Congressional Budget Office
Cost Estimate

June 24, 2019

At a Glance

H.R. 2113, Prescription Drug STAR Act

As ordered reported by the House Committee on Ways and Means on April 9, 2019

By Fiscal Year, Millions of Dollars	2019	2019-2024	2019-2029
Direct Spending (Outlays)	0	-677	-1,727
Revenues	0	0	0
Deficit Effect	0	-677	-1,727
Spending Subject to Appropriation (Outlays)	0	0	0

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

The bill would

- Require prescription drug manufacturers to provide information to the Secretary of Health and Human Services (HHS) about the factors (including expenditure and revenue items) that contribute to increases in drug prices that exceed thresholds established in the bill
- Require drug manufacturers to disclose information about samples provided to physicians
- Direct the Secretary of HHS to study spending on drugs furnished in hospitals and to publish data about prices and discounts under Medicare Part D
- Require drug manufacturers to report the sales prices used to calculate payments for drugs covered under Medicare Part B

Estimated budgetary effects would primarily stem from

- Requiring drug manufacturers to report prices used to calculate Medicare payment rates for their products administered in physicians' offices and hospital outpatient departments
- Appropriating $3 million to the Secretary of HHS to study hospitals' drug costs

Areas of significant uncertainty include accurately projecting

- The ways that new disclosure requirements would affect the behavior of drug manufacturers or medical providers
- Drug manufacturers' responses to possible changes in the regulatory status of certain products

Detailed estimate begins on the next page.

Bill Summary

H.R. 2113 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. 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. 2113 is shown in Table 1. The costs of the legislation fall within budget function 570 (Medicare).

Table 1.
Estimated Budgetary Effects of H.R. 2113

	By Fiscal Year, Millions of Dollars												
	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2019-2024	2019-2029
Increases or Decreases (-) in Direct Spending													
Require Manufacturers to Report Drug Pricing With Respect to Drugs Under the Medicare Program													
Estimated Budget Authority	0	-20	-150	-170	-170	-170	-190	-200	-210	-230	-220	-680	-1,730
Estimated Outlays	0	-20	-150	-170	-170	-170	-190	-200	-210	-230	-220	-680	-1,730
Report on Inpatient Hospital Drug Costs													
Budget Authority	0	3	0	0	0	0	0	0	0	0	0	3	3
Estimated Outlays	0	3	0	0	0	0	0	0	0	0	0	3	3
Total Changes in Direct Spending													
Estimated Budget Authority	0	-17	-150	-170	-170	-170	-190	-200	-210	-230	-220	-677	-1,727
Estimated Outlays	0	-17	-150	-170	-170	-170	-190	-200	-210	-230	-220	-677	-1,727

Components may not sum to totals because of rounding.

Basis of Estimate

H.R. 2113 would increase the information available to the Secretary of HHS, researchers, and the general public about prescription drug prices and spending. For this estimate, CBO assumes that the bill will be enacted near the end of fiscal year 2019.

Direct Spending

Two provisions of H.R. 2113 would affect direct spending.

Require Manufacturers to Report Drug Pricing with Respect to Drugs Under the Medicare Program. The bill would enhance reporting requirements for manufacturers of products covered under Part B. CMS uses such data to calculate average sales prices (ASPs)—the average prices at which manufacturers sell their products. ASPs are the basis of Medicare's payments for infused and injected drugs. When ASP data are not available for a drug—for example, when it is first marketed and no sales have occurred—Medicare's payments usually are based on the Wholesale Acquisition Cost (WAC). WACs are generally higher than ASPs. The bill would make changes, as described below, which would have the effect of establishing the ASP for some drugs that are currently paid for based on the WAC. CBO estimates those changes would reduce federal spending by $1.7 billion over the 2019-2029 period.

To ensure full reporting of ASP data to the Secretary and thus enable ASP-based payment, manufacturers with drug rebate agreements (as required for drugs that are covered by state Medicaid programs) also must report their ASP data to CMS, with some exceptions. In particular, under current law, the Medicaid rebate applies to products that are approved as drugs under the Federal Food, Drug, and Cosmetic Act. Among the products that do not require Medicaid rebate agreements and that are therefore exempt from ASP reporting are those that incorporate hyaluronic acid, which is used to treat osteoarthritis of the knee. The Food and Drug Administration (FDA) regulates such products as medical devices, not as drugs, although Medicare pays for them as drugs. Medicare Part B currently covers several such products. Recently, some manufacturers of those products stopped reporting ASP data to CMS. As a result, Medicare is paying for a subset of hyaluronic acid products based on their higher WACs.[1]

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 manufacturers to report ASP data would reduce direct spending by about $3.6 billion over the 2019-2029 period, a result of lower, ASP-based benchmarks for Part B drug payment.

However, in December 2018, the FDA published a notice in which it indicated that it is considering regulating hyaluronic acid products as drugs, not as devices.[2] The implications of that notice for products currently on the market are unclear. It is possible that current products would be considered drugs and require rebate agreements, thus triggering

1. For more information, see Medicare Payment Advisory Commission, The MedPAC Blog, "Improving Medicare's payment for Part B drugs: Requiring pharmaceutical manufacturer reporting of sales price data," June 14, 2019, http://www.medpac.gov/-blog-/requiring-reporting-of-sales-price-data/2019/06/14/payment-for-part-b-drugs

2. See Food and Drug Administration, "Intent to Consider the Appropriate Classification of Hyaluronic Acid Intra-articular Products Intended for the Treatment of Pain in Osteoarthritis of the Knee Based on Scientific Evidence," *Federal Register* (December 18, 2018), vol. 83, no. 242, pp. 64844-64845, https://go.usa.gov/xyx3Q.

mandatory ASP reporting. Accounting for the possibility that the FDA could decide to regulate those products as drugs, CBO has lowered its estimated savings of this bill to $1.7 billion over the 2019-2029 period, to reflect a 50 percent probability that the hyaluronic acid products would come to be regulated as drugs under current law.

Report on Inpatient Hospital Drug Costs. The bill also would appropriate $3 million to the Secretary of HHS to study spending for drugs used by hospital inpatients. CBO estimates that implementing that provision would increase direct spending by $3 million over the 2019-2029 period (see Table 1).

Reporting and Penalties. Other provisions of the bill would require other reporting by pharmaceutical manufacturers:

- 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 $10,000 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 to enable providers to start patients on drugs and to save patients from initial costs and pharmacy visits.
- 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 information confidential. H.R. 2113 would direct the Secretary to make that information public after two years, with restrictions on plan- or drug-specific information.

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 the bill would have no budgetary effect.[3]

3. In general, however, such penalties, once collected, may be spent without further appropriation action. As a result, CBO usually estimates new mandatory outlays in an amount that offsets those revenues.

Spending Subject to Appropriation

Many of the activities required by H.R. 2113 would add to the responsibilities of the Secretary of HHS in managing Medicare and in 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. 2113 would not significantly increase the department's workload and thus implementing the bill would not result in significant additional discretionary costs.

Uncertainty

It is possible that the information made available under H.R. 2113 could change the behavior of drug manufacturers or medical providers in ways that CBO did not anticipate. For example, requiring manufacturers to report their sample distributions could make them less likely to provide samples, or it could make providers less willing to accept them. However, CBO estimates that any such behavioral effect would be small enough to have no significant budgetary effect.

As noted above, the FDA regulatory status of certain products is uncertain, and CBO's estimate reflects the possibility that their classification could change in such a way that manufacturers would be required to report ASP data rather than WAC data. If, however, FDA regulations do not change, savings would probably be higher than CBO has estimated.

Pay-As-You-Go Considerations

The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. The net changes in outlays that are subject to those pay-as-you-go procedures are shown in Table 1.

Increase in Long-Term Deficits: None

Mandates

H.R. 2113 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). Participation in Medicare is voluntary for private entities. Therefore, the reporting requirements in the bill arising from participation in those programs would not constitute private-sector mandates as defined in UMRA.

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