HB13-1121

Colorado Legislative Council Staff Fiscal Note

STATE and LOCAL FISCAL IMPACT

Drafting Number:	LLS 13-0189	**Date:**	January 30, 2013
Prime Sponsor(s):	Rep. Schafer; Murray Sen. Heath; Roberts	**Bill Status:**	House Health, Insurance and Environment
		Fiscal Analyst:	Clare Pramuk (303-866-2677)

TITLE: CONCERNING THE ABILITY OF A PHARMACIST TO SUBSTITUTE A BIOSIMILAR PRODUCT FOR A PRESCRIBED BIOLOGICAL PRODUCT WHEN CERTAIN CONDITIONS ARE SATISFIED.

Fiscal Impact Summary	FY 2013-2014	FY 2014-2015
State Revenue		
State Expenditures	See State and Local Expenditures section.	
FTE Position Change		
Effective Date: August 7, 2013, if the General Assembly adjourns on May 8, 2013, as scheduled, and no referendum petition is filed.		
Appropriation Summary for FY 2013-2014: None required.		
Local Government Impact: See State and Local Expenditures section.		

Summary of Legislation

Biological products are used to prevent, treat, or cure diseases. These include vaccines, viruses, blood and blood components, gene therapy, and proteins. Biological products are generally made from human and/or animal materials as opposed to drugs made through chemical processes. The federal Affordable Care Act allows for the licensure of biological products that are biosimilar to, or interchangeable with, already licensed biological products.

This bill allows pharmacists to substitute a biosimilar product for a prescribed biological product if:

- the federal Food and Drug Administration (FDA) has determined that the biosimilar product is interchangeable with the prescribed biological product;
- the practitioner who prescribed the biological product has not prohibited a substitution; and
- the biosimilar product costs less than the biological product.

A biosimilar product that is higher in price may be substituted if the prescribed biological product is not available.

Pharmacists making such substitutions are required to notify the practitioner of the substitution within three days and maintain records of the substitution for at least five years. Pharmacists must communicate with the purchaser orally and in writing and label the container with information about the substituted biosimilar product when making a substitution.

The Board of Pharmacy will maintain a link on its website to the FDA website that identifies approved biosimilar products once that becomes available.

State and Local Expenditures

This bill will have no fiscal impact in the near term as no biological products have been approved as biosimilar or interchangeable to date. The FDA is currently establishing standards for the licensing of these products and has no projected date for the first biosimilar product to be on the market. When biosimilar products are approved, the Medicaid program and state and local group health plans are expected to see savings in prescription drug costs.

Departments Contacted

Corrections	Health Care Policy and Financing
Public Health and Environment	Regulatory Agencies