Congressional Budget Office
Cost Estimate

October 29, 2020

H.R. 5668, Making Objective Drug Evidence Revisions for New Labeling Act of 2020

As ordered reported by the House Committee on Energy and Commerce on July 15, 2020

By Fiscal Year, Millions of Dollars	2021	2021-2025	2021-2030
Direct Spending (Outlays)	0	0	0
Revenues	0	0	0
Increase or Decrease (-) in the Deficit	0	0	0
Spending Subject to Appropriation (Outlays)	*	*	not estimated

Statutory pay-as-you-go procedures apply?	No	**Mandate Effects**	
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2031?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	Yes, Under Threshold

* = between zero and $500,000.

Under current law, labels on generic drugs must match those of their corresponding reference brand drug. H.R. 5668 would allow the Secretary of Health and Human Services to require label updates for certain generic drugs once the reference drug's patents and exclusivities expire, new information is available, and the Secretary determines that the public health would benefit from the updated label. The bill also would require the Secretary to report to the Congress every four years on the number and types of such determinations made and on the number of times manufacturers disagreed with those determinations.

CBO expects that over the 2021-2025 period, implementing H.R. 5668 would require the work of less than one full-time staff member of the Food and Drug Administration. CBO estimates the cost would fall below $500,000 over the 2021-2025 period, although the amount could be higher if the Secretary determines that a significant number of labels require updates. Any spending would be subject to the availability of appropriated funds.

H.R. 5668 would impose a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA) by requiring manufacturers of certain drugs to update product labels. Because this requirement is not expected to apply to a large number of products in the first few years, CBO estimates that the aggregate cost would fall below the private-sector threshold established in UMRA ($168 million in 2020, adjusted annually for inflation).

On July 16, 2019, CBO transmitted a cost estimate for S. 1895, the Lower Health Care Costs Act, as ordered reported by the Senate Committee on Health, Education, Labor, and Pensions on June 26, 2019. Section 213 of S. 1895 is similar to H.R. 5668, and CBO's estimates of their costs are the same.

The CBO staff contacts for this estimate are Ellen Werble (for federal costs) and Andrew Laughlin (for mandates). The estimate was reviewed by Leo Lex, Deputy Director of Budget Analysis.