ESB 5935 - H AMD TO APP COMM AMD (H2640.1) **452**
By Representative Cody

ADOPTED 4/14/2015

On page 2, line 1 of the amendment, after "product" strike "licensed" and insert ":

(a) Licensed"

On page 2, beginning on line 4 of the amendment, after "262(k)(4)" strike all material through "book" on line 7 and insert "; or

(b) Approved based on an application filed under section 505(b) of the federal food, drug, and cosmetic act that is determined by the federal food and drug administration to be therapeutically equivalent to an approved 505(b) biological product and is included in the 505(b) list maintained by the pharmacy quality assurance commission pursuant to section 5 of this act"

Beginning on page 3, line 11 of the amendment, strike all of sections 4 and 5 and insert the following:

"NEW SECTION. **Sec. 4.** A new section is added to chapter 69.41 RCW to read as follows:

(1) Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee must make an entry of the specific product provided to the patient, including either the name of the product and the manufacturer or the federal food and drug administration's national drug code, provided that the name of the product and the name of the manufacturer are accessible to a practitioner in an electronic records system that can be electronically accessed by the patient's practitioner through:

(a) An interoperable electronic medical records system;

(b) An electronic prescribing technology;

(c) A pharmacy benefit management system; or

(d) A pharmacy record.

(2) Entry into an electronic records system, as described in subsection (1) of this section, is presumed to provide notice to the

practitioner. Otherwise, the pharmacist must communicate to the practitioner the specific product provided to the patient, including the name of the product and manufacturer, using facsimile, telephone, electronic transmission, or other prevailing means.

(3) No entry or communication pursuant to this section is required if:

(a) There is no interchangeable biological product for the product prescribed;

(b) A refill prescription is not changed from the product dispensed on the prior filling of the prescription; or

(c) The pharmacist or the pharmacist's designee and the practitioner communicated before dispensing and the communication included confirmation of the specific product to be provided to the patient, including the name of the product and the manufacturer.

(4) This section expires August 1, 2020.

NEW SECTION. **Sec. 5.** A new section is added to chapter 69.41 RCW to read as follows:

The pharmacy quality assurance commission shall maintain a link on its web site to the current list of all biological products determined by the federal food and drug administration as interchangeable. The commission shall maintain a list of all biological products approved as therapeutically equivalent by the federal food and drug administration through the approval process specified in 505(b) of the federal food, drug, and cosmetic act. The commission shall make the 505(b) list accessible to pharmacies."

EFFECT: (1) Adds biological products approved under section 505(b) of the federal food, drug, and cosmetic act and listed by the pharmacy quality assurance commission (commission) to the definition of "interchangeable." Removes references to the "Purple Book" from the definition of "interchangeable."

(2) Directs the commission to maintain a list of all biological products approved by the federal food and drug administration as "therapeutically equivalent" under section 505(b) of the federal food, drug, and cosmetic act. Directs the commission to make the list available to pharmacies.

(3) Requires that any electronic records system used by a pharmacist to enter information about a dispensed biological product be capable of being electronically accessed by the practitioner, including an interoperable electronic medical records system,

electronic prescribing technology, pharmacy benefit management system, or pharmacy record.

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