



March 4, 2015

The Honorable Laurie Monnes Anderson
Chair
Senate Committee on Health Care
Oregon Senate
900 Court Street NE
S-413
Salem, OR 97301

RE: Senate Bill 147

Dear Senator Monnes Anderson:

The Academy of Managed Care Pharmacy (AMCP) is opposed to Senate Bill 147 unless it is amended to delete those provisions that would place unnecessary restrictions on the substitution of biosimilars determined to be interchangeable with reference biologic products by the U.S. Food and Drug Administration (FDA). By definition, an interchangeable means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product [42 U.S.C. 262 (i)(3)].

AMCP is a national professional association of pharmacists and other health care practitioners, including 80 members in Oregon, who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's nearly 7,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

Biologic products are already playing an important role in today's health care system both in terms of scientific improvements in the treatment of disease and in increased drug costs. The high costs of many of these products threaten patient access to important therapies and place a strain on payers trying to manage prescription drug spending. Since the introduction of biosimilars in 2006, the European Union has experienced an average price reduction of 30 percent for products with competition from biosimilars, and it is reasonable to expect a similar impact in the United States.

Specifically ORS 689.522 (1)(d) and (2)(a) are problematic because they would subject FDA approved interchangeable biological products to notifications not required for any other FDA drug category dispensed. Additional notifications by the pharmacist are required that are an unnecessary and timely burden.

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The requirement that the pharmacist must enter certain information into an interoperable health records system if available, or if not, then by facsimile, telephone, or email is not required for any other drug category. While the overall health care industry continues to increase its use of electronic technology, it has not yet reached a level of participation by a majority of prescribers and pharmacies.

At this time, the use of an interoperable health records system or other means of electronic communication between prescribers and pharmacists is not the primary method of communication. In fact, written communications continues to be the primary method. Further, the requirement to use electronic technology is not required for any other category of drug dispensed and, as mentioned, is not reflective of the electronic transmission capability of many prescribers and pharmacists.

These restrictions are not currently in force for the substitution of any other category of drug substitution. Yet, consistent with other drugs, interchangeable biological products can only enter the market after approval of the FDA. In order to be categorized as interchangeable, the product must meet very specific safety standards. AMCP believes the burdensome restrictions in ORS 689.522 (1)(d) and (2)(a) are intended to discourage substitution, potentially costing patients and payers unnecessary sums of money, and threatening patient access to safe and more affordable treatments.

For these reasons, AMCP believes that these restrictive notification requirements in ORS 689.522 (1)(d) and (2)(a) will discourage substitution, which only benefits those entities offering more costly biologic drugs. This will potentially increase medication costs to patients and payers and, thereby, threatens patient access to more affordable treatments. This category of drugs will bring value to your constituents as patients and payers by enhancing access to safe and lower cost medications.

We appreciate the opportunity to share our views on Senate Bill 147. We respectfully urge you to amend it by deleting ORS 689.522 (1)(d) and (2)(a). However, if those provisions remain in the bill, then AMCP urges you to vote against its passage. If you have any additional questions, you may contact AMCP's Vice President of Government Affairs, Lauren Fuller, at (703) 683-8416 or lfuller@amcp.org.

Sincerely,



Edith A. Rosato, R.Ph., IOM
Chief Executive Officer

cc: Members of the Senate Committee on Health Care