LAWS OF ALASKA

2018

Source
HCS SB 32(FIN)

Chapter No.
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AN ACT

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

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BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

THE ACT FOLLOWS ON PAGE 1

AN ACT

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

*** Section 1.** AS 08.80.030 is amended by adding a new subsection to read:

(c) The board shall post and maintain a link to the United States Food and Drug Administration's list of all currently approved interchangeable biological products on the board's Internet website.

*** Sec. 2.** AS 08.80.294 is amended to read:

Sec. 08.80.294. Information about equivalent generic drugs and interchangeable biological products. (a) In addition to other information that may be required under state or federal laws or regulations, a pharmacist, when dispensing a brand-name prescription drug order **that is**

(1) not a biological product, shall include the generic drug name that is an equivalent drug product for the drug dispensed**;**

(2) a biological product, shall include the dispensed product's

(A) proprietary name, if available; or

(B) proper name.

(b) The generic drug name **or proprietary or proper biological product name** required under (a) of this section shall be placed directly on the container's label near the brand name.

*** Sec. 3.** AS 08.80.294 is amended by adding a new subsection to read:

(c) In this section,

(1) "proper name" means a name that reflects scientific characteristics of the product such as chemical structure and pharmacological properties;

(2) "proprietary name" means a name that is trademarked and registered for private use.

*** Sec. 4.** AS 08.80.295 is amended to read:

Sec. 08.80.295. Substitution of equivalent drug products or interchangeable biological products. (a) Unless the prescription indicates that it is to be dispensed only as written, the pharmacist may, with the consent of the patient, substitute an equivalent drug product **or interchangeable biological product**.

(b) A pharmacist who substitutes an equivalent drug product **or interchangeable biological product** in compliance with this section and applicable regulations incurs no greater liability in filling the prescription than would be incurred in filling the prescription by dispensing the prescribed name brand product.

*** Sec. 5.** AS 08.80.295 is amended by adding new subsections to read:

(c) Except as provided in (d) of this section, if an interchangeable biological product exists for a biological product prescribed to a patient, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner information regarding the biological product provided to the patient, including the name and manufacturer of the biological product. The communication must be provided within three business days after dispensing the biological product as follows:

(1) by making an entry that is electronically accessible to the prescribing 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; or

(2) if the pharmacist or the pharmacist's designee is unable to make an entry through one of the means provided under (1) of this subsection, by facsimile transmission, telephone communication, electronic mail transmission, or transmission by other prevailing means, to the prescribing practitioner.

(d) The dispensing pharmacist or the pharmacist's designee is not required to communicate information under (c) of this section if the dispensed biological product is a refill of a prescription and is the same as the biological product that was dispensed on the previous filling of the prescription.

(e) Entry into an electronic records system as described under (c)(1) of this section is presumed to provide notice to the prescribing practitioner.

(f) A pharmacist shall maintain a record of a dispensed biological product for a minimum of two years after the date of the dispensing.

(g) In this section, "designee" means an agent or employee of the dispensing pharmacist whom the dispensing pharmacist has authorized to communicate the information required under (c) of this section.

*** Sec. 6.** AS 08.80.480(34) is amended to read:

(34) **"substitute"** ["SUBSTITUTION"] means to dispense**,** without the prescriber's expressed authorization,

(A) an equivalent drug product in place of the prescribed drug**;**

or

(B) an interchangeable biological product in place of the prescribed biological product;

*** Sec. 7.** AS 08.80.480 is amended by adding new paragraphs to read:

(37) "biological product" means a product that is applicable to the prevention, treatment, or cure of a disease or condition of human beings, and is a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized

polypeptide, or analogous product, or arsphenamine or derivative of arsphenamine or any other trivalent organic arsenic compound;

(38) "interchangeable biological product" means a biological product that the United States Food and Drug Administration has determined

(A) meets the standards for interchangeability under 42 U.S.C. 262(k)(4); or

(B) is therapeutically equivalent to another biological product under the most recent edition or supplement of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations.

*** Sec. 8.** The uncodified law of the State of Alaska is amended by adding a new section to read:

TRANSITION: REGULATIONS. The Board of Pharmacy may adopt regulations necessary to implement the changes made by this Act. The regulations take effect under AS 44.62 (Administrative Procedure Act), but not before the effective date of the relevant provision of this Act implemented by the regulation.

*** Sec. 9.** Section 8 of this Act takes effect July 1, 2018.

*** Sec. 10.** Except as provided in sec. 9 of this Act, this Act takes effect January 1, 2019.