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

STAFF MEASURE SUMMARY **CARRIER: Rep. Nosse**

House Committee On Health Care

Fiscal: Has minimal fiscal impact
Revenue: No Revenue Impact

Action Date: 02/08/16
Action: Do Pass With Amendments. (Printed A-Eng.)
Meeting Dates: 02/03, 02/08
Vote:
Yeas: 7 - Buehler, Clem, Greenlick, Kennemer, Keny-Guyer, Lively, Nosse
Exc: 2 - Hayden, Weidner
Prepared By: Sandy Thiele-Cirka, Committee Administrator

WHAT THE MEASURE DOES:
Requires pharmacy or pharmacist that dispenses biological product to report certain information electronically or to the prescribing practitioner. Provides exceptions. Aligns the definition of biological product with the federal definition. Establishes January 2, 2022 sunset date on notification requirement. Declares an emergency, effective on passage.

ISSUES DISCUSSED:
- Another access tool for patients
- Impact of biosimilar substitutions
- Role of the pharmacist in patient medication management
- Importance of physician-pharmacist communications
- Role of interchangeable biologics
- Proposed amendments
- Pharmacists-physicians communication
- Concerns relating to adding another administrative barrier
- Current Federal Drug Administration process

EFFECT OF COMMITTEE AMENDMENT:
Aligns the definition of biological product with the federal definition. Establishes January 2, 2022 sunset date on notification requirement.

BACKGROUND:
The U.S. Food and Drug Administration 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.