Alaska State Legislature

SESSION ADDRESS:
Alaska State Capitol
Juneau Alaska 99801
907-465-3743
800-565-3743
Sen.Shelley.Hughes@akleg.gov

INTERIM ADDRESS:
600 E Railroad Avenue
Wasilla AK 99654
907-376-3725

Senator Shelley Hughes
Senate District F – Greater Palmer, Chugiak, Peters Creek, Eklutna, Fairview Loop, Gateway, Butte, Lazy Mountain

SB 32 Interchangeable Biological Products

Sectional Analysis

"An Act relating to biological products; relating to the practice of pharmacy; relating to the Board of Pharmacy; and providing for an effective date."

Sec. 1 – AS 08.80.030
Adds a new subsection requiring the Board of Pharmacy to have a link on the board's website to the United States Food and Drug Administration's (FDA) list of approved interchangeable biological products.

Sec. 2 – AS 08.80.294
Amends this section by requiring a pharmacist to include on the label of a biological product container the proprietary or proper name of the biological product. This section also includes language to differentiate between drugs that are and are not biological products to ensure that statutes regarding equivalent generic drugs are not substantively changed.

Sec. 3 – AS 08.80.294
Adds a new subsection to define the term "proper name" being the name that reflects scientific characteristics of a biological product. This new subsection also defines "proprietary name" which is the trademarked and registered name of the product.

Sec. 4 – AS 08.80.295
Adds language to differentiate between equivalent drug products and interchangeable biological products.

Sec. 5 – AS 08.80.295
Adds new subsections to provide guidelines as to how pharmacists or their designee will need to communicate with a prescribing doctor when dispensing a biological or interchangeable biological product if an interchangeable product is available.

Under subsection (c), a pharmacist must communicate to the prescribing doctor the name and manufacturer of the biological product provided to the patient. This communication must happen within three days after dispensing the product by an entry through an interoperable electronic medical records system, an electronic prescribing technology, a pharmacy benefit management system, or a pharmacy record. If an entry under this subsection is not possible, the pharmacist may communicate by e-mail, telephone, fax, or by any other prevailing means.

Under subsection (d) provides an exception to the communication requirement under (c) if the dispensed biological product is a refill of the prescription and is the same biological product. Subsection (e) provides that communication provided under (c)(1) of this section is providing notice to the prescribing doctor. Under subsection (f), a pharmacist is required to maintain a record for two years after a biological product is dispensed. Finally subsection (g) defines "designee" as an agent or employee of a pharmacist who has been authorized to communicate information under subsection (c).

Sec. 6 – AS 08.80.480(34)

Changes language, and gives option to change the term "drug" and "equivalent drug" to "biological product" and "interchangeable biological product".

Sec. 7 AS 08.80.480

Adds new subsection (37) to define term "biological product".

Adds new subsection (36) to define term "interchangeable biological product" as a biological product as determined by the United States Food and Drug Administration.

Under subsection (A) provides that it meets the standard for interchangeability under US code (Regulation of biological products, Safety standards for determining interchangeability).

Under subsection (B) provides that it is therapeutically equivalent in the most recent edition of the United States Food and Drug Administration evaluations.

Sec. 8 AS 08.80.480

Amends this section by adding transition regulations if necessary to implement changes made by this Act. Having changes take place in accordance with AS 44.62 (Administrative Procedure Act) but not before the effective date of this Act.

Sec. 9 AS 08.80.480

Adds language that section 8 of this Act takes effect July 1, 2017.

Sec. 10 AS 08.80.480

Adds language that this Act will take effect January 1, 2018, except for a provided in section 9.

Staff contact: Aimee Bushnell, (907) 465-3743