ONE HUNDRED FIFTH LEGISLATURE - FIRST SESSION - 2017 COMMITTEE STATEMENT

LB481

Hearing Date:	Thursday February 02, 2017
Committee On:	Health and Human Services
Introducer:	Kuehn
One Liner:	Provide for drug product selection for interchangeable biological products

Roll Call Vote - Final Committee Action:

Advanced to General File

Vote Results:

Aye:	7	Senators Williams	Crawford,	Erdman,	Howard,	Kolterman,	Linehan,	Riepe,
Nay: Absent:								
Present	Not Voting:							

Verbal Testimony:	
Proponents:	Representing:
Senator John Kuehn	Introducer
Dr. Brad Jordan	Amgen
Harry Gewanter, MD	Alliance for Safe Biologic Medicines
Jackie Newman	Arthritis Foundation
Allyson Johnson	Arthritis Foundation
Phil Kozera	Bio Nebraska Life Sciences Association
Coleen Nielsen	Express Scripts
Berend Koops	Merck and Co.
Kathy Siefken	Nebraska Grocery Industry Association
Susan Zalenski	Johnson and Johnson
Opponents:	Representing:
Neutral:	Representing:

Summary of purpose and/or changes:

LB 481 allows pharmacists to substitute interchangeable biological products for prescribed biological products. Requires communication between the pharmacists and patient to of drug selection. Requires communication between pharmacist and prescriber to ensure notice of change.

SECTION BY SECTION:

Section (1): Amends Section 38-2801 of the Nebraska Drug Product Selection Act to add additional sections.

Section (2): Amends Section 28-2802 to add additional sections.

Section (3): Amends Section 38-28,110 and strikes definitions for "brand name", "chemically equivalent", "drug product", "drug product select", "equivalent" and "generic".

Section (4): Defines "biological product".

Section (5): Defines "brand name".

Section (6): Defines "chemically equivalent".

Section (7): Defines "drug product".

Section (8): Defines "drug products select".

Section (9): Defines "equivalent".

Section (10): Defines "generic".

Section (11): Defines "interchangeable biological product".

Section (12): Amends Section 38-28,109 to add interchangeable biological products for the purpose of the Nebraska Drug Product Selection Act.

Section (13): Amends Section 38-28,111 to mandate pharmacists who receive a prescription and chooses to dispense an interchangeable biological product must advise the patient or patient's caregiver the drug product selection has occurred. Within three business days of dispensing a biological product, the dispensing pharmacist or designee is required to make an entry that is electronically accessible to prescriber. The electronic entry is presumed notice to the prescriber. If the pharmacist does not make an electronic entry, the pharmacist is required to communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission or other means. Communication is not required if there is no interchangeable biological product approved by the FDA or a refill prescription is not changed from the product dispensed prior to filling.

Section (14): Amends Section 38-28,112 to add interchangeable biological product for drug product selection and effects on reimbursement.

Section (15): Amends Section 38-28,113 to strike drug product language.

Section (16): Amends Section 38-28,116 to mandate the Department of Health and Human Services maintain a list of all biological products the FDA has determined to be interchangeable biological products on its website.

Section (17): Operative date January 1, 2018.

Section (18): Repeals Sections 38-2801, 38-2802, 38-28,109, 38-28,110, 38-28,111, 38-28,112, 38-28,113, and 38-28,116.

Merv Riepe, Chairperson