78th Oregon Legislative Assembly - 2016 Regular Session **MEASURE: HB 4105 B**

STAFF MEASURE SUMMARY **CARRIER: Sen. Kruse**

Senate Committee On Health Care

Fiscal: Has minimal fiscal impact
Revenue: No Revenue Impact

Action Date: 02/18/16
Action: Do Pass With Amendments To The A-Eng Bill. (Printed B-Eng.)
Meeting Dates: 02/18
Vote:
Yeas: 4 - Knopp, Kruse, Monnes Anderson, Shields
Nays: 1 - Steiner Hayward
Prepared By: Sandy Thiele-Cirka, Committee Administrator

WHAT THE MEASURE DOES:
Requires pharmacy or pharmacist that dispenses biological product to communicate certain information electronically or to the prescribing practitioner. Provides exceptions. Aligns the definition of biological product with the federal definition. Changes terms to align with Board of Pharmacy definitions. Sunsets the notification requirement on January 2, 2022. Declares an emergency, effective on passage.

ISSUES DISCUSSED:
- Provisions of the bill
- Federal Drug Administration (FDA) process
- The need to reinstate the prescriber communication
- Proposed amendments
- Maintain the communication between physicians and patients
- Concerns relating to the imposing administrative requirements
- Potential of increased pharmacy budgets to benefit plans

EFFECT OF COMMITTEE AMENDMENT:
Changes terms “nursing homes” and “assisted living facilities” to “long term care facility” and “community-based care facility” to align with Board of Pharmacy language. Changes the term “describe” to “define” the biological products that may be substituted for other biological products approved by FDA.

BACKGROUND:
The U.S. Food and Drug Administration (FDA) defines biosimilars as a type of biological product that is licensed (approved) by FDA because they are similar to an already FDA-approved biological product, known as the biological reference product, and have been shown to have no clinically meaningful differences from the reference product. In Europe, many of these biosimilars are already circulating, and they may start entering the U.S. market as early as next year.