



CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

June 24, 2016

H.R. 3250 **DXM Abuse Prevention Act of 2015**

As ordered reported by the House Committee on Energy and Commerce on April 27, 2016

SUMMARY

H.R. 3250 would prohibit the sale of certain over-the-counter drug products containing dextromethorphan (DXM) to individuals under the age of 18 and would restrict the distribution of unfinished DXM. The bill would also authorize civil penalties if those restrictions are not followed. CBO estimates that the Food and Drug Administration's (FDA's) programs to enforce compliance with the bill's prohibitions would cost \$232 million over the 2017-2021 period, assuming appropriation of the necessary amounts. In addition, CBO estimates that the bill would increase revenues from civil penalties by less than \$500,000 over the 2017-2026 period because we expect that retailers and other distributors will abide by the bill's restrictions.

Pay-as-you-go procedures apply because enacting H.R. 3250 would affect revenues. CBO estimates that enacting H.R. 3250 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

The bill would impose an intergovernmental and private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA) on retailers that sell over-the-counter drugs containing DXM. The bill would impose additional private-sector mandates on purchasers of over-the-counter drugs containing DXM and purchasers and sellers of unfinished DXM. Based on information from FDA and industry sources, CBO estimates that the cost of complying with the mandates would fall below the annual thresholds established in UMRA for intergovernmental and private-sector mandates (\$77 million and \$154 million in 2016, respectively, adjusted annually for inflation).

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary effect of H.R. 3250 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					2017-
	2017	2018	2019	2020	2021	2021

CHANGES IN SPENDING SUBJECT TO APPROPRIATION

Estimated Authorization Level	20	41	64	66	68	259
Estimated Outlays	14	33	55	63	66	232

Notes: H.R. 3250 would also increase revenues; however, CBO estimates those increases would be insignificant. Components may not sum to totals because of rounding.

BASIS OF ESTIMATE

H.R. 3250 would require all retailers who sell products containing DXM to have a verification system in place to ensure that those products are not sold to persons less than 18 years of age without a prescription. The bill would require FDA to create a program to enforce those restrictions.

The FDA is responsible for similar activities under the Tobacco Retail Compliance Check Program. Through that program, FDA contracts with states to assist in inspecting the verification systems of retailers that sell tobacco products. In fiscal year 2015, FDA awarded about \$45 million in contracts to participating states for these purposes. Assuming that FDA would develop a similar enforcement program for DXM sales and appropriation of the necessary amounts, CBO estimates that implementing H.R. 3250 would cost \$232 million over the 2017-2021 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. CBO estimates that the net changes in revenues that are subject to those pay-as-you-go procedures would not be significant.

INCREASE IN LONG-TERM DIRECT SPENDING AND DEFICITS

CBO estimates that enacting the legislation would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT

The bill would impose intergovernmental and private-sector mandates as defined in UMRA. Based on information from FDA and industry sources, CBO estimates that the cost of complying with the mandates would fall below the annual thresholds established in UMRA for intergovernmental and private-sector mandates (\$77 million and \$154 million in 2016, respectively, adjusted annually for inflation).

Mandates That Affect Both Public and Private Entities

The bill would require retailers that sell over-the-counter drugs containing DXM to implement a verification system to ensure that purchasers of those drugs are at least 18 years old. Affected retailers would include pharmacies and convenience stores at public institutions, although they make up a fraction of the total number of entities affected by the bill. According to data from the Census Bureau, hundreds of thousands of entities sell over-the-counter drugs. However, based on information from industry sources, CBO expects that most sales of products with DXM occur in states with laws that already prohibit sales to minors or are sold by retailers with company policies that prohibit such sales. Consequently, CBO expects that many retailers already comply with the bill's requirements. Moreover, based on a review of the regulatory cost analyses of similar federal requirements, CBO estimates that the incremental cost to the industry of complying with the mandate would not be significant relative to the annual thresholds in UMRA.

Mandates That Affect Private Entities Only

The bill would impose a private-sector mandate on some individuals by requiring them to show identification to purchase over-the-counter drugs containing DXM. Additionally, the bill would impose a mandate on individuals under the age of 18 by prohibiting them from purchasing such products. CBO estimates that the cost of showing identification would be negligible. Additionally, CBO estimates that the cost to comply with the prohibition would be minimal because a minor would generally be able to either buy a substitute product or have other individuals (for example, a parent or guardian) purchase products with DXM for them if needed.

The bill also would impose a mandate by requiring any entity that possesses or receives unfinished DXM to be registered, licensed, or approved under federal or state law to practice pharmacy, engage in pharmaceutical production, or manufacture or distribute drug ingredients. Based on information from industry sources, CBO estimates that the cost of the mandate would be minimal, because entities that possess or receive unfinished DXM are typically registered, licensed, or approved under those federal or state laws. The bill would also impose a mandate on sellers of unfinished DXM by requiring them to confirm that the buyer is legally allowed to make the purchase. This verification process would

require additional administrative work for sellers, but CBO estimates that the cost would be negligible.

ESTIMATE PREPARED BY:

Federal Costs: Ellen Werble

Impact on State, Local, and Tribal Governments: Leo Lex

Impact on the Private Sector: Amy Petz

ESTIMATE APPROVED BY:

Holly Harvey

Deputy Assistant Director for Budget Analysis