

State of Wisconsin



2017 Senate Bill 575

Date of enactment: **March 28, 2018**

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2017 WISCONSIN ACT 149

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

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

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

102.425 (1) (c) "Drug product equivalent" has the meaning given in s. 450.13 (4) (1e).

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

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

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

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

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

450.11 (4g) (a) 2. "Drug product equivalent" has the meaning given in s. 450.13 (4) (1e).

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

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

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

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

1. "Brand name" has the meaning given in s. 450.122 (1) (a).

2. "Interchangeable biological product" has the meaning given in s. 450.135 (1).

3. "Proper name" has the meaning given in s. 450.122 (1) (b).

(b) 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 under sub. (4) (a) may include both the proper name of the interchangeable biological product and the brand name specified in the prescription order.

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

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

SECTION 8. 450.122 of the statutes is created to read:
450.122 Labeling of biological products. (1) In this section:

(a) "Brand name" means the name, other than the proper name, that the labeler of a biological product

* Section 991.11, WISCONSIN STATUTES: Effective date of acts. "Every act and every portion of an act enacted by the legislature over the governor's partial veto which does not expressly prescribe the time when it takes effect shall take effect on the day after its date of publication."

places on its commercial container at the time of packaging.

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

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

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

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

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

(1e) DEFINITION. In this section, "drug product equivalent" means a drug product that is designated the therapeutic equivalent of another drug product by the federal food and drug administration as set forth in the latest edition of or supplement to the federal food and drug administration's Approved Drug Products with Therapeutic Equivalence Evaluations.

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

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

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

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

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

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

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

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

SECTION 14. 450.135 of the statutes is created to read:
450.135 Using interchangeable biological product in dispensing prescriptions. (1) DEFINITION. In this section, "interchangeable biological product" means a biological product that the federal food and drug administration has licensed and has determined meets the standards for interchangeability pursuant to 42 USC 262 (k) (4) or has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the federal food and drug administration's Approved Drug Products with Therapeutic Equivalence Evaluations.

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

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

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

(5) COMMUNICATION OF BIOLOGICAL PRODUCT DISPENSED. Within 5 business days after the dispensing of a

biological product, the dispensing pharmacist or the pharmacist's designee shall do one of the following:

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

1. An interoperable electronic medical records system.
2. An electronic prescribing technology.
3. A pharmacist benefit management system.
4. A pharmacy record.

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

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

(6) LIMITATION OF LIABILITY. A pharmacist who dis-

penses a prescription with an interchangeable biological product under this section assumes no greater liability than would be incurred had the pharmacist dispensed the prescription with the biological product prescribed.

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

- (a) The patient's individual physician.
- (b) The patient's advanced practice nurse prescriber, if the advanced practice nurse prescriber has entered into a written agreement to collaborate with a physician.
- (c) The patient's physician assistant.

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

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

