

MAINE STATE LEGISLATURE

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129th MAINE LEGISLATURE

FIRST REGULAR SESSION-2019

Legislative Document

No. 659

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.

A handwritten signature in cursive script that reads "Robert B. Hunt".

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.

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

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

3 **1-A. Biological product.** "Biological product" has the same meaning as in 42
4 United States Code, Section 262.

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

6 **14-A. Interchangeable biological product.** "Interchangeable biological product"
7 means a biological product that the federal Food and Drug Administration has:

8 A. Licensed and determined meets the standards for interchangeability pursuant to
9 42 United States Code, Section 262(k)(4); or

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

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

14 **31-A. Proper name.** "Proper name," as it relates to a biological product, means the
15 nonproprietary name for a biological product designated by the federal Food and Drug
16 Administration for use on each package of the product.

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

19 **§13781. Generic and therapeutically equivalent substitution**

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

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

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

10 Except with regard to a patient who is paying for a drug or biological product with
11 the patient's own resources, if a written prescription issued by a practitioner in this State
12 does not contain the box described in this section, a pharmacist shall substitute a generic
13 and therapeutically equivalent drug for the drug or an interchangeable biological product
14 for the biological product specified on the prescription if the substituted drug or
15 interchangeable biological product is distributed by a business entity doing business in
16 the United States that is subject to suit and the service of legal process in the United
17 States and the price of the substituted drug or interchangeable biological product does not
18 exceed the price of the drug or biological product specified by the practitioner, unless a
19 practitioner has handwritten on the prescription form, along with the practitioner's
20 signature, "dispense as written," "DAW," "brand," "brand necessary" or "brand medically
21 necessary"; except that, when the cost of a prescription is to be reimbursed under the
22 MaineCare program pursuant to Title 22, chapter 855, the pharmacist shall substitute a
23 generic and therapeutically equivalent drug or an interchangeable biological product only
24 when the Department of Health and Human Services has determined that the substitute
25 drug or interchangeable biological product would be a more cost-effective alternative
26 than the drug or biological product prescribed by the practitioner. Except for prescribed
27 drugs listed under the Comprehensive Drug Abuse Prevention and Control Act of 1970,
28 21 United States Code, Section 812, as amended, as Schedule II drugs, with regard to a
29 patient who is paying for a drug or biological product with the patient's own resources, a
30 pharmacist shall inquire about the patient's preference for either the brand-name drug or
31 generic and therapeutically equivalent drug or for either the prescribed biological product
32 or interchangeable biological product and dispense the drug or biological product that the
33 patient prefers.

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

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

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

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

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

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

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

35 SUMMARY

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