



Legislative  
Council Staff

*Nonpartisan Services for Colorado's Legislature*

**SB 18-023**

**FISCAL NOTE**

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<b>Drafting Number:</b>	LLS 18-0239	<b>Date:</b>	January 18, 2018
<b>Prime Sponsors:</b>	Sen. Martinez Humenik Rep. Ginal	<b>Bill Status:</b>	Senate Health and Human Services
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**Bill Topic:** PROMOTE OFF-LABEL USE PHARMACEUTICAL PRODUCTS

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**Summary of Fiscal Impact:**

<input type="checkbox"/> State Revenue	<input type="checkbox"/> TABOR Refund
<input checked="" type="checkbox"/> State Expenditure ( <i>minimal</i> )	<input type="checkbox"/> Local Government
<input type="checkbox"/> State Transfer	<input type="checkbox"/> 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.

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**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.

**Effective Date**

The bill takes effect August 8, 2018, if the General Assembly adjourns on May 9, 2018, as scheduled, and no referendum petition is filed.

**State and Local Government Contacts**

Health Care Policy and Financing  
Judicial  
Personnel

Information Technology  
Law  
Regulatory Agencies