78th OREGON LEGISLATIVE ASSEMBLY – 2015 Regular Session **MEASURE: SB 147**

PRELIMINARY STAFF MEASURE SUMMARY

CARRIER:

Senate Committee on Senate Health Care

REVENUE: No revenue impact (introduced)
FISCAL: May have fiscal impact, statement not yet issued

Action:
Vote:
Yeas:
Nays:
Exc.:
Prepared By: Zena Rockowitz, Administrator
Meeting Dates: 3/4, 4/20

WHAT THE MEASURE DOES: Broadens prescription substitution requirements from biosimilar to biological products. **P**rohibits substitution of biological products with biological products by pharmacy or pharmacist unless name and manufacturer of product is communicated to dispensing practitioner. Requires entry of information into interoperable electronic medical records system, electronic prescription technology, pharmacy record that is electronically accessible by prescribing practitioner, or another means. Specifies that communication is not required if prescription is refill and biological product is the same as last time it was filled or refilled. Removes definitions. Requires Board to adopt rules defining "biological product" to be consistent with specified U.S. law, and "interchangeable" to be consistent with specified U.S. law, or as determined by U.S. Food and Drug Administration. Rem

ISSUES DISCUSSED:

- Federal Drug Administration approval of biosimilar products
- Provider notification to promote patient safety
- Determining consensus on time frame for notification
- Physician authority to prevent substitutions
- Cost of biological products and biosimilar products

EFFECT OF COMMITTEE AMENDMENT: -1 Amendment: Adds that pharmacy, pharmacist, or pharmacy designee is not required to communicate to the prescribing practitioner the specific biological product dispensed to patient if the U.S. Federal Drug Administration has not approved an interchangeable biological product prescribed. Clarifies that interchangeable biological products may be substituted for other products and adds that U.S. Food and Drug Administration must determine drugs therapeutically equivalent.

BACKGROUND: Biotechnology medicines are made using living cells to produce proteins that can be used to treat diseases. These medicines, referred to as biologics, are composed of large, highly complex molecules that can be larger and more complex than chemical drugs. Common biologics include human growth hormone, injectable treatments for arthritis and psoriasis, and the Hepatitis B vaccine. Biologic drugs are more difficult to replicate than the chemically produced generics of other drugs due to their complexity. These copies of biologic medicines are called biosimilars because they are similar to a biologic medicine, yet not an exact copy. In 2010, the Biologics Price Competition and Innovation Act (BPCIA) authorized the Food and Drug Administration (FDA) to approve biosimilars. The BPCIA also allows the FDA to designate a biosimilar as interchangeable with a reference biologic drug. Senate Bill 460-A passed in 2013 to allow biosimilar products to be substituted for original biologic medicine if the biosimilar has been FDA approved; requires the pharmacist to notify the prescribing practitioner and patient of the substitution; and requires the pharmacist to maintain a record of the substitution for at least three years.