2015 DRAFTING REQUEST

| DIII | | | | | | |
|----------|---|-----------------------|--|----------------------|---------------------|----------|
| Receive | ed: 1/29/2010 | 6 | | Received By: | mduchek | |
| For: | Leah Vu | kmir (608) 266-2 | 2512 | Same as LRB: | -4676 | |
| May Co | entact: | | | By/Representing: | Mattias | |
| Subject: | : Occupat | ional Reg misc | | Drafter: | mduchek | |
| | | | | Addl. Drafters: | | |
| | | | | Extra Copies: | | |
| Request | via email: ter's email: copy (CC) to: | YES Sen.Vukmi | ir@legis.wisco | nsin.gov | | |
| Pre Top | pic: | | | | | |
| No spec | rific pre topic giv | en | | | | |
| Topic: | | | | | | - |
| Prescrip | otion refills | | | | | |
| Instruc | tions: | | ······································ | | | |
| See atta | ched | · | | | 0.6 | |
| Draftin | g History: | | | | Pina | |
| Vers. | <u>Drafted</u> | Reviewed | Proofed | Submitted | <u>Jacketed</u> | Required |
| /? | mduchek 1/29/2016 | aernsttr 1/29/2016 | | | e | |
| /P1 | mduchek 2/2/2016 | anienaja 2/2/2016 | | mbarman 1/29/2016 | | |
| /1 | | | | lparisi 2/2/2016 | lparisi 2/2/2016 | |
| FE Sent | For: | | | • | | * |

<**END>**

Duchek, Michael

| From: Sent: To: | Gugel, Mattias Friday, January 29, 2016 10:59 AM Duchek, Michael |
|-------------------------------------|---|
| Subject: | Re: Pharmacy injections bill |
| If we could get nev | v #s, that'd be great. |
| Sent from my iPho | ne |
| > On Jan 29, 2016, | at 10:58 AM, Duchek, Michael < Michael. Duchek@legis. wisconsin.gov > wrote: |
| > | |
| | nt new LRB numbers for both or can one of them stay as the same number? |
| > | |
| > -Mike | |
| > Original Mass | |
| >Original Mess > From: Gugel, Ma | |
| - - | uary 29, 2016 9:14 AM |
| | nael <michael.duchek@legis.wisconsin.gov></michael.duchek@legis.wisconsin.gov> |
| > Subject: Pharmac | |
| > | y injections sin |
| > Mike, | |
| > | |
| > Please see the at | tached drafting notes for hopefully a final pass at this bill. |
| > | |
| | uld like the pharmacy injections and the pharmacy refill changes as two separate bills instead of one s, could you split the two issues for me? |
| > . | |
| > Thanks - Mattias | |
| > | |
| > Mattias Gugel | |
| > Legislative Aide | |
| > State Sen. Leah V | |
| > 5th Senate Distric | II. |
| > (608) 266-2512 | |
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State of Misconsin 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

AN ACT to renumber and amend 450.11 (5); to amend 450.02 (2g) (b), 450.035 (1r), 450.035 (1r), 450.035 (1t) and 450.035 (1t); to repeal and recreate 450.11 (5) (title); and to create 450.11 (5) (b) of the statutes; relating to: the administration by injection of prescribed drugs by pharmacists, prescription 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

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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:

SECTION 1. 450.02 (2g) (b) of the statutes, as affected by 2015 Wisconsin Act 55, is amended to read:

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

Section 2. 450.035 (1r) of the statutes is amended to read:

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

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

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

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

Section 4. 450.035 (1t) of the statutes is amended to read:

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

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

SECTION 5. 450.035 (1t) of the statutes, as affected by 2015 Wisconsin Act (this act), is amended to read:

450.035 (1t) A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g) may not administer a prescribed drug product or device unless he or she has successfully completed a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council for Pharmacy Education or the board. A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g) may administer a prescribed drug product or device under this subsection only under the direct supervision of a pharmacist who has successfully completed a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council for Pharmacy Education or the board. A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or

| (g) who administers a prescribed drug product or device under this subsection shall |
|--|
| comply with the requirements and procedures established in rules promulgated by |
| the board under s. 450.02 (2g) (b). The person or his or her agent shall also, within |
| 30 days after the person administers a prescribed drug product or device under this |
| subsection, notify the prescribing practitioner or enter the information in a patient |
| record system shared by the prescribing practitioner. |
| Section 6. 450.11 (5) (title) of the statutes is repealed and recreated to read: |
| 450.11 (5) (title) Refills. |
| Section 7. 450.11 (5) of the statutes is renumbered 450.11 (5) (c) and amended |
| to read: |
| 450.11 (5) (c) No prescription may be renewed except as designated on the |
| prescription order. An accurate record of renewal refill dispensing shall be |
| maintained showing the date and amount. |
| (a) No prescription may be renewed refilled unless the requirements of sub. (1) |
| and, if applicable, sub. (1m) have been met and written, oral, or electronic |
| authorization has been given by the prescribing practitioner. Unless the prescribing |
| practitioner 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, 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 prescribing practitioner in the original |
| prescription order including any refills, subject to par. (b). |
| SECTION 8. 450.11 (5) (b) of the statutes is created to read: |
| 450.11 (5) (b) The authority of a prescribing practitioner or pharmacist to |
| authorize refills of controlled substances is subject to s. 961.38. |

| SECTION 9. No | onstatutorv | provisions. |
|---------------|-------------|-------------|
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(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 Misconsin 2015 - 2016 LEGISLATURE

101-29 toDAT Ч 638/Г1 LRB-**2**7.74/РЭ MED:amn

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

AN ACT to renumber and amend 450.11 (5); to amend 450.02 (2g) (b), 450.035

(1r), 450.035 (1r), 450.035 (1t) and 450.035 (1t); to repeal and recreate 450.11

(5) (title); and to create 450.11 (5) (b) of the statutes; relating to: the administration by injection of prescribed drugs by pharmacists, prescription refills, and providing an exemption from emergency rule procedures.

Analysis by the Legislative Reference Bureau

allows

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

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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.

order is medically necessary. The bill does not affect provisions retills of For further information see the **state** fiscal estimate, which will be printed as controlled an appendix to this bill.

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

SECTION 1. 450.02 (2g) (b) of the statutes, as affected by 2015 Wisconsin Act 55, is amended to read:

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

SECTION 2. 450.035 (17) of the statutes is amended to read:

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

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

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

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

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

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

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

SECTION 5. 450.035 (1t) of the statutes, as affected by 2015 Wisconsin Act (this act), is amended to read:

450.035 (1t) A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g) may not administer a prescribed drug product or device unless he or she has successfully completed a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council for Pharmacy Education or the board. A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g) may administer a prescribed drug product or device under this subsection only under the direct supervision of a pharmacist who has successfully completed a course of study and training in administration technique conducted by a course provider approved by the Accreditation Council for Pharmacy Education or 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 |
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| 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.

except as follows:

(END)

| (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,

(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.

Duchek, Michael

From:

Gugel, Mattias

Sent:

Tuesday, February 02, 2016 5:07 PM Duchek, Michael

To: 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 Misconsin 2015 - 2016 LEGISLATURE

ا LRB-4638/گِر MED:amn&ahe

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION



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1 AN ACT to renumber and amend 450.11 (5); and to repeal and recreate 450.11

(5) (title) of the statutes; **relating to:** prescription refills.

Analysis by the Legislative Reference Bureau

This bill allows 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, no prescription may be renewed except as designated on a prescription order. This 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. The bill does not affect provisions in current law that prohibit or limit refills of controlled substances.

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

- **Section 1.** 450.11 (5) (title) of the statutes is repealed and recreated to read:
- 4 450.11 (5) (title) Refiles.

| .1 | Section 2. 450.11 (5) of the statutes is renumbered 450.11 (5) (b) and amended |
|----|--|
| 2 | to read: |
| 3 | 450.11 (5) (b) No prescription may be renewed except as designated on the |
| 4 | prescription order. An accurate record of renewal refill dispensing shall be |
| 5 | maintained showing the date and amount. |
| 6 | (a) No prescription may be renewed refilled unless the requirements of sub. (1) |
| 7 | and, if applicable, sub. (1m) have been met and written, oral, or electronic |
| 8 | authorization has been given by the prescribing practitioner. Unless the prescribing |
| 9 | practitioner has specified in the prescription order that dispensing a prescribed drug |
| 10 | in an initial amount followed by periodic refills as specified in the prescription order |
| 11 | is medically necessary, a pharmacist may exercise his or her professional judgment |
| 12 | to dispense varying quantities of the prescribed drug per fill up to the total number |
| 13 | of dosage units as authorized by the prescribing practitioner in the original |
| 14 | prescription order including any refills. |
| | |

(END)