



State of Wisconsin
2019 - 2020 LEGISLATURE

LRB-5232/3
SWB:ahe&skw

2019 ASSEMBLY BILL 1011

March 20, 2020 - Introduced by Representatives VINING, SPREITZER, ANDERSON, BROSTOFF, CABRERA, FIELDS, HEBL, KOLSTE, NEUBAUER, OHNSTAD, SHANKLAND, SINICKI, STUBBS, SUBECK and ZAMARRIPA, cosponsored by Senators HANSEN, JACQUE, LARSON, RINGHAND, SCHACHTNER, SMITH, L. TAYLOR and WIRCH. Referred to Committee on Health.

1 **AN ACT** *to renumber and amend* 450.13 (1e); *to amend* 102.425 (1) (c), 450.11
2 (4g) (a) 2. and 450.13 (title); and *to create* 20.435 (1) (ck), 256.158, 450.13 (1e)
3 (b) and 450.13 (5m) of the statutes; **relating to:** epinephrine for ambulances,
4 therapeutic interchange for drug products prescribed to counteract
5 anaphylaxis, and making an appropriation.

Analysis by the Legislative Reference Bureau

This bill requires that the Department of Health Services purchase and provide to ambulance service providers without charge a set of two epinephrine auto-injectors or a set of two draw-up epinephrine kits for each ambulance operating in the state. Under the bill, an ambulance service provider means an ambulance service provider that is a public agency, volunteer fire department, or nonprofit corporation. The bill also requires that, on an ongoing basis, DHS must, upon request, provide replacement sets to ambulance service providers.

Also, for drug products prescribed to counteract anaphylaxis, this bill allows, if certain conditions are met, a pharmacist to substitute a drug product with another drug product in the same therapeutic class 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. 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

ASSEMBLY BILL 1011

another drug product in the same therapeutic class 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 or 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 class substitutions allowed under the bill do not apply to biological products.

For further information see the *state and local* fiscal estimate, which will be printed as an appendix to this bill.

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

1 **SECTION 1.** 20.435 (1) (ck) of the statutes is created to read:

2 20.435 (1) (ck) *Epinephrine for ambulances.* A sum sufficient for the
3 department of health services to purchase and provide epinephrine for ambulances
4 under s. 256.158.

5 **SECTION 2.** 102.425 (1) (c) of the statutes is amended to read:

6 102.425 (1) (c) “Drug product equivalent” has the meaning given in s. 450.13
7 (1e) (a).

8 **SECTION 3.** 256.158 of the statutes is created to read:

9 **256.158 Epinephrine for ambulances. (1)** In this section:

10 (a) “Ambulance service provider” means an ambulance service provider that is
11 a public agency, volunteer fire department, or nonprofit corporation.

12 (b) “Draw-up epinephrine” means epinephrine that is administered
13 intramuscularly using a needle and syringe and drawn up from a vial or ampule.

14 (c) “Draw-up epinephrine kit” means a single-use vial or ampule of draw-up
15 epinephrine and a syringe for administration to a patient.

ASSEMBLY BILL 1011

1 **(2)** From the appropriation under s. 20.435 (1) (ck), the department shall
2 purchase and provide to ambulance service providers without charge a set of 2
3 epinephrine auto-injectors or a set of 2 draw-up epinephrine kits for each
4 ambulance operating in the state. On an ongoing basis, the department shall, upon
5 request from an ambulance service provider, provide to the ambulance service
6 provider a replacement set of 2 epinephrine auto-injectors or a set of 2 draw-up
7 epinephrine kits. The department shall allow the ambulance service provider to
8 choose between epinephrine auto-injectors and draw-up epinephrine kits.

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

10 450.11 **(4g)** (a) 2. “Drug product equivalent” has the meaning given in s. 450.13
11 (1e) (a).

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

13 **450.13** (title) **Using drug product equivalent in dispensing**
14 **prescriptions; therapeutic exchange for drug products prescribed to**
15 **counteract anaphylaxis.**

16 **SECTION 6.** 450.13 (1e) of the statutes is renumbered 450.13 (1e) (intro.) and
17 amended to read:

18 450.13 **(1e)** ~~DEFINITION~~ DEFINITIONS. (intro.) In this section, “drug:

19 (a) “Drug product equivalent” means a drug product that is designated the
20 therapeutic equivalent of another drug product by the federal food and drug
21 administration as set forth in the latest edition of or supplement to the federal food
22 and drug administration’s Approved Drug Products with Therapeutic Equivalence
23 Evaluations.

24 **SECTION 7.** 450.13 (1e) (b) of the statutes is created to read:

ASSEMBLY BILL 1011**SECTION 7**

1 450.13 **(1e)** (b) “Therapeutic class” means a group of similar drug products that
2 are used to treat a specific condition.

3 **SECTION 8.** 450.13 (5m) of the statutes is created to read:

4 450.13 **(5m)** THERAPEUTIC INTERCHANGE FOR DRUGS COUNTERACTING ANAPHYLAXIS.

5 (a) Notwithstanding subs. (1s) to (4), for a drug product prescribed to counteract
6 anaphylaxis, a pharmacist may substitute a drug product with another drug product
7 in the same therapeutic class that would, in the opinion of the pharmacist, have a
8 substantially equivalent therapeutic effect even though the substitute drug product
9 is not a drug product equivalent, provided all of the following conditions are met:

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

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

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

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

ASSEMBLY BILL 1011

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

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

10 a. An interoperable electronic medical records system.

11 b. An electronic prescribing technology.

12 c. A pharmacist benefit management system.

13 d. A pharmacy record.

14 2. If a pharmacist is unable to make an entry as provided in subd. 1.,
15 communicate the drug product substitute dispensed to the prescribing practitioner
16 using facsimile, telephone, electronic transmission, or another prevailing means,
17 except that communication under this paragraph is not required if a refill of the drug
18 product is not changed from the product dispensed on the prior filling of the
19 prescription.

20 (d) Notwithstanding pars. (a) to (c), a pharmacist who dispenses a drug product
21 prescribed for a patient in a hospital may, for a drug product prescribed to counteract
22 anaphylaxis, substitute a drug product with another drug product in the same
23 therapeutic class that would in the opinion of the pharmacist, have a substantially
24 equivalent therapeutic effect even though the substitute drug product is not a drug
25 product equivalent, if the pharmacist dispenses the drug product substitute in

ASSEMBLY BILL 1011

1 accordance with written guidelines or procedures previously established by a
2 pharmacy and therapeutics committee of the hospital and approved by the hospital's
3 medical staff and use of the drug product substitute has been approved for a patient
4 during the period of the patient's stay within the hospital by any of the following:

- 5 1. The patient's individual physician.
- 6 2. The patient's advanced practice nurse prescriber, if the advanced practice
7 nurse prescriber has entered into a written agreement to collaborate with a
8 physician.
- 9 3. The patient's physician assistant.

10 (END)