Congressional Budget Office
Cost Estimate

September 16, 2024

At a Glance

H.R. 1352, Increasing Access to Biosimilars Act of 2023

As ordered reported by the House Committee on Energy and Commerce on December 6, 2023

By Fiscal Year, Millions of Dollars	2024	2024-2029	2024-2034
Direct Spending (Outlays)	0	233	227
Revenues	0	0	0
Increase or Decrease (-) in the Deficit	0	233	227
Spending Subject to Appropriation (Outlays)	0	0	not estimated

Increases *net direct spending* in any of the four consecutive 10-year periods beginning in 2035?	No	Statutory pay-as-you-go procedures apply?	Yes
Increases *on-budget deficits* in any of the four consecutive 10-year periods beginning in 2035?	No	**Mandate Effects**	
		Contains intergovernmental mandate?	No
		Contains private-sector mandate?	No

The bill would

- Direct the Department of Health and Human Services to implement a demonstration project that would increase Medicare payment rates for biosimilar products covered under Medicare Part B

Estimated budgetary effects would mainly stem from

- Increasing Medicare payment rates for biosimilars
- Preventing increases in cost sharing for beneficiaries

Areas of significant uncertainty include

- Predicting payment rates under the demonstration
- Identifying which biosimilars would be used in the demonstration
- Projecting effects on biosimilar use and prices after the demonstration

Detailed estimate begins on the next page.

Bill Summary

H.R. 1352 would direct the Department of Health and Human Services (HHS) to implement a three-year demonstration project in which payment rates for biosimilar drugs under Medicare Part B (Medical Insurance) would rise during the demonstration period. Biosimilars are drugs that are similar enough to biologic drugs that they can be used instead of the original products, which are produced from organisms rather than by chemical synthesis. Under the bill, the Secretary of HHS could not implement the demonstration project unless the chief actuary of the Centers for Medicare & Medicaid Services (CMS) could certify that payments under the demonstration would not increase Medicare spending.

Estimated Federal Cost

The estimated budgetary effect of H.R. 1352 is shown in Table 1. The costs of the legislation fall within budget function 570 (Medicare).

Table 1.
Estimated Budgetary Effects of H.R. 1352

	By Fiscal Year, Millions of Dollars												
	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2024-2029	2024-2034
Increases in Direct Spending													
Estimated Budget Authority	0	0	59	79	70	25	-1	-3	-1	-1	*	233	227
Estimated Outlays	0	0	59	79	70	25	-1	-3	-1	-1	*	233	227

Components do not sum to totals because of rounding; * = between -$500,000 and $500,000.

Basis of Estimate

For this estimate, CBO assumes that H.R. 1352 will be enacted by the end of fiscal year 2024 and that the demonstration project would be conducted in calendar years 2026, 2027, and 2028. CBO anticipates that the project would include only biosimilars with prices below those of the reference drugs. To develop the estimate, CBO referred to the average sales price (ASP) of biologics and biosimilars covered under Medicare Part B as reported for April 2024.[1]

CBO estimates that there is a 50 percent probability that the bill's demonstration project would not be implemented because CMS's chief actuary would not certify that the demonstration did not result in higher spending for Medicare. CBO estimates a 50 percent probability that the demonstration would be implemented. If the demonstration did proceed,

1. See Centers for Medicare & Medicaid Services, "Medicare Part B Drug Average Sales Price: ASP Pricing Files, April 2024 ASP Pricing File" (final file, June 21, 2024), https://tinyurl.com/ybh7azpk.

CBO estimates, the outcome would be a higher probability for increases than for decreases in spending.

Background

Medicare Part B covers drugs that are administered via infusion or injection in clinical settings such as a physicians' offices or hospital outpatient departments. Providers purchase the drugs from manufacturers, wholesalers, and other third parties, and Medicare makes reimbursements to those providers.

Under current law, Medicare's payments are based on the ASP—the price received by the manufacturer, inclusive of specified discounts, plus a 6 percent markup. For biosimilars, the rate is the ASP plus a percentage of the reference drug's ASP. If the ASP of the innovator biologic is $100 and the ASP of the biosimilar is $80, for example, the Medicare payment for the innovator product is $106 and the payment for the biosimilar is $88.[2] Because the add-on percentage is based on the innovator product's price, providers are not financially disadvantaged if they choose the biosimilar.[3]

Medicare Part B currently reimburses providers for more than 20 biosimilar products—many of which already have largely replaced innovator products: For some drugs, more than 75 percent of use is in biosimilars. Medicare's payments for biosimilars—as a share of innovator payment rates—vary widely. In some cases, the rate for a biosimilar is higher than the innovator price; in others, it can be more than 60 percent lower.

H.R. 1352 would allow HHS significant discretion in adjusting payment rates for biosimilars. CBO expects that payments for lower-priced biosimilars would rise modestly. Those higher payments would make using biosimilars more profitable to physicians, which could encourage providers to substitute lower-cost biosimilars for higher-cost biologics. Although that change could reduce federal spending, CBO expects that the substitution effects would be limited because providers already have a significant financial incentive to use biosimilars.

Direct Spending

On net, CBO estimates, H.R. 1352 would increase direct spending by $227 million over the 2024-2034 period through a combination of higher traditional Medicare spending on biologics and higher payments to Medicare Advantage plans. (Spending in Medicare Advantage is linked to spending in fee-for-service Medicare; when spending in traditional Medicare rises, spending for Medicare Advantage rises as well.) H.R. 1352 would direct

2. For new biologics, the add-on is 8 percent; it lasts for five years. That add-on applies only if the biosimilar ASP is lower than the innovator ASP. After five years, the add-on is 6 percent.

3. Nonfinancial reasons can influence providers' choices, however. For example, a health plan might prefer the innovator biologic, which means that a participating provider would tend to stock that product.

HHS to implement a demonstration in which the Medicare rate for biosimilar drugs under Medicare Part B would rise for a period of three years.

Under the demonstration, HHS would increase the add-on percentage, resulting in a biosimilar payment rate that is somewhere between the current biosimilar payment and the innovator payment. CBO analyzed various scenarios for the demonstration by modeling larger or smaller changes in payment rates and rates of use for particular drugs.

In evaluating the likelihood of each scenario, CBO considered the trade-off between payment rates and use. Increasing the add-on payment could encourage more use of biosimilars but also would erode the budgetary savings from using lower-cost products; CBO assigned a low probability to those scenarios. CBO also assigned a low probability to scenarios with a small increase in payment rates but large shifts in use. Weighing those considerations, CBO anticipates that the most likely scenario is a small increase in the payment rate—to ASP plus 10 percent—and a small increase in the rate of biosimilar use.

Accounting for various scenarios, CBO estimates that the demonstration would lead to an increase in direct spending of about $520 million over the 2025-2034 period, about half of which would result from higher payments to Medicare Advantage plans. In general, the increase in direct spending would be partially offset by some new biosimilar use, some of which would persist after the demonstration. The effect of a rise in biosimilar use would be a reduction in direct spending of about $70 million over the 2024-2034 period, CBO estimates. The net effect would be an increase in direct spending of about $450 million over the 2024-2034 period.

Because participation in the demonstration would be voluntary, CBO expects that providers would participate if it was in their interest to do so. Therefore, the cost of paying more to providers already using biosimilars would likely exceed the savings from encouraging greater biosimilar use by providers who currently choose innovator products.

CBO also accounted for a scenario in which there was no demonstration because CMS's chief actuary determined that the bill's requirement to not increase federal spending could not be met. It is not clear to CBO that HHS could design a demonstration meeting that condition. If cost sharing cannot be used to offset increased direct spending under the demonstration, the federal government would need to cover more than 80 percent of the actual cost of the services beneficiaries receive, which would increase federal spending.

CBO estimated the effect of not having a demonstration by reducing the direct spending estimate by 50 percent. CBO thus estimates that enacting H.R. 1352 would increase direct spending by $227 million over the 2024-2034 period.

Uncertainty

CBO's estimate for H.R. 1352 is subject to considerable uncertainty, some of it arising from underlying factors for the availability and pricing of biosimilars. CBO based its estimate on

April 2024 Medicare payment rates and on data about the use of particular drugs from calendar year 2022, the most recent year for which data were available. Actual payment rates and use could be different by the time the demonstration is implemented. In addition, CMS reports new ASP-based payment rates every quarter (January, April, July, and October). CBO's estimate is based on the assumption that HHS would use the most recent rates available in designing the demonstration and would not modify the demonstration if underlying payment rates changed during the three-year demonstration period.

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 federal spending that are subject to those pay-as-you-go procedures are shown in Table 1.

Increase in Long-Term Net Direct Spending and Deficits

CBO estimates that enacting H.R. 1352 would not increase net direct spending or deficits in any of the four consecutive 10-year periods beginning in 2035.

Mandates

The bill contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act.

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