



State of Wisconsin
2017 - 2018 LEGISLATURE

LRB-4734/1
MED:klm

2017 ASSEMBLY BILL 679

November 29, 2017 - Introduced by Representatives ROHRKASTE, SPIROS, KOLSTE, ANDERSON, BERCEAU, R. BROOKS, CONSIDINE, CROWLEY, FELZKOWSKI, FIELDS, HORLACHER, JACQUE, KOYENGA, KREMER, KRUG, KUGLITSCH, OHNSTAD, SARGENT, SINICKI, SKOWRONSKI, SPREITZER, THIESFELDT, TUSLER, SUBECK and EDMING, cosponsored by Senators VUKMIR, CARPENTER, CRAIG, OLSEN, VINEHOUT, BEWLEY and MARKLEIN. Referred to Committee on Health.

1 **AN ACT** *to renumber and amend* 450.13 (1); *to amend* 102.425 (1) (c), 450.11
2 (4g) (title), 450.11 (4g) (a) 2., 450.13 (2), 450.13 (3) and 450.13 (5) (intro.); and
3 **to create** 450.01 (1z), 450.11 (4g) (c), 450.11 (4i), 450.12 (4), 450.122, 450.13 (6)
4 and 450.135 of the statutes; **relating to:** the treatment of biological products
5 for various purposes under the pharmacy practice law.

Analysis by the Legislative Reference Bureau

This bill makes a number of changes to the pharmacy practice laws regarding the prescribing and dispensing of biological products, including changes to address the dispensing of interchangeable biological products.

Current state law contains a number of provisions that address the dispensing of drug product equivalents in lieu of the specific drug product described. Specifically, current law allows a pharmacist to dispense the “drug product equivalent” of a drug prescribed if the drug product equivalent is lower in price to the consumer than the drug product prescribed, unless the prescribing practitioner specifically indicates on the prescription order that no substitution of the drug product prescribed may be made. Current law defines “drug product equivalent” as a drug product that the federal Food and Drug Administration, which regulates drugs pursuant to the Federal Food, Drug, and Cosmetic Act, has determined is therapeutically equivalent to the drug product prescribed. Current law also provides that if a pharmacist, pursuant to a prescription order that specifies a drug product by its brand name, dispenses the drug product equivalent of the drug product

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specified in the prescription order, the label required for the drug may include both the generic name of the drug product equivalent and the brand name specified in the prescription order, unless the prescribing practitioner requests that the brand name be omitted from the label.

This bill creates provisions similar to those described above that apply with respect to biological products, which are regulated somewhat differently from other drugs by the FDA under the federal Public Health Service Act. Specifically, the bill allows a pharmacist to dispense an interchangeable biological product in lieu of the biological product prescribed if the interchangeable biological product is lower in price to the consumer than the biological product prescribed, unless the prescribing practitioner specifically indicates on the prescription order that no substitution of the biological product prescribed may be made. The bill defines “interchangeable biological product” as a biological product that the FDA has determined is therapeutically equivalent to the biological product prescribed or that the FDA has licensed and determined meets standards for interchangeability pursuant to provisions in federal law. The bill further establishes requirements for pharmacists who dispense biological products to make an entry into an electronic records system or to otherwise communicate to the prescribing practitioner regarding the biological product dispensed, subject to certain exceptions. The bill provides that if a pharmacist, pursuant to a prescription order that specifies a biological product by its brand name, dispenses the interchangeable biological product of the biological product specified in the prescription order, the label required for the drug may include both the proper name of the interchangeable biological product and the brand name specified in the prescription order.

Current law also contains provisions regarding the labeling of prescription drugs, including requirements that certain information be contained on the commercial container of a prescription drug. The bill creates a similar provision that applies only to biological products, which includes a requirement that certain information to be contained on the commercial container of the biological product, including the brand name, if any, of the biological product, and the proper name of the biological product.

The provisions newly created in the bill apply only to biological products. The bill modifies the provisions under current law that apply to drugs generally so that they apply only to drugs that are not biological products.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

1 **SECTION 1.** 102.425 (1) (c) of the statutes is amended to read:

2 102.425 (1) (c) “Drug product equivalent” has the meaning given in s. 450.13
3 ~~(1)~~ (1e).

4 **SECTION 2.** 450.01 (1z) of the statutes is created to read:

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1 450.01 **(1z)** “Biological product” has the meaning given in 42 USC 262 (i).

2 **SECTION 3.** 450.11 (4g) (title) of the statutes is amended to read:

3 450.11 **(4g)** (title) BRAND NAME PERMITTED ON LABEL; DRUGS AND DRUG PRODUCTS.

4 **SECTION 4.** 450.11 (4g) (a) 2. of the statutes is amended to read:

5 450.11 **(4g)** (a) 2. “Drug product equivalent” has the meaning given in s. 450.13

6 ~~(1)~~ (1e).

7 **SECTION 5.** 450.11 (4g) (c) of the statutes is created to read:

8 450.11 **(4g)** (c) This subsection does not apply to a prescription order for a
9 biological product.

10 **SECTION 6.** 450.11 (4i) of the statutes is created to read:

11 450.11 **(4i)** BRAND NAME PERMITTED ON LABEL; BIOLOGICAL PRODUCTS. (a) In this
12 section:

13 1. “Brand name” has the meaning given in s. 450.122 (1) (a).

14 2. “Interchangeable biological product” has the meaning given in s. 450.135 (1).

15 3. “Proper name” has the meaning given in s. 450.122 (1) (b).

16 (b) If a pharmacist, pursuant to a prescription order that specifies a biological
17 product by its brand name, dispenses the interchangeable biological product of the
18 biological product specified in the prescription order, the label required under sub.
19 (4) (a) may include both the proper name of the interchangeable biological product
20 and the brand name specified in the prescription order.

21 **SECTION 7.** 450.12 (4) of the statutes is created to read:

22 450.12 **(4)** This section does not apply with respect to biological products.

23 **SECTION 8.** 450.122 of the statutes is created to read:

24 **450.122 Labeling of biological products.** (1) In this section:

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1 (a) "Brand name" means the name, other than the proper name, that the labeler
2 of a biological product places on its commercial container at the time of packaging.

3 (b) "Proper name" means the nonproprietary name for a biological product
4 designated by the federal food and drug administration licensure for use upon each
5 package of the product.

6 (2) The manufacturer's or distributor's commercial container of every
7 biological product delivered to any pharmacist, practitioner, hospital, or nursing
8 home shall bear a label containing the proper name of the biological product, the
9 brand name of the biological product, if any, the name and address of the
10 manufacturer of the biological product and, if different from the manufacturer, the
11 name and address of the distributor of the biological product.

12 (3) Every prescription order or medication profile record for a biological
13 product shall include the brand name, if any, and the name of the manufacturer of
14 the biological product.

15 **SECTION 9.** 450.13 (1) of the statutes is renumbered 450.13 (1s) and amended
16 to read:

17 450.13 (1s) DRUG PRODUCT OR EQUIVALENT TO BE USED. Except as provided in sub.
18 (2), a pharmacist shall dispense every prescription using either the drug product
19 prescribed or its drug product equivalent, if its drug product equivalent is lower in
20 price to the consumer than the drug product prescribed, and shall inform the
21 consumer of the options available in dispensing the prescription.

22 **(1e) DEFINITION.** In this section, "drug product equivalent" means a drug
23 product that is designated the therapeutic equivalent of another drug product by the
24 federal food and drug administration as set forth in the latest edition of or

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1 supplement to the federal food and drug administration's Approved Drug Products
2 with Therapeutic Equivalence Evaluations.

3 **SECTION 10.** 450.13 (2) of the statutes is amended to read:

4 450.13 (2) EXCEPTION. A ~~prescriber~~ prescribing practitioner may indicate, by
5 writing on the face of the prescription order or, with respect to a prescription order
6 transmitted electronically, by designating in electronic format the phrase "No
7 substitutions" or words of similar meaning or the initials "N.S.", that no substitution
8 of the drug product prescribed may be made under sub. (1) (1s). If such indication
9 is made, the pharmacist shall dispense the prescription with the specific drug
10 product prescribed. No preprinted statement regarding drug product substitution
11 may appear on the face of the prescription order.

12 **SECTION 11.** 450.13 (3) of the statutes is amended to read:

13 450.13 (3) ~~RENEWED~~ REFILLED PRESCRIPTIONS. Prescriptions dispensed with a
14 drug product equivalent may be ~~renewed~~ refilled with a different drug product
15 equivalent only if the pharmacist informs the consumer of the change.

16 **SECTION 12.** 450.13 (5) (intro.) of the statutes is amended to read:

17 450.13 (5) USE OF DRUG PRODUCT EQUIVALENT IN HOSPITALS. (intro.) Subsections
18 (1) (1s) to (4) do not apply to a pharmacist who dispenses a drug product equivalent
19 that is prescribed for a patient in a hospital if the pharmacist dispenses the drug
20 product equivalent in accordance with written guidelines or procedures previously
21 established by a pharmacy and therapeutics committee of the hospital and approved
22 by the hospital's medical staff and use of the drug product equivalent has been
23 approved for a patient during the period of the patient's stay within the hospital by
24 any of the following:

25 **SECTION 13.** 450.13 (6) of the statutes is created to read:

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1 450.13 (6) APPLICABILITY. This section does not apply with respect to a
2 prescription for a biological product.

3 **SECTION 14.** 450.135 of the statutes is created to read:

4 **450.135 Using interchangeable biological product in dispensing**
5 **prescriptions. (1) DEFINITION.** In this section, “interchangeable biological product”
6 means a biological product that the federal food and drug administration has
7 licensed and has determined meets the standards for interchangeability pursuant
8 to 42 USC 262 (k) (4) or has determined is therapeutically equivalent as set forth in
9 the latest edition of or supplement to the federal food and drug administration’s
10 Approved Drug Products with Therapeutic Equivalence Evaluations.

11 **(2) BIOLOGICAL PRODUCT OR INTERCHANGEABLE BIOLOGICAL PRODUCT TO BE USED.**
12 Except as provided in sub. (3), a pharmacist shall dispense every prescription using
13 either the biological product prescribed or an interchangeable biological product, if
14 the interchangeable biological product is lower in price to the consumer than the
15 biological product prescribed, and shall inform the consumer of the options available
16 in dispensing the prescription.

17 **(3) EXCEPTION.** A prescribing practitioner may indicate, by writing on the face
18 of the prescription order or, with respect to a prescription order transmitted
19 electronically, by designating in electronic format the phrase “No substitutions” or
20 words of similar meaning or the initials “N.S.,” that no substitution of the biological
21 product prescribed may be made under sub. (2). If such indication is made, the
22 pharmacist shall dispense the prescription with the specific biological product
23 prescribed. No preprinted statement regarding biological product substitution may
24 appear on the face of the prescription order.

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1 **(4) REFILLED PRESCRIPTIONS.** Prescriptions dispensed with an interchangeable
2 biological product may be refilled with a different interchangeable biological product
3 only if the pharmacist informs the consumer of the change.

4 **(5) COMMUNICATION OF BIOLOGICAL PRODUCT DISPENSED.** Within 5 business days
5 after the dispensing of a biological product, the dispensing pharmacist or the
6 pharmacist's designee shall do one of the following:

7 (a) Make an entry of the specific product provided to the patient, including the
8 name of the product and the manufacturer. Entry into an electronic records system
9 as described in this paragraph is presumed to provide notice to the prescribing
10 practitioner. The communication shall be conveyed by making an entry that is
11 electronically accessible to the prescribing practitioner through one of the following:

- 12 1. An interoperable electronic medical records system.
- 13 2. An electronic prescribing technology.
- 14 3. A pharmacist benefit management system.
- 15 4. A pharmacy record.

16 (b) If a pharmacist is unable to make an entry as provided in par. (a),
17 communicate the biological product dispensed to the prescribing practitioner using
18 facsimile, telephone, electronic transmission, or another prevailing means, except
19 that communication under this paragraph is not required if any of the following
20 applies:

- 21 1. There is no interchangeable biological product for the product prescribed.
- 22 2. A refill of the biological product is not changed from the product dispensed
23 on the prior filling of the prescription.

24 **(6) LIMITATION OF LIABILITY.** A pharmacist who dispenses a prescription with an
25 interchangeable biological product under this section assumes no greater liability

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1 than would be incurred had the pharmacist dispensed the prescription with the
2 biological product prescribed.

3 **(7) USE OF INTERCHANGEABLE BIOLOGICAL PRODUCT IN HOSPITALS.** Subsections (2)
4 to (6) do not apply to a pharmacist who dispenses an interchangeable biological
5 product that is prescribed for a patient in a hospital if the pharmacist dispenses the
6 interchangeable biological product in accordance with written guidelines or
7 procedures previously established by a pharmacy and therapeutics committee of the
8 hospital and approved by the hospital's medical staff and use of the interchangeable
9 biological product has been approved for a patient during the period of the patient's
10 stay within the hospital by any of the following:

11 (a) The patient's individual physician.

12 (b) The patient's advanced practice nurse prescriber, if the advanced practice
13 nurse prescriber has entered into a written agreement to collaborate with a
14 physician.

15 (c) The patient's physician assistant.

16 **(8) APPLICABILITY.** This section applies only with respect to prescriptions for
17 biological products.

18 **(9) LINKS TO BE MAINTAINED BY BOARD.** The board shall maintain links on the
19 department's Internet site to the federal food and drug administration's lists of all
20 currently approved interchangeable biological products.

21 **(END)**