Congressional Budget Office
Cost Estimate

September 17, 2019

At a Glance

H.R. 2296, METRIC Act

As ordered reported by the House Committee on Energy and Commerce on July 17, 2019

By Fiscal Year, Millions of Dollars	2019	2019-2024	2019-2029
Direct Spending (Outlays)	0	-1,380	-3,490
Revenues	0	0	0
Increase or Decrease (-) in the Deficit	0	-1,380	-3,490
Spending Subject to Appropriation (Outlays)	0	*	Not estimated

Statutory pay-as-you-go procedures apply?	Yes	**Mandate Effects**	
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2030?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	No

* = between zero and $500,000

The bill would

- Require pharmaceutical manufacturers to explain price increases for their products
- Instruct the Secretary of Health and Human Services to make available to the public information about discounts available to pharmacy benefit managers (PBMs)
- Direct the Federal Trade Commission to study the pharmaceutical supply chain
- Expand pharmaceutical manufacturers' reporting of their averages sales prices to Medicare
- Permit the HHS Secretary to disclose information about prescription drug samples to select federal agencies
- Prohibit pharmaceutical manufacturers from giving samples of opioids to physicians and other prescribers
- Make more information available to Medicare beneficiaries and providers about prescription drug options

Estimated budgetary effects would primarily stem from

- Requiring drug manufacturers to report more data on average sales prices to Medicare

Detailed estimate begins on the next page.

Bill Summary

H.R. 2296 would require prescription drug manufacturers to submit information—including data about drug prices, price increases, and distribution of samples—to the Department of Health and Human Services (HHS). In addition, the bill would direct the Secretary of HHS to publish information about prescription drug prices and discounts.

Estimated Federal Cost

The estimated budgetary effect of H.R. 2296 is shown in Table 1. The costs of the legislation fall within budget function 570 (Medicare).

Table 1.
Estimated Budgetary Effects of H.R. 2296

	By Fiscal Year, Millions of Dollars												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2019-2024	2019-2029
Decreases (-) in Direct Spending													
Estimated Budget Authority	0	-50	-300	-340	-340	-350	-380	-400	-420	-470	-440	-1,380	-3,490
Estimated Outlays	0	-50	-300	-340	-340	-350	-380	-400	-420	-470	-440	-1,380	-3,490

Basis of Estimate

For this estimate, CBO assumes that the bill will be enacted near the end of fiscal year 2019.

Direct Spending

In total, CBO estimates that enacting H.R. 2296 would reduce direct spending by $3.5 billion over the next ten years. Almost all of those savings would stem from one provision as discussed below.

Require Manufacturers to Report Drug Pricing with Respect to Drugs Under the Medicare Program. The bill would increase reporting requirements for manufacturers of products covered under Part B. The Center for Medicare & Medicaid Services (CMS) uses such data to calculate average sales prices (ASPs)—the average prices at which manufacturers sell their products. CMS uses ASPs to calculate Medicare payments for infused and injected drugs. When ASP data are not available for a drug—in general, for the six-month period beginning when it is first marketed or if the ASP data are otherwise unavailable—Medicare's payments usually are based on the Wholesale Acquisition Cost (WAC). WACs are generally higher than ASPs. The bill would direct, through changes described below, that the ASP be used as the basis of calculating Medicare payments for some drugs instead of the WAC. CBO estimates those changes would reduce federal spending by about $3.5 billion over the 2019-2029 period.

The bill would require manufacturers to report ASP data about drugs that are currently classified as medical devices by the Food and Drug Administration (FDA). Current law requires manufacturers with drug rebate agreements (as required for drugs that are covered by state Medicaid programs) to report their ASP data, but products that the FDA regulates as medical devices, do not require Medicaid rebate agreements. Consequently, they are exempt from ASP reporting. Some manufacturers of those products have stopped reporting ASPs to CMS.[1]

The only products currently covered by that exception incorporate hyaluronic acid, used for osteoarthritis of the knee. CBO analyzed data from the CMS website concerning payment for and use of hyaluronic acid products, along with information on the difference between their ASPs (when they were available) and WACs. CBO estimates that requiring those manufacturers to report ASP data would result in the use of lower, ASP-based benchmarks for Part B drug payment and would reduce direct spending.

Reporting and Penalties. Several provisions of the bill would require other reporting to HHS by drug manufacturers; enacting those provisions would not have a significant cost, CBO estimates.

- Drug manufacturers would have to explain increases in drug prices that exceed a threshold amount established in the bill. The manufacturer also would be obliged to report how much it had spent on manufacturing the drug, its overall investments in research and development, and its net profits for the drug from the time of introduction to the market. Failure to submit that information could subject the manufacturer to a civil monetary penalty of $75,000 for each day that the manufacturer did not report.
- The bill would require drug manufacturers to report data about drug samples they supply to providers for starting patients on drugs and saving them from initial costs and pharmacy visits. The HHS Secretary would make that information available upon request to select federal agencies, including the HHS Inspector General, the Medicare Payment Advisory Commission (MedPAC), and CBO. H.R. 2296 also would prevent the distribution of opioids through samples.
- Under current law, health plans and pharmacy benefit managers that participate in Medicare Part D or in the health insurance marketplaces established under the Affordable Care Act (ACA) must report to the Secretary on the aggregated amounts they negotiate in discounts, rebates, and price concessions. The ACA requires the Secretary to keep that

1. For more information, see Medicare Payment Advisory Commission, the MedPAC blog, “Improving Medicare’s payment for Part B drug: Requiring manufacturer reporting of sales price data,” June 14, 2019, www.medpac.gov/-blog-/requiring-reporting-of-sales-price-data/2019/06/14/payment-for-part-b-drugs

information confidential. H.R. 2296 would direct the Secretary to make that information public after two years, with restrictions on plan- or drug-specific information.

- The bill would require the Federal Trade Commission (FTC) to report to the Congress on the pharmaceutical supply chain and mergers within the industry. The FTC would report within one year of enactment of the legislation.

CBO estimates that requiring manufacturers to report on drug samples and discounts would not affect Medicare spending or spending by other payers. Although the legislation would impose civil monetary penalties on manufacturers who fail to meet new reporting requirements, CBO expects that all manufacturers would meet reporting requirements. Therefore, CBO estimates that no penalties would be collected and enacting that provision would have no budgetary effect.[2]

H.R. 2296 also would require Medicare and prescription drug plans (PDP) that participate in Part D to develop tools that allow beneficiaries and providers to compare prescription drug choices at the time a prescription is written. For example, the provider and beneficiary would be able to see if a specific drug was included on the formulary of the beneficiary's prescription drug plan (PDP). CBO estimates that the provision of information would not have a significant effect on spending for prescription drugs under Medicare Part D. In addition, the provision would codify a final rule issued by the Administration.

Spending Subject to Appropriation

Many of the activities required by H.R. 2296 would add to the responsibilities of the Secretary of HHS in managing Medicare and overseeing the health insurance marketplaces. Funding for most program management activities is subject to appropriation. In CBO's judgment, the new activities required by H.R. 2296 would not significantly increase the department's workload, and thus implementing the bill would not result in significant additional discretionary costs. In the same way, CBO estimates that the studies required of FTC and MedPAC would not significantly increase those agencies' workload.

Pay-As-You-Go Considerations: None.

Increase in Long-Term Deficits: None.

Mandates: None.

2. In general, such penalties, if collected, may be spent without further appropriation action.

Previous CBO Estimate

On June 24, 2019, CBO published an estimate for H.R. 2113, the Prescription Drug STAR Act, which also included a provision requiring manufacturers to report ASP data to the HHS Secretary. In that estimate, CBO's estimate reflected recent regulatory guidance from the Food and Drug Administration (FDA) about possible reclassification of a specific product, hyaluronic acid, which is regulated as a device. Regulating hyaluronic acid products as drugs could affect whether their manufacturers report ASP data to HHS. Since publishing that estimate, CBO has learned that any FDA reclassification would not affect products already on the market. Therefore, CBO's estimated savings for the ASP reporting provision in H.R. 2296 are higher than the savings estimated in H.R. 2113.[3]

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3. See Congressional Budget Office, H.R. 2113, the Prescription Drug STAR Act, www.cbo.gov/publication/55392