75th OREGON LEGISLATIVE ASSEMBLY - 2009 Regular Session **MEASURE: SB 876 A**
STAFF MEASURE SUMMARY **CARRIER: Sen. Telfer**
Senate Committee on Human Services & Rural Health Policy

REVENUE: No revenue impact
FISCAL: Fiscal statement issued

Action:		Do Pass as Amended and Be Printed Engrossed
Vote:		4 - 1 - 0
	Yeas:	Kruse, Telfer, Verger, Morrisette
	Nays:	Monnes Anderson
	Exc.:	0
Prepared By:		Jennifer Kellar, Administrator
Meeting Dates:		4/6, 4/8, 4/22, 4/27

WHAT THE MEASURE DOES: Requires Department of Human Services to pay for brand name, rather than generic, immunosuppressant drugs when prescribed by a licensed practitioner in connection with organ transplants. Provides definition of "narrow therapeutic index drug" and specifies timeframe and process for category determination. Declares emergency, takes effect upon passage.

ISSUES DISCUSSED:

- Risk loss of federal matching funds if price paid for any drug exceeds maximum allowed by Federal Upper Limit when generics are available
- Measure potentially circumvents the Federal Drug Administration's regulatory process for drug approval and safety of generic drugs
- Enables certain manufacturers to protect market share of brand-name drugs and prevent generic competition
- Measure provides blanket protection to entire class of brand drugs prior to evaluation of clinical evidence
- Steps Department of Human Services has in place to protect people who are stable on brand drugs
- Countrywide surge of legislative proposals to undermine generic drug substitution laws
- Current ability of physicians to insist patients be dispensed the brand version of a drug if medically necessary
- Current availability of equivalent generic drugs
- Discussion on viability of fiscal impact statement issued
- Concern by Department of Human Services regarding 180-day patent expiration requirement to define as narrow therapeutic index drug

EFFECT OF COMMITTEE AMENDMENT: Provides definition of "narrow therapeutic index drug" and specifies that the Department of Human Services, within 180 days after the United States Patent expires on an immunosuppressant drug used in connection with an organ transplant, must determine whether the drug is a narrow therapeutic index drug. Requires the department to dispense and pay for the brand name, rather than generic drug, when prescribed by a licensed practitioner. Adds provision that if the United States patent on an immunosuppressant drug used in connection with an organ transplant expired on or after July 1, 2007, and before the effective date of Senate Bill 876-A, the Department of Human Services shall determine whether the drug is a narrow therapeutic index drug as defined in ORS 414.325(9)(c) before January 1, 2010. Adds emergency clause.

BACKGROUND: Oregon's current state pharmacy practice law regulates generic substitutions for brand name pharmaceuticals. For drugs with generic alternatives, federal Medicaid law requires states to pay no more than the Federal Upper Limit for the drugs. The Food and Drug Administration (FDA) has a pre-approval methodology for bioequivalency testing for generic products. In tracking side effects and adverse drug events, the FDA has determined there is no difference between brands and generics it has approved. Generic products are required to fall within the same bioequivalency standards as the FDA allows brand name manufacturers to have within their own lot-to-lot variations. Innovators of brand name drugs reformulate their products and are held to the identical bioequivalence tests by the FDA.