State of Wisconsin
2019 - 2020 LEGISLATURE

LRB-5232/P4
SWB:ahe

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

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

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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 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, upon request from an ambulance service provider for a set of epinephrine auto-injectors to replace a used or expired epinephrine auto-injector for an ambulance, DHS must provide to the ambulance service provider a replacement set of two epinephrine auto-injectors.

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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 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:

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

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

SECTION 2. 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 (1e) (a).

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

256.158 Epinephrine for ambulances. (1) In this section, "ambulance service provider" means an ambulance service provider that is a public agency, volunteer fire department, or nonprofit corporation.

(2) From the appropriation under s. 20.435 (1) (ck), the department shall purchase and provide to ambulance service providers without charge a set of 2 epinephrine auto-injectors for each ambulance operating in the state. On an

ongoing basis, the department shall, upon request from an ambulance service provider for a set of epinephrine auto-injectors to replace a used or expired epinephrine auto-injector for an ambulance, provide to the ambulance service provider a replacement set of 2 epinephrine auto-injectors.

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 (1e) (a).

SECTION 5. 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 6. 450.13 (1e) of the statutes is renumbered 450.13 (1e) (intro.) and amended to read:

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

(a) "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 7. 450.13 (1e) (b) of the statutes is created to read:

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

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

450.13 **(5m)** 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 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, 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 the phrase "No therapeutic class substitutions" or words of similar meaning or the initials "N.T.C.S." 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. No preprinted statement regarding drug product substitution may appear on the face of the prescription order.

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 are modified to allow for an equivalent amount of drug product to be dispensed as 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 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, 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)

Walkenhorst Barber, Sarah

From: Palzewicz, Maddie
Sent: Thursday, February 13, 2020 9:28 AM
To: Walkenhorst Barber, Sarah
Subject: Epinephrine bill edits
Attachments: epi bill language_ssedits.docx

Hi Sarah,

I know I already requested the introductory form of the bill, but can I add in these edits to the bill? Starting at page 4, line 5.

Let me know if that is possible. Thank you!

-Maddie

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 ~~the phrase "No therapeutic class substitutions" or words of similar meaning or the initials "N.T.C.S."~~ 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. ~~No preprinted statement regarding drug product substitution may appear on the face of the prescription order.~~

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 ~~an~~ equivalent ~~amount of drug product to be~~ dispensing to what was originally~~ed as~~ prescribed.

1/24

LRB 19-5232

Per Maddie (Rep Vining's office)

Modify draft to:

* Have DHS replace epi pens as needed, continuous supply
  - can require request from ambulance service provider

* Have hospital pharmacies operate as they would for therapeutic equivalents / drug product equivalents

State of Wisconsin
2019 - 2020 LEGISLATURE

LRB-5232/1
SWB:ahe

2019 BILL

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(END)

Per Maddie:

* Add option for ambulance service provider to receive draw-up epinephrine (instead of auto-injectors)

* Leave option to ambulance service provider, not DHS

State of Wisconsin
2019 - 2020 LEGISLATURE

LRB-5232/2
SWB:ahe&skw

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INSERT 2-11

(b) "Draw-up epinephrine" means epinephrine to be administered intramuscularly using a needle and syringe and drawn up from a vial or ampule.

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

(END INSERT 2-11)

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 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.

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(END)

Barman, Mike

From: Walkenhorst Barber, Sarah
Sent: Tuesday, March 03, 2020 2:27 PM
To: Ernst-Treutel, Alexis; Barman, Mike
Subject: Jacket for 5232/3

Hi Lexi and Mike,

Just thought I'd email you both as I'm not sure who has the file at the moment. Rep. Vining's office would like to have the /3 of LRB 5232 jacketed right away when it comes through, if you could!

Thanks,
Sarah

Sarah Walkenhorst Barber
Senior Legislative Attorney
Wisconsin Legislative Reference Bureau
P.O. Box 2037
Madison, WI 53701-2037
(608) 504-5826
sarah.walkenhorstbarber@legis.wisconsin.gov

Walker, Dan

From: LRB.Legal
To: Rep.Vining
Subject: Draft review: LRB -5232/3
Attachments: 19-5232/3

State of Wisconsin - Legislative Reference Bureau

One East Main Street - Suite 200 - Madison

The attached draft was prepared at your request. Please review it carefully to ensure that it satisfies your intent. If you have any questions concerning the draft or would like to have it redrafted, please contact Sarah Walkenhorst Barber, Legislative Attorney, at (608) 504-5826, at sarah.walkenhorstbarber@legis.wisconsin.gov, or at One East Main Street, Suite 200.

We will re-jacket this draft for introduction in the Assembly.

If a jacket is needed immediately, please let us know in your response e-mail so we know to immediately jacket the proposal for you.

If the last paragraph of the analysis states that a fiscal estimate will be prepared, the LRB will submit a request to DOA when the draft is introduced. You may obtain a fiscal estimate on the draft prior to introduction by contacting our program assistants at LRB.Legal@legis.wisconsin.gov or at (608) 266-3561. If you requested a fiscal estimate on an earlier version of this draft and would like to obtain a fiscal estimate on the current version before it is introduced, you will need to request a revised fiscal estimate from our program assistants.

Please call our program assistants at (608) 266-3561 if you have any questions regarding this email.