II of H.R. 3 as introduced on September 19, 2019 and includes a technical update to the previous estimate of Title I.

This memorandum summarizes the Office of the Actuary's (OACT's) estimates of Titles I and II of H.R. 3, "Lower Drug Costs Now Act of 2019," which was introduced on September 19, 2019. Included are estimates of the proposal's effects on Medicare, Medicaid, the Federal Health Insurance Marketplace, and elements of the national health expenditures. We will update this analysis to include the effects of Title III of the legislation as time permits.

Summary

Federal Budget Impacts

OACT considered impacts of the legislation on the Federal Budget, and Table 1 shows the change in spending for the key Federal programs. The results reflect the Fiscal Year 2020 Mid-Session Review baseline, which does not incorporate the effects of sequestration after 2021. Over the period 2020-2029, the estimated impacts include a decrease in overall Federal spending of $341 billion, $304 billion of which is attributable to Medicare Part D, $35 billion to Medicare Part B, and $4 billion to the Marketplace, while Federal Medicaid spending would increase by $2 billion.

Table 1: Estimated *Federal* Costs (+) or Savings (−) for Fiscal Years 2020-2029
(in billions)

Fiscal Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2020-29
Total Federal[1]	**$0.3**	**$0.9**	**−$17.4**	**−$33.5**	**−$37.9**	**−$41.4**	**−$45.1**	**−$50.6**	**−$55.9**	**−$60.1**	**−$340.7**
Medicare Part D	0.1	0.5	−16.0	−30.5	−33.9	−36.6	−40.0	−45.0	−49.6	−53.3	−$304.2
Medicare Part B	0.1	0.2	−1.6	−3.1	−3.8	−4.4	−4.9	−5.4	−6.2	−6.4	−$35.4
Medicaid	0.1	0.2	0.0	0.0	0.0	0.1	0.3	0.5	0.6	0.7	$2.4
Marketplace	0.0	0.0	0.2	0.1	−0.1	−0.5	−0.6	−0.7	−0.8	−1.1	−$3.5

[1] Does not include impacts for Federal employee benefits.

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

Market Impacts

OACT also considered the overall impact on all parts of the market, using the national health expenditure (NHE) projections as the basis for developing these estimates. Unlike the Federal Budget estimates presented in table 1 and in the balance of this memorandum, these estimates are on a calendar-year basis and are net of sequestration. Table 2 shows the impacts of the legislation on payers—households, Governments, and private businesses.

Table 2: 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 Spending (NHE) [1]	**$1.0**	**$2.5**	**−$13.6**	**−$38.0**	**−$54.1**	**−$69.1**	**−$80.8**	**−$92.1**	**−$105.0**	**−$120.5**	**−$569.6**
Household	**0.3**	**0.7**	**5.7**	**−3.6**	**−9.4**	**−15.4**	**−18.9**	**−22.4**	**−26.5**	**−30.8**	**−120.2**
Out-of-Pocket (OOP)[2]/Cost Sharing	0.1	0.3	1.5	−3.8	−7.6	−11.4	−14.1	−16.4	−18.8	−21.3	−91.4
Premium	0.2	0.4	4.2	0.1	−1.8	−4.0	−4.8	−6.1	−7.6	−9.5	−28.8
Federal Government[3]	**0.5**	**1.2**	**−23.8**	**−35.1**	**−40.8**	**−43.4**	**−48.2**	**−52.9**	**−58.2**	**−65.7**	**−366.3**
State Government[3]	**0.1**	**0.3**	**1.2**	**0.4**	**−1.7**	**−4.7**	**−6.5**	**−8.0**	**−9.6**	**−11.3**	**−40.1**
Private Business	**0.2**	**0.3**	**3.3**	**0.3**	**−2.2**	**−5.7**	**−7.2**	**−8.7**	**−10.6**	**−12.7**	**−43.1**

[1] Includes spending for prescription drugs purchased in retail settings and Medicare and Medicaid spending in non-retail settings, particularly expenditures associated with Medicare Part B physician-administered drugs. Does not reflect spending in other non-retail settings, in particular expenditures paid for through private health insurance.
[2] Includes spending paid directly by the consumer at the point of sale.
[3] Includes impacts on Government programs and on Governments as employers.

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

As shown in table 2, the estimated impacts include a decrease in overall spending of $570 billion over the 10-year period, $120 billion of which is attributable to households, $366 billion to the Federal Government, $40 billion to State Government, and $43 billion to private businesses.

Table 3 shows the impacts of the proposed legislation on market segments—Medicare Part D, Medicaid, Medicare Part B drugs, the commercial private health insurance (PHI) market, other public programs, and the uninsured. The proposal would directly affect each of these components, and the interactions among them are complex.

Table 3: 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)	**$1.0**	**$2.5**	**−$13.6**	**−$38.0**	**−$54.1**	**−$69.1**	**−$80.8**	**−$92.1**	**−$105.0**	**−$120.5**	**−$569.6**
Medicare (Parts B and D)[1]	**0.4**	**1.2**	**−22.5**	**−38.1**	**−46.4**	**−52.1**	**−59.6**	**−66.7**	**−74.3**	**−84.1**	**−442.2**
Enrollees (Parts B and D)	0.1	0.4	2.6	−3.2	−5.6	−7.4	−8.8	−10.6	−12.4	−14.4	−59.3
Part D Retail Prescription OOP	0.1	0.2	0.9	−2.5	−4.6	−6.3	−7.9	−9.3	−10.7	−12.1	−52.3
Premiums (Parts B and D)	0.1	0.2	2.0	−0.1	−0.3	−0.2	0.0	−0.3	−0.6	−1.1	−0.2
Part B Cost Sharing[2]	0.0	0.0	−0.4	−0.7	−0.7	−0.8	−0.9	−1.0	−1.1	−1.2	−6.7
Federal Government	0.3	0.9	−25.1	−35.2	−39.9	−42.0	−46.7	−51.0	−55.9	−62.8	−357.4
State Government	—	0.0	0.1	0.3	−0.9	−2.8	−4.1	−5.1	−6.0	−7.0	−25.5
Medicaid	**0.2**	**0.3**	**−0.1**	**0.0**	**−0.1**	**0.3**	**0.5**	**0.8**	**1.0**	**1.1**	**4.0**
Beneficiary	—	—	—	—	—	—	—	—	—	—	—
OOP	—	—	—	—	—	—	—	—	—	—	—
Premium	—	—	—	—	—	—	—	—	—	—	—
Federal Government	0.1	0.2	−0.1	0.0	−0.1	0.2	0.4	0.6	0.6	0.7	2.6
State Government	0.1	0.1	0.0	0.0	0.0	0.1	0.2	0.3	0.3	0.4	1.4
Private Health Insurance (PHI)[3]	**0.4**	**0.9**	**8.2**	**0.3**	**−6.8**	**−16.2**	**−20.5**	**−24.6**	**−29.7**	**−35.2**	**−123.1**
Enrollee	0.2	0.3	3.0	−0.2	−3.2	−7.1	−8.9	−10.5	−12.6	−14.7	−53.8
OOP	0.1	0.1	0.8	−0.5	−1.7	−3.3	−4.2	−4.7	−5.5	−6.2	−25.2
Premium	0.1	0.2	2.2	0.2	−1.5	−3.8	−4.8	−5.8	−7.1	−8.4	−28.6
Federal Government	0.0	0.1	0.8	0.1	−0.5	−1.4	−1.7	−2.1	−2.5	−3.0	−10.3
State Government	0.1	0.1	1.2	0.1	−0.8	−2.1	−2.6	−3.2	−3.9	−4.7	−15.9
Private Business	0.2	0.3	3.3	0.3	−2.2	−5.7	−7.2	−8.7	−10.6	−12.7	−43.1
Other Government Programs and Those without Insurance	**0.0**	**0.1**	**0.7**	**−0.2**	**−0.7**	**−1.1**	**−1.3**	**−1.6**	**−2.0**	**−2.3**	**−8.3**

[1] Spending for Medicare coverage for Part D enrollees and spending for physician-administered drugs for Medicare Part B enrollees.
[2] Represents all Part B cost sharing, even if the Medicare enrollee were to purchase supplemental coverage for these costs.
[3] Does not reflect prescription drug spending in non-retail settings, such as spending by hospitals, physicians, and other health care providers. Includes supplemental coverage spending for Part D enrollees.

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

Description

The legislation aims to address the disparity between brand-name prescription drugs in the United States compared to other countries and the level of price increases on those drugs that has been observed in recent years. The legislation would grant the Secretary of Health and Human Services (HHS) the authority to negotiate prices with drug manufacturers, set a boundary on those negotiations along with a penalty for failure to negotiate, and create an inflation rebate paid by drug manufacturers for certain Medicare Part B and Part D drugs.

The negotiation component of the legislation requires that the Secretary of HHS negotiate at least 25 drugs per year beginning in 2023. These drugs must be brand-name agents with no generic competition and must be selected from the 125 highest-spending drugs in Medicare Part D or from the 125 highest-spending drugs outside of Part D. The negotiation must arrive at a price no greater than 120 percent of the average price in Australia, Canada, France, Germany, and the United Kingdom. Crucially, the resulting negotiated price must apply to all sectors of the U.S. drug market, including the private sector and the determination of Medicaid best price. Under the proposal, in the event that the Secretary and the manufacturer could not agree on a price, the manufacturer would be required to pay a penalty starting at 65 percent of the total U.S. sales to the Treasury and rising to 95 percent after three quarters.

The inflation rebate component of the legislation establishes a new payment from drug manufacturers to the Federal Government for drugs in Medicare Part B or Medicare Part D that have price increases in excess of the Consumer Price Index (CPI) inflation rate. This rebate would be effective on January 1, 2022 and would account for price increases after 2016. For Part D drugs, the calculation of the inflation rebate would be based on average manufacturer price (AMP), while Part B rebates would be based on Average Sales Price (ASP).

Key Assumptions—Negotiation

To develop our estimates, we considered the responses to the legislation by manufacturers and consumers, the Secretary's ability to negotiate drug prices and requirements for doing so, and the current disparity between drug prices in developed countries and the U.S. For the negotiated price provisions, we needed to account for the projected impacts on three main components: list prices, manufacturer rebates, and trends.

The penalty of up to 95 percent of total U.S. sales is so significant that we assumed that all brand-name manufacturers would participate in the negotiations. The negotiated prices are specified in the proposal to apply to Medicare Parts B and D, Medicaid, and the private sector. While many factors are identified that the Secretary must consider, the proposed legislation places a firm limit on the upper bound of negotiations: 120 percent of the average of prices across Canada, France, Germany, Japan, Australia, and the United Kingdom. As there is no historical experience regarding negotiations between the Secretary and drug manufacturers, we assumed that the negotiations would result in the lesser of 120 percent of the international price or the current Part D price less manufacturer rebates. It is possible that the Secretary would be able to negotiate greater discounts than this on some of the drugs, but results could vary from one HHS Secretary to the next, and manufacturers would likely utilize their full bargaining leverage to remain as close to the statutory upper limit as possible. Additionally, reductions to 120 percent of the international price would represent a significant change for many prices, and it could be more challenging for the Secretary to negotiate greater reductions when these provisions initially became effective.

We assumed that the Secretary would select 25 drugs per year based on the highest net spending in Part B and Part D, as the legislation directs the Secretary to prioritize drugs with the greatest potential Federal savings. To determine the impact of switching to the lesser of 120 percent of the international price or the current Part D price less rebates, we examined drug price relativities for a representative sample of brand-name drugs from Medicare Part D and Part B experience by comparing the list price in the U.S. to the international pricing data obtained from the IHS Markit

PharmOnline International database. Because the international price data contained wide variations for the countries identified in the legislation, and because the data set may not fully account for dosing differences or other nuances of foreign nation prices, we chose the maximum available price for a comparable dose and administration. In addition, because the effects on the distribution system payments between the manufacturer and the retailer are unclear and unprecedented, we assumed that the relativities between U.S. and international prices persist throughout the payment system of their respective components. For example, if the current price of a Part D drug is $100 and the international price is $50, we assumed that the gross cost for the drug after the negotiation is $50 multiplied by 1.2, or $60.

We observed substantial differences between international prices by cost and rebate level for particular drugs. Accordingly, we separated the results from the representative sample of drugs we examined into three categories: specialty drugs with low rebates, specialty drugs with high rebates, and other brand-name drugs. Because the legislation specifies that the top 125 highest net spending Medicare Part D brand-name drugs without generic competitors are eligible for negotiation, we found that all such drugs were in one of these three categories.

As we considered what measures drug manufacturers could take to limit the full impact of the negotiated price changes, we concluded that they would use their capability and leverage to either obscure or increase international prices. These results could be accomplished by persuading other countries to accept higher list prices accompanied by additional rebates or by otherwise establishing complicated payment arrangements that could mask the ultimate price of a drug paid by a foreign country. Such arrangements exist today, as countries establish an initial price paid per use and then subsequently reconcile to a different price based on total volume. These manufacturer responses are reflected in our assumptions as a gradual increase in international prices and a corresponding decrease in discount levels. The assumptions on gross cost discounts for negotiated drugs, by category, are shown in table 4.

Table 4: Assumed Gross Price Discounts from Negotiations

Calendar Year	2023	2024	2025	2026	2027	2028	2029
Specialty, Low Rebate	45%	35%	25%	15%	15%	15%	15%
Specialty, High Rebate	43%	37%	31%	25%	25%	25%	25%
Other Brands	72%	62%	51%	41%	41%	41%	41%

Note: Discounts shown reflect net price reductions to account for 120 percent of international prices.

As the statutory requirement for manufacturers to negotiate their prices with the Secretary took effect, we expect that they would significantly reduce rebate levels to compensate for the lost revenue on list prices at the time the drug was negotiated. At the same time, the incentives to use rebates rather than list prices to achieve a desired competitive result would remain the same. For the category with the highest rebate, we assumed that there would be a gradual increase in rebate levels following the initial decrease after negotiation. This result reflects Part D sponsors' continued incentives to prefer rebates to lower point-of-sale prices as time elapses. Table 5 shows the change in rebates, expressed as a percentage of the rebate level prior to the legislation.

Table 5: Post-Negotiation Percentage Point (or Percentage) Change in Rebate Levels Relative to Current

Calendar Year	2023	2024	2025	2026	2027	2028	2029
Specialty, Low Rebate	−100%	−100%	−100%	−100%	−100%	−100%	−100%
Specialty, High Rebate	−95%	−95%	−95%	−95%	−95%	−95%	−95%
Other Brands	−90%	−89%	−88%	−87%	−86%	−85%	−84%

We also considered the potential impacts on trend from three sources: (i) the possibility of higher new drug launch costs, (ii) the requirement that negotiated prices increase by no more than the change in the CPI, and (iii) induced utilization from lower beneficiary cost sharing. To quantify the impact of higher launch prices, we assumed that 2 percent of Medicare Part D gross costs were for new drugs based on the historical pattern and that manufacturers would increase prices for these drugs by 25 percent. This assumption accounted for the possibility that manufacturers would raise the prices on truly novel products and that they would launch additional drugs with minimal differences to current products. To implement the effect of limiting price increases on negotiated drugs, we used a CPI assumption of 2.6 percent per year, resulting in a reduction of approximately 0.5 percent per year in price increases across all drugs. Induced utilization has a comparatively small impact, which we estimated based on historical differences in utilization between the low-income and non-low-income Medicare Part D beneficiaries. Table 6 shows the additive impact of these three adjustments to the baseline trend by year.

Table 6: Trend Increases (+) or Decreases (−) in Calendar Years 2020-2029

Calendar Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Trend Impact	0.3%	0.5%	0.5%	−0.6%	−0.5%	−0.2%	−0.6%	−0.7%	−0.8%	−0.9%

Key Assumptions—Inflation Rebate

The inflation rebate provisions of the legislation apply only to Medicare Parts B and D, but we expect other segments of the prescription drug market to be affected indirectly. In Part D, the provisions would establish a payment to the Part D trust fund for the differences between the observed increases in the AMP and the CPI-level increase. The legislation specifies calendar year 2016 as the starting price level. As the inflation rebate provisions would take effect in 2022 and the negotiation provisions would be implemented in 2023, there would be one year in which all drugs would be subject to the inflation rebate, and there would be a gradual transition to a smaller subset of drugs subject to the inflation rebate as more drugs became negotiated. For 2021 and later, we assumed a 2.6-percent annual CPI increase.

Because the inflation rebate provisions do not apply to private market sales, we assumed that manufacturers would attempt to recover some of the new rebate payments through increased list prices. In 2022, the negotiated prices from the legislation would not be in effect, and therefore we assumed that manufacturers would recover 25 percent of the inflation rebate through list price changes in all markets. As negotiated prices phased in over time on an increasing number of drugs, manufacturers would have less opportunity to change list prices and would face the risk that drugs with dramatic price increases could then be targets for negotiation. Accordingly, we gradually decreased the assumed recovery percentage to 15 percent, as shown in table 7. The

15-percent assumption also takes into account the possibility that manufacturers would opt to raise prices on non-negotiated brand-name drugs in response to the entire legislative proposal.

Table 7: Inflation Rebate Recovery Percentage in Calendar Years 2020-2029

Calendar Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Inflation Rebate Recovered	0%	0%	25%	20%	15%	15%	15%	15%	15%	15%

As the assumed list price changes would cause increases in the amount of inflation rebates due from manufacturers, we assumed that they would take additional actions to offset these rebates. In particular, reducing the rebates paid to pharmacy benefit managers and insurers would increase the net price that a manufacturer received for a drug without increasing the inflation rebates. Using as a reference the 2008-2012 period when rebate growth was relatively stable, we assumed that manufacturers would further reduce rebates beyond their reaction to the negotiation provisions—with the result that, in 2029, total Direct and Indirect Remuneration (DIR) would decrease from approximately 30 percent of gross drug costs to approximately 26 percent of gross drug costs in response to Title II. In conjunction with the negotiation assumptions described above DIR would decrease to approximately 15 percent of gross costs in Part D by 2029. We also assumed a 5-percent rebate reduction in the PHI market so that commercial rebates would compose a similar but slightly lower percentage of gross drug costs by 2029 compared to Part D.

Medicare Part D Impacts

The Part D effects are shown separately for the negotiation provisions, the inflation rebate provisions, and in total.

Negotiation Provision Results from 10-Year Impact Analysis

The legislative provisions on negotiation are estimated to result in decreased costs for both beneficiaries and the Federal Government. Fundamentally, there would be two major changes from the legislation: lower drug costs at the point of sale and a large reduction in manufacturer rebates as manufacturers compensated for the lower list prices. In addition, the negotiation impacts would include changes to price trends from restrictions on price changes for negotiated drugs, induction effects from the lower costs at the point of sale, and expected growth in new drug costs, as described in the *Key Assumptions—Negotiation* section. We also note that the beneficiary cost-sharing responsibility measures the change in cost sharing under the Defined Standard benefit, excluding the manufacturer gap discount, for non-low-income beneficiaries. In practice, other components—such as additional employer contributions or enhanced Part D coverage—reduce the actual out-of-pocket expenditures by beneficiaries. We did not separately quantify these amounts because they are in excess of basic Part D coverage.

Table 8 shows estimated Part D expenditures, on a fiscal-year cash basis before sequestration, for Medicare beneficiaries, the Part D program, and the Federal Government, as well as State clawback payments for Medicare beneficiaries who have full Medicaid benefits.

Table 8: Estimated Federal and Beneficiary Costs (+) or Savings (−) due to *Negotiation Provisions* for *Medicare Part D* in Fiscal Years 2020-2029 (in billions)

Fiscal Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2020-29
Beneficiary Costs	**$0.1**	**$0.4**	**$0.7**	**−$7.1**	**−$11.9**	**−$14.5**	**−$17.0**	**−$19.6**	**−$21.1**	**−$27.0**	**−$116.9**
Cost-Sharing Responsibility	0.1	0.3	0.5	−5.8	−10.0	−12.5	−15.2	−17.5	−18.6	−24.0	−$102.6
Premium	0.0	0.1	0.2	−1.2	−1.9	−2.0	−1.9	−2.1	−2.5	−3.0	−$14.3
Part D Costs	**0.1**	**0.5**	**1.1**	**−7.6**	**−11.6**	**−16.7**	**−20.1**	**−23.7**	**−28.5**	**−27.9**	**−$134.3**
Direct Subsidy	0.0	0.0	0.1	2.9	4.5	5.8	7.2	7.8	9.2	8.3	$45.9
Reinsurance	0.1	0.3	0.6	−7.0	−9.7	−12.5	−14.5	−16.4	−18.9	−18.0	−$96.1
Low-Income Cost-Sharing Subsidy	0.1	0.2	0.4	−3.2	−6.1	−9.6	−12.3	−14.6	−18.2	−17.5	−$80.7
Low-Income Premium Subsidy	0.0	0.0	0.0	−0.3	−0.4	−0.5	−0.4	−0.5	−0.6	−0.7	−$3.4
Federal Impact	**0.1**	**0.5**	**1.1**	**−7.8**	**−10.9**	**−14.2**	**−16.0**	**−18.5**	**−22.3**	**−20.8**	**−$108.8**
State Clawback Impact	—	0.0	0.1	0.1	−0.7	−2.6	−4.1	−5.2	−6.1	−7.1	−$25.6

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

Direct subsidy costs are estimated to increase by $46 billion, as the reduction in manufacturer rebates would have a greater effect on the direct subsidy than the price reductions. Because of the lower costs at the point of sale, utilizing beneficiaries would receive a benefit at the point of sale through reduced cost sharing. Low-income cost-sharing subsidies would also be reduced dramatically as a result of this dynamic. Similarly, a large decrease in catastrophic costs due to lower prices would lead to lower reinsurance costs and a small reduction in premiums. In total, Part D costs would be reduced by an estimated $134 billion over the 10-year period. Of this amount, Federal spending would be reduced by $109 billion, and State spending would be reduced by $26 billion.

For Part D beneficiaries, the negotiation provisions would reduce spending by an estimated $117 billion, as shown in table 8. Both the beneficiary cost-sharing responsibility and the Part D premiums would be reduced—because of the same interaction between rebates and point-of-sale costs mentioned above—though the vast majority of savings ($103 billion) would be due to cost sharing. The small decrease in premiums occurs because the portion of the beneficiary premium that is attributable to reinsurance decreases more than the bid portion increases.

We recognize that the Secretary may be able to negotiate prices below the upper limit for some drugs. Because there is no precedent for these negotiations, we did not have a basis for assuming additional negotiation savings. Under the upper limit there would still be significant reductions to drug prices, and we expect that manufacturers would use the full extent of their negotiation expertise to restrict negotiations beyond this limit. To illustrate the sensitivity of this assumption, we estimated that to the extent that the Secretary could negotiate the average drug price to be 110 percent of the international price, Federal Part D savings would increase from an estimated $109 billion, as shown in table 8, to approximately $121 billion.

Inflation Rebate Provision Results from 10-Year Impact Analysis

The inflation rebate provisions of the legislation would impose a rebate, effective January 1, 2022, to be paid to the Part D trust fund for price increases since 2016 that are greater than inflation, for all Part D drugs. In response to this requirement, manufacturers could either increase list prices or reduce rebates to offset some of these payments. We expect manufacturers to exercise both of these options, but because an increase in list prices would result in increased inflation rebate liability, we assumed that they would place more weight on rebate reductions than on price increases.

This behavior would lead to decreases in manufacturer rebates and increases in prices at the point of sale. The inflation rebate provisions would result in higher spending for beneficiaries and savings for the Federal Government. Part D costs would decrease by $194 billion over the 10-year period, almost entirely attributable to the estimated inflation rebate of $296 billion. Direct subsidy costs and reinsurance costs would increase by $49 billion and $43 billion, respectively. The reductions in Part D costs would result in lower Federal Government spending ($195 billion) and increased State spending ($2 billion). Beneficiary spending would increase by $30 billion, with premiums increasing by $24 billion primarily as a result of the substantial rebate reduction and cost-sharing responsibility increasing by $6 billion due to higher list prices. The estimated impacts are shown in table 9 on a fiscal-year cash basis.

Table 9: Estimated Federal and Beneficiary Costs (+) or Savings (−) due to *Inflation Provisions* for *Medicare Part D* in Fiscal Years 2020-2029 (in billions)

Fiscal Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2020-29
Beneficiary Costs	**$0.0**	**$0.0**	**$2.6**	**$3.2**	**$3.5**	**$3.6**	**$3.9**	**$4.2**	**$4.4**	**$4.9**	**$30.2**
Cost-Sharing Responsibility	—	—	0.7	0.6	0.7	0.7	0.7	0.8	0.8	0.9	$6.0
Premium	0.0	0.0	1.8	2.6	2.8	2.9	3.2	3.4	3.7	3.9	$24.3
Part D Costs	**0.0**	**0.0**	**−17.1**	**−22.6**	**−22.8**	**−22.2**	**−23.7**	**−26.1**	**−26.9**	**−32.2**	**−$193.6**
Direct Subsidy	0.0	0.0	4.1	5.2	5.1	6.0	6.4	6.9	8.0	7.3	$48.9
Reinsurance	—	—	3.2	4.1	4.5	5.5	6.0	6.0	7.1	6.5	$42.9
Low-Income Cost-Sharing Subsidy	—	—	0.5	0.6	0.5	0.6	0.6	0.7	0.8	0.7	$5.0
Low-Income Premium Subsidy	0.0	0.0	0.5	0.6	0.6	0.7	0.8	0.8	1.0	0.9	$6.0
Inflation Rebate	0.0	—	−25.4	−33.2	−33.6	−34.9	−37.5	−40.6	−43.7	−47.5	−$296.4
Federal Impact	**0.0**	**0.0**	**−17.1**	**−22.7**	**−23.0**	**−22.4**	**−24.0**	**−26.5**	**−27.2**	**−32.5**	**−$195.4**
State Clawback Impact	—	—	—	0.1	0.2	0.3	0.3	0.3	0.3	0.3	$1.9

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

To better describe and explain the impacts from the components of the legislation, we estimated the effects of the negotiation and inflation provisions separately and discretely. The combined results of both the inflation and negotiation proposals are estimated to amount to beneficiary savings of $87 billion, Part D savings of $328 billion, Federal Government savings of $304 billion, and State Government savings of $24 billion over the 10-year period, as shown on a fiscal-year cash basis in table 10.

Table 10: Estimated Federal and Beneficiary Costs (+) or Savings (−) due to *Negotiation and Inflation Provisions* for *Medicare Part D* in Fiscal Years 2020-2029 (in billions)

Fiscal Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2020-29
Beneficiary Costs	**$0.1**	**$0.4**	**$3.2**	**−$3.9**	**−$8.4**	**−$10.9**	**−$13.1**	**−$15.5**	**−$16.6**	**−$22.1**	**−$86.7**
Cost-Sharing Responsibility	0.1	0.3	1.2	−5.2	−9.3	−11.8	−14.4	−16.8	−17.8	−23.0	−$96.7
Premium	0.0	0.1	2.0	1.3	0.8	1.0	1.3	1.3	1.2	0.9	$10.0
Part D Costs	**0.1**	**0.5**	**−16.0**	**−30.3**	**−34.4**	**−38.9**	**−43.8**	**−49.8**	**−55.4**	**−60.1**	**−$327.9**
Direct Subsidy	0.0	0.0	4.1	8.1	9.7	11.8	13.6	14.7	17.2	15.5	$94.8
Reinsurance	0.1	0.3	3.8	−2.9	−5.2	−7.0	−8.5	−10.4	−11.8	−11.6	−$53.1
Low-Income Cost-Sharing Subsidy	0.1	0.2	0.9	−2.6	−5.5	−9.0	−11.7	−13.9	−17.4	−16.8	−$75.7
Low-Income Premium Subsidy	0.0	0.0	0.6	0.3	0.2	0.3	0.3	0.3	0.3	0.2	$2.6
Inflation Rebate	—	—	−25.4	−33.2	−33.6	−34.9	−37.5	−40.6	−43.7	−47.5	−$296.4
Federal Impact	**0.1**	**0.5**	**−16.0**	**−30.5**	**−33.9**	**−36.6**	**−40.0**	**−45.0**	**−49.6**	**−53.3**	**−$304.2**
State Clawback Impact	—	0.0	0.1	0.2	−0.5	−2.3	−3.8	−4.9	−5.8	−6.7	−$23.7

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

Methodology

Using the international price relativities described in the *Key Assumptions—Negotiation* section, we modeled the anticipated effects of the negotiation provisions and determined an estimate of the negotiated price by drug and year for all of the Part D drugs eligible for negotiation. Then, for each year from the effective date to the end of the budget window, we modeled the effects of these price changes on 2017 Prescription Drug Event (PDE) data. Using beneficiary-level experience, we calculated each beneficiary's progression through the phases of the Part D Defined Standard benefit under the negotiated prices, including the anticipated effects to benefit parameters such as the deductible and the initial coverage limit. This modeling produced estimated impacts to the gross drug cost, plan costs, and catastrophic costs by year, separately for low-income and non-low-income populations.

We applied the results from the beneficiary modeling to our 10-year Part D benefit model and added further adjustments to account for the trend and rebate changes described in the key assumptions. We then used this model to project the impacts of the negotiation provisions for the 10-year budget window across the Part D program. We note that some drugs would be negotiated later than fiscal year 2029, which is the end of the budget window, and would continue to produce savings.

To estimate the magnitude of the inflation rebate, we relied on the pattern of Medicaid inflation rebates since 2016. Since both the proposed Part D rebate and the existing Medicaid rebate are based on the AMP, the Medicaid pattern offered the best basis for our estimates. The Medicaid inflation rebates were developed using (i) gross Medicaid drug spending projections that reflect trends in projected overall gross drug prices (based on the national health expenditures) and (ii) net Medicaid drug spending projections that account for the base and inflationary Medicaid rebates.

The total rebate was then calculated as the difference between the gross and net costs. We estimated the statutory portion of the rebates as 24 percent of the total rebate, projected the inflation rebate as the remainder, and subtracted the 2016 inflation rebate from subsequent years to convert the inflation rebates to the basis specified in the legislation. We then took the resulting inflation rebate percentage of gross cost and adjusted for the percentage of gross cost that we expect to be negotiated in each year.

After estimating the inflation rebate percentage of gross cost, we applied this amount to the projected gross cost in the Part D benefit model. To account for the expected manufacturer price increases, we estimated the total U.S. prescription drug market using values from the NHE projections. We then calculated the increase necessary for the manufacturers to recoup a percentage of the inflation rebate amount under the proposal and applied that result to the Part D projections. Because this price increase in turn increases the inflation rebate, we iterated this process until the price increases across the entire market balanced the expected recovery percentage for each year. We then applied the manufacturer rebate reduction described in the *Key Assumptions—Negotiation* section and calculated the resulting cost impacts.

In developing these estimates, we made several assumptions regarding how the legislation would be implemented and operationalized. In particular, we assumed that the negotiated prices would be used throughout the existing distribution system and would not radically alter the relationships among Part D sponsors, pharmacy benefit managers, or pharmacies. This analysis does not consider changes to the Part D benefit structure in Title III of the proposed legislation.

Medicare Part B Impacts

Results from 10-Year Impact Analysis

The legislation would also significantly affect Part B separately payable drugs. While a small cost increase is estimated for 2020 and 2021 due to the expected growth in new drug spending, overall the proposal would result in considerable savings for both beneficiaries and the Federal Government across the budget window. Table 11 shows the projected impacts by year, on a fiscal-year cash basis.

Table 11: Estimated Federal and Beneficiary Costs (+) or Savings (−) for *Medicare Part B Drugs* in Fiscal Years 2020-2029 (in billions)

Fiscal Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2020-29
Federal Impact	**$0.1**	**$0.2**	**−$1.6**	**−$3.1**	**−$3.8**	**−$4.4**	**−$4.9**	**−$5.4**	**−$6.2**	**−$6.4**	**−$35.4**
Beneficiary Impact	**0.0**	**0.1**	**−0.8**	**−1.6**	**−2.0**	**−2.3**	**−2.5**	**−2.8**	**−3.1**	**−3.3**	**−18.3**
Cost Sharing	0.0	0.0	−0.3	−0.6	−0.7	−0.8	−0.9	−1.0	−1.1	−1.2	−6.5
Premium offset	0.0	0.1	−0.5	−1.0	−1.3	−1.5	−1.6	−1.8	−2.1	−2.1	−11.8

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

Methodology and Assumptions

Medicare pays the ASP plus 6 percent for most Part B drugs. The ASP is based on manufacturers' sales to all purchasers, net of manufacturer rebates, discounts, and price concessions. Using the Healthcare Common Procedure Coding System (HCPCS) from 2016, we

measured the price trend by drug code to estimate the impact of the inflation rebate provisions of the proposal. Based on the 2017 spending levels, we categorized drugs eligible for the negotiation provisions by year. We then estimated the impact of these negotiations using the international price relativity, accounting for expected manufacturer international price changes by year.

Medicaid Impacts

Results from 10-Year Impact Analysis

Table 12 shows the estimated Medicaid impacts of the proposal for calendar years 2020-2029. Prescription drug expenditures (net of rebates) are estimated to increase by $4 billion during this period, while Federal Government expenditures on Medicaid prescription drugs (net of rebates) would increase by $2 billion and State expenditures would increase by $1 billion. We expect that there would be no direct impact on Medicaid beneficiaries' expenditures because the cost-sharing responsibility is minimal and would likely not be affected by any price changes resulting from this proposal.

Table 12: Estimated Federal and State Costs (+) or Savings (−) for *Medicaid* in Fiscal Years 2020-2029 (in billions)

Fiscal Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2020-29
Total	**$0.1**	**$0.3**	**$0.0**	**−$0.1**	**−$0.1**	**$0.2**	**$0.5**	**$0.8**	**$0.9**	**$112**	**$3.7**
Negotiation	**0.1**	**0.3**	**0.3**	**0.5**	**0.5**	**0.8**	**1.1**	**1.4**	**1.6**	**1.8**	**$8.4**
Increased launch prices	0.1	0.3	0.3	0.4	0.4	0.4	0.4	0.4	0.5	0.5	$3.6
Drug price negotiations	0.0	0.0	0.0	0.1	0.1	0.4	0.7	1.0	1.2	1.3	$4.7
Inflation rebate	**0.0**	**0.0**	**−0.3**	**−0.3**	**−0.3**	**−0.4**	**−0.4**	**−0.4**	**−0.4**	**−0.4**	**−$2.8**
Medicare buy-in	**0.0**	**0.0**	**−0.1**	**−0.2**	**−0.2**	**−0.2**	**−0.3**	**−0.3**	**−0.3**	**−0.3**	**−$1.8**
Net Federal Impact	0.1	0.2	0.0	0.0	0.0	0.1	0.3	0.5	0.6	0.7	$2.4
Net State Impact	0.0	0.1	0.0	0.0	0.0	0.1	0.2	0.3	0.3	0.4	$1.3

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

Most of the estimated increase in Medicaid expenditures is due to the price negotiations for Medicare prescription drugs. We project that these negotiations would increase Medicaid prescription drug expenditures (net of rebates) by $5 billion over the 10-year period. To understand why this increase would occur, it is important to understand that there are generally two parts to the statutory prescription drug rebates in Medicaid. The first part is the base rebate, which is the greater of (i) the AMP multiplied by 23.1 percent (for brand-name drugs) and (ii) the AMP minus the best price. (The determination of the AMP and best price can be complex and is not described in detail in this memorandum.) To the extent that prescription drug prices decrease, the base rebate also decreases; however, the base rebate would never be expected to decrease by more than the decrease in the AMP.

The second part of the rebate is the inflationary rebate, which is equal to the difference between (i) the AMP and (ii) the AMP when the drug was initially launched increased by the change in

the CPI over time. For drugs with relatively large inflationary rebates, decreases in the AMP reduce these rebates dollar for dollar. Thus, in cases in which the Medicaid program also receives an inflationary rebate, a decrease in drug prices can result in a decrease in the rebate amount that is larger than the reduction in the drug price, leading to a net increase in drug expenditures. Under this proposal, gross drug expenditures (excluding any rebates) would decrease by $38 billion, but rebates would decrease by $42 billion, resulting in a net increase in expenditures of $5 billion, as shown in table 12.

In addition, there are effects from higher launch prices, which are projected to increase Medicaid expenditures for prescription drugs (net of rebates) by $4 billion during 2020-2029, as table 12 shows. Although higher prices for prescription drugs would result in additional prescription drug expenditures, the spending increase would be reduced in part by higher rebate amounts on those drugs. Medicaid payments for Medicare Part B premiums would also decrease by $2 billion, as a result of the Part B impacts discussed above.

Conversely, increased prescription drug prices related to the inflation rebate adjustment under the proposal would decrease Medicaid prescription drug expenditures (net of rebates) by $3 billion. While the increase in prescription drug prices is projected to increase gross expenditures (prior to rebates) by $13 billion, prescription drug rebates are projected to increase by $16 billion.

Methodology

Using the results of the analysis on Part D drug price changes due to direct negotiations with manufacturers, along with available drug rebate data, we modeled the changes to Medicaid drug prices and rebates. We took the estimated change in drug prices (table 4) and recalculated the average Medicaid price paid and the base and inflation rebates for each drug. We assumed that the relative price changes due to direct negotiations would lower each drug's AMP, best price, and average Medicaid price paid. We assumed no change in utilization under the proposal, because we do not expect Medicaid beneficiaries to be affected by any price or rebate changes (due to the minimal cost-sharing requirements in Medicaid).

To account for higher launch prices, we increased the prescription drug expenditure trend by the same percentage as under Part D (assuming that 2 percent of expenditures each year were for new drugs and that prices for these drugs would increase by 25 percent, as described previously). We assumed that these new drugs would be subject to the statutory rebates (which amount to 23.1 percent off of the AMP) but that the higher prices would not lead to any inflationary rebates.

To project the impacts of the inflationary rebates, we assumed that prescription drug prices would increase by the same percentage that they would for PHI plans. This increase would result in higher statutory rebates along with higher inflationary rebates, and, for existing drugs, it would potentially lead to additional inflationary rebates as well.

Private Health Insurance Impacts

Since the proposal would affect spending in all segments of the U.S. drug market, we estimated impacts for those with PHI coverage; those covered by other public payers, such as the

Department of Defense and the Department of Veterans Affairs; and the uninsured. PHI enrollees are estimated to save $54 billion over 2020-2029 (table 3)—$25 billion in OOP savings and $29 billion in the form of lower premiums. These savings are the net result of (i) lower brand-name prices (because of negotiation) and their associated lower price trends, partially offset by reductions in the level of rebates paid by manufacturers; (ii) higher brand-name prices associated with higher expected launch prices and higher list prices to partially offset the Medicare inflation rebate; and (iii) induced utilization from lower cost sharing. Other sponsors of PHI coverage are expected to experience savings as well, such as Federal and State Governments ($26 billion) and private businesses ($43 billion) (table 3). Those covered by other public programs and those with no insurance are also expected to benefit from the changes related to lower list prices through negotiation. Savings for these segments of the market are projected to total $8 billion over the 2020-2029 period (table 3), with most of these savings attributed to those without insurance.

Methodology

We estimated total U.S. prescription drug spending and non-Medicare and non-Medicaid spending (including PHI, OOP, and other public expenditures) using the 2018-2027 NHE projections, extended to 2029.[1] The estimates associated with enrollees of given types of coverage (and the uninsured) were derived using relationships observed on a sponsor basis (households, Federal Government, State and local Governments, and private businesses) from those same data, supplemented with survey data (where applicable).

To account for the applicable estimated rebate percentages, we adjusted the estimates of gross PHI drug expenditures and other public drug spending. The impacts of price negotiation were developed on a drug-by-drug basis using market shares from the 2017 Truven MarketScan data. We used assumptions for the price negotiation component, as well as expected changes in rebates, and behavioral assumptions regarding launch prices, the Medicare inflation rebate, and induction that were consistent with those described in the *Key Assumptions* sections. As we did with the Medicare estimates, we assumed that the negotiated prices would be used throughout the existing distribution system and that they would not radically alter the relationships among commercial insurers, pharmacy benefit managers, or pharmacies. Additionally, we assumed that the employee would fully benefit from the price reductions through lower cost sharing and that premium reductions would be shared according to the baseline employer and employee contribution ratio.

Marketplace Impacts

To calculate the impacts 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 $4 billion for calendar years 2020-2029. We estimate that the projected 2029 gross premium of $873 per month would be reduced by $13. Our projected impacts on Federal spending are shown in table 13 on a fiscal-year cash basis.

[1] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html

Table 13: Estimated Federal Costs (+) or Savings (−) for *Marketplace* in Fiscal Years 2020-2029 (in billions)

Fiscal Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2020-29
Federal Impact	$0.0	$0.0	$0.2	$0.1	−$0.1	−$0.5	−$0.6	−$0.7	−$0.8	−$1.1	−$3.5

Conclusion

We estimate that Titles I and II of H.R. 3, "Lower Drug Costs Now Act of 2019," would have broad effects on the prescription drug market in the United States. The overall impact would be a significant savings as manufacturers reduced prices and paid for price inflation in excess of the CPI. While there would be savings overall for the Federal Government, Medicare beneficiaries, and the PHI market, Medicaid costs are projected to increase. The legislation would represent a dramatic and unprecedented shift in how the prescription drug market operates.

In developing our estimates, we made assumptions to account for manufacturer and consumer behavior, but actual responses may differ from our assumptions. We also assumed that the current distribution system would remain in place, but key actors—such as pharmacy benefit managers, wholesalers, and insurers—may adopt new business strategies in reaction to the legislation. Moreover, the Secretary's ability to negotiate with manufacturers is untested and may lead to results that are different from what we have assumed. Because of the potential for actual experience to differ from these assumptions, and because of the substantial changes to the drug market under the legislation as well as any unanticipated effects, there is a significant degree of uncertainty in our estimates.

Blake Pelzer
Associate, Society of Actuaries
Deputy Director, Parts C&D Actuarial Group

Paul Spitalnic
Associate, Society of Actuaries
Member, American Academy of Actuaries
Chief Actuary