OREGON MEDICAL ASSOCIATION

MEMORANDUM

To: Sen. Laurie Monnes-Anderson, Chair, Senate Committee on Health Care
Sen. Jeff Kruse, Vice-Chair, Senate Committee on Health Care
Members of the Senate Committee on Health Care

From: Courtni Dresser, OMA Government Relations

Date: March 4, 2015

Re: Support of SB 147- Biological Product Substitution Notification

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The OMA supports SB 147 as a necessary bill to ensure provider notification when biological substitution becomes an available option for pharmacists. The FDA is expected to approve the first copy of a biological product (*often referred to as a biosimilar*) later this year, and expects to approve other biosimilars shortly thereafter with the possibility of "interchangeable" designations (*meaning they can be substituted by a pharmacist without the approval of a physician*).

In 2013, the OMA supported SB 460 which codified in Oregon statute a process for the safe substitution of interchangeable biological products (*biosimilars*), contingent on the approval of the FDA. One of the key provisions of that bill that the OMA strongly supported – *notifying the prescribing physician of the product substituted by the pharmacist* – sunsets this year. SB 147 makes this important provision permanent.

Provider notification of a biological substitution is an important patient safety issue. The OMA is concerned that the lack of a set timeframe, currently defined only as a "reasonable amount time", could have adverse results if the notification is not timely enough for a patient's provider to appropriately manage their condition and adjust their medication. We would like to work with you and the other stakeholders to reach consensus on a set timeframe for notification by the pharmacist to the provider.

Patients on biological products (whether brand or a biosimilar) are typically being treated for chronic illnesses that require active and ongoing care management. Knowing exactly what product they are on is essential to providing high quality, cost effective care both in the short and long-term. We believe the burden to notify providers to be manageable for pharmacists. Only a small number of biological products is expected to be approved in the next few years that will require notification, and for the most part, these products are dispensed by pharmacists in places that have the capability and/or resources to easily provide this communication back to the treating provider.

Thank you for your consideration of our concerns and we are happy to work collaboratively with other stakeholders to better define a "reasonable amount of time".

11740 SW 68th Parkway, Suite 100
Portland, Oregon 97223-9038
phone 503.619.8000
fax 503.619.0609
www.theOMA.org