SB15-071

Colorado Legislative Council Staff Fiscal Note

STATE FISCAL IMPACT

Drafting Number:	LLS 15-0482	**Date:**	January 26, 2015
Prime Sponsor(s):	Sen. Jahn; Hill Rep. McCann; Landgraf	**Bill Status:**	Senate Health & Human Services
		Fiscal Analyst:	Lauren Schreier (303-866-3523)

BILL TOPIC: PHARMACIST TO SUBSTITUTE INTERCHANGEABLE BIOLOGICAL DRUG

Fiscal Impact Summary*	FY 2015-2016	FY 2016-2017
State Revenue		
State Expenditures	Minimal workload increase. See State Expenditures section.	
FTE Position Change		
Appropriation Required: None.		

** This summary shows changes from current law under the bill for each fiscal year.*

Summary of Legislation

Under current law, a pharmacist can substitute chemical drugs of the same generic drug type if the pharmacist determines that the substituted drug is therapeutically equivalent to and interchangeable with the prescribed drug. The bill permits a pharmacist to also substitute biological drug products that are similarly equivalent and interchangeable with the prescribed biological product. Biological drug products covered by the bill are generally made from human and/or animal materials, but the bill does not apply to most vaccines and immunizations.

Under the bill, a pharmacist may substitute a biological product for another prescribed biological product if:

- the federal Food and Drug Administration (FDA) has determined that the biological product is interchangeable with the prescribed biological product;
- the biological product costs the purchaser less than the prescribed biological product;
- the prescribing practitioner has not prohibited the pharmacist from making a substitution; and
- the pharmacist communicates information to the prescribing practitioner about the specific biological product dispensed to the patient in a reasonable time frame. This requirement does not apply to certain situations, as specified in the bill.

The pharmacist must also communicate in writing and orally with the patient about the biological product substitution. This disclosure requirement does not apply to institutionalized patients.

Further, the bill requires the State Board of Pharmacy within the Department of Regulatory Agencies (DORA) to maintain a link on their website to FDA resources identifying approved biological products.

Background

The federal Biologics Price Competition and Innovation Act of 2009 created an abbreviated licensure pathway for biological products classified as "biosimilar" to or "interchangeable" with an existing FDA-licensed biological product. On January 7, 2015, an FDA advisory panel recommended the approval of a single biologics license application for a biosimilar drug product to an existing FDA-licensed biological product. At the writing of this fiscal note, no biological products have been listed by the FDA on its website.

State Expenditures

The bill may increase workload in the DORA by a minimal amount. The State Board of Pharmacy will be responsible for monitoring approved biological products by the FDA and updating their website accordingly. This can be achieved within the normal course of business and does not require new appropriations.

Effective Date

The bill takes effect upon signature of the Governor, or upon becoming law without his signature.

State and Local Government Contacts

Regulatory Agencies	Public Health and Environment
Health Care Policy and Financing	