129th MAINE LEGISLATURE

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H.P. 480 House of Representatives, February 7, 2019

An Act Regarding the Use of Interchangeable Biological Products

Reference to the Committee on Health Coverage, Insurance and Financial Services suggested and ordered printed.

ROBERT B. HUNT
Clerk

Presented by Representative PERRY of Calais.
Cosponsored by Senator GRATWICK of Penobscot and
Representatives: ARATA of New Gloucester, CRAVEN of Lewiston, O'CONNOR of Berwick, Senator: MOORE of Washington.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 32 MRSA §13702-A, sub-§1-A is enacted to read:

1-A. Biological product. "Biological product" has the same meaning as in 42 United States Code, Section 262.

Sec. 2. 32 MRSA §13702-A, sub-§14-A is enacted to read:

14-A. Interchangeable biological product. "Interchangeable biological product" means a biological product that the federal Food and Drug Administration has:

A. Licensed and determined meets the standards for interchangeability pursuant to 42 United States Code, Section 262(k)(4); or

B. Determined is therapeutically equivalent as set forth in the most recent edition of or supplement to the federal Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations" or a successor publication.

Sec. 3. 32 MRSA §13702-A, sub-§31-A is enacted to read:

31-A. Proper name. "Proper name," as it relates to a biological product, means the nonproprietary name for a biological product designated by the federal Food and Drug Administration for use on each package of the product.

Sec. 4. 32 MRSA §13781, as amended by PL 2007, c. 85, §§1 and 2, is further amended to read:

§13781. Generic and therapeutically equivalent substitution

A written prescription issued by a practitioner in this State may contain a box in the lower right-hand corner of the prescription form. The following words must appear to the left of this box: "Any drug ~~which~~ that is the generic and therapeutic equivalent of the drug or any biological product that is an interchangeable biological product of the biological product specified above in this prescription must be dispensed, provided that no check mark ( ) has been handwritten in the box in the lower right-hand corner."

Except with regard to a patient who is paying for a drug or biological product with the patient's own resources, any pharmacist receiving a prescription in which no handwritten check mark ( ) is found in the box provided shall substitute a generic and therapeutically equivalent drug for the drug or an interchangeable biological product for the biological product specified on the prescription if the substituted drug or interchangeable biological product is distributed by a business entity doing business in the United States that is subject to suit and the service of legal process in the United States and the price of the substituted drug or interchangeable biological product does not exceed the price of the drug or biological product specified by the practitioner; except that, when the cost of a prescription is to be reimbursed under the MaineCare program pursuant to Title 22, chapter 855, the pharmacist shall substitute a generic and therapeutically equivalent drug or an interchangeable biological product only when the Department of Health and Human Services has determined that the substitute drug or

interchangeable biological product would be a more cost-effective alternative than the drug or biological product prescribed by the practitioner. Except for prescribed drugs listed under the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 United States Code, Section 812, as amended, as Schedule II drugs, with regard to a patient who is paying for a drug or biological product with the patient's own resources, a pharmacist shall inquire about the patient's preference for either the brand-name drug or generic and therapeutically equivalent drug or for either the prescribed biological product or interchangeable biological product and dispense the drug or biological product that the patient prefers.

Except with regard to a patient who is paying for a drug or biological product with the patient's own resources, if a written prescription issued by a practitioner in this State does not contain the box described in this section, a pharmacist shall substitute a generic and therapeutically equivalent drug for the drug or an interchangeable biological product for the biological product specified on the prescription if the substituted drug or interchangeable biological product is distributed by a business entity doing business in the United States that is subject to suit and the service of legal process in the United States and the price of the substituted drug or interchangeable biological product does not exceed the price of the drug or biological product specified by the practitioner, unless a practitioner has handwritten on the prescription form, along with the practitioner's signature, "dispense as written," "DAW," "brand," "brand necessary" or "brand medically necessary"; except that, when the cost of a prescription is to be reimbursed under the MaineCare program pursuant to Title 22, chapter 855, the pharmacist shall substitute a generic and therapeutically equivalent drug or an interchangeable biological product only when the Department of Health and Human Services has determined that the substitute drug or interchangeable biological product would be a more cost-effective alternative than the drug or biological product prescribed by the practitioner. Except for prescribed drugs listed under the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 United States Code, Section 812, as amended, as Schedule II drugs, with regard to a patient who is paying for a drug or biological product with the patient's own resources, a pharmacist shall inquire about the patient's preference for either the brand-name drug or generic and therapeutically equivalent drug or for either the prescribed biological product or interchangeable biological product and dispense the drug or biological product that the patient prefers.

Any pharmacist who substitutes a generic and therapeutically equivalent drug or an interchangeable biological product under this section shall inform the person to whom the drug or interchangeable biological product is dispensed of the substitution. When any substitution is made under this section, the pharmacist shall cause all information as required by section 13794, the name of the generic and therapeutically equivalent drug, and the name or abbreviation of the drug manufacturer or distributor of that substitute drug ~~and all other information as required by section 13794~~ or, in the case of an interchangeable biological product, the proper name and the name of the manufacturer of the interchangeable biological product, to appear on the container label of the drug or interchangeable biological product dispensed.

This section does not apply to prescriptions ordered by practitioners for patients in hospitals when those prescriptions are filled by a hospital pharmacy or in any institution where a formulary system is established.

Within 5 business days after a pharmacist dispenses a biological product, the dispensing pharmacist or the pharmacist's designee shall enter in an electronic records system that is electronically accessible to the practitioner who prescribed the biological product the specific biological product dispensed, including the name of the biological product and the manufacturer. For purposes of this paragraph, "electronic records system" means an interoperable electronic medical records system, an electronic prescribing technology, a pharmacist benefit management system or an electronic pharmacy record. Entry into an electronic records system as described in this paragraph is presumed to provide notice to the practitioner. If a pharmacist cannot make an entry in an electronic records system, the pharmacist shall notify the practitioner of the specific biological product dispensed by facsimile, telephone, electronic transmission or other similar means. Notice to a practitioner under this paragraph is not required if the federal Food and Drug Administration has not approved an interchangeable biological product for the product prescribed or a refill prescription is not changed from the biological product dispensed on the prior filling of the prescription.

The board shall maintain a link on the board's publicly accessible website to the current list of all biological products determined by the federal Food and Drug Administration to be an interchangeable biological product.

For the purposes of this section, "drug" does not include biological products.

Sec. 5. 32 MRSA §13794, first ¶, as amended by PL 1999, c. 130, §14, is further amended to read:

Every drug dispensed pursuant to prescription, whether for a legend drug or not, must carry on the label the following information: the prescription number; the date of filling; the patient's name; directions for use; the name and strength of the drug and the amount dispensed, including either the brand name of the drug or, if a generic and therapeutically equivalent drug or interchangeable biological product is dispensed ~~it~~ the label must be in accordance with section 13781; the beyond use date of the drug; the name of the practitioner prescribing the drug; and the name, address and telephone number of the pharmacy where the prescription was compounded and dispensed. For purposes of this section, "beyond use date" means a date beyond which the contents of the prescription are not recommended to be used.

SUMMARY

This bill provides for pharmacist substitution of interchangeable biological products for prescribed biological products in a manner similar to the current regulation of generic drug substitution. The bill defines "biological product" and "interchangeable biological product."