2019 DRAFTING REQUEST

Bill

For:	**Robyn Vining (608) 266-9180**	Drafter:	**swalkenh**
By:	**Maddie**	Secondary Drafters:	
Date:	**1/2/2020**	May Contact:	

Same as LRB:

Submit via email: **YES**
Requester's email: **Rep.Vining@legis.wisconsin.gov**
Carbon copy (CC) to: **tamara.dodge@legis.wisconsin.gov**
sarah.walkenhorstbarber@legis.wisconsin.gov

Pre Topic:

No specific pre topic given

Topic:

Epinephrine for ambulances and therapeutic substitutions

Instructions:

See attached

Drafting History:

Vers.	Drafted	Reviewed	Submitted	Jacketed	Required
/?	swalkenh 1/21/2020	aernsttr 1/21/2020			
/P1	swalkenh 1/27/2020		lparisi 1/21/2020		
/P2	swalkenh 2/6/2020	aernsttr 1/27/2020	jmurphy 1/27/2020		
/P3	swalkenh 2/10/2020	aernsttr 2/6/2020	wjackson 2/6/2020		State S&L
/P4		aernsttr	mbarman		State

Vers.	Drafted	Reviewed	Submitted	Jacketed	Required
		2/10/2020	2/10/2020		S&L
/1	swalkenh 2/13/2020		jmurphy 2/12/2020	jmurphy 2/12/2020	State S&L
/2	swalkenh 3/3/2020	swinder 2/13/2020	lparisi 2/13/2020	lparisi 2/13/2020	State S&L
/3		aernsttr 3/3/2020	dwalker 3/3/2020	dwalker 3/3/2020	State S&L

FE Sent For: at intro

<END>

1/2

Call w/ Maddie from Rep. Vining's office

1) Direct DHS to purchase a set of autoinjectors for each ambulance in WI

2) Allow therapeutic interchange to substitute drugs by pharmacist
(Prescriber must opt in to substitute)
For drugs prescribed to counteract anaphylaxis caused by an allergic reaction

Dodge, Tamara

From: Palzewicz, Maddie
Sent: Thursday, January 02, 2020 11:42 AM
To: Dodge, Tamara
Subject: RE: Bill draft request

Hi Tami,

Here is the information for the bill draft-

Part 1: DHS provides epinephrine auto-injector to all ambulances
Part 2: Therapeutic interchange language for epinephrine (or anaphylaxis prevention drugs- however it fits in the statutory language!)

Therapeutic interchange language from Idaho: https://legislature.idaho.gov/wp-content/uploads/sessioninfo/2018/legislation/H0339.pdf
More info: https://www.jmcp.org/doi/pdf/10.18553/jmcp.2018.24.12.1260

Thank you!

Maddie Palzewicz
Office of Representative Robyn Vining
Room 321 West
608-266-9180

From: Dodge, Tamara <Tamara.Dodge@legis.wisconsin.gov>
Sent: Monday, December 30, 2019 2:23 PM
To: Palzewicz, Maddie <Maddie.Palzewicz@legis.wisconsin.gov>
Subject: RE: Bill draft request

Maddie,

I am available either Thursday or Friday at any time. You can either give me a call or I can stop by your office.

Tami
608-504-5808 (direct)

Sent from my Verizon, Samsung Galaxy smartphone

-------- Original message --------
From: "Palzewicz, Maddie" <Maddie.Palzewicz@legis.wisconsin.gov>
Date: 12/30/19 2:08 PM (GMT-06:00)
To: "Dodge, Tamara" <Tamara.Dodge@legis.wisconsin.gov>

Subject: Bill draft request

Good afternoon,

I was wondering if you are available to talk today or on Thursday or Friday about a bill our office would like to have drafted.

Let me know what time works best for you. Thank you!

Maddie Palzewicz
Office of Representative Robyn Vining
Room 321 West
608-266-9180

State Approaches to Therapeutic Interchange in Community Pharmacy Settings: Legislative and Regulatory Authority

Thomas Vanderholm, PharmD; Donald Klepser, PhD, MBA; and Alex J. Adams, PharmD, MPH

SUMMARY

Therapeutic interchange is the act of switching a prescribed drug for another drug in the same therapeutic class that is believed to be therapeutically similar but may be chemically different. Therapeutic interchange is different from generic substitution in that it does *not* occur between therapeutically equivalent products; instead, products are substituted for those that are likely to have a substantially equivalent therapeutic effect generally at a lower cost. Therapeutic interchange is common in institutional settings across the United States but rarely occurs in community pharmacy settings without a pharmacist first contacting the original prescriber and requesting a new prescription in order to facilitate a change.

As of 2018, Arkansas, Idaho, and Kentucky have passed laws to enable therapeutic interchange in community pharmacy settings. In general, these laws require the original prescriber to opt-in to allow therapeutic interchange, and the pharmacist generally must leverage the formulary of the patient's health plan to guide decision making within the same therapeutic class. These 3 states require that the pharmacist notify the original prescriber of any interchange in order to ensure a complete and accurate medication record. When appropriately structured, state laws enabling therapeutic interchange in community pharmacy settings allow pharmacists to use their medication expertise to save valuable time and enhance patient care while reducing health care costs.

J Manag Care Spec Pharm. 2018;24(12):1260-63

Rising drug prices are a significant driver of total health care costs, with an 8% drug price increase expected in 2018.[1] One tool to combat rising drug prices is therapeutic interchange, the act of switching a prescribed drug for another drug in the same therapeutic class that is believed to be therapeutically similar but may be chemically different. Therapeutic interchange is differentiated from generic substitution in that it does *not* occur between therapeutically equivalent products; instead, products are substituted for those that are likely to have a substantially equivalent therapeutic effect, generally at a lower cost.[2]

One study has found that in statin medications alone, there was a 10% cost saving in a 2-year period due to therapeutic interchange.[3] A second study found that therapeutic interchange saved a managed care organization a mean of $20.31 per prescription filled and saved patients a mean of $14.76 per prescription filled.[4] Johansen and Richardson (2016) estimated potential savings of therapeutic interchange and projected savings of $73 billion in excess branded drug overuse.[5]

Therapeutic interchange has been a common practice in institutional settings and has been in use at more than 80% of hospitals since 2002.[6,7] In these settings, formularies are developed by an interdisciplinary pharmacy and therapeutics committee where health care practitioners decide which medications are appropriate for interchange. Institutional pharmacists can freely interchange products in accordance with the formulary.

Less common is the practice of therapeutic interchange in community pharmacy settings. Currently, a pharmacist must contact the original prescriber and request a new prescription in order to facilitate a change, which results in delayed patient care and imposes an administrative burden on both parties.[8-10] Community pharmacies do not have closed formularies nor formulary committees to leverage for therapeutic interchange. Prescribers may, however, be able to authorize therapeutic interchange on a patient-by-patient basis in community pharmacy settings by allowing pharmacists to leverage the formulary of the patient's health plan. This approach can replicate the safeguards established within an institutional setting while saving money and reducing bureaucratic hassles. To date, 3 states have adopted this practice into law. The purpose of this article is to explore the legislative and regulatory considerations in authorizing therapeutic interchange in community pharmacy settings.

Considerations for Policy Development

Several organizations have published position statements outlining under what circumstances therapeutic interchange should take place.[11-16] These organizations represent patient and disease advocacy groups and pharmacy, physician, and managed care organizations. Although each position statement was published separately, a consensus appears to have been independently reached among multiple organizations around the following points:

1. Therapeutic interchange should only be used for medications expected to provide a substantially similar benefit to those desired from the originally prescribed medication.[11-15]
2. Therapeutic interchange is appropriate where there is some type of evidence-based formulary, developed with the input of interdisciplinary health professions, to help facilitate decision making.[11,13-15]
3. Interchange should be considered in light of therapeutic benefit foremost, followed by cost considerations.[11,12,15]

TABLE 1 Summary of Current U.S. Legislation

Parameter	Idaho[21]	Kentucky[19]	Arkansas[20]
Does the prescriber have to opt-in?	Yes	Yes	Yes
Does the substitution have to be in compliance with the health plan formulary?	Yes, unless in the case of a patient without health insurance, in which case the intent is to lower the cost to the patient while maintaining safety	Yes	No, the pharmacist may substitute a drug that is at a lower cost to the patient
Does the patient have to opt-in?	Yes	No	Yes
If a substitution is made, must the original prescriber be notified?	Yes	Yes	Yes
Are any drugs explicitly excluded?	Yes, biologics and narrow therapeutic index drugs	No	No

4. Patients should be notified of and agree to any change before dispensing the medication.[11,15]
5. Pharmacies should retain records of any interchange performed.[12,13]
6. Physicians should be notified of interchange within a reasonable time period after the change occurs.[11,13]
7. There should be some mechanism in place to exclude patients and medications from interchange when clinically inappropriate.[11,12,15]

Concerns regarding therapeutic interchange generally focus on certain circumstances or practices, not blanket opposition. Perhaps the most widely expressed concern regards patient safety as it relates to narrow therapeutic index drugs, particularly for psychoactive medications, which can have different actions and effects even in the same therapeutic class.[15,16] In addition, some have noted that pharmacists should have a conversation with the physician about which medication they will dispense *before* dispensing it.[17] Finally, some have expressed concerns that physicians may be confused about how therapeutic interchange differs from brand-generic substitution and may not be sure what they are opting-in to.[17]

Current Legal Authority in the United States

Therapeutic interchange could occur in the 17 states that allow population-specific collaborative practice agreements (CPAs), although there are practical impediments to doing so.[18] There are currently only 3 states with legislation authorizing therapeutic interchange in community pharmacy settings outside of a CPA: Arkansas, Kentucky, and Idaho.[19-21] A summary of the core elements of the laws in each of these states is outlined in Table 1.

In 2003, Kentucky was the first state to pass a law authorizing this practice. Arkansas followed suit in 2015, and Idaho's legislation took effect on July 1, 2018. Arkansas and Idaho have adopted an identical definition of "therapeutic class" to guide interchange: "A group of similar drug products that have the same or similar mechanisms of action and are used to treat a specific condition."

All 3 states require that the physician opt-in to the interchange; thus, the decision to allow interchange is at the discretion of the original prescriber on a patient-by-patient basis. In Kentucky, for example, the prescriber must write "formulary compliance approval" on the prescription or check a box to that effect, whereas in Arkansas and Idaho, the physician must write "therapeutic substitution allowed" or make "a similar designation."

Idaho and Kentucky require that the substitution be in compliance with the patient's health plan formulary, such as changing from a nonpreferred drug to a preferred drug. Arkansas states that the substitution must be to a drug "that is at a lower cost to the patient." Idaho adapts this lower cost language for patients who do not have health plan coverage, allowing switches to a lower-cost drug in these instances. Kentucky is silent on how to handle interchange for patients without an insurer.

All 3 states require notification back to the original prescriber of any interchange in order to ensure a complete and accurate medication record. Arkansas and Kentucky require this notification within 24 business hours. Idaho requires notification within 5 days, which synchronizes this notification with that required for drugs that Idaho pharmacists can independently prescribe.[22] Only Idaho explicitly prohibits interchange for narrow therapeutic index drugs and biological products, since a separate state law governs substitution of biosimilars.

Review of Canadian Pharmacy Law

Currently, 7 of 13 Canadian provinces and territories allow therapeutic interchange by law (Nova Scotia, Prince Edward Island, Newfoundland, Saskatchewan, Alberta, British Columbia, and New Brunswick).[23] These laws vary by province, but on the least restrictive end, therapeutic interchange is permissible even without physician opt-in; therefore, interchange can be the default position for the pharmacist.[24] Similarly, in some provinces, notification is only provided to the original prescriber when the change is deemed "clinically significant." The prescriber retains the ability to opt-out of the interchange by indicating "do not adapt" or a similar designation on the prescription.

Discussion

Getting therapeutic interchange legislation passed can be a difficult prospect, as indicated by only 3 states having such laws

TABLE 2 Opportunities to Address Concerns Regarding Therapeutic Interchange

Concern	Potential Policy Response
Narrow therapeutic index drugs can pose patient safety issues, as a small change in blood concentration can lead to a major difference in patient response.	Policy can expressly prohibit interchange for narrow therapeutic index drugs. Idaho law states: "Nothing in this section shall apply to…narrow therapeutic index drugs." Idaho law further defined narrow therapeutic index drugs as "a drug where a small difference in dose or blood concentration may lead to serious therapeutic failures or adverse drug reactions."
Pharmacists should have a conversation with the physician about which medication they will dispense *before* dispensing it.	Policy can require a physician to opt-in on the original prescription. This proactive prescriber opt-in, which occurs before dispensing, retains prescriber autonomy but removes the hassle of the pharmacist having to contact the prescriber for common sense interchanges when the patient's health plan has a different preferred drug in the same therapeutic class.
Physicians may be confused about how therapeutic interchange differs from brand-generic substitution and may not be sure what they are opting-in to.	Brand-generic substitution has become a default that prescribers can opt-out of. In 2016, nearly 3.9 billion generic prescriptions were dispensed in the United States.[27] Requiring a prescriber to opt-in to therapeutic interchange creates a suitable distinction between the 2 concepts.

that enable the practice in community pharmacy settings. The core elements of these existing state laws closely align with the tenants put forth in the position statements issued by patient advocacy groups and pharmacy, physician, and managed care organizations.

Legislation can be and has been structured to address core issues. First, leveraging a health plan's formulary as the basis for interchange within a therapeutic class can appropriately balance therapeutic benefits with cost considerations. This leveraging can further eliminate the perception of conflict of interest associated with pharmacists switching medications. Second, physician opt-in allows patient-by-patient decisions on therapeutic interchange. Simply put, if a physician wants a patient to be on a specific drug, he or she simply does not have to indicate "therapeutic substitution allowed" on the prescription. Third, laws can respect the tenets of informed choice by requiring the patient's agreement to any change. In Idaho, for example, the law requires the pharmacist to "clearly inform" the patient of any differences in the drug products and specify that "the patient may refuse the substitution."[21]

Of note, several Canadian provinces have laws that are more progressive than those in the United States, whereby the default is to allow interchange, and the physician has to opt-out if he or she does not want a product to be changed. Even with this practice, Canada has a safe track record. In the first year that therapeutic interchange was allowed in British Columbia, pharmacists performed 3,713 substitutions.[25] The most commonly substituted medications included rabeprazole (n=1,098), beclomethasone (n=211), and naproxen (n=161). No safety issues have been reported.[25,26]

The most significant concern expressed over therapeutic interchange concerns narrow therapeutic index drugs. Legislation can explicitly exclude these from interchange, as Idaho did in law. Even without an express carve out, Arkansas and Kentucky practically exempt these drug categories, since it is unlikely that prescribers and patients would each separately opt-in to such a substitution, and equally unlikely that a pharmacist would offer. Table 2 includes a list of policy considerations that may address historical concerns over therapeutic interchange.

Conclusions

Therapeutic interchange allows pharmacists to use their medication expertise, to save valuable time, and enhance patient care while reducing health care costs. In doing so, patient safety has not been shown to be compromised. While theoretical concerns have been raised, they have been safely and effectively addressed in Arkansas, Idaho, and Kentucky, and no known reports of patient harm have resulted in these states (Arkansas and Kentucky have had more than 10 years of combined practice experience). Thus, more jurisdictions may consider appropriately structured therapeutic interchange laws (e.g., prescriber opt-in, limited to drugs in the same therapeutic class, leverage the health plan formulary, and require prescriber notification) in the years ahead.

Authors

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DISCLOSURES

No funding supported the writing of this article. The authors have nothing to disclose.

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LEGISLATURE OF THE STATE OF IDAHO

Sixty-fourth Legislature Second Regular Session - 2018

IN THE HOUSE OF REPRESENTATIVES

HOUSE BILL NO. 339

BY HEALTH AND WELFARE COMMITTEE

AN ACT

RELATING TO PHARMACY; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1768, IDAHO CODE, TO ESTABLISH PROVISIONS REGARDING CERTAIN DRUG PRODUCT SUBSTITUTIONS.

Be It Enacted by the Legislature of the State of Idaho:

SECTION 1. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a NEW SECTION, to be known and designated as Section 54-1768, Idaho Code, and to read as follows:

54-1768. PRESCRIBER-AUTHORIZED SUBSTITUTION. (1) A licensed prescriber may authorize a pharmacist to substitute a drug with another drug in the same therapeutic class that would, in the opinion of the pharmacist, have a substantially equivalent therapeutic effect even though the substitute drug is not a therapeutic equivalent drug, provided the following conditions are met:

(a) The prescriber has clearly indicated that drug product substitution is permissible by indicating "therapeutic substitution allowed" or by making a similar designation;

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

(c) The patient opts in to the drug product substitution, and the pharmacist clearly informs the patient of the differences in the drug products and specifies that the patient may refuse the substitution; and

(d) If a drug product substitution is made:

(i) The prescriber's directions are modified to allow for an equivalent amount of drug to be dispensed as prescribed; and

(ii) The pharmacist shall notify the patient's original prescriber of the drug product substitution within five (5) business days of dispensing the prescription.

(2) Nothing in this section shall apply to biological products, as set forth in section 54-1769, Idaho Code, or to narrow therapeutic index drugs.

(3) For purposes of this section:

(a) "Drug product substitution" means dispensing a drug product other than the drug product originally prescribed.

(b) "Narrow therapeutic index drug" means a drug where a small difference in dose or blood concentration may lead to serious therapeutic failures or adverse drug reactions.

(c) "Therapeutic class" means a group of similar drug products that have the same or similar mechanisms of action and are used to treat a specific condition.

(d) "Therapeutic equivalent drug" means a product assigned an "A" code by the federal food and drug administration (FDA) in the "Approved Products with Therapeutic Equivalence Evaluations" (orange book) and animal drug products published in the FDA's "Approved Animal Drug Products" (green book).

State of Wisconsin
2019 - 2020 LEGISLATURE

LRB-5232/?
SWB:...

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

AN ACT ...; **relating to:** epinephrine for ambulances and therapeutic interchange for drugs prescribed to counteract anaphylaxis.

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 2 epinephrine auto-injectors for each ambulance operating in the state. Also, for drugs prescribed to counteract anaphylaxis, this bill allows a prescribing practitioner to authorize a pharmacist to substitute a drug with another drug in the same therapeutic class that would, in the opinion of the pharmacist, have a substantially equivalent therapeutic effect even though the substitute drug 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. For drugs prescribed to counteract anaphylaxis, this bill allows, under certain circumstances, substitution of a drug in the same therapeutic class that is not a drug product equivalent. As with substitution of drug product equivalents under current law, the 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:

Insert 2-1

SECTION 1. 256.158 of the statutes is created to read:

256.158 Epinephrine for ambulances. 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.

Insert 2-4

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

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

drug products prescribed

History: 1985 a. 146; 1991 a. 114; 1997 a. 27; 2005 a. 187; 2011 a. 161; 2017 a. 149.

change components

RN 450.13 (1e) Cintro.)

SECTION 3. 450.13 (1e) of the statutes is amended to read:

450.13 **(1e)** ~~DEFINITION~~ DEFINITIONS. (Cintro.) 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 4. 450.13 (1e) (b) and (c) of the statutes are created to read:

450.13 **(1e)** (b) "Narrow therapeutic index drug (product)" means a drug (product) where a small difference in dose or blood concentration may lead to serious therapeutic failures or adverse drug reactions.

(c) "Therapeutic class" means a group of similar drug products that have the same or similar mechanisms of action and are used to treat a specific condition.

SECTION 5. 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 prescribing practitioner may authorize a pharmacist to substitute a drug with another drug in the same therapeutic class that would, in the opinion of the pharmacist, have a substantially equivalent therapeutic effect even though the substitute drug is not a therapeutically equivalent drug, provided all of the following conditions are met:

1. The prescriber has clearly indicated that drug product substitution is permissible 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 "therapeutic class substitution allowed" or words of similar meaning.

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

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

(b) If a pharmacist substitutes a drug product prescribed to counteract anaphylaxis under this section, the pharmacist must ensure all of the following occur:

1. The prescriber's directions are modified to allow for an equivalent amount of drug to be dispensed as prescribed.

2. The patient's original prescriber of the drug product is notified of the substitution within 5 business days of dispensing the prescription.

(c) This subsection does not apply with respect to a prescription for any narrow therapeutic index drug.

****NOTE: Current law includes an exception for biological products that will also apply to the new provisions in the bill. Current law, however, does not have an exception for prescriptions for narrow therapeutic index drugs (a provision included in the model language). As such, I included an exception, but limited to the new subsection created in the bill. Please let me know if you would like this exception to be applied more broadly (like the exception for biological products) so that it would apply to all drug product substitutions.

****NOTE: This draft creates an additional exception for drug substitution within the statute relating to drug product equivalents. The statute, as it relates to substitution of a drug product equivalent generally, includes a specific procedure under sub. (5) for hospital pharmacists. I have not, in this version of the draft, made that procedure applicable to the therapeutic class substitution allowed under the bill. Please let me know if you would like to have that procedure apply or if you would like to discuss.

1 **(END)**

2019-2020 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-5232/?ins
SWB:...

INSERT 2-1 sa ✓

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 (1e) (a).

(END INSERT 2-1)

INSERT 2-4

SECTION 2. 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).

(END INSERT 2-4)

State of Wisconsin
2019 - 2020 LEGISLATURE

LRB-5232/P1
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*** 256.158, 450.13 (1e) (b) and (c) and 450.13 (5m) of the statutes; **relating to:** epinephrine for ambulances and therapeutic interchange for drug products prescribed to counteract anaphylaxis.

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 for each ambulance operating in the state. Also, for drug products prescribed to counteract anaphylaxis, this bill allows a prescribing practitioner to authorize 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. 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. For drug products prescribed to counteract anaphylaxis, this bill allows, under certain circumstances, substitution of a drug in the same therapeutic class that is not a drug product equivalent. As with substitution of drug product

equivalents under current law, the 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. 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 2. 256.158 of the statutes is created to read:

256.158 Epinephrine for ambulances. 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.

SECTION 3. 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 4. 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 5. 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 6. 450.13 (1e) (b) and (c) of the statutes are created to read:

450.13 **(1e)** (b) "Narrow therapeutic index drug product" means a drug product where a small difference in dose or blood concentration may lead to serious therapeutic failures or adverse drug reactions.

(c) "Therapeutic class" means a group of similar drug products that have the same or similar mechanisms of action and are used to treat a specific condition.

SECTION 7. 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 prescribing practitioner may authorize 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 equivelant, provided all of the following conditions are met:

1. The prescriber has clearly indicated that drug product substitution is permissible 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 "therapeutic class substitution allowed" or words of similar meaning.

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

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

(b) If a pharmacist substitutes a drug product prescribed to counteract anaphylaxis under this subsection, the pharmacist must ensure all of the following occur:

1. The prescriber's directions are modified to allow for an equivalent amount of drug product to be dispensed as prescribed.

2. The patient's original prescriber of the drug product is notified of the substitution within 5 business days of dispensing the prescription.

(c) This subsection does not apply with respect to a prescription for any narrow therapeutic index drug product.

****NOTE: Current law includes an exception for biological products that will also apply to the new provisions in the bill. Current law, however, does not have an exception for prescriptions for narrow therapeutic index drugs (a provision included in the model language). As such, I included an exception, but limited to the new subsection created in the bill. Please let me know if you would like this exception to be applied more broadly (like the exception for biological products) so that it would apply to all drug product substitutions.

****NOTE: This draft creates an additional exception for drug substitution within the statute relating to drug product equivalents. The statute, as it relates to substitution of a drug product equivalent generally, includes a specific procedure under sub. (5) for hospital pharmacists. I have not, in this version of the draft, made that procedure applicable to the therapeutic class substitution allowed under the bill. Please let me know if you would like to have that procedure apply or if you would like to discuss.

(END)

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LRB-5232/P2ins
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INSERT ANALYSIS A

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 2 epinephrine auto-injectors.

(END INSERT ANALYSIS A)

INSERT ANALYSIS B

The bill also provides that, under the same conditions applicable to drug product equivalents under current law, a pharmacist who dispenses a drug product 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.

(END INSERT ANALYSIS B)

INSERT 2-7

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.

(END INSERT 2-7)

INSERT 4-12

(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 INSERT 4-12)

2/10/2026

Per Maddie, do a /P3 version:

* Add sum sufficient appropriation to fund epinephrine for ambulances (and for therapeutic interchange, if needed)

* Define ambulance service provider to include public and those that contract with public, not private "for profit" companies

* Incorporate notification to prescriber provision more similar or already in ch. 450 (for example, d appropriation the notification used in biological product section) 450.135 (5)

instead of language from model

State of Wisconsin
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LRB-5232/P2
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*** 256.158, 450.13 (1e) (b) and (c) and 450.13 (5m) of the statutes; **relating to:** epinephrine for ambulances and therapeutic interchange for drug products prescribed to counteract anaphylaxis.

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 for each ambulance operating in the state. 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. Also, for drug products prescribed to counteract anaphylaxis, this bill allows a prescribing practitioner to authorize 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, under the same conditions applicable to drug product equivalents under current law, a pharmacist who dispenses a drug product 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. 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. For drug products prescribed to counteract anaphylaxis, this bill allows, under certain circumstances, substitution of a drug in the same therapeutic class even though it is *not* a drug product equivalent. As with substitution of drug product equivalents under current law, the 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. 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 2. 256.158 of the statutes is created to read:

256.158 Epinephrine for ambulances. 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 3. 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 4. 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 5. 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 6. 450.13 (1e) (b) and (c) of the statutes are created to read:

450.13 **(1e)** (b) "Narrow therapeutic index drug product" means a drug product where a small difference in dose or blood concentration may lead to serious therapeutic failures or adverse drug reactions.

(c) "Therapeutic class" means a group of similar drug products that have the same or similar mechanisms of action and are used to treat a specific condition.

SECTION 7. 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 prescribing practitioner may authorize 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, provided all of the following conditions are met:

1. The prescriber has clearly indicated that drug product substitution is permissible 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 "therapeutic class substitution allowed" or words of similar meaning.

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

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

(b) If a pharmacist substitutes a drug product prescribed to counteract anaphylaxis under this subsection, the pharmacist must ensure all of the following occur:

1. The prescriber's directions are modified to allow for an equivalent amount of drug product to be dispensed as prescribed.

2. The patient's original prescriber of the drug product is notified of the substitution within 5 business days of dispensing the prescription.

(c) This subsection does not apply with respect to a prescription for any narrow therapeutic index drug product.

(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)

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LRB-5232/P3ins
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INSERT ANALYSIS

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

(END INSERT ANALYSIS)

INSERT 2-1

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.

(END INSERT 2-1)

INSERT 2-5

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

(END INSERT 2-5)

INSERT 4-16

(c) Within 5 business days after the dispensing 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.

(END INSERT 4-16)

WISCONSIN LEGISLATIVE REFERENCE BUREAU

Information Services 608-266-0341—Legal Services 608-266-3561

LRB

Per Maddie:

Page 3 (Section 7) - Eliminate "narrow therapeutic index drug product" definition as unnecessary
SUB-A As a result, can also eliminate Pg 5 lines 20-21 (par. (d))

Pg 4, line 1 - modify therapeutic class definition to take out mechanisms of action language

Pg 4, line 11 - change to an "opt-out" system

State of Wisconsin
2019 - 2020 LEGISLATURE

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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 (c) 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.

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 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.

Also, for drug products prescribed to counteract anaphylaxis, this bill allows a prescribing practitioner to authorize 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, under the same conditions applicable to drug product equivalents under current law,

a pharmacist who dispenses a drug product 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. 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. For drug products prescribed to counteract anaphylaxis, this bill allows, under certain circumstances, substitution of a drug in the same therapeutic class even though it is *not* a drug product equivalent. As with substitution of drug product equivalents under current law, the 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) and (c) of the statutes are created to read:

450.13 **(1e)** (b) "Narrow therapeutic index drug product" means a drug product where a small difference in dose or blood concentration may lead to serious therapeutic failures or adverse drug reactions.

(c) "Therapeutic class" means a group of similar drug products that have the same or similar mechanisms of action and 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 prescribing practitioner may authorize 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, provided all of the following conditions are met:

1. The prescriber has clearly indicated that drug product substitution is permissible 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 "therapeutic class substitution allowed" or words of similar meaning.

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

3. The patient opts in to the drug product substitution, and the pharmacist clearly informs the patient of the differences in the drug products and specifies that the patient 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) This subsection does not apply with respect to a prescription for any narrow therapeutic index drug product.

(e) Notwithstanding pars. (a) to (d), 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)

2019-2020 DRAFTING INSERT
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LRB-5232/P4ins
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INSERT 4-10

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.

(END INSERT 4-10)

Walkenhorst Barber, Sarah

From: Rep.Vining
Sent: Wednesday, February 12, 2020 4:42 PM
To: LRB.Legal
Cc: Walkenhorst Barber, Sarah
Subject: RE: Draft review: LRB -5232/P4

I would like to request the bill draft for introduction.

Thank you!

Maddie Palzewicz
Office of Representative Robyn Vining
Room 321 West
608-266-9180

From: LRB.Legal <lrblegal@legis.wisconsin.gov>
Sent: Monday, February 10, 2020 5:11 PM
To: Rep.Vining <Rep.Vining@legis.wisconsin.gov>
Subject: Draft review: LRB -5232/P4

Following is the PDF version of draft LRB -5232/P4.