

2015 DRAFTING REQUEST

Bill

Received: 1/29/2016 Received By: mduchek
For: Leah Vukmir (608) 266-2512 Same as LRB: -4675
May Contact: By/Representing: Mattias
Subject: Occupational Reg. - misc Drafter: mduchek
Addl. Drafters:
Extra Copies:

Submit via email: YES
Requester's email: Sen.Vukmir@legis.wisconsin.gov
Carbon copy (CC) to:

Pre Topic:

No specific pre topic given

Topic:

Pharmacist administration of drugs by injection

Instructions:

See attached

per MED

Drafting History:

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
/?	mduchek 1/29/2016	aernstr 1/29/2016	_____			
/P1	mduchek 2/2/2016	anienaja 2/2/2016	_____	mbarman 1/29/2016		State
/1			_____	lparisi 2/2/2016	lparisi 2/2/2016	State

FE Sent For:

*at intro
2/9/16*

<END>

Duchek, Michael

From: Gugel, Mattias
Sent: Friday, January 29, 2016 10:59 AM
To: Duchek, Michael
Subject: Re: Pharmacy injections bill

If we could get new #s, that'd be great.

Sent from my iPhone

> On Jan 29, 2016, at 10:58 AM, Duchek, Michael <Michael.Duchek@legis.wisconsin.gov> wrote:

>

> Sure. Do you want new LRB numbers for both or can one of them stay as the same number?

>

> -Mike

>

> -----Original Message-----

> From: Gugel, Mattias

> Sent: Friday, January 29, 2016 9:14 AM

> To: Duchek, Michael <Michael.Duchek@legis.wisconsin.gov>

> Subject: Pharmacy injections bill

>

> Mike,

>

> Please see the attached drafting notes for hopefully a final pass at this bill.

>

> Also, my boss would like the pharmacy injections and the pharmacy refill changes as two separate bills instead of one bill as it currently is, could you split the two issues for me?

>

> Thanks - Mattias

>

> Mattias Gugel

> Legislative Aide

> State Sen. Leah Vukmir

> 5th Senate District

> (608) 266-2512



State of Wisconsin
2015 - 2016 LEGISLATURE

LRB-2774/P3

MED:amn

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

Please make the following edits/considerations:

1. Delete highlighted text 1) removing the 30 day window but leaving the notification and 2) page 5 lines 23-25. Pharmacists are required to follow federal and state controlled substance laws for any action so we don't believe it needs to be repeated again in this provision; however, if a comment could be added reiterating that point in the LRB summary, we would appreciate that greatly. Essentially, the authorization for changing from a 30 day to a 90 day supply without prescriber approval is not applicable to any controlled substance based on state and federal law.
2. Section 9. The PEB already has rulemaking authority over that statute, does there need to be additional rule making required/authorized? If not, we prefer that section be stricken.
3. Please remove the 2019 sunset

1 **AN ACT** *to renumber and amend* 450.11 (5); *to amend* 450.02 (2g) (b), 450.035
2 (1r), 450.035 (1r), 450.035 (1t) and 450.035 (1t); *to repeal and recreate* 450.11
3 (5) (title); and *to create* 450.11 (5) (b) of the statutes; **relating to:** the
4 administration by injection of prescribed drugs by pharmacists, prescription
5 refills, and providing an exemption from emergency rule procedures.

Analysis by the Legislative Reference Bureau

This bill makes changes to the pharmacy practice law, including 1) allowing a pharmacist or pharmacy student to administer an injectable prescribed drug to a patient outside of the context of teaching the patient self-administration techniques; and 2) allowing a pharmacist to dispense prescribed drugs in quantities and fills that vary from the quantities and fills specified in a prescribing practitioner's prescription order, unless the prescriber specifies that adherence to the prescription order is medically necessary.

Under current law, a pharmacist or pharmacy student 1) may not administer by injection a prescribed drug product or device that is not a vaccine unless he or she has successfully completed a course of study and training in administration technique (training course); 2) may administer such a prescribed drug product or device only in the course of teaching self-administration techniques to a patient; and 3) must, when administering such a drug product or device, comply with requirements and procedures established in rules promulgated by the Pharmacy Examining Board. Additionally, a pharmacy student may only administer such a

prescribed drug product or device under the direct supervision of a pharmacist who has also successfully completed a training course.

This bill eliminates the limitation providing that a pharmacist or pharmacy student may administer such a prescribed drug product or device only in the course of teaching self-administration techniques to a patient. However, the bill requires a pharmacist or pharmacy student, or his or her agent, within 30 days after the pharmacist or pharmacy student administers a prescribed drug product or device to a patient, to notify the prescribing practitioner or enter the information in a patient record system shared by the prescribing practitioner. The bill sunsets this requirement effective January 1, 2019.

Also under current law, no prescription may be renewed except as designated on a prescription order. The bill deletes this provision and instead provides that a pharmacist may exercise his or her professional judgment to dispense varying quantities of the prescribed drug per fill up to the total number of dosage units as authorized by the prescriber in the original prescription including any refills, unless the prescriber has specified in the prescription order that dispensing a prescribed drug in an initial amount followed by periodic refills as specified in the prescription order is medically necessary.

For further information see the *state* 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.** 450.02 (2g) (b) of the statutes, as affected by 2015 Wisconsin Act 55,
2 is amended to read:

3 450.02 (2g) (b) The board shall promulgate rules that establish requirements
4 and procedures for the administration of a drug product or device, as defined in s.
5 450.035 (1g), by a pharmacist under s. 450.035 (1r) or by another person under s.
6 450.035 (1t).

7 **SECTION 2.** 450.035 (1r) of the statutes is amended to read:

8 450.035 (1r) A pharmacist may not administer by injection a prescribed drug
9 product or device unless he or she has successfully completed a course of study and
10 training in ~~injection~~ administration technique conducted by a course provider
11 approved by the Accreditation Council for Pharmacy Education or the board. –A

1 ~~pharmacist may administer a prescribed drug product or device under this~~
2 ~~subsection only in the course of teaching self-administration techniques to a patient.~~
3 A pharmacist who administers a prescribed drug product or device under this
4 subsection shall comply with the requirements and procedures established in rules
5 promulgated by the board under s. 450.02 (2g) (b). The pharmacist or his or her agent
6 shall also, within 30 days after the pharmacist administers a prescribed drug
7 product or device under this subsection, notify the prescribing practitioner or enter
8 the information in a patient record system shared by the prescribing practitioner.

9 **SECTION 3.** 450.035 (1r) of the statutes, as affected by 2015 Wisconsin Act
10 (this act), is amended to read:

11 **450.035 (1r)** A pharmacist may not administer by injection a prescribed drug
12 product or device unless he or she has successfully completed a course of study and
13 training in administration technique conducted by a course provider approved by the
14 Accreditation Council for Pharmacy Education or the board. A pharmacist who
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16 with the requirements and procedures established in rules promulgated by the board
17 under s. 450.02 (2g) (b). ~~The pharmacist or his or her agent shall also, within 30 days~~
18 ~~after the pharmacist administers a prescribed drug product or device under this~~
19 ~~subsection, notify the prescribing practitioner or enter the information in a patient~~
20 ~~record system shared by the prescribing practitioner.~~

21 **SECTION 4.** 450.035 (1t) of the statutes is amended to read:

22 **450.035 (1t)** A person engaged in the practice of pharmacy under s. 450.03 (1)
23 (f) or (g) may not administer a prescribed drug product or device unless he or she has
24 successfully completed a course of study and training in administration technique
25 conducted by a course provider approved by the Accreditation Council for Pharmacy

1 Education or the board. A person engaged in the practice of pharmacy under s.
2 450.03 (1) (f) or (g) may administer a prescribed drug product or device under this
3 subsection only under the direct supervision of a pharmacist who has successfully
4 completed a course of study and training in administration technique conducted by
5 a course provider approved by the Accreditation Council for Pharmacy Education or
6 the board, ~~and only in the course of teaching self-administration techniques to a~~
7 ~~patient.~~ A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g)
8 who administers a prescribed drug product or device under this subsection shall
9 comply with the requirements and procedures established in rules promulgated by
10 the board under s. 450.02 (2g) (b). The person or his or her agent shall also, within
11 30 days after the person administers a prescribed drug product or device under this
12 subsection, notify the prescribing practitioner or enter the information in a patient
13 record system shared by the prescribing practitioner.

14 **SECTION 5.** 450.035 (1t) of the statutes, as affected by 2015 Wisconsin Act ...
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16 450.035 (1t) A person engaged in the practice of pharmacy under s. 450.03 (1)
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19 conducted by a course provider approved by the Accreditation Council for Pharmacy
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21 450.03 (1) (f) or (g) may administer a prescribed drug product or device under this
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23 completed a course of study and training in administration technique conducted by
24 a course provider approved by the Accreditation Council for Pharmacy Education or
25 the board. A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or

1 (g) who administers a prescribed drug product or device under this subsection shall
2 comply with the requirements and procedures established in rules promulgated by
3 the board under s. 450.02 (2g) (b). The person or his or her agent shall also, within
4 30 days after the person administers a prescribed drug product or device under this
5 subsection, notify the prescribing practitioner or enter the information in a patient
6 record system shared by the prescribing practitioner.

7 **SECTION 6.** 450.11 (5) (title) of the statutes is repealed and recreated to read:

8 450.11 (5) (title) REFILLS.

9 **SECTION 7.** 450.11 (5) of the statutes is renumbered 450.11 (5) (c) and amended
10 to read:

11 450.11 (5) (c) ~~No prescription may be renewed except as designated on the~~
12 ~~prescription order.~~ An accurate record of renewal refill dispensing shall be
13 maintained showing the date and amount.

14 (a) No prescription may be renewed refilled unless the requirements of sub. (1)
15 and, if applicable, sub. (1m) have been met and written, oral, or electronic
16 authorization has been given by the prescribing practitioner. Unless the prescribing
17 practitioner has specified in the prescription order that dispensing a prescribed drug
18 in an initial amount followed by periodic refills as specified in the prescription order
19 is medically necessary, a pharmacist may exercise his or her professional judgment
20 to dispense varying quantities of the prescribed drug per fill up to the total number
21 of dosage units as authorized by the prescribing practitioner in the original
22 prescription order including any refills, subject to par. (b).

23 **SECTION 8.** 450.11 (5) (b) of the statutes is created to read:

24 450.11 (5) (b) The authority of a prescribing practitioner or pharmacist to
25 authorize refills of controlled substances is subject to s. 961.38.

SECTION 9. Nonstatutory provisions.

(1) Using the procedure under section 227.24 of the statutes, the pharmacy examining board shall promulgate rules to account for the treatment by this act of sections 450.02 (2g) (b) and 450.035 (1r) and (1t) of the statutes, for the period before the effective date of any corresponding permanent rules, but not to exceed the period authorized under section 227.24 (1) (c) of the statutes, subject to extension under section 227.24 (2) of the statutes. Notwithstanding section 227.24 (1) (a), (2) (b), and (3) of the statutes, the board is not required to provide evidence that promulgating a rule under this subsection as an emergency rule is necessary for the preservation of the public peace, health, safety, or welfare and is not required to provide a finding of emergency for a rule promulgated under this subsection.

SECTION 10. Effective dates. This act takes effect on the day after publication, except as follows:

(1) **SUNSET OF NOTIFICATION REQUIREMENT.** The treatment of section 450.035 (1r) (by SECTION 3) and (1t) (by SECTION 5) of the statutes takes effect on January 1, 2019.

(END)



State of Wisconsin
2015 - 2016 LEGISLATURE

In 1-29
TODAY

4637/P1
LRB-2774/P3
MED:amn

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

1 **AN ACT to renumber and amend** 450.11 (5); **to amend** 450.02 (2g) (b), 450.035
2 (1r), 450.035 (1r), 450.035 (1t) and 450.035 (1t); **to repeal and recreate** 450.11
3 (5) (title); and **to create** 450.11 (5) (b) of the statutes; **relating to:** the
4 administration by injection of prescribed drugs by pharmacists, prescription
5 refills, and providing an exemption from emergency rule procedures.

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This bill makes changes to the pharmacy practice law, including 1) allowing a pharmacist or pharmacy student to administer an injectable prescribed drug to a patient outside of the context of teaching the patient self-administration techniques; and 2) allowing a pharmacist to dispense prescribed drugs in quantities and fills that vary from the quantities and fills specified in a prescribing practitioner's prescription order, unless the prescriber specifies that adherence to the prescription order is medically necessary. *g allows*

Under current law, a pharmacist or pharmacy student 1) may not administer by injection a prescribed drug product or device that is not a vaccine unless he or she has successfully completed a course of study and training in administration technique (training course); 2) may administer such a prescribed drug product or device only in the course of teaching self-administration techniques to a patient; and 3) must, when administering such a drug product or device, comply with requirements and procedures established in rules promulgated by the Pharmacy Examining Board. Additionally, a pharmacy student may only administer such a

prescribed drug product or device under the direct supervision of a pharmacist who has also successfully completed a training course.

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For further information see the *state* 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:

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(END)



Duchek, Michael

From: Gugel, Mattias
Sent: Tuesday, February 02, 2016 5:07 PM
To: Duchek, Michael
Subject: Pharmacy Bills

Mike,

Could we please prepare LRB-4637/P1 and LRB 4638/P1 for introduction and jacket them?

Thanks - Mattias

Mattias Gugel
Legislative Aide
State Sen. Leah Vukmir
5th Senate District
(608) 266-2512



State of Wisconsin
2015 - 2016 LEGISLATURE

LRB-4637/PJ
MED:amn&ahe

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

SAV ✓

1 **AN ACT to amend** 450.02 (2g) (b), 450.035 (1r) and 450.035 (1t) of the statutes;
2 **relating to:** the administration by injection of prescribed drugs by
3 pharmacists.

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12 ~~pharmacist may administer a prescribed drug product or device under this~~
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18 under this subsection, notify the prescribing practitioner or enter the information in
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8 completed a course of study and training in administration technique conducted by
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12 who administers a prescribed drug product or device under this subsection shall
13 comply with the requirements and procedures established in rules promulgated by
14 the board under s. 450.02 (2g) (b). The person or his or her agent shall also, after the
15 person administers a prescribed drug product or device under this subsection, notify
16 the prescribing practitioner or enter the information in a patient record system
17 shared by the prescribing practitioner.

18 (END)