



CONGRESSIONAL BUDGET OFFICE  
U.S. Congress  
Washington, DC 20515

*Phillip L. Swagel, Director*

October 11, 2019

Honorable Frank Pallone Jr.  
Chairman  
Committee on Energy and Commerce  
U.S. House of Representatives  
Washington, DC 20515

*Re: Effects of Drug Price Negotiation Stemming From Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare*

Dear Mr. Chairman:

In response to your request, the Congressional Budget Office and the staff of the Joint Committee on Taxation (JCT) have been analyzing the effects of H.R. 3, the Lower Drug Costs Now Act of 2019, as introduced on September 19, 2019. This letter describes a preliminary estimate of the effects of title I of the bill on federal direct spending and revenues related to Part D of Medicare, the outpatient drug benefit. CBO is working on analyses of other effects of that title and of other titles of the bill, but that work is not complete.

Title I of H.R. 3 would require manufacturers of certain prescription drugs to negotiate prices with the Secretary of Health and Human Services (HHS). Prices for those drugs could not exceed 120 percent of the average price in certain other countries. Other provisions also would affect prices for drugs, including limits on prices of drugs for which international prices are not available. If manufacturers did not enter into negotiations or agree to prices by specified dates or if they did not meet other conditions, they would be subject to an excise tax of up to 95 percent of the sales of those drugs.

CBO estimates that applying the provisions in title I to prescription drugs covered under Part D of Medicare would reduce federal direct spending for Medicare by \$345 billion over the 2023-2029 period (see Table 1). JCT estimates that revenue collections from the excise tax in title I would not be significant. The largest savings would come from lower prices for existing drugs that are sold internationally, for which the price ceiling would be binding in most but not all cases, CBO estimates.

The lower prices under the bill would immediately lower current and expected future revenues for drug manufacturers, change manufacturers' incentives, and have broad effects on the drug market. A manufacturer that was dissatisfied with a negotiation could

pull a drug out of the U.S. market entirely, though CBO expects that would be unlikely for drugs already being sold in the United States. Manufacturers would initially set list prices of some new drugs in the U.S. higher than under existing law, although the net prices paid by consumers over time could be lower in many such cases.

CBO also expects that enactment of title I of H.R. 3 would affect prescription drug prices in other countries, with foreign prices expected to rise in response to the link between those prices and prices in the United States. CBO further expects some new drugs would not be introduced in other countries or would be introduced in a limited set of other countries for which drug manufacturers can sell at sufficiently high prices—an effect that again reflects the feedback by which selling at low prices in other countries leads to lower U.S. prices. Over time, drug manufacturers might put in place mechanisms by which they can charge relatively high prices in other countries to avoid feedback that lowers U.S. prices while providing other forms of compensation that effectively reduce the net price of drugs in other countries. Those international effects would lessen the effectiveness of title I in reducing the level and growth of drug prices.

In addition to the effects on the federal budget, CBO anticipates, the bill would affect the use and availability of drugs over time. In the short term, lower prices would increase use of drugs and improve people's health. In the longer term, CBO estimates that the reduction in manufacturers' revenues from title I would result in lower spending on research and development and thus reduce the introduction of new drugs. CBO's analysis of the bill is not complete; its preliminary estimate is that a reduction in revenues of \$0.5 trillion to \$1 trillion would lead to a reduction of approximately 8 to 15 new drugs coming to market over the next 10 years. (The Food and Drug Administration approves, on average, about 30 new drugs annually, suggesting that about 300 drugs might be approved over the next 10 years.) The overall effect on the health of families in the United States that would stem from increased use of prescription drugs but decreased availability of new drugs is unclear.

Continuing analysis of the effects of title I on other federal programs and on the commercial market will allow CBO and JCT to provide additional information. The agencies expect additional effects to include lower premiums in the commercial market and a corresponding increase in federal revenues. Also, because the agencies have not yet completed their estimates for the other titles of H.R. 3, CBO's estimates presented here exclude interactions with other provisions of the bill. The agencies' preliminary conclusion is that those other titles would further reduce direct spending and increase revenues over the 2023-2029 period.

CBO has not completed an estimate of the resources necessary for HHS to enter the negotiation process or meet other requirements of title I. Provision of those resources would be subject to appropriation action.

### **Background and Major Provisions of Title I**

Under current law, the Secretary of HHS may not interfere in negotiations between drug manufacturers and prescription drug plans (PDPs) that deliver the Part D benefit or require a particular formulary or price structure for PDP payments for drugs.<sup>1</sup>

Title I of H.R. 3 would require manufacturers of specific prescription drugs to negotiate with the Secretary for the prices of those drugs or face an excise tax on the sales of those drugs. Those negotiations would be designed to result in what the bill calls maximum fair prices, which would be available to health plans that participate in Medicare Part D and to health plans in the commercial market. The prices also would be available to Part D beneficiaries at the point of sale and to individuals enrolled in commercial insurance plans.

Maximum fair prices could not exceed 120 percent of the average price—called the average international market, or AIM, price—for a given drug in Australia, Canada, France, Germany, Japan, and the United Kingdom. The maximum fair price of a drug without an AIM price could not exceed 85 percent of the average manufacturer price (AMP), which is defined under section 1927(k)(1) of the Social Security Act as the manufacturers' average price charged to wholesalers and pharmacists for the retail class of trade. Thus, drugs without an AIM price would be subject to different rules about prices than other drugs.

To facilitate the negotiation process, H.R. 3 would grant the Secretary access to relevant data from manufacturers and other sources. For example, manufacturers would be required to provide the Secretary information about international prices or sales of a specific drug.

H.R. 3 would establish a target price for each drug equal to the lowest price available in any of the six reference countries or 80 percent of the AMP for a drug without a foreign price. If a manufacturer offered the target price or lower during the negotiation process, that amount would become the maximum fair price.

The Secretary would choose at least 25 drugs for negotiation each year beginning in 2021 for maximum fair prices that would be used in Part D in 2023. That list would be drawn from the 125 single-source drugs (drugs without generic or biosimilar competitors) with the highest federal spending in Part D and with the highest net spending in the commercial market (that is, spending net of rebates provided by drug manufacturers). The Secretary also would negotiate prices for insulin products in the first year. In later years,

---

1. Part D coverage is delivered through stand-alone PDPs or plans that integrate drug coverage with other benefits through Medicare Advantage, often called MA-PDs. For this estimate, the term *plan* includes both types of coverage. The noninterference clause is contained in section 1860D-11(i) of the Social Security Act.

a drug's maximum fair price would be set to increase by the overall inflation rate and would remain in effect until the drug faced generic or biosimilar competition.

H.R. 3 would establish rules for renegotiating maximum fair prices. It also would require payments to the Treasury when an AIM price for a drug subsequently becomes available for a drug that was initially marketed in the United States but not in any of the reference countries.

Pharmaceutical manufacturers that do not comply with certain requirements of title I would be subject to an excise tax on all sales of the selected drug.<sup>2</sup> The amount of tax would be a percentage of the price of each sale that would start at 65 percent, would increase by 10 percentage points for each 90 days of noncompliance, and would be capped at 95 percent. The Secretary of the Treasury would have the authority under an anti-abuse rule to determine that sales occurred during a day in a noncompliance period if the manufacturer structured sales specifically to avoid the excise tax.<sup>3</sup>

Manufacturers would be prohibited from deducting the excise tax payments in determining their income taxes. Thus, the combination of income taxes and excise taxes on the sales could cause the drug manufacturer to lose money if the drug was sold in the United States.

The legislation also includes civil monetary penalties for manufacturers that sell drugs at prices higher than the maximum fair price.

Because of the excise tax provisions in the bill, this analysis differs from some past analyses in which CBO concluded that providing broad negotiation authority by itself would probably have a negligible effect on federal spending. CBO has noted:

The key factor in determining whether negotiations would lead to price reductions is the leverage that the Secretary [of HHS] would have to secure larger price concessions from drug manufacturers than competing PDPs currently obtain. Negotiation is likely to be effective only if it is accompanied by some source of pressure on drug manufacturers to secure price concessions. For example, authority to establish a formulary could be a source of pressure. In the absence of

---

2. The excise tax applies to manufacturers, producers, and importers of selected drugs—all referred to in this analysis as manufacturers.

3. For example, if the first day of a noncompliance period was June 16, 2021, and the manufacturer reported all sales for that year on June 15, the Secretary could invoke the anti-abuse rule and recharacterize such sales as occurring on June 16.

such pressure, the Secretary's ability to issue credible threats or take other actions in an effort to obtain significant discounts would be limited.<sup>4</sup>

The provision of title I that would levy an excise tax for not entering into negotiations or for not agreeing to a maximum fair price provides leverage for the Secretary; it differentiates this analysis from previous ones.

### **Basis of Estimate**

For this analysis, CBO assumes that H.R. 3 would be enacted near the end of 2019 and that the process of negotiating selected drugs would begin in 2021. The resulting prices would take effect in 2023. CBO constructed its estimate for title I of H.R. 3 through a multiple-step process:

- Estimate current Part D spending on the 125 drugs with the highest net spending in Part D to identify drugs eligible for and likely to be included in negotiations.
- Analyze drug prices in the six reference countries, which involved reviewing data from multiple sources and separating drugs that have an international price from those that do not.
- Exclude spending for drugs that will face generic competition by 2023 from the list of 125 drugs and add spending to represent new drugs that will come to market.
- Compare 120 percent of the international price, when available, with the net 2017 Part D price. Use the drugs for which the difference between spending under net Part D prices and spending under international prices would be the greatest. CBO used those drugs, plus all insulin products, to create a group of drugs for which spending would be subject to negotiation in the first year.
- Develop a negotiation model that simulates the interactions of the Secretary and the drug companies to determine prices for drugs selected for negotiation involving international prices.
- Translate the output from that model into reductions in prices for prescription drugs subject to negotiation.
- Analyze the difference between the net Part D price and 85 percent of the AMP for drugs without international prices and estimate price reductions for those drugs for which the net Part D price exceeds 85 percent of the AMP.

---

4. See Congressional Budget Office, letter to the Honorable Charles Grassley concerning negotiation over drug prices in Medicare (May 17, 2019), pp. 1-2, [www.cbo.gov/publication/55270](http://www.cbo.gov/publication/55270). For more on Medicare price negotiation, see Congressional Budget Office, cost estimate for S. 3, the Medicare Prescription Drug Price Negotiation Act of 2007 (April 16, 2007), [www.cbo.gov/publication/18564](http://www.cbo.gov/publication/18564), and letter to the Honorable Ron Wyden, on issues regarding price negotiation in Medicare (April 10, 2007), [www.cbo.gov/publication/18550](http://www.cbo.gov/publication/18550).

- Adjust the estimate to account for manufacturers' responses to negotiated prices for selected drugs, which could affect prices as well as volume.
- Account for plans' responses to the opportunity to use the negotiated prices in their Part D offerings.

In general, the discussion that follows focuses on the effect of title I on total spending by all payers for benefits covered under the Part D program (see Table 2). The exception is at the end of the analysis, where CBO provides a preliminary estimate of the federal budgetary effect on Medicare.

As part of the estimating process, CBO consulted stakeholders, including representatives of the pharmaceutical industry and health plans and experts in the pharmaceutical marketplace and Part D. Although their input was important to understanding the incentives that would be created by the legislation and the likely outcomes, this analysis reflects CBO's assessments. Where the language in H.R. 3 is not clear, CBO discussed intent with Congressional staff and then made its own assessment about how those provisions would be implemented.

**Drugs Subject to Negotiation.** To estimate the effects of title I, CBO identified the drugs with the highest net spending in Part D, using data from 2017, the most recent year for which data are available. CBO has data on the drugs at the top of that list—both their list prices (that is, before any rebates or discounts that lower the cost to plans) and their net prices (that is, after rebates and discounts). CBO used those data to generate a list of the 125 drugs with highest spending in Medicare Part D, plus insulin products.

Because the legislation specifies 2023 as the first year negotiated prices would be in effect for Part D plans, CBO removed spending associated with drugs that will face generic (or biosimilar) competition between now and 2023 and added spending to reflect the introduction of new drugs that will reach the market by 2023.<sup>5</sup> After making those adjustments and using its current baseline projections of growth in prices and use in Part D, CBO estimates that spending for the remaining top 125 Part D drugs will be about \$68 billion in 2023, and it projected spending on those drugs under current law for the remainder of the 2024-2029 budget projection period.<sup>6</sup> CBO then divided that list of 125 drugs into those with an international price and those without.

**Foreign Price Comparison.** CBO conducted its own research and reviewed data on prescription drug prices, including data from a study published by the Committee on

---

5. Under the definition of single-source drugs in title I of H.R. 3, the arrival of a generic drug would automatically remove a drug from the pool of drugs subject to negotiation.

6. For CBO's current baseline projections for Medicare Part D, see Congressional Budget Office, "Details About Baseline Projections for Selected Programs, Medicare" (May 2, 2019), <https://go.usa.gov/xVeCU>.

Ways and Means and a study published in *Health Affairs*.<sup>7</sup> Using those data, CBO compared the net Medicare Part D price of drugs that could be subject to negotiation in Part D with the prices available in the six reference countries. Some of the drugs available with a foreign price in 2017 were available in all six countries, others were available in fewer countries, and some drugs were available in just one country. CBO's estimate reflects the assumption that the availability of at least one foreign price would be sufficient to create an AIM price for purposes of negotiation.

**Drugs With an International Price Comparison.** Because H.R. 3 would direct the Secretary to focus on drugs for which the potential savings would be the greatest when comparing Part D prices and foreign prices, CBO used those drugs from the list of 125 with the largest differentials between spending at net Part D prices and at 120 percent of international prices to estimate spending for the first group subject to negotiation. CBO also added all insulin products to that list, as mandated by H.R. 3. In 2017, Part D spending for that first group of drugs was about \$30 billion, CBO estimates, accounting for about 45 percent of spending for drugs on the list of 125 and about 25 percent of total Part D spending.

CBO then projected net spending for groups of drugs initially negotiated in each of the remaining years of the 2024-2029 period. In constructing those groups, CBO accounted for two factors:

- Some drugs on the current list of 125 will face generic competition by 2029 (the final year of CBO's baseline projection period); and
- Spending on some of the new drugs that enter the market will be sufficient to make them eligible for negotiation between manufacturers and the Secretary of HHS.

Because of the focus on drugs with high spending in the initial years of negotiation, spending for subsequent groups would tend to be lower, and thus potential savings for those groups also would tend to be lower. Over time, greater experience of HHS with the process of selecting drugs and negotiating prices could enable the Secretary to increase the number of drugs selected for negotiation.

---

7. See staff of the House Committee on Ways and Means, *A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices* (September 2019), <https://go.usa.gov/xVeff> (PDF, 1.2 MB); and So-Yeon Kang and others, "Using External Reference Pricing in Medicare Part D to Reduce Drug Price Differentials With Other Countries," *Health Affairs*, vol. 38, no. 5 (May 2019), pp. 804-811, <http://tinyurl.com/y4eejm6m>.

**Negotiation When International Prices Are Available.** CBO constructed a negotiation simulation to estimate resulting prices (accounting for the excise tax levied for not entering into negotiations or for not agreeing to a maximum fair price), in two main steps.

First, CBO estimated the distribution of prices projected to result in the absence of upper and lower limits. That distribution was estimated using a Nash bargaining model, commonly used to predict the outcome of two-party negotiations over the price of a good or service.<sup>8</sup> Prices were determined in the model based on the gains to each party from a completed negotiation, relative to a failed negotiation. The model's inputs consisted of current Part D drug prices, the price of alternative therapies (drugs that treat the same condition), and the value of negotiated drugs in extending life or improving health.<sup>9</sup>

The gain to the government from a successful negotiation was estimated to be the price of the next-best alternative therapy, plus the incremental value of using the drug instead of the alternative, measured in dollars. The manufacturer's gain was estimated to be the revenue from selling the drug. CBO and JCT anticipated that manufacturers would discontinue sales in the United States if the excise tax was levied on a drug, resulting in no revenue in that case. CBO assigned equal bargaining power to the two parties, on average, although sometimes that would not be the case. Thus, CBO anticipates that the two parties would, on average, divide equally the value resulting from a successful negotiation. In the model, that amount is equal to the price of the alternative plus the incremental value of using the drug. For example, if there was no corresponding alternative, CBO estimated that the negotiated price—given the possibility of paying the excise tax if the negotiation failed—would equal one-half of the dollar value that use of that drug would provide for extending life or improving the health of its user.

Second, CBO projected that upper and lower limits on prices would bind. In the model, negotiations are constrained by the limits specified in title I: For drugs for which international prices are available, the drug must cost no more than 120 percent of the AIM price and no less than 100 percent of the lowest price in any of the six reference

---

8. For more information, see Ken Binmore, Ariel Rubinstein, and Asher Wolinsky, "The Nash Bargaining Solution in Economic Modelling" *RAND Journal of Economics*, vol. 17, no. 2 (Summer 1986), pp. 176–188. [www.jstor.org/stable/2555382](http://www.jstor.org/stable/2555382). For a recent assessment of the performance of the model in predicting hospital prices, see Christopher Garmon, "The Accuracy of Hospital Merger Screening Methods," *RAND Journal of Economics*, vol. 48, no. 4 (Winter 2017), pp. 1068-1102, <https://doi.org/10.1111/1756-2171.12215>.

9. Although the Secretary would use different information from the data CBO used, the model was used to approximate the valuation that would occur. To estimate the incremental value of treatments, CBO used data from the Institute for Clinical and Economic Review. The value used for an additional year of life was \$400,000. The value used for improved health, measured as willingness to pay for an additional quality-adjusted year of life, was \$520,000. Both values are consistent with standard values recommended by a variety of federal agencies.

countries. If the negotiation simulation produced a price above 120 percent of the AIM price, the maximum fair price was set equal to the upper limit.

Using the model, CBO computed an index to characterize the average maximum fair price compared with its corresponding AIM price. That index is the average of the ratio of maximum fair price to the AIM price for all current drugs to which the maximum fair price formula can be applied. For some drugs, the data are insufficient to compute the maximum fair price formula. CBO estimates that negotiations for such drugs would be similar to those for the average drug for which a formula can be computed. CBO estimates that most prices would equal the upper limit, although some would not. According to the model, the average of negotiations for the 2023 group of drugs yields a maximum fair price that is 114 percent of the AIM price.

For some drugs with high prices but low value compared with alternatives, the Secretary might conclude that the appropriate price is less than the target price (the lowest price in a reference country). In that unlikely case, CBO expects, the manufacturer would offer the target price. Title I would require the Secretary to accept that offer; that outcome is incorporated into CBO's estimates.

**Drug Manufacturers' Response to Negotiation Involving International Prices.** CBO then analyzed the effects of the negotiation process on drug manufacturers and their pricing and marketing decisions in the United States and the AIM countries. CBO expects that the manufacturers of drugs selected for inclusion on the list would have some ability to adjust their prices once chosen by the Secretary. Over time, manufacturers also would try to reduce the amount of sales subject to negotiated prices. This estimate reflects CBO's assessment that manufacturers could find ways to mitigate—at least partially—the effects of the legislation on their revenues.

Under current law, manufacturers charge different prices based on purchasers' willingness to pay for a particular drug when they are able to do so. That can occur with consumers in a foreign country who may not be willing to spend as much, on average, as U.S. consumers are for a prescription drug—perhaps because of lower income, arrangements specific to local markets, or different consumer preferences. Instead of charging a high price and selling only a small quantity of a drug in some foreign market segments, drug manufacturers lower their prices in those markets.

Title I would create financial incentives for pharmaceutical manufacturers and foreign governments to limit the difference between the U.S. price and the foreign price that the manufacturer must disclose to the Secretary. CBO expects that drug manufacturers would generally raise their prices outside the United States over time for certain drugs. (Doing so would increase the upper bound on negotiated prices.) Because the legislation would require that manufacturers give a large portion of the U.S. market access to lower prices linked to foreign prices, CBO anticipates that manufacturers would be less willing to

offer the same discounts in foreign countries that they do now under current law.<sup>10</sup> CBO also expects that manufacturers would seek to limit how the discounts that they offer in foreign markets would be reflected in the prices used by the Secretary in negotiations.

The actions of drug manufacturers in foreign countries under the bill would be partially constrained by foreign governments, CBO expects. For example, those governments might restructure contracts and impose statutory requirements. Such changes could limit changes in net foreign prices or create larger differences between prices used to calculate AIM and net foreign prices actually paid.

CBO also expects manufacturers of new drugs to launch those drugs at higher prices in the United States to compensate, at least partially, for the results of negotiation. That response is reflected in CBO's estimate of the effects of negotiation and AMP-based pricing.

**Effect of Negotiation Involving International Prices on Drug Prices in Part D.** CBO then estimated net spending for drugs with the international prices selected for negotiation under title I. CBO estimates that reducing prices to 114 percent of the AIM price, on average, would reduce—by nearly 55 percent—the prices for the first group of drugs subject to negotiation. Because the first group would be selected on the basis of having the largest difference between prices in the United States and the reference countries, CBO estimates that the difference between 114 percent of the AIM price and U.S. prices is smaller for drugs that would constitute subsequent groups—about 50 percent for the second and 40 percent for the third and subsequent groups of drugs.

CBO estimated spending for each group of drugs with negotiated prices in the years after the establishment of maximum fair prices through 2029. To do so, CBO used the consumer price index for all urban consumers, or CPI-U, as specified in the bill. By comparing spending for drugs with prices as negotiated under title I with spending under current law, CBO estimates that negotiation for drugs with an AIM price would reduce spending by about \$276 billion over the 2023-2029 period. The first group of drugs would account for a large share of those savings—about two-thirds over that period.

Some of the drugs included in an annual group could compete against products outside that group. For example, many drugs are used to treat rheumatoid arthritis, and it is possible that one or two might be included in a given group, leaving the others for future negotiation. In such cases, CBO anticipates, the availability of maximum fair prices for

---

10. A “best price” provision established by the Omnibus Budget Reconciliation Act of 1990 gave Medicaid access to the lowest price paid by any private purchaser in the United States. CBO’s analysis found that the the largest discounts offered on many brand-name drugs shrank as a result of that provision. For more information, see Congressional Budget Office, letter to the Honorable Charles Grassley concerning the rebate Medicaid receives on brand-name prescription drugs (June 21, 2005), [www.cbo.gov/publication/16646](http://www.cbo.gov/publication/16646).

some drugs would prompt manufacturers of competing products to offer prescription drug plans greater discounts than they would in the absence of negotiation. CBO estimates that those lower prices for drugs that compete with drugs that have a maximum fair price would lead to a small increase in total savings—about \$10 billion over the 2023-2029 period.

**Existing Drugs Without Average International Market Prices.** CBO’s analysis also accounted for the fact that AIM prices would not be available for some drugs; the maximum fair prices for such drugs would be 85 percent of the AMP.

In 2023, for drugs on the list of 125 with the highest Part D spending that do not have an AIM price but do have a Part D net price above 85 percent of the AMP, CBO expects that the Secretary of HHS would engage in minimal negotiation, given the lack of information on international prices. As a result, the maximum fair price would be set at 85 percent of the AMP, a pricing strategy analogous to the statutory rebate used in Medicaid. Prices for those drugs would increase with inflation, unless negotiated after establishment of an AIM price. Over the 2023-2029 period, lowering Part D prices to 85 percent of the AMP for the 2023 group of relevant drugs would reduce total spending in the Part D program by \$40 billion, CBO estimates.

**New Drugs Without Average International Market Prices.** CBO also accounted for the entry of drugs without international prices in future years. CBO anticipates that prices for such a drug would be set at 85 percent of its AMP. CBO expects that manufacturers of drugs likely to be selected for negotiation would set a launch price—and thus establish an initial AMP—that would be higher than under current law. Nevertheless, CBO estimates, spending for those drugs would be lower than under current law, because that increase in AMP would offset only part of the savings that would result from paying 85 percent of the AMP. Over time, CBO expects, some of those drugs would be introduced in the six reference countries and thus an AIM price would be available. Accounting for AMP-based prices and eventual AIM-based prices, CBO estimates savings of \$61 billion for this group of drugs over the 2023-2029 period.

Once a drug’s AIM price is available, its manufacturer would repay the difference between the AMP and 200 percent of the AIM price. CBO analyzed current price differentials, considered the time lag until a drug is first introduced in one of the reference countries, and modeled manufacturers’ pricing strategies under those conditions. On that basis, CBO anticipates that manufacturers would, upon first foreign introduction, set the foreign price higher than 50 percent of the AMP so that repayment would not be triggered. Therefore, CBO does not estimate any budgetary effect from the repayment provision.

**Effect on Pharmaceutical Research and Development.** CBO also estimates that pharmaceutical manufacturers’ earnings would decline under title I, and manufacturers

would reduce spending on research and development as a result. Although CBO has not completed its analysis of the bill's implications for new-drug development, its preliminary estimate is that a reduction in revenues over the next 10 years of \$0.5 trillion to \$1 trillion would lead to a reduction of 8 to 15 new drugs coming to market.<sup>11</sup> It is difficult to know in advance the nature of these drugs or to quantify the effect of foregone innovation on health.

**Effect on Part D Plans.** Under current law, Part D plans negotiate with drug companies concerning prices and coverage. For example, a drug company might offer a 35 percent discount from a drug's list price in return for placement of that drug on a prescription drug plan's preferred formulary tier. Placement on a preferred tier usually results in lower cost sharing for beneficiaries and greater use of the drug. Drug manufacturers generally offer discounts in the form of rebates (retrospective payments to plans) and plans use those rebates to reduce beneficiaries' premiums.<sup>12</sup>

CBO expects that the negotiation process between the Secretary of HHS and manufacturers would have several implications for Part D plans. First, in many cases, maximum fair prices would be at or below the current net prices that PDPs can negotiate with drug companies. Those plans might be able to negotiate additional discounts through management tools, including preferred formulary status and prior authorization, as they do under current law. CBO estimates that those additional discounts would be small. PDPs are not required to cover drugs with maximum fair prices, but CBO expects that lower prices would make those drugs attractive to plans.

Second, maximum fair prices must be available to Part D beneficiaries at the point of sale. For title I, CBO estimated that manufacturers' discounts would generally continue to be in the form of rebates from drug companies to PDPs, not as reductions to manufacturers' list prices, and that plans would pass those discounts along to beneficiaries. (Reductions in manufacturers' list prices would reduce manufacturers' revenues for sales not subject to the maximum fair price.)

---

11. Those estimates are based on Pierre Dubois and others, "Market Size and Pharmaceutical Innovation," *RAND Journal of Economics*, vol. 46, no. 4 (Winter 2015), pp. 844-871, <https://doi.org/10.1111/1756-2171.12113>; Margaret E. Blume-Kohout and Neeraj Sood, "Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development," *Journal of Public Economics*, vol. 97 (January 2013), pp. 327-336, <https://doi.org/10.1016/j.jpubeco.2012.10.003>; and Daron Acemoglu and Joshua Linn, "Market Size in Innovation: Theory and Evidence From the Pharmaceutical Industry," *Quarterly Journal of Economics*, vol. 119, no. 3 (August 2004), pp. 1049-1090, <https://www.jstor.org/stable/25098709>.

12. Plans do not purchase drugs directly; Part D beneficiaries fill prescriptions through pharmacies. Determining payments from plans to pharmacies is a separate transaction from that between manufacturers and plans; pharmacies cannot usually purchase drugs at prices that reflect negotiated discounts. For more on the rebate system, see Ross Margulies, "Origins of the Current Rebate System and Implications of Changes to Existing Safe Harbor Regulations" (presentation at Alliance for Health Policy, November 28, 2018), <http://tinyurl.com/y6a28l2k>.

Overall, CBO expects, PDPs would generally pay less for prescription drugs with maximum fair prices than they do for those drugs under current law. CBO also expects beneficiaries' premiums and cost sharing would be lower under title I because of lower plan drug costs. (CBO has not yet quantified the average reduction.)

**Implementation Costs.** Title I of H.R. 3 would require that Part D cost sharing be based on the maximum fair price and that pharmacies be repaid for any difference between their acquisition cost and the maximum fair price. Because CBO estimates that manufacturers would not reduce list prices to the maximum fair price, manufacturers would instead repay pharmacies, either directly or through plans. After discussing this provision with stakeholders and experts in the prescription drug market, CBO concluded that the existing system of rebates and discounts does not easily facilitate those new transactions between manufacturers, pharmacies, and plans. The resources needed to create and operate such a system would increase total spending by about \$3 billion over the 2023-2029 period, CBO estimates.

**Total Effect on Federal Spending for Medicare Part D.** In CBO's analysis, changes in drug prices in Part D would be fully reflected in plan bids and cost-sharing for beneficiaries who are entitled to low-income subsidies.<sup>13</sup> Accounting for the effects of the negotiation process on drug prices, drug manufacturers' responses, and Part D plan behavior, CBO estimates that, on net, title I would decrease total spending for Part D by about \$369 billion over the 2023-2029 period. Beneficiaries' premiums and cost sharing would be lower under title I of H.R. 3. After accounting for their savings, CBO estimates that title I would decrease federal direct spending on Part D by about \$303 billion.

**Effect of Changes in Prescription Drug Use Among Part D Beneficiaries.** Prescription drug prices affect out-of-pocket costs. Beneficiaries who decide not to fill some prescriptions because of high costs could be more likely to fill prescriptions and adhere to their prescribed drug regimens if costs were lower, as CBO anticipates they would be under title I. CBO estimates that the additional Part D use arising from the provision would increase federal spending for beneficiaries who are not enrolled in the low-income subsidy program over the 2020–2029 period by about \$27 billion.

**Reduction in Spending for Other Medical Services.** Policy changes that increase Medicare beneficiaries' use of prescription drugs would reduce spending for other Medicare services in CBO's assessment. CBO estimates that a 1 percent increase in the quantity of prescriptions filled would reduce spending for services covered by Medicare Part A and Part B (Hospital Insurance and Medical Insurance) by about 0.2 percent.

---

13. On average, the federal government pays 75 percent of the cost of Part D benefits and beneficiaries pay 25 percent. The government pays virtually all costs for beneficiaries who receive low-income subsidies.

Because title I generally would reduce out-of-pocket spending for prescription drugs, CBO anticipates that beneficiaries would fill more prescriptions. In turn, title I would reduce federal direct spending on Medicare's Parts A and B by about \$42 billion over the 2023-2029 period.<sup>14</sup>

**Excise Tax for Noncompliance.** JCT analyzed the excise tax outlined in section 102 of title I of H.R. 3 as described above.

JCT does not estimate any significant increase in revenues from the excise tax specified in title I. Given the potential financial impact of the excise tax, JCT expects, all manufacturers would either participate in the negotiation process or pull a particular drug out of the U.S. market entirely.

**Civil Monetary Penalties.** CBO does not estimate any increase in revenues from imposition of civil monetary penalties. CBO anticipates that manufacturers that agree to maximum fair prices would make those prices available as required by title I.

### **Uncertainty**

Because the negotiation process described in title I would represent significant changes to Medicare Part D, CBO's estimate is subject to considerable uncertainty, in particular as follows:

- The Secretary of HHS could implement the provisions of title I in ways that differ from CBO's interpretation. For example, in implementing the negotiation process, the Secretary could choose drugs on a class-by-class basis (for example, all drugs that treat rheumatoid arthritis) to leverage competition among the manufacturers. CBO's analysis is based on the share of the total Part D market that would be affected; it does not reflect a list of specific drugs negotiated at a specific point in time.
- The responses of PDPs to the negotiated prices could differ from those CBO anticipates.
- Pharmaceutical manufacturers might respond to the negotiation process in ways that CBO has not considered.
- Exchange rates may fluctuate in ways that significantly affect foreign prices relative to U.S. prices. In addition, foreign price inflation could be different from historical trends.
- Enactment of title I could result in litigation. CBO's analysis reflected that possibility by reducing the estimate of expected savings for the first three years

---

14. For more on this topic, see Congressional Budget Office, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services* (November 2012), [www.cbo.gov/publication/43741](http://www.cbo.gov/publication/43741).

Honorable Frank Pallone Jr.  
Page 15

(2023-2025) and by increasing the savings in the subsequent three years by a corresponding amount. The actual effects could be smaller or larger.

I hope this preliminary analysis is useful to the Congress in its deliberations. As noted above, our analysis of H.R. 3 is ongoing. If you have any questions, please contact me.

Sincerely,



Phillip L. Swagel  
Director

Enclosure

cc: Honorable Greg Walden  
Ranking Member  
Committee on Energy and Commerce

Honorable Richard Neal  
Chairman  
Committee on Ways and Means

Honorable Kevin Brady  
Ranking Member  
Committee on Ways and Means

Honorable Bobby Scott  
Chairman  
Committee on Education and Labor

Honorable Virginia Foxx  
Ranking Member  
Committee on Education and Labor

**Table 1.**  
**Preliminary Estimate of Changes in Federal Spending on Medicare Under Title I of H.R. 3**

	By Fiscal Year, Billions of Dollars										2020-2029
	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	
	<b>Decreases (-) in Direct Spending</b>										
Changes in Federal Spending for Medicare Part D benefits	n.a.	n.a.	n.a.	-8	-14	-18	-51	-65	-83	-63	-303
Reduction in Spending for Other Medical Services <sup>a</sup>	n.a.	n.a.	n.a.	-1	-2	-3	-7	-8	-9	-11	-42
<b>Total Changes</b>	<b>n.a.</b>	<b>n.a.</b>	<b>n.a.</b>	<b>-9</b>	<b>-17</b>	<b>-21</b>	<b>-58</b>	<b>-73</b>	<b>-93</b>	<b>-74</b>	<b>-345</b>

Sources: Congressional Budget Office; staff of the Joint Committee on Taxation.

Components may not sum to totals because of rounding; n.a. = not applicable.

For this analysis, CBO assumes that H.R. 3 would be enacted near the end of 2019. All estimates are consistent with CBO's May 2, 2019, Medicare baseline projections.

- a. CBO estimates that an increase in the number of prescriptions filled by beneficiaries would cause Medicare's spending on medical services to decline. This medical offset reduces spending in Parts A and B of Medicare (Hospital Insurance and Medical Insurance). See Congressional Budget Office, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services* (November 2012), [www.cbo.gov/publication/43741](http://www.cbo.gov/publication/43741).

**Table 2.**  
**Preliminary Estimate of Changes in Total Spending on Prescription Drugs Covered by Medicare Part D Under Title I of H.R. 3**

	By Fiscal Year, Billions of Dollars										2020-2029
	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	
	<b>Increases or Decreases (-) in Total Spending</b>										
Existing Drugs, With AIM Prices, Selected for Negotiation	n.a.	n.a.	n.a.	-9	-15	-18	-50	-61	-73	-50	-276
Existing Drugs Without AIM Prices, Selected for Payment at 85 Percent of the AMP	n.a.	n.a.	n.a.	-1	-2	-2	-7	-9	-11	-8	-40
New Drugs Selected for Payment at 85 Percent of the AMP <sup>a</sup>	n.a.	n.a.	n.a.	0	-1	-2	-7	-12	-20	-20	-61
Other Effects <sup>b</sup>	n.a.	n.a.	n.a.	0	0	0	1	2	2	1	7
<b>Total Changes</b>	<b>n.a.</b>	<b>n.a.</b>	<b>n.a.</b>	<b>-10</b>	<b>-17</b>	<b>-22</b>	<b>-62</b>	<b>-79</b>	<b>-102</b>	<b>-77</b>	<b>-369</b>
<b>Memorandum:</b>											
Changes in Federal Spending for Part D Benefits	n.a.	n.a.	n.a.	-8	-14	-18	-51	-65	-83	-63	-303

Sources: Congressional Budget Office; staff of the Joint Committee on Taxation.

Components may not sum to totals because of rounding.

For this analysis, CBO assumes that H.R. 3 would be enacted near the end of 2019. All estimates are consistent with CBO's May 2, 2019, Medicare baseline projections. Estimates include changes in Part D spending for all payers, including cost sharing and premiums paid by beneficiaries.

AIM price = average international market price; AMP = average manufacturer price; n.a. = not applicable.

- a. Those drugs could be selected for negotiation based on the AIM price.
- b. Other effects include new administrative costs for prescription drug plans, increased use of prescription drugs, and additional discounts negotiated by plans.