77th OREGON LEGISLATIVE ASSEMBLY – 2013 Regular Session **MEASURE: SB 460 A**
STAFF MEASURE SUMMARY **CARRIER: Sen. Monnes Anderson**
Senate Committee on Health Care & Human Services

REVENUE: No revenue impact
FISCAL: Minimal fiscal impact, no statement issued

Action:		Do Pass as Amended and Be Printed Engrossed
Vote:		4 - 0 - 1
	Yeas:	Knopp, Kruse, Shields, Monnes Anderson
	Nays:	0
	Exc.:	Steiner Hayward
Prepared By:		Sandy Thiele-Cirka, Administrator
Meeting Dates:		2/28, 4/11, 4/16

WHAT THE MEASURE DOES: Restricts substitution of biosimilar product for prescribed biological product. Clarifies biological product and corresponding licensed biosimilar product are interchangeable. Deletes "prescribing practitioner" from record retention requirement. Sunsets physician notification requirement January 1, 2016. Operative on January 1, 2014. Declares emergency, effective on passage.

ISSUES DISCUSSED:
- Explanation on biosimilars and biologics
- Future potential for biologic medicines
- State's authority to establish standards for biosimilar substitution
- Concerns from generic manufacturers and industry representatives
- Potential for prescription drug cost reductions
- Proposed amendments

EFFECT OF COMMITTEE AMENDMENT: Clarifies biological product a and licensed biosimilar product are interchangeable. Deletes "prescribing practitioner" from record retention requirement. Establishes sunset date of January 1, 2016 for physician notification.

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. 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 FDA to designate a biosimilar as interchangeable with a reference biologic drug.

Senate Bill 460-A allows biosimilar product may 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.