State of Wisconsin
2023 - 2024 LEGISLATURE

LRB-5197/1
JPC:amn

2023 ASSEMBLY BILL 849

December 22, 2023 – Introduced by Representatives VINING, C. ANDERSON, J. ANDERSON, CLANCY, CONLEY, CONSIDINE, DRAKE, EMERSON, JOERS, MADISON, OHNSTAD, ORTIZ-VELEZ, RATCLIFF, SHANKLAND and SINICKI, cosponsored by Senators SPREITZER, SMITH, TAYLOR, WIRCH and AGARD. Referred to Committee on Health, Aging and Long-Term Care.

AUTHORS SUBJECT TO CHANGE

AN ACT ***to amend*** 450.13 (title); and ***to create*** 450.13 (5n) of the statutes; **relating to:** therapeutic interchange for drug products prescribed to counteract anaphylaxis.

Analysis by the Legislative Reference Bureau

This bill allows a pharmacist to substitute a drug product prescribed to counteract anaphylaxis with another drug product that would, in the opinion of the pharmacist, have a substantially equivalent therapeutic effect even though the substitute drug product is *not* a drug product equivalent if certain conditions are met. The bill also provides that a pharmacist who dispenses a drug product for a patient in a hospital may, for a drug product prescribed to counteract anaphylaxis, under the same conditions applicable for drug product equivalents under current law, substitute a drug product with another drug product that would, in the opinion of the pharmacist, have a substantially equivalent therapeutic effect even though the substitute drug product is not a drug product equivalent. Current law defines a "drug product equivalent" as 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 the supplement to the federal Food and Drug Administration's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the Orange Book. As with substitution of drug

product equivalents under current law, the therapeutic substitutions allowed under the bill do not apply to biological products.

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

SECTION 1. 450.13 (title) of the statutes is amended to read:

450.13 (title) **Using drug product equivalent in dispensing prescriptions; therapeutic exchange for drug products prescribed to counteract anaphylaxis.**

SECTION 2. 450.13 (5n) of the statutes is created to read:

450.13 **(5n)** THERAPEUTIC INTERCHANGE FOR DRUGS COUNTERACTING ANAPHYLAXIS. (a) Notwithstanding subs. (1s) to (4), for a drug product prescribed to counteract anaphylaxis, a pharmacist may substitute a drug product with another drug product that would, in the opinion of the pharmacist, have a substantially equivalent therapeutic effect even though the substitute drug product is not a drug product equivalent, provided all of the following conditions are met:

1. A prescribing practitioner has not indicated, by writing on the face of the prescription order or, with respect to a prescription order transmitted electronically, by designating in electronic format that a substitution of the drug product prescribed may not be made under this subsection. If such indication is made, the pharmacist shall dispense the prescription with the specific drug product prescribed.

2. The drug product substitution is intended to ensure formulary compliance with the consumer's health insurance plan or, in the case of a consumer without insurance, to lower the cost to the patient while maintaining safety.

3. The consumer opts in to the drug product substitution, and the pharmacist clearly informs the consumer of the differences in the drug products and specifies that the consumer may refuse the substitution.

(b) If a pharmacist substitutes a drug product prescribed to counteract anaphylaxis under this subsection, the pharmacist must ensure that the prescriber's directions and quantity are modified to allow for equivalent dispensing to what was originally prescribed.

(c) Within 5 business days after the dispensing of a drug product substitute under this subsection, the dispensing pharmacist or the pharmacist's designee shall do one of the following:

1. Make an entry of the specific drug 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:

a. An interoperable electronic medical records system.

b. An electronic prescribing technology.

c. A pharmacist benefit management system.

d. A pharmacy record.

2. If a pharmacist is unable to make an entry as provided in subd. 1., communicate the drug product substitute dispensed to the prescribing practitioner using facsimile, telephone, electronic transmission, or another prevailing means, except that communication under this paragraph is not required if a refill of the drug

product is not changed from the product dispensed on the prior filling of the prescription.

(d) Notwithstanding pars. (a) to (c), a pharmacist who dispenses a drug product prescribed for a patient in a hospital may, for a drug product prescribed to counteract anaphylaxis, substitute a drug product with another drug product that would, in the opinion of the pharmacist, have a substantially equivalent therapeutic effect even though the substitute drug product is not a drug product equivalent, if the pharmacist dispenses the drug product substitute 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 substitute has been approved for a patient during the period of the patient's stay within the hospital by any of the following:

1. The patient's individual physician.

2. The patient's advanced practice nurse prescriber, if the advanced practice nurse prescriber has entered into a written agreement to collaborate with a physician.

3. The patient's physician assistant.

(END)