SB 18-023

Legislative Council Staff
Nonpartisan Services for Colorado's Legislature

FINAL FISCAL NOTE

Drafting Number:	LLS 18-0239	**Date:**	September 5, 2018
Prime Sponsors:	Sen. Martinez Humenik Rep. Ginal	**Bill Status:**	Postponed Indefinitely
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Bill Topic: PROMOTE OFF-LABEL USE PHARMACEUTICAL PRODUCTS

Summary of Fiscal Impact:

- ☐ State Revenue
- ☒ State Expenditure *(minimal)*
- ☐ State Transfer
- ☐ TABOR Refund
- ☐ Local Government
- ☐ Statutory Public Entity

This bill allows pharmaceutical manufacturers to promote the off-label use of FDA-approved pharmaceutical products. The bill increases state workload in FY 2018-19 by a minimal, one-time amount.

Appropriation Summary: No appropriation is required.

Fiscal Note Status: The fiscal note reflects the introduced bill. This bill was not enacted into law; therefore, the impacts identified in this analysis do not take effect.

Summary of Legislation

Under federal law, the Food and Drug Administration (FDA) is responsible for approving pharmaceutical products that may be sold in the United States, and the FDA approval process focuses on a specific use of the drug in treating a specific condition or conditions. This bill defines "off-label use" as the use of an FDA-approved prescription drug, biological product, or device in a manner other than the use approved by the FDA.

Under the bill, pharmaceutical manufacturers and their representatives are allowed to truthfully promote off-label uses of pharmaceutical products. The State Board of Pharmacy is prohibited from taking disciplinary action against a manufacturer for promoting off-label uses, including revoking or failing to renew a manufacturer's license. The bill specifies that health insurance carriers and other third-party payers are not required to provide coverage for the cost of off-label uses of a prescription drug, biological product, or device.

State Expenditures

The bill will result in a minimal, one-time increase in workload for the Department of Regulatory Agencies in FY 2018-19 to update rules and perform outreach to licensed pharmaceutical manufacturers concerning the changes in the bill. This work can be accomplished within existing appropriations.

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Effective Date

The bill was postponed indefinitely by the Senate Health and Human Services Committee on February 15, 2018.

State and Local Government Contacts

Health Care Policy and Financing	Information Technology
Judicial	Law
Personnel	Regulatory Agencies