



PHARMACY EXAMINING BOARD

Contact: Dan Williams (608) 266-2112
Room 121A 1400 East Washington Avenue, Madison, WI 53703
July 22, 2015

Notice: The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a description of the action and deliberation of the Board.

AGENDA

11:00 A.M.

Or immediately following the pharmacy rules committee meeting.

OPEN SESSION – CALL TO ORDER – ROLL CALL

- A. Adoption of Agenda (1-4)**
- B. Approval of Minutes of June 3, 2015 (5-9)**
- C. Administrative Updates – Discussion and Consideration**
 - 1) Staff Updates
 - 2) Board Member – Term Expiration Date
 - a. Franklin LaDien – 7/1/2016
 - b. Terry Maves – 7/1/2018
 - c. Charlotte Rasmussen – 7/1/2014
 - d. Thaddeus Schumacher – 7/1/2019
 - e. Kristi Sullivan – 7/1/2016
 - f. Philip Trapskin – 7/1/2017
 - g. Cathy Winters – 7/1/2017
- D. Variances**
 - 1) Requests
 - a. Froedtert Hospital Pharmacy **(10-14)**
 - b. Morton LTC Pharmacy **(14-46)**
 - c. Omnicare Pharmacy of La Crosse **(47-52)**
 - d. Fort Healthcare Pharmacy **(53-58)**
- E. Legislation/Administrative Rule Matters – Discussion and Consideration (59-68)**
 - 1) Pending Projects
 - a. Phar 8 Relating to Recording Name and Health Care Facility Definition
 - b. Phar 2, 4 Relating to Application and Examination
 - c. Phar 5 Relating to Renewal and Reinstatement
 - d. Phar 6 Relating to Temperature and Humidity Controls

- e. Phar 14 Relating to Practice of Pharmacy
- f. Phar 7 Relating to Practice of Pharmacy
- g. Phar 15 Relating Compounding
- h. Phar 1, 8 Relating to Definitions and Controlled Substances
- 2) Update on Legislation
 - a. Act 34 Relating to Optometrist Prescribing Hydrocodone Combination Products **(63)**
 - b. Act 35 Relating to Epinephrine **(64-66)**
 - c. Act 40 Relating to Therapeutic Alternate Drug Selections in Correctional System **(67)**
 - d. AB 228 Relating to Definition of Tetrahydrocannabinols (CBD)
- 3) Update on Legislation and Pending or Possible Rulemaking Projects
 - a. Track and Trace Pedigree System
- 4) Goal List **(68)**

F. Speaking Engagement(s), Travel, or Public Relations Request(s)

G. Informational Items

H. **Items Received After Preparation of the Agenda**

- 1) Introductions, Announcements and Recognition
- 2) Presentations of Petition(s) for Summary Suspension
- 3) Presentation of Proposed Stipulation(s), Final Decision(s) and Order(s)
- 4) Presentation of Proposed Final Decision and Order(s)
- 5) Informational Items
- 6) Division of Legal Services and Compliance (DLSC) Matters
- 7) Education and Examination Matters
- 8) Credentialing Matters
- 9) Practice Questions/Issues
- 10) Legislation/Administrative Rule Matters
- 11) Speaking Engagement(s), Travel, or Public Relations Request(s)
- 12) Prescription Drug Monitoring Program Information
- 13) Consulting with Legal Counsel
- 14) **Liaison Report(s)**
 - a. CE Liaison: Terry Maves
 - b. Credentialing Liaison(s): Terry Maves, Cathy Winters
 - c. Digest Liaison: Philip Trapskin
 - d. Legislative Liaison: Philip Trapskin, Thaddeus Schumacher, Terry Maves
 - e. DLSC Liaison: Thaddeus J. Schumacher, Cathy Winters
 - f. PAP Liaison: Franklin LaDien
 - g. Monitoring Liaison: Franklin LaDien
 - h. PHARM Rep to CSB: Franklin LaDien
 - i. Variance Report Liaison: Philip Trapskin, Cathy Winters
 - j. PHARM Rep to SCAODA: Charlotte Rasmussen
 - k. Screening Panel: Cathy Winters, Franklin LaDien, Charlotte Rasmussen
 - l. PDMP Workgroup: Terry Maves, Philip Trapskin

I. Public Comments

CONVENE TO CLOSED SESSION to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85 (1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85 (1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.).

J. **Deliberation on Division of Legal Services and Compliance (DLSC) Matters**

- 1) **Proposed Stipulations, Final Decision and Orders**
 - a. 13 PHM 010 (P.S.) **(39-75)**
 - b. 14 PHM 042 (K.P.K.) **(76-81)**
- 2) **Administrative Warnings**
 - a. 15 PHM 016 (C.C.) **(82-83)**
- 3) **Case Closings**
 - a. 13 PHM 065 **(84-87)**
 - b. 14 PHM 060 **(88-89)**
 - c. 14 PHM 094 **(90-91)**
 - d. 14 PHM 098 **(92-93)**
 - e. 14 PHM 100 **(94-95)**
 - f. 14 PHM 106 **(96-97)**
 - g. 14 PHM 108 **(98-99)**
 - h. 14 PHM 110 **(100-101)**
 - i. 14 PHM 111 **(102-103)**
 - j. 14 PHM 116 **(104-105)**
 - k. 14 PHM 117 **(106-107)**
- 4) **APPEARANCE – DSPS DLSC Staff – Case Advisor Guidance (108)**
- 5) **Monitoring (109-139)**
 - a. Erin Orth, R.Ph. – Requesting Modification (Impairment) **(111-139)**

K. **Deliberation on Proposed Final Decision and Order in the Matter of the Application for Pharmacist License of Delora Pufall (DHA Case # SPS-14-0041)(DLSC Case # 14 PHM 039) (140-153)**

L. **Deliberation on Credentialing Matters**

- 1) **Application Review(s)**
 - a. Z.S. – Multi–State Pharmacy Jurisprudence Examination (MPJE) Retake **(154-168)**

M. **Deliberation of Items Received After Preparation of Agenda**

- 1) **Credential Issues and/or Reviews**
- 2) **Application Review**
- 3) **Education and Examination Matters**
- 4) **Disciplinary Matters**
- 5) **Professional Assistance Procedure (PAP) Matters**

- 6) Monitoring Matters
- 7) Administrative Warnings
- 8) Review of Administrative Warning
- 9) Proposed Stipulations, Final Decisions and Orders
- 10) Proposed Final Decisions and Orders
- 11) Orders Fixing Costs/Matters Related to Costs
- 12) Petitions for Summary Suspension
- 13) Designation of Hearing Examiner
- 14) Case Closings
- 15) Case Status Report
- 16) Petitions for Re-Hearing
- 17) Motions

N. Consult with Legal Counsel

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

O. **Voting on Items Considered or Deliberated upon in Closed Session, if Voting is Appropriate**

P. **Board Meeting Process (Time Allocation, Agenda Items) – Discussion and Consideration**

ADJOURNMENT

The next scheduled meeting is September 23, 2015.

**PHARMACY EXAMINING BOARD
MEETING MINUTES
June 3, 2015**

PRESENT: Franklin LaDien, Terry Maves, Charlotte Rasmussen, Thaddeus Schumacher, Kristi Sullivan, Philip Trapskin, Cathy Winters

STAFF: Dan Williams – Executive Director, Nilajah Madison-Head – Bureau Assistant, Sharon Henes – Administrative Rules Coordinator, and other Department staff

CALL TO ORDER

Thaddeus Schumacher, Chair, called the meeting to order at 10:06 a.m. A quorum was confirmed.

ADOPTION OF AGENDA

Amendments to the Agenda:

- *Remove Item C. 1)a.: “APPEARANCE: DSPS Deputy Secretary Jay Risch and Assistant Deputy Secretary Eric Esser”*

MOTION: Kristi Sullivan moved, seconded by Cathy Winters, to adopt the agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF MARCH 25, 2015

MOTION: Phillip Trapskin moved, seconded by Terry Maves, to approve the minutes of March 25, 2015 as published. Motion carried unanimously.

VARIANCES

Reports

University of Wisconsin Hospital and Clinics

MOTION: Cathy Winters moved, seconded by Charlotte Rasmussen, the Board acknowledges the withdrawal of the Tech-Check-Tech Variance request dated 05/15/2015 submitted by University of Wisconsin Hospital and Clinics. Motion carried. Recused: Phillip Trapskin.

MOTION: Cathy Winters moved, seconded by Charlotte Rasmussen, to renew the terms of the first dose Tech-Check-Tech Variance Request submitted by University of Wisconsin Hospital and Clinics, approved in May of 2014, with standard reporting requirements (January 2016 and July 2016). The renewal will last until 07/31/2016. Motion carried. Recused: Phillip Trapskin.

(Phillip Trapskin recused himself and left the room for deliberation and voting in the matter of University of Wisconsin Hospital and Clinics)

Requests

O'Connell Pharmacy

MOTION: Cathy Winters moved, seconded by Franklin LaDien, the Board acknowledges the withdrawal of the Variance Request submitted by O'Connell Pharmacy. Motion carried unanimously.

LTC Rx, Inc.

MOTION: Phillip Trapskin moved, seconded by Terry Maves, to table the Variance Request submitted by LTC Rx, Inc. until such time as the Board receives the following information: the average ratio of pharmacists to technicians on a monthly basis and whether the pharmacy is an "open" or "closed" door facility. The Board invites a representative from LTC Rx, Inc. to be available at the next Board meeting to discuss their request. Motion carried unanimously.

LEGISLATIVE AND ADMINISTRATIVE RULE MATTERS

Draft of Phar 1 and 8 Relating to Definitions and Controlled Substances

MOTION: Phillip Trapskin moved, seconded by Kristi Sullivan, to authorize The Chair to approve the revision of Phar 1 and 8 relating to definitions and controlled substances for posting of economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

Proposals for Phar 18 Relating to Act 199

MOTION: Franklin LaDien moved, seconded by Terry Maves, to approve the amended changes to the letter drafted for DSPS Secretary Dave Ross regarding Act 199 and authorize the Chair to send the amended letter. Motion carried unanimously.

CLOSED SESSION

MOTION: Cathy Winters moved, seconded by Kristi Sullivan, to convene to closed session to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85 (1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85 (1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.). Thaddeus Schumacher, Chair, read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Franklin LaDien-yes; Terry Maves-yes, Charlotte Rasmussen-yes; Thaddeus Schumacher-yes; Kristi Sullivan- yes; Philip Trapskin-yes; Cathy Winters-yes. Motion carried unanimously.

The Board convened into Closed Session at 12:57 p.m.

RECONVENE TO OPEN SESSION

MOTION: Franklin LaDien moved, seconded by Terry Maves, to reconvene into open session. Motion carried unanimously.

The Board reconvened into Open Session at 3:33 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED ON IN CLOSED SESSION

MOTION: Kristi Sullivan moved, seconded by Cathy Winters, to affirm all motions made in closed session. Motion carried unanimously.

DIVISION OF LEGAL SERVICES AND COMPLIANCE (DLSC) MATTERS

Proposed Stipulations, Final Decisions and Orders

Attorney Sandra Nowack

MOTION: Phillip Trapskin moved, seconded by Kristi Sullivan, to accept the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against:

1. Daniel Zatarski, R.Ph. - 13 PHM 055, 14 PHM 057, and 14 PHM 075
2. MD Custom Rx - 13 PHM 055, 14 PHM 057, and 14 PHM 075
3. OK Compounding, LLC. - 14 PHM 073
4. Monica Zatarski, R.Ph - 14 PHM 075
5. David L. Kleingartner, R.Ph. - 14 PHM 082

Motion carried unanimously.

Attorney Cody Wagner

MOTION: Charlotte Rasmussen moved, seconded by Kristi Sullivan, to accept the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against:

1. Precision Pharmacy - 14 PHM 134, 15 PHM 005, 15 PHM 030
2. DermaTran Health Solutions - 14 PHM 139

Motion carried unanimously.

Administrative Warnings

Attorney Sandra Nowack

14 PHM 055 – Walgreens #02927

MOTION: Phillip Trapskin moved, seconded by Charlotte Rasmussen, to issue an Administrative Warning in the matter of DLSC case number 14 PHM 055 – Walgreens # 02927. Motion carried. Recused: Franklin LaDien.

(Franklin LaDien recused himself and left the room for deliberation and voting in the matter of DLSC case number 14 PHM 055 – Walgreens # 02927)

Attorney Cody Wagner

MOTION: Franklin LaDien moved, seconded by Charlotte Rasmussen, to reject the Administrative Warnings and instead close for Prosecutorial Discretion (P2) in the following matters:

1. 14 PHM 090 (A.S.P.)
2. 14 PHM 091 (A.H.S.)
3. 14 PHM 096 (C.P.S.)
4. 14 PHM 097 (C.P.S.)
5. 14 PHM 101 (H.D.C.)
6. 14 PHM 102 (L.F.P.)
7. 14 PHM 103 (L.H.P.)
8. 14 PHM 104 (L.O.P.)
9. 14 PHM 114 (V.S.C.P.)
10. 14 PHM 115 (W.P.)
11. 14 PHM 118 (C.C.H.P. and J.J.W.)
12. 14 PHM 121 (P.P.A.L. and M.K.S.)
13. 14 PHM 123 (S.A.H.P. and J.J.S.)
14. 14 PHM 124 (V.H.P. and G.L.B.)

Motion carried unanimously.

Case Closings

Attorney Sandra Nowack

MOTION: Phillip Trapskin moved, seconded by Kristi Sullivan, to close the DLSC cases for the reasons outlined below:

1. 14 PHM 002 – Prosecutorial Discretion (P2)
2. 14 PHM 020 - Prosecutorial Discretion (P7)
3. 14 PHM 021 - Prosecutorial Discretion (P7)
4. 14 PHM 024 - Prosecutorial Discretion (P7)
5. 14 PHM 026 - Prosecutorial Discretion (P7)
6. 14 PHM 027 - Prosecutorial Discretion (P7)
7. 14 PHM 028 - Prosecutorial Discretion (P7)
8. 14 PHM 029 - Prosecutorial Discretion (P7)
9. 14 PHM 030 - Prosecutorial Discretion (P7)
10. 14 PHM 042 - Prosecutorial Discretion (P7)
11. 14 PHM 088 – No Violation (NV)

Motion carried unanimously.

Attorney Jim Polewski

MOTION: Terry Maves moved, seconded by Charlotte Rasmussen, to close the DLSC cases for the reasons outlined below:

1. 13 PHM 041 - Prosecutorial Discretion (P6)
2. 14 PHM 147 - Prosecutorial Discretion (P7)

Motion carried unanimously.

Monitoring

Dirk Larson, R.Ph. – Requesting Modification (Impairment)

MOTION: Phillip Trapskin moved, seconded by Franklin LaDien, to deny the request of Dirk Larson, R.Ph. for reduction in drug and alcohol screens to 12 and one annual hair, as well as an increase in PIC hours. Instead, the Board grants a reduction in drug and alcohol screens to 28 and one annual hair. **Reason for Denial:** Currently not working as a pharmacist and not compliant with the terms of the Board Order (09/12/2012). Motion carried unanimously.

Erin Orth, R.Ph. – Requesting License (Impairment)

MOTION: Franklin LaDien moved, seconded by Charlotte Rasmussen, to deny the request of Erin Orth, R.Ph. for full licensure. **Reason for Denial:** The Board requires further compliance under the current terms of the Board Order and will require a request for and successful completion of a period of PIC hours before full licensure will be considered. Motion carried unanimously.

ADJOURNMENT

MOTION: Terry Maves moved, seconded by Franklin LaDien, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 3:42 p.m.

July 6nd, 2015

Thaddeus Schumacher, PharmD
Chair, Pharmacy Examining Board
Department of Regulation and Licensing
State of Wisconsin
PO Box 8935
Madison, WI 53708-8935

Dear Dr. Schumacher,

Froedtert & the Medical College of Wisconsin, Froedtert Hospital Department of Pharmacy is writing to request an addendum to our current variance restricting the final verification of a product's accuracy to a pharmacist. Our current variance allows trained pharmacy technicians to complete the final accuracy verification for a unit dose medication filled by another technician during a cart-fill process. We are proposing to implement a first dose tech-check-tech (TCT) program, in which trained pharmacy technicians would provide the final accuracy verification for a unit dose medication through a scanning process for first doses of a new medication order. Therefore, an addendum to our current variance would allow trained pharmacy technicians to check unit dose medications labeled as a first dose, in addition to the medications dispensed in the cart-fill process.

Froedtert Hospital recently completed a two phase study, "Technician Barcode Verification as an Alternative to a Pharmacists' Visual Check of First Doses in an Acute Care Setting," to better understand the utility of a technician barcode scanning validation process for first dose medications. All first dose medications were included with the exception of products without correlating product specific barcodes (manufacturer or custom built). The majority of these excluded doses were compounded sterile products and custom preparations. In summary, the study showed no significant difference in the accuracy of first dose verification when comparing the two methods. In addition, we concluded that the final first dose verification process occurred ~4 minutes faster when using technician barcode scanning. In essence we were able to show that through leveraging our current technology we were able to maintain gold standard efficacy as well as decrease the product final verification time.

The final verification for validity, completeness, and appropriateness of the medication order continues to remain the responsibility of a pharmacist. The accuracy of labeling a product with a barcode also remains the responsibility of the pharmacist. Froedtert Hospital utilizes bedside barcode scanning during the drug administration phase, adding an additional layer of safety. This serves as a final check that the right product and dose reaches the right patient at the right time. Pharmacists are responsible for verifying a technician's accuracy through an ongoing quality assurance program. Re-validation and training plans are in place for technicians who fall below acceptable accuracy rates.

I have attached an executive summary outlining the first dose tech-check-tech program for your review. Thank you for your consideration of this request.

Sincerely,



Philip Brummond, PharmD, MS
Director of Pharmacy
Froedtert Hospital
414-805-4007
philip.brummond@froedtert.com

Executive Summary

Background

As technology continues to advance, a variety of mechanisms to assist in maintaining the accuracy and safety of the medication dispensing process have been implemented. In 2014, Froedtert Hospital implemented a barcode TCT program upon receiving an approved variance from the Pharmacy Examining Board. The variance allows a trained pharmacy technician to complete the final check of medications filled via a cart-fill process while maintaining a 99.8% checking accuracy. This variance allowed qualified and trained pharmacy technicians to provide the final medication check through a barcode scanning process for cart-fill dispenses picked by another pharmacy technician. Medications are initially barcode scanned when picked from a carousel or unit-dose packager then rescanned after being loaded into patient-specific bins to ensure that the right medication is prepared for the correct patient. We have validated this process by checking over 200,000 doses with >99.8% accuracy. This implementation has enhanced patient care by ensuring the accuracy of cart-fill medications thereby providing our patients continued excellence in safety as well as increased the time pharmacists spend performing clinical services in patient centered areas, increasing patient access to their pharmacist. In light of these advancements and the success of the Froedtert Hospital TCT program, expansion to first dose TCT was identified as a goal for the pharmacy department.

Proposal

To implement a program expanding the current Froedtert Hospital TCT program to allow properly trained and validated pharmacy technicians to utilize barcode scanning technology to provide the final verification of first dose medications dispensed from semi-automated dispensing technology. Further, to maintain a quality assurance program evaluating technician barcode scanning final verification accuracy for both cart-fill and first dose medications through quality assurance checks completed by pharmacists.

Description of Proposed System

Pharmacy technicians will undergo practical and didactic as outlined by the PSW TCT Toolkit to understand and demonstrate knowledge in unit dose medication systems and product verification. Following practical and didactic training and competency assessment, the technicians will then independently check at least 2,500 filled doses, encompassing both cart-fill and first dose medications, in a minimum of 5 separate audits to represent the validation period. All doses checked by the technician during this validation period will be double checked by a pharmacist to ensure the technicians ability to achieve a checking accuracy rate of at least 99.8%. Upon successful completion of both training phases these technicians will then be prepared to perform TCT. These validated technicians will be responsible for checking the accuracy of all first dose and cart-fill medications during their scheduled shifts. Each day, a pharmacist will continue to provide a quality assurance check of 10% of the total doses checked by each technician. The accuracy rates of the technicians will be evaluated on an ongoing basis to confirm each technician in the program is maintaining a 99.8% accuracy rate. Re-validation and training will be completed as necessary. Technicians who do not successfully demonstrate the ability to maintain their accuracy rate will be removed from the TCT program.

Benefits

1. Ensure the accuracy of first dose dispensing processes through multiple barcode scanning processes to provide the highest level of safety for our patients.
2. Decrease first dose processing time facilitating getting medications to our patients sooner.
3. Increase time allocated to pharmacists performing clinical services in patient centered areas and increasing patient access to their pharmacist.

Current Progress and Next Steps

1. Receive Pharmacy Examining Board approval for an addendum to the Froedtert Hospital current tech-check-tech variance to implement a first dose tech-check-tech program.
2. Train and validate pharmacy technicians to allow them to check both cart-fill and first dose medication dispenses from semi-automated dispensing technology.
3. Maintain a quality assurance program to ensure 10% of daily doses are double checked by pharmacists for each technician in the program.
4. Collect data on technician accuracy and report to the PEB.

Wisconsin Department of Safety and Professional Services

Mail To: P.O. Box 8935
 Madison, WI 53708-8935
 FAX #: (608) 261-7083
 Phone #: (608) 266-2112

1400 E. Washington Avenue
 Madison, WI 53703
 E-Mail: web@dps.wi.gov
 Website: http://dps.wi.gov

PHARMACY EXAMINING BOARD

PHARMACY VARIANCE REQUEST FORM

COMPLETED FORM MUST BE SUBMITTED AND APPROVED BY THE BOARD AT THEIR NEXT REGULARLY SCHEDULED MEETINGS AND THIS MAY TAKE AN EXTENDED PERIOD OF TIME FOR APPROVAL. PLEASE SUBMIT FORM REQUESTS IN ADVANCE TO ENSURE NO FURTHER DELAYS. All variance requests should be submitted to the Board at least 15 working days prior to the next regularly scheduled Board meeting in order to be placed on the agenda for that meeting. View the department website at <http://dps.wi.gov> for information regarding the dates of regularly scheduled Board meetings. *If any specific act or practice for which a variance was granted is subsequently proposed to be modified the Board must be notified first and a new variance obtained for that modified act or practice.*

<input type="checkbox"/> NEW PHARMACY <input checked="" type="checkbox"/> EXISTING PHARMACY	TYPE OF PHARMACY: <input type="checkbox"/> COMMUNITY <input checked="" type="checkbox"/> INSTITUTIONAL	CURRENT WI LICENSE NUMBER: <u>6250-42</u>
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DBA: Name or title under which business is operated. (This must be the name on the pharmacy label.) <u>Friedert Memorial Lutheran</u>	TELEPHONE NO. (414) 805-2690 FAX NO. (414) 805-2626
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PHARMACY ADDRESS: number, street, city, zip code
9200 W. Wisconsin Ave #26099 Milwaukee WI 53226

A variance that is granted by the Board is only valid for the specific licensed pharmacy location to which the variance applies and for the specific acts to which the variance applies at that location. If any specific act or practice for which a variance was granted is subsequently discontinued the Board must be notified in order that the variance can be rescinded for that specific licensed pharmacy location.

CONTACT NAME OF PERSON REQUESTING VARIANCE <u>Philip Brummond</u> (please print)	TELEPHONE NO. (414) 805-4007
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EMAIL ADDRESS PHILIP.BRUMMOND@ <u>Friedert.com</u>	HOURS AVAILABLE M → F 0800 - 1700	Do you wish to appear before the board for questions? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
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Indicate the specific administrative rule and variance requested. (List all administrative codes below that apply.)

WI Administrative Rule	Variance Requested
<u>7.01(1)(c) & (d)</u>	<u>tech-check-tech program</u>

NOTE – A variance may only be granted if it is authorized in the rule.

Explain why the variance is necessary and specifically indicate how the requested activity or practice will differ from what is authorized by the rule. (Attach a description to this form.)

- a. For each specific activity or practice involved indicate the specific rule for which a variance is being sought, and the authority which authorizes the variance.
- b. Specifically identify how the proposed variance will meet professional standards for patient safety and confidentiality, including specifically each step in the prescription order handling/dispensing process to address: security, work flow delineation and accountability and pharmacist supervision over each step in the process.



June 19, 2015

The Department of Safety and Professional Services
Pharmacy Examining Board
P.O. Box 8935
Madison, WI 53708-8935

Dear Members of the Pharmacy Examining Board,

I am writing to request a variance to Wisconsin Administrative Code Phar 7.01(3) for Morton LTC Pharmacy (Wisconsin pharmacy license #9299-42). This code states that a pharmacist may supervise no more than 4 pharmacy technicians engaged in compounding and dispensing activities.

Morton LTC Pharmacy (license number #8679-42) has received a 'notice to vacate' our current location from the Wisconsin Department of Transportation, related to the Highway 441 reconstruction project. We will be moving our current pharmacy at 712 Midway Road in Menasha, WI, to 201 E. Bell Street in Neenah, WI, on Sunday, August 2, 2015.

In accordance with Phar 7.01(3) sub (1), our current location in Menasha has been granted a variance, allowing a technician to pharmacist ratio of up to 10:1, while not exceeding an average of 4:1 in any calendar month. This was granted for indefinite continuation on 12/3/08. We are requesting the same variance be granted for when we are required to move to our new location in Neenah. A new state license has already been approved for the new location (#9299-42).

With the variance in place for our soon to be closed location, we have been staying within the approved ratios. For example, in May 2015, we had 1739.8 pharmacist hours worked, and 6364.04 technician hours worked. This is an average ratio of 3.65:1. In April 2015, we had an average ratio of 3.5:1; and in March 2015, we had an average ratio of 3.6:1. We currently have 14 full time and part time pharmacists on staff (approximately 10 FTE). We currently have 47 full time and part time technicians on staff (approximately 36 FTE).

Morton LTC is a closed-door, long term care institutional pharmacy, serving patients in skilled nursing facilities and assisted living environments. The prescriptions we fill are bubble packed and delivered directly to facilities. Due to the fact we do not have walk-up customers, and the extra time and labor it takes to bubble pack the medications, we feel we can safely exceed the 4:1 technician to pharmacist ratio.

Pharmacy: 712 Midway Road Menasha, WI 54952 (920) 886-2908
Administrative Office: 706 Midway Road Menasha, WI 54952 (920) 727-3853
Mailing Address: P.O. Box 778 Neenah, WI 54956

We have a workflow in place to make sure all prescriptions are properly checked by a pharmacist and to ensure patient safety. The majority of our prescriptions are received via fax, and converted to document images on our computer system. An order entry technician enters the prescriptions onto the patient profile. The order then moves to a pharmacist, where they will verify (per Phar 7.01) and initial it. The medication is then packaged and labeled by a daily fill technician. The final product is then checked and initialed by a pharmacist. Once verified, it is transferred to the delivery area. We also have a cycle fill department which packages ongoing medications (monthly refills), which are then checked and initialed by a pharmacist.

Our hours of operation are 7am to 8pm on Monday thru Friday, 8am to 5pm Saturday, and 9am to 5pm on Sunday. We start at 7am with 1 pharmacist, and 4 technicians. We then have varying shifts throughout the day, to cover our peak delivery times (we currently have deliveries leaving the building at noon, 3pm, and 6pm). Once the evening delivery is finished, we have 1 pharmacist and 1 technician staffed until close. Saturdays are staffed with 4 technicians, and 2 pharmacists. Sundays are staffed with 4 technicians and 1 pharmacist.

Since we are already operating under this variance, I feel that we have shown that we can safely and effectively meet the patients' needs by exceeding the 4:1 ratio while never exceeding a 10:1 ratio. In addition, the new facility will provide many workflow and security enhancements such as better pharmacy/technician adjacencies and an access restricted controlled substance room.

Thank you for your consideration of our variance. We would greatly appreciate if this request could be handled during the July 2015 board meeting. Please contact me at tprice@mortonlfc.com or at 920-722-1378 with any questions. I can be present at the board meeting to answer any questions, if needed.

Best Regards,



Tim Price R. Ph.
Pharmacy Manager
(920) 886-2908

Wisconsin Department of Safety and Professional Services

Mail To: P.O. Box 8935
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 FAX #: (608) 261-7083
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 Website: http://dps.wi.gov

PHARMACY EXAMINING BOARD

PHARMACY VARIANCE REQUEST FORM

COMPLETED FORM MUST BE SUBMITTED AND APPROVED BY THE BOARD AT THEIR NEXT REGULARLY SCHEDULED MEETINGS AND THIS MAY TAKE AN EXTENDED PERIOD OF TIME FOR APPROVAL. PLEASE SUBMIT FORM REQUESTS IN ADVANCE TO ENSURE NO FURTHER DELAYS. All variance requests should be submitted to the Board at least 15 working days prior to the next regularly scheduled Board meeting in order to be placed on the agenda for that meeting. View the department website at <http://dps.wi.gov> for information regarding the dates of regularly scheduled Board meetings. If any specific act or practice for which a variance was granted is subsequently proposed to be modified the Board must be notified first and a new variance obtained for that modified act or practice.

<input checked="" type="checkbox"/> NEW PHARMACY (Relocation) <input type="checkbox"/> EXISTING PHARMACY	TYPE OF PHARMACY: <input type="checkbox"/> COMMUNITY <input checked="" type="checkbox"/> INSTITUTIONAL	CURRENT WI LICENSE NUMBER: 9299-92
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DBA: Name or title under which business is operated. (This must be the name on the pharmacy label.) Morton LTC	TELEPHONE NO. (920) 886-2908 FAX NO. (920) 722-1530
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PHARMACY ADDRESS: number, street, city, zip code
 201 E. Bell St, Neenah, WI 54956

A variance that is granted by the Board is only valid for the specific licensed pharmacy location to which the variance applies and for the specific acts to which the variance applies at that location. If any specific act or practice for which a variance was granted is subsequently discontinued the Board must be notified in order that the variance can be rescinded for that specific licensed pharmacy location.

CONTACT NAME OF PERSON REQUESTING VARIANCE Timothy J. Price (please print)	TELEPHONE NO. (920) 722-1378
--	---------------------------------

EMAIL ADDRESS tjprice@mortonltc.com	HOURS AVAILABLE Mon/Tues/Thur/Fri 8-6	Do you wish to appear before the board for questions? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> (unless Requested)
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Indicate the specific administrative rule and variance requested. (List all administrative codes below that apply.)

WI Administrative Rule	Variance Requested
7.01(3)	Technician: Pharmacist Station
	from 4:1 to 10:1

NOTE - A variance may only be granted if it is authorized in the rule.

Explain why the variance is necessary and specifically indicate how the requested activity or practice will differ from what is authorized by the rule. (Attach a description to this form.)

- For each specific activity or practice involved indicate the specific rule for which a variance is being sought, and the authority which authorizes the variance.
- Specifically identify how the proposed variance will meet professional standards for patient safety and confidentiality, including specifically each step in the prescription order handling/dispensing process to address: security, work flow delineation and accountability and pharmacist supervision over each step in the process.

Wisconsin Department of Safety and Professional Services

I/We declare that the foregoing statements are true and correct to the best of my/our knowledge and belief; the variance applied for is to cover only the pharmacy indicated above and at the location(s) specified; and that I/we will comply with the provisions of the Wisconsin Statutes and the Rules of the Pharmacy Examining Board.



Requester Signature

RPh/Manager
Title

6/19/15
Date

Timothy J. Price

Printed Name of person signing above

Jim Doyle
Governor

WISCONSIN DEPARTMENT OF
REGULATION & LICENSING

1400 E Washington Ave
PO Box 8935
Madison WI 53708-8935

Celia M. Jackson
Secretary



Email:
web@dri.state.wi.us
Voice: 608-266-2112
FAX: 608-267-0644
TTY: 608-267-2416

December 7, 2007

MR KURT S HOLM RPH
DIRECTOR OF PHARMACY
MORTON PHARMACY
201 EAST BELL STREET
NEENAH WI 54957-0778

Dear Mr. Holm:

After your appearance at the December 5 meeting, the Wisconsin Pharmacy Examining Board decided to grant your technician ratio variance request for Morton Pharmacy, license #8679-42, at 712 Midway Road, Menasha, WI. The variance allows a technician ratio that at no time exceeds 10:1, and at no time exceeds a 4:1 ratio average in any calendar month.

As you know, the Board also requires a performance report within one year along with a request to continue the variance. The first report is due at the Department at least 15 working days in advance of the December meeting.

The variance is null and void if the pharmacy at any time ceases to be a closed pharmacy.

Sincerely,

A handwritten signature in black ink that reads "Tom Ryan".

Tom Ryan
Director, Bureau of Health Professions

c: Kris Hendrickson
Division of Credentialing



Monday, November 17, 2008

Mr. Tom Ryan, Bureau Director
Pharmacy Examining Board
1400 E. Washington Ave.
Madison, WI 53703

Re: Morton Pharmacy Technician/Pharmacist Ratio Variance
712 Midway Road, Menasha WI 54952
Pharmacy License Number 8679-42

Mr. Ryan:
Pharmacy Examining Board Members:

Enclosed with this letter are the reports of technician and pharmacy staffing hours for our long term care closed pharmacy for the period beginning 12/02/07 through 11/01/08. The data for 11/02/08 to date is not yet available because our payroll person is still processing the payroll for pay period that ended on 11/15/08 for this payday on Friday of this week.

This is a brief explanation of the reports and the data that may make them easier to understand.

- The reports are all taken from actual payroll data for each 2 week pay period. The report compiles the actual hours of all technicians and pharmacists for each day, with the ratio for each day as well as totals for the period and the actual ratio for that 2 week period. Attached to each report are the actual payroll reports printed by our payroll manager from the pay roll monitoring system that all employees use entering and leaving the pharmacy. If hours are not entered, people do not get paid, so I am very confident that this data is accurate.
- The data only shows the hours that technicians are working, not what type of work they are actually doing. Since most technicians do some regular work that would not be classified as actual technician work requiring a pharmacist supervision, it is very likely that actual technician work hours and therefore pharmacist/technician ratios are somewhat higher than actual.
- The work that pharmacists spend consulting at served facilities is not included on these reports. Only actual hours worked in the pharmacy are included. Early in

Pharmacist and Technician Hours 712-LTC 2008

Tech #	S	M	T	W	R	F	S	S	M	T	W	R	F	S	S	M	T	W	R	F	S	
1	8/24	8/25	8/26	8/27	8/28	8/29	8/30	8/31	9/1	9/2	9/3	9/4	9/5	9/6								
2		10.5	8.8	7.82	7.7	6.05				8.88	8.7	4.83	9.91									
3	4			8.18	8.57	8.28				9.82		10.6	7.43	1.63								
4		9.23		8.08	8.62	8.57				8.18												
5		8.08	8.13	8.15	8.1	8.09				8.16	8.15	8.2	8.17	6.68								
6		7.03	6.07	5.1	5.23					6.1	6.08	6										
7		9.83	8.27	8.03	7.97	7.98				8.2	8.05	7.97	8.12									
8		9.89	9.2	8.88	7.83	8.42				9.47	9.1	9.12	9.22									
9		9.32	8.37	1	8.28	2.35	7.07	4.13		8.35	9.32	8.15	8.28									
10		9.52	8.37	8.12	8.28	8.18				8.48	7.78	8.1	8.28									
11		2.75		3		9.75					2.78	8.68										7.73
12																						2 Week Total
Total	4	76.15	57.21	71.56	63.97	67.67	7.07	4.13	0	75.58	59.96	71.65	60.81	16.04								635.8

RPh #	1	2	3	4	5	6	Total
1	2.48	11.85	5.03	3.27			
2		12.77					
3		5.07	5.03				
4		2.02					
5							
6							
Total	5.03	17.6	19.86	16.49	15.44	15.4	188.52

Daily Ratio	0.80	4.33	2.88	4.34	4.14	4.39	1.02	0.67	#DIV/0!	4.59	4.02	4.15	2.09	2.04	3.37
2 Week Ratio															

Pharmacist and Technician Hours 712-LTC

Date	Technician Hours	Pharmacist Hours	Monthly Ratio
Jun-08			
6/1 to 6/14	742.83	193.1	3.85
6/15 to 6/28	774.36	194.96	3.97
29-Jun	8.41	5.58	1.84
30-Jun	67.52	14.83	4.55
Totals	1593.12	408.47	Mo. Ratio 3.90

Pharmacist and Technician Hours 712-LTC

Date	Technician Hours	Pharmacist Hours	Monthly Ratio
Sep-08			
2-Sep	75.58	13.47	4.59
3-Sep	59.96	14.91	4.02
4-Sep	71.65	17.28	4.12
5-Sep	60.81	29.03	2.09
6-Sep	16.04	7.88	2.04
9/7 to 9/20	717.41	186.5	3.85
21-Sep	6.32	7.17	0.88
22-Sep	75.44	15.12	4.99
23-Sep	65.52	14.97	4.38
24-Sep	66.03	15.8	4.18
25-Sep	77.14	15.2	5.08
26-Sep	73.81	17.67	4.32
27-Sep	13.83	7.35	1.88
28-Sep	4.08	4.25	0.96
29-Sep	64.61	14.6	4.43
30-Sep	71.02	13	5.46
Totals	1519.25	394.2	3.85

Pharmacist and Technician Hours 712-LTC

Date	Technician Hours	Pharmacist Hours	Monthly Ratio
Aug-08			
1-Aug	73.92	16.03	4.61
2-Aug	13.86	9.56	1.45
3-Aug	4.08	5.5	6.74
4-Aug	76.62	10.33	7.42
5-Aug	76.61	16.7	4.51
6-Aug	85.24	23.02	3.70
7-Aug	86.85	12.75	6.81
8-Aug	61.58	13.79	4.47
9-Aug	16.69	7.57	2.20
8/10 to 8/23	777.02	202.2	3.84
24-Aug	4	5.03	0.80
25-Aug	76.15	17.6	4.33
26-Aug	57.21	19.86	2.88
27-Aug	71.56	16.49	4.34
28-Apr	63.97	15.44	4.14
29-Apr	67.67	15.4	4.39
30-Aug	7.07	6.93	1.02
31-Aug	4.13	6.2	0.67
Totals	1624.23	420.4	Mo. Ratio 3.86

Pharmacist and Technician Hours 712-LTC

Date	Technician Hours	Pharmacist Hours	Monthly Ratio
Sep-08			
2-Sep	75.58	13.47	4.59
3-Sep	59.96	14.91	4.02
4-Sep	71.65	17.28	4.12
5-Sep	60.81	29.03	2.09
6-Sep	16.04	7.88	2.04
9/7 to 9/20	717.41	186.5	3.85
21-Sep	6.32	7.17	0.88
22-Sep	75.44	15.12	4.99
23-Sep	65.52	14.97	4.38
24-Sep	66.03	15.8	4.18
25-Sep	77.14	15.2	5.08
26-Sep	73.81	17.67	4.32
27-Sep	13.83	7.35	1.88
28-Sep	4.08	4.25	0.96
29-Sep	64.61	14.6	4.43
30-Sep	71.02	13	5.46
Totals	1519.25	394.2	Mo. Ratio 3.85

Pharmacist and Technician Hours 712-LTC

Amended 11/23/08

Date
Oct-08
1-Oct
2-Oct
3-Oct
4-Oct
10/5 to 10/18
10/19 to 10/31
Totals

Technician Hours
66.14
71.62
75.57
14.76
757.74
743.44
1729.27

Pharmacist Hours
15.92
17.33
14.48
8.8
191.57
185.72
433.82

Mo. Ratio	Monthly Ratio
	4.15
	4.13
	5.22
	1.68
	3.96
	4.00
Mo. Ratio	3.98

Pharmacist and Technician Hours 712-LTC

Date
Jun-08
6/1 to 6/14
6/15 to 6/28
29-Jun
30-Jun
Totals

Technician Hours
742.83
774.36
8.41
67.52
1593.12

Pharmacist Hours
193.1
194.96
5.58
14.83
408.47

Monthly Ratio
3.85
3.97
1.84
4.55
Mo. Ratio 3.90

Pharmacist and Technician Hours 712-LTC

Date	Technician Hours	Pharmacist Hours	Monthly Ratio
Jul-08			
1-Jul	87.35	17.7	5.08
2-Jul	80.56	15.87	5.08
3-Jul	65.44	16.2	4.04
5-Jul	11.47	7.13	1.61
6-Jul	4.38	4.67	0.94
7-Jul	67.19	15.94	4.22
9-Jul	64.88	15.27	4.25
10-Jul	71.24	19.04	3.74
11-Jul	74.74	14.57	5.13
12-Jul	14.67	7.7	1.91
7/13 to 7/26	714.13	188.71	3.46
27-Jul	5.53	4.42	1.25
28-Jul	83.69	13.87	6.03
29-Jul	71.29	15.17	4.7
30-Jul	73.49	18.33	4.01
31-Jul	85.32	26.5	3.22
Totals	1575.37	401.09	Mo Ratio 3.93

Pharmacist and Technician Hours 712-LTC

Date	Technician Hours	Pharmacist Hours	Monthly Ratio
Jan-08			
2-Jan	50.69	20.5	2.47
3-Jan	56.72	16	3.55
4-Jan	55.13	27	2.04
5-Jan	10.43	7	1.49
6-Jan	0	4	0
7-Jan	47.39	22	2.15
8-Jan	50.78	17.57	2.89
9-Jan	31.93	14.5	2.2
10-Jan	57.44	15.08	3.81
11-Jan	40.85	18.45	2.21
1/13 to 1/26	659.5	224.47	2.94
27-Jan	4.42	7.81	0.57
28-Jan	50.95	22.97	2.22
29-Jan	57.02	20.6	2.77
30-Jan	39.54	18.7	2.11
31-Jan	30.77	13.85	2.22
Totals	1243.56	470.5	Mo Ratio 2.64

Pharmacist and Technician Hours 712-LTC

Date	Technician Hours	Pharmacist Hours	Ratio
Feb-08			
1-Feb	42.39	18.35	2.31
2-Feb	11.72	7.93	1.48
3-Feb	0	6.9	0
4-Feb	58.61	19.81	2.96
5-Feb	53.08	20.71	2.56
6-Feb	39.15	27.15	1.44
7-Feb	46.39	18.62	2.49
8-Feb	64.7	20.72	3.12
9-Feb	13.6	7.8	1.81
2/10 to 2/23	738.99	226.99	3.26
24-Feb	8.5	5.42	1.57
25-Feb	76.06	18.02	4.22
26-Feb	60.47	17.13	3.53
27-Feb	64.52	15.15	4.26
28-Feb	67.06	16.32	4.11
29-Feb	76.08	21.44	3.64
Totals	1421.32	468.46	3.03

Pharmacist and Technician Hours 712-LTC

Date	Technician Hours	Pharmacist Hours	Monthly Ratio
Mar-08			
1-Mar	20.45	7.98	2.56
2-Mar	4.13	6.55	0.63
3-Mar	61.4	23.47	2.62
4-Mar	55.83	25.92	2.15
5-Mar	61.31	10.7	5.73
6-Mar	77.9	21.05	3.7
7-Mar	79.82	21.18	3.77
8-Mar	23.47	8.15	2.88
3/9 to 3/22	747.47	232.31	3.22
23-Mar	0	0	0
24-Mar	71.11	14.41	5
25-Mar	66.12	20.26	3.3
26-Mar	60.94	16.83	3.62
27-Mar	85.17	16.94	5.03
28-Mar	77.14	21.82	3.54
29-Mar	17.6	9.13	1.93
30-Mar	5.47	5.98	0.91
3-Jan	92.12	25.71	3.58
Totals	1607.45	488.39	Mo. Ratio 3.29

Pharmacist and Technician Hours 712-LTC

Date
Apr-08
1-Apr
2-Apr
3-Apr
4-Apr
5-Apr
4/6 to 4/19
20-Apr
21-Apr
22-Apr
23-Apr
24-Apr
25-Apr
26-Apr
27-Apr
28-Apr
29-Apr
30-Apr
Totals

Technician Hours
72.63
88.26
62.55
81.15
19.45
736.23
7.83
81.61
65.65
77.95
74.35
79.34
17.67
4.13
54.94
17.83
80.92
1622.49

Pharmacist Hours
19.36
27.01
17.35
21.1
13.83
199.19
7.33
25.33
17.64
16.75
15.77
16.09
7.28
4.22
26.97
15.35
15.25
465.82

Monthly Ratio
3.75
3.27
3.61
3.85
1.41
3.7
1.07
3.22
3.72
4.65
4.71
4.93
2.43
0.98
2.04
4.68
5.31
Mo. Ratio 3.48

Pharmacist and Technician Hours Z12-LTC

Date
May-08
1-May
2-May
3-May
5/4 to 5/17
5/18 to 5/31
Totals

Technician Hours
58.7
78.63
18.51
722.8
704.08
1582.72

Pharmacist Hours
15.56
16.63
8.65
188.67
172.47
401.98

Monthly Ratio
3.77
4.73
2.14
3.83
4.08
Mo. Ratio
3.94

Dec 2007 VARIANCE REQUEST

**MORTON PHARMACY – NEENAH, WI
KURT S. HOLM, R.PH.**

Kurt S. Holm, R.Ph. and Kathy Ruhsam joined the Board to answer questions.

MOTION: Greg Weber moved, seconded by Jeanne Severson, to grant a one year variance to Morton Pharmacy, license # 8679-42, at 712 Midway Rd, Menasha, WI, allowing a technician ratio that never exceeds 10-1, and does not exceed a 4/1 ratio average in any calendar month. The Board further requires a performance report within one year along with a request to continue the variance. The variance is null and void if the pharmacy at any time ceases to be a closed pharmacy. Motion carried unanimously.

12/3/08

MORTON PHARMACY TECHNICIAN/PHARMACIST RATIO VARIANCE

Kurt Holm appeared before the Board to request a variance for technician/pharmacist ratio.

MOTION: Tim Boehmer moved, seconded by Amy Mattila, to grant the variance request for renewal from Morton's Pharmacy for an indefinite period of time with the knowledge that if Morton's decides to modify they must petition the Board. Motion carried unanimously.



Omnicare Pharmacy of La Crosse

3235 Airport Road La Crosse, WI 54603
Phone: 866-275-0531 Fax: 877-260-1378

June 25, 2015

Thaddeus Schumacher, PharmD
Chair, Pharmacy Examining Board
Department of Safety and Professional Services
1400 E. Washington Avenue, Box 8935
Madison, WI 53708-8935

Dear Dr. Schumacher,

Omnicare Pharmacy of La Crosse is requesting a variance to section Phar 7.01(1)(d) and 7.015(3)(a) of the State of Wisconsin pharmacy regulations to allow the implementation of a Tech-Check-Tech program for checking manually picked unit dose barcoded medications. This program would allow qualified and trained pharmacy technicians to provide the final check by scanning barcoded medications that are manually picked by another pharmacy technician against barcoded prescription labels which are specifically coded to the barcoded medications. The policy and procedure for this program is attached.

Our Tech-Check-Tech program would allow pharmacists to dedicate more time to clinical activities and improving patient care. At the same time, safeguards would be in place to ensure that the accuracy of barcoded medications is not compromised. Prior to becoming validated and providing the final check on any medications, the pharmacy technicians must demonstrate that they can check at least 1500 doses with at least 99.8% accuracy. In addition, a pharmacist will provide the final check on a minimum of 10% of all medications that a validated pharmacy technician checks. The validated pharmacy technicians will be required to maintain an accuracy rate of at least 99.8% while checking medications.

Thank you for your consideration of this variance request. I would like to request an appearance at the July 22nd, 2015 Pharmacy Examining Board meeting to discuss this variance request. I look forward to meeting with you and discussing this program further.

Sincerely,

Uchechukwu Eze, RPh.
Omnicare of La Crosse
3235 Airport Road,
La Crosse, WI 54603
608-781-7900
Uchechukwu.Eze@omnicare.com

Wisconsin Department of Safety and Professional Services

Mail To: P.O. Box 8935
Madison, WI 53708-8935

FAX #: (608) 261-7083
Phone #: (608) 266-2112

1400 E. Washington Avenue
Madison, WI 53703

E-Mail: web@dps.wi.gov
Website: http://dps.wi.gov

PHARMACY EXAMINING BOARD

PHARMACY VARIANCE REQUEST FORM

COMPLETED FORM MUST BE SUBMITTED AND APPROVED BY THE BOARD AT THEIR NEXT REGULARLY SCHEDULED MEETINGS AND THIS MAY TAKE AN EXTENDED PERIOD OF TIME FOR APPROVAL. PLEASE SUBMIT FORM REQUESTS IN ADVANCE TO ENSURE NO FURTHER DELAYS. All variance requests should be submitted to the Board at least 15 working days prior to the next regularly scheduled Board meeting in order to be placed on the agenda for that meeting. View the department website at <http://dps.wi.gov> for information regarding the dates of regularly scheduled Board meetings. If any specific act or practice for which a variance was granted is subsequently proposed to be modified the Board must be notified first and a new variance obtained for that modified act or practice.

<input type="checkbox"/> NEW PHARMACY <input checked="" type="checkbox"/> EXISTING PHARMACY	TYPE OF PHARMACY: <input type="checkbox"/> COMMUNITY <input checked="" type="checkbox"/> INSTITUTIONAL	CURRENT WI LICENSE NUMBER: <u>8474 - 42</u>
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DBA: Name or title under which business is operated. (This must be the name on the pharmacy label.) <u>Omnicare Of Lacrosse</u>	TELEPHONE NO. <u>(866) 275-0531</u> FAX NO. <u>(877) 260-1378</u>
--	--

PHARMACY ADDRESS: number, street, city, zip code
3235 Airport Road, La Crosse, WI 54603

A variance that is granted by the Board is only valid for the specific licensed pharmacy location to which the variance applies and for the specific acts to which the variance applies at that location. If any specific act or practice for which a variance was granted is subsequently discontinued the Board must be notified in order that the variance can be rescinded for that specific licensed pharmacy location.

CONTACT NAME OF PERSON REQUESTING VARIANCE <u>Uchechukwu Eze</u> (please print)	TELEPHONE NO. <u>(608) 406-7272</u>
---	--

EMAIL ADDRESS <u>Uchechukwu.Eze@omnicare.com</u>	HOURS AVAILABLE <u>10:30am - 7pm</u>	Do you wish to appear before the board for questions? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
---	---	--

Indicate the specific administrative rule and variance requested. (List all administrative codes below that apply.)

WI Administrative Rule	Variance Requested
<u>Administrative Code</u> <u>Phar 7.01(1)(d),</u> <u>Phar 7.015(3)(a)</u>	<u>To allow qualified and trained Pharmacy Technicians provide the final check on bar coded medications that are manually picked by another pharmacy technician.</u>

NOTE - A variance may only be granted if it is authorized in the rule.

Explain why the variance is necessary and specifically indicate how the requested activity or practice will differ from what is authorized by the rule. (Attach a description to this form.)

- For each specific activity or practice involved indicate the specific rule for which a variance is being sought, and the authority which authorizes the variance.
- Specifically identify how the proposed variance will meet professional standards for patient safety and confidentiality, including specifically each step in the prescription order handling/dispensing process to address: security, work flow delineation and accountability and pharmacist supervision over each step in the process.

Tech – Check – Tech Program Policy and Procedure June 2015

Definitions

Tech-Check-Tech (TCT) – the process by which a technician verifies barcoded medications for distribution that another technician has filled by scanning the barcoded medication against the corresponding barcoded prescription label.

Validated Pharmacy Technician (VPT) – a technician who has successfully completed the TCT training program and has proven they can accurately verify medications picked by other technicians

VPT Candidate – a technician currently completing the TCT training program with the goal of becoming a VPT

POLICY

1. A TCT program is to be created for the following reasons:
 - a. The program will elevate the professional role and standards of pharmacy technicians
 - b. By utilizing VPTs to perform TCT duties, it will allow additional pharmacist time to be shifted from distributive functions to cognitive functions
 - c. A TCT program cannot be used as a means to decrease pharmacist staffing
2. A variance approval must be obtained from the Wisconsin Pharmacy Examining Board (PEB) prior to implementing TCT
3. A full-time Wisconsin licensed pharmacist at the site of practice will be identified as the TCT program coordinator and will be responsible for assuring compliance with associated policies and procedures
4. A complete list of technicians who have completed the TCT program and are in good standing should be kept by the TCT program coordinator
5. A quality assurance program shall be implemented to guarantee continued compliance and accuracy of the established TCT program at Omnicare Pharmacy of La Crosse.

PROCEDURE

1. Program Setup and Structure

- a. State approval
 - i. A variance approval must be obtained from the Wisconsin Pharmacy Examining Board (PEB) prior to implementing TCT
 - ii. All documentation received from the PEB for written approval or variance approval will be kept in the site's records
 - iii. Variance approvals and exemptions shall be reassessed when there is a change in regulations or a major change in practice at the site
- b. Site-specific leadership
 - i. The Pharmacy shall designate a coordinator for the TCT program:
 - The designated coordinator should be a Wisconsin licensed pharmacist

- The designated coordinator should be a full-time employee at Omnicare Pharmacy of La Crosse
- ii. At least one Trainer for the TCT program will be designated:
 - Designated trainers should be a Wisconsin licensed pharmacist or VPT who is routinely involved in the TCT program
 - Designated trainers should be full-time employees at Omnicare Pharmacy of La Crosse

2. VPT Eligibility

To be eligible to receive VPT status and participate in the technician checking program, a technician must meet the following conditions:

- a. A pharmacy technician working full time with at least one year of technician experience, trained at this institution on repackaging, labeling and dispensing and be a Certified Pharmacy Technician (CPhT).
- b. The technician will successfully complete the didactic self-learning packet including reading and assessment questions.
The technician will successfully complete the practical criteria checklist, which is a guideline for the one-on-one simulated training.
- c. The technician will achieve 99.8% accuracy in checking at least 1500 consecutive doses in at least 3 separate audits during the validation.

3. Training

a. Didactic Training

Training will include reading and successfully completing the assessment questions in the tech-check-tech program self-learning packet. The training is on the medication safety, medication use process, dosage forms, packaging and repackaging. Technicians are required to score 90% or greater on the assessment questions.

b. Practical Training

Technicians will complete simulated practical training with a pharmacist. The training pharmacist will provide written and verbal feedback noting additional areas of training needed for the technician. The trainer and trainee will be required to date and initial each item on the checklist when the training is complete.

4. Validation

For initial validation, the technician must attain a 99.8% accuracy rate in checking at least 1500 consecutive doses, during at least 3 separate audits.

- a. The audit process will consist of a registered pharmacist checking the accuracy of each medication tote after the technician has checked them. Any errors resulting from improper checking will be documented and given to the senior technician who will enter the errors into the technician validation database. The pharmacist auditor will discuss the errors with the technician.
- b. During the validation process the pharmacist evaluating the technician will artificially introduce errors at a minimum rate of 0.2% (3 doses per 1500). The pharmacist coordinating the audit will keep a record of the introduced errors to ensure they are removed prior to distribution. Artificially introduced errors will

include an occurrence of wrong drug, wrong dose, wrong dosage form, extra / insufficient quantity, omitted medications and an expired dose.

- c. All audit results will be maintained within the tech-check-teck program database.
- d. If a technician misses more than 3 errors per 15000 doses, they fail the validation.
- e. If a technician cannot achieve the required 99.8% accuracy level in checking 1500 consecutive doses after two months of training, the technician will no longer be eligible to participate in the technician checking program.
- f. Upon successful completion of the validation (99.8% accuracy rate) the technician will be recognized as a Validated Pharmacy Technician.

5. Quality Assurance (QA) Process

- a. A pharmacist working in the pharmacy will perform daily QA audits on 10% of the barcoded medications checked by the VPT prior to delivery to the nursing homes.
- b. All errors discovered by the pharmacist conducting the audit will be recorded and discussed with the VPT. The senior technician is responsible for tracking all QA audits in the QA database.

6. VTC Ongoing Standards

- a. If the accuracy of the VPT is less than 99.8% over the lesser of a 6 month period or for the first 2000 double checked doses within a 6 month period, the VPT is required to be re-trained and re-validated (1500 doses, 99.8% accuracy).
- b. If the accuracy of the VPT is less than 99.8% on more than 4 occasions in a year, the VPT will be relieved from their VPT checking status for a 6 month period. The VPT may be re-trained and re-validated after the 6 month period.
- c. If the re-validated VPT has less than 99.8% accuracy on any occasion during the three months following their six-month leave, they will be permanently removed from their VPT status.
- d. If a VPT does not check for more than two months, re-validation (99.8% accuracy, 1500 doses) should be done with the first check upon return. If the VPT does not check for 4 months, they must be re-trained and re-validated.
- e. A VPT shall not under any circumstance perform a final check on any non-barcoded medication, IV's or compounded medications.



July 8, 2015

Pharmacy Examining Board
Department of Regulation and Licensing
1400 East Washington Avenue
Madison, WI 53703

I am requesting a variance to Phar 7.09 (f) requiring the pharmacist check for accuracy.

The only change from the variance requested on 3/3/2010 is that we have changed automated dispensing machines from Pyxis PARx System to Cerner Rx Station. Both systems depend on bar coding for accuracy. The meds are scanned in the pick before loading to Rx Station and again at the Rx station before load and refills. These meds are again scanned at the bedside before administering to the patient. All activities are electronically tracked in the Cerner Rx Station.

I have enclosed the original letter requesting a variance to use the Pyxis PARx system (dated 3/3/2010) the only difference is that we will be changing from the PARx system to the Cerner Rx Station for our dispensing machines.

Respectfully,

Merlin Borchardt RPh
Pharmacy Manager
Fort HealthCare Pharmacy
License No. 8762-40
611 Sherman Avenue East
Fort Atkinson, WI 53538
920-568-5147 Office
920-568-6035 Fax
Merlin.borchardt@forthc.com

Wisconsin Department of Safety and Professional Services

Mail To: P.O. Box 8935
Madison, WI 53708-8935

1400 E. Washington Avenue
Madison, WI 53703

FAX #: (608) 261-7083
Phone #: (608) 266-2112

E-Mail: web@dps.wi.gov
Website: http://dps.wi.gov

PHARMACY EXAMINING BOARD

PHARMACY VARIANCE REQUEST FORM

COMPLETED FORM MUST BE SUBMITTED AND APPROVED BY THE BOARD AT THEIR NEXT REGULARLY SCHEDULED MEETINGS AND THIS MAY TAKE AN EXTENDED PERIOD OF TIME FOR APPROVAL. PLEASE SUBMIT FORM REQUESTS **IN ADVANCE** TO ENSURE NO FURTHER DELAYS. All variance requests should be submitted to the Board at least 15 working days prior to the next regularly scheduled Board meeting in order to be placed on the agenda for that meeting. View the department website at <http://dps.wi.gov> for information regarding the dates of regularly scheduled Board meetings. *If any specific act or practice for which a variance was granted is subsequently proposed to be modified the Board must be notified first and a new variance obtained for that modified act or practice.*

<input type="checkbox"/> NEW PHARMACY <input checked="" type="checkbox"/> EXISTING PHARMACY	TYPE OF PHARMACY: <input type="checkbox"/> COMMUNITY <input checked="" type="checkbox"/> INSTITUTIONAL	CURRENT WI LICENSE NUMBER: <div style="border-bottom: 1px solid black; padding: 2px 0;">4961-042</div>
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DBA: Name or title under which business is operated. (This must be the name on the pharmacy label.) <div style="border-bottom: 1px solid black; padding: 2px 0;">Fort Health Care</div>	TELEPHONE NO. (920) 568-5145 FAX NO. (920) 568-6035
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PHARMACY ADDRESS: number, street, city, zip code

611 Sherman Ave East, Fort Atkinson, WI 53538

A variance that is granted by the Board is only valid for the specific licensed pharmacy location to which the variance applies and for the specific acts to which the variance applies at that location. If any specific act or practice for which a variance was granted is subsequently discontinued the Board must be notified in order that the variance can be rescinded for that specific licensed pharmacy location.

CONTACT NAME OF PERSON REQUESTING VARIANCE <div style="border-bottom: 1px solid black; padding: 2px 0;">MERWIN BORCHARDT</div> <small>(please print)</small>	TELEPHONE NO. <div style="border-bottom: 1px solid black; padding: 2px 0;">(920) 568-5147</div>
---	--

EMAIL ADDRESS <div style="border-bottom: 1px solid black; padding: 2px 0;">MERWIN.BORCHARDT@FORTHC.COM</div>	HOURS AVAILABLE <div style="border-bottom: 1px solid black; padding: 2px 0;">M-P 8-3</div>	Do you wish to appear before the board for questions? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
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Indicate the specific administrative rule and variance requested. (List all administrative codes below that apply.)

WI Administrative Rule	Variance Requested
Phar 7.09 (5)	Pharmacy for accuracy (see attached)

NOTE - A variance may only be granted if it is authorized in the rule.

Explain why the variance is necessary and specifically indicate how the requested activity or practice will differ from what is authorized by the rule. (Attach a description to this form.)

- For each specific activity or practice involved indicate the specific rule for which a variance is being sought, and the authority which authorizes the variance.
- Specifically identify how the proposed variance will meet professional standards for patient safety and confidentiality, including specifically each step in the prescription order handling/dispensing process to address: security, work flow delineation and accountability and pharmacist supervision over each step in the process.

Wisconsin Department of Safety and Professional Services

I/We declare that the foregoing statements are true and correct to the best of my/our knowledge and belief; the variance applied for is to cover only the pharmacy indicated above and at the location(s) specified; and that I/we will comply with the provisions of the Wisconsin Statutes and the Rules of the Pharmacy Examining Board.

Merlin Borchardt
Requester Signature

Pharmacy Manager Title 7/9/15 Date

MERLIN BORCHARDT
Printed Name of person signing above



copy of
Pres Variance
Dated
3/3/10

March 3, 2010

Pharmacy Examining Board
Department of Regulation and Licensing
1400 East Washington Avenue
Madison, WI 53703

Dear Sirs:

I am requesting a variance to Phar 7.09 (f) requiring the pharmacist check for accuracy.

We use the Pyxis PARx System which uses bar code scanning technology via an EDA (enterprise digital assistant) to automate and track the pick, refill, and load activities of our Pyxis automated dispensing machines. The PARx system can reduce errors during the refill process by preventing the wrong medication from being chosen in the pharmacy or refilled into the wrong pocket at the automated dispensing machine. The pick, refill, and load activities are under the general supervision of a licensed pharmacist (Phar 7.09 (e)). All activities are electronically tracked in the Pyxis PARx System.

I believe the bar-code check by the technician at the time of pick, and again at the time of refill of the automated dispensing machine is sufficient to award a variance to the pharmacist check requirement. We also use bar code medication verification at point of administration in all of our inpatient units within the hospital and have extensive quality improvement mechanisms to track and correct issues with our medication distribution system.

Respectfully,

Christopher Barron RPh
Pharmacy Manager
Fort HealthCare Pharmacy
License No. 4961-042
611 Sherman Avenue East
Fort Atkinson, WI 53538
920-568-5147 office
920-568-6035 fax
chris.barron@forthc.com

Wisconsin Department of Regulation & Licensing

Mail To: P.O. Box 8935
Madison, WI 53708-8935

FAX #: (608) 261-7083
Phone #: (608) 266-2112

1400 E. Washington Avenue
Madison, WI 53703

E-Mail: web@drl.state.wi.us
Website: http://drl.wi.gov

PHARMACY EXAMINING BOARD

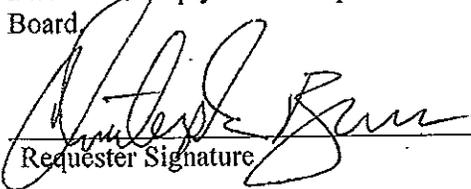
PHARMACY VARIANCE REQUEST FORM

COMPLETED FORM MUST BE SUBMITTED AND APPROVED BY THE BOARD AT THEIR NEXT REGULARLY SCHEDULED MEETINGS AND THIS MAY TAKE AN EXTENDED PERIOD OF TIME FOR APPROVAL. PLEASE SUBMIT FORM REQUESTS IN ADVANCE TO ENSURE NO FURTHER DELAYS. All variance requests should be submitted to the Board at least 15 working days prior to the next regularly scheduled Board meeting in order to be placed on the agenda for that meeting. View the department website at <http://drl.wi.gov> for information regarding the dates of regularly scheduled Board meetings. If any specific act or practice for which a variance was granted is subsequently proposed to be modified the Board must be notified first and a new variance obtained for that modified act or practice.

<input type="checkbox"/> NEW PHARMACY <input checked="" type="checkbox"/> EXISTING PHARMACY		TYPE OF PHARMACY: <input type="checkbox"/> COMMUNITY <input checked="" type="checkbox"/> INSTITUTIONAL		CURRENT WI LICENSE NUMBER: <u>4961-042</u>	
DBA: Name or title under which business is operated. (This must be the name on the pharmacy label.) <u>Fort HealthCare</u>			TELEPHONE NO. <u>(970) 568-5147</u>		FAX NO. <u>(970) 568-6035</u>
PHARMACY ADDRESS: number, street, city, zip code <u>611 Sherman Avenue East, Ft. Atkinson, WI 53538</u>					
A variance that is granted by the Board is only valid for the specific licensed pharmacy location to which the variance applies and for the specific acts to which the variance applies at that location. If any specific act or practice for which a variance was granted is subsequently discontinued the Board must be notified in order that the variance can be rescinded for that specific licensed pharmacy location.					
CONTACT NAME OF PERSON REQUESTING VARIANCE <u>Christopher Barron</u> <small>(please print)</small>			TELEPHONE NO. <u>(970) 568-5147</u>		
EMAIL ADDRESS <u>Chris.barron@forthealthcare.com</u>		HOURS AVAILABLE <u>M-F 8-5</u>		Do you wish to appear before the board for questions? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
Indicate the specific administrative rule and variance requested. (List all administrative codes below that apply.)					
WI Administrative Rule <u>Phar 7.09(f)</u>		Variance Requested <u>pharmacist check for accuracy (see attachment)</u>			
NOTE - A variance may only be granted if it is authorized in the rule.					
Explain why the variance is necessary and specifically indicate how the requested activity or practice will differ from what is authorized by the rule. (Attach a description to this form.)					
a. For each specific activity or practice involved indicate the specific rule for which a variance is being sought, and the authority which authorizes the variance.					
b. Specifically identify how the proposed variance will meet professional standards for patient safety and confidentiality, including specifically each step in the prescription order handling/dispensing process to address: security, work flow delineation and accountability and pharmacist supervision over each step in the process.					

Wisconsin Department of Regulation & Licensing

I/We declare that the foregoing statements are true and correct to the best of my/our knowledge and belief; the variance applied for is to cover only the pharmacy indicated above and at the location(s) specified; and that I/we will comply with the provisions of the Wisconsin Statutes and the Rules of the Pharmacy Examining Board.


Requester Signature

Pharmacy Manager
Title

3-2-10
Date

Christopher Barron
Printed Name of person signing above

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: 7 July 2015 Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Pharmacy Examining Board			
4) Meeting Date: 22 July 2015	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Legislation and Rule Matters – Discussion and Consideration 1. Pending Projects a. Phar 8 Relating to Recording Name and Health Care Facility Definition b. Phar 2, 4 Relating to Application and Examination c. Phar 5 Relating to Renewal and Reinstatement d. Phar 6 Relating to Temperature and Humidity Controls e. Phar 14 Relating to Practice of Pharmacy f. Phar 7 Relating to Practice of Pharmacy g. Phar 15 Relating to Compounding h. Phar 1, 8 Relating to Definitions and Controlled Substances 2. Update on Legislation a. Act 34 Relating to Optometrist Prescribing Hydrocodone Combination Products b. Act 35 Relating to Epinephrine c. Act 40 Relating to Therapeutic Alternate Drug Selections in Correctional System d. AB 228 Relating to Definition of Tetrahydrocannabinols (CBD) 3. Update on Legislation and Pending and Possible Rulemaking Projects a. Track and Trace Pedigree System 4. Goal List	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both		8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:
10) Describe the issue and action that should be addressed:			

**State of Wisconsin
Department of Safety & Professional Services**

11)

Authorization

Sharon Henes

Signature of person making this request

Date

Supervisor (if required)

Date

Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date

Directions for including supporting documents:

1. This form should be attached to any documents submitted to the agenda.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, Provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

State of Wisconsin



2013 Assembly Bill 445

Date of enactment: April 7, 2014
Date of publication*: April 8, 2014

2013 WISCONSIN ACT 199

AN ACT to amend 450.19 (2) (b); and to create 450.11 (1b), 450.11 (9) (bm) and 450.19 (2m) of the statutes; relating to: identification presentation, name recording, monitoring for certain prescription drugs, and authorizing the exercise of rule-making authority.

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

SECTION 1. 450.11 (1b) of the statutes is created to read:

450.11 (1b) IDENTIFICATION CARD REQUIRED FOR CERTAIN CONTROLLED SUBSTANCES. (a) In this subsection:

1. "Health care facility" means a facility, as defined in s. 647.01 (4); any hospital, nursing home, community-based residential facility, county home, county infirmary, county hospital, county mental health complex, or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.03, 50.032, 50.033, 50.034, 50.35, 51.08, or 51.09; a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42, or 252.10; and any other facility identified by the board by rule.

2. "Identification card" means any of the following:

- An operator's license issued under ch. 343 or under a comparable law of another state.
- An identification card issued under s. 343.50 or under a comparable law of another state.
- An identification card issued by a U.S. uniformed service.
- A U.S. or foreign passport.

(b) Except as provided under par. (e), a controlled substance included in schedule II or III of ch. 961 may not be dispensed, and may not be delivered to a representa-

tive of the ultimate user, without an identification card belonging to the person to whom the drug is being dispensed or delivered.

(bm) A pharmacist or other person dispensing or delivering a drug shall legibly record the name on each identification card presented under par. (b) to the pharmacist or other person, and the name of each person to whom a drug is dispensed or delivered subject to par. (e) 2., and shall maintain that record for a time established by the board by rule or, for a record that is subject to s. 450.19, until the name is delivered to the board under s. 450.19, whichever is sooner.

(c) If the person to whom a drug subject to par. (b) is being delivered is not the ultimate user of the drug, the person delivering the drug may ask the ultimate user of the drug to designate a person who is authorized to pick up the drug on behalf of the ultimate user and may inform the person to whom the drug is being delivered that his or her identification is being recorded.

(d) A pharmacist is immune from any civil or criminal liability and from discipline under s. 450.10 for any act taken by the pharmacist in reliance on an identification card that the pharmacist reasonably believed was authentic and displayed the name of the person to whom the drug was being delivered if the sale was made in good faith.

* Section 991.11, WISCONSIN STATUTES: Effective date of acts. "Every act and every portion of an act enacted by the legislature over the governor's partial veto which does not expressly prescribe the time when it takes effect shall take effect on the day after its date of publication."

(e) No identification card is required under par. (b) if any of the following applies:

1. The drug is administered or dispensed directly to the ultimate user by a practitioner.
2. The pharmacist or other person dispensing or delivering the drug has personal knowledge of the person to whom the drug is dispensed or delivered and that the person is the ultimate user or the ultimate user's authorized representative.
3. The drug is delivered to a health care facility to be administered in the health care facility.

(f) The board may, by rule, establish an exemption from the requirements under this subsection for the delivery of a drug by mail if the board determines that the exemption is necessary.

SECTION 2. 450.11 (9) (bm) of the statutes is created to read:

450.11 (9) (bm) A violation of sub. (1b) is not punishable under par. (a) or (b).

SECTION 3. 450.19 (2) (b) of the statutes is amended to read:

450.19 (2) (b) Identify specific data elements to be contained in a record documenting the dispensing of a prescription drug, including the method of payment and, subject to sub. (2m), the name recorded under s. 450.11 (1b) (bm). In identifying specific data elements, the board shall consider data elements identified by similar programs in other states and shall ensure, to the extent possible, that records generated by the program are easily shared with other states.

SECTION 4. 450.19 (2m) of the statutes is created to read:

450.19 (2m) (a) The rules promulgated under sub. (2) may not require that a record delivered to the board before 2 years after the effective date of this paragraph ... [LRB inserts date], contain the name recorded under s. 450.11 (1b) (bm).

(b) After consultation with representatives of licensed pharmacists and pharmacies, and subject to the approval of the secretary, the board may delay the requirement that a record delivered to the board contain the name recorded under s. 450.11 (1b) (bm) for an additional period beyond the date specified in par. (a).

State of Wisconsin



2015 Senate Bill 74

Date of enactment: **July 1, 2015**
Date of publication*: **July 2, 2015**

2015 WISCONSIN ACT 34

AN ACT *to amend* 961.39 (3) (b); and *to create* 961.39 (2m) of the statutes; **relating to:** prescriptions for controlled substances issued by optometrists and providing an exemption from emergency rule procedures.

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

SECTION 1. 961.39 (2m) of the statutes is created to read:

961.39 (2m) Notwithstanding sub. (1), may prescribe, dispense, or administer any of the following, if permitted for prescription or administration under the rules promulgated under s. 449.18 (6) (cm):

(a) Not more than 300 milligrams of hydrocodone per 100 milliliters or per 100 grams or not more than 15 milligrams per dosage unit, with a four-fold or greater quantity of an isoquinoline alkaloid of opium.

(b) Not more than 300 milligrams of hydrocodone per 100 milliliters or per 100 grams or not more than 15 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

SECTION 2. 961.39 (3) (b) of the statutes is amended to read:

961.39 (3) (b) The indicated use of the controlled substance included in schedule III, IV, or V so prescribed

or the indicated use of the controlled substance under sub. (2m) (a) or (b) so prescribed.

SECTION 3. Nonstatutory provisions.

(1) Using the procedure under section 227.24 of the statutes, the department of safety and professional services may promulgate rules under section 449.18 (6) (cm) of the statutes to account for section 961.39 (2m) of the statutes, as created by this act, 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 department 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 991.11, WISCONSIN STATUTES: Effective date of acts. "Every act and every portion of an act enacted by the legislature over the governor's partial veto which does not expressly prescribe the time when it takes effect shall take effect on the day after its date of publication."

State of Wisconsin



2015 Senate Bill 139

Date of enactment: **July 1, 2015**
Date of publication*: **July 2, 2015**

2015 WISCONSIN ACT 35

AN ACT *to amend* 448.03 (2) (q), 450.11 (1), 450.11 (3) and 450.11 (4) (a) 5. a.; and *to create* 255.07 and 450.11 (4) (a) 5. d. of the statutes; **relating to:** supply and use of epinephrine auto-injectors by certain authorized entities.

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

SECTION 1. 255.07 of the statutes is created to read:

255.07 Life-saving allergy medication; use of epinephrine auto-injectors. (1) **DEFINITIONS.** In this section:

(a) "Administer" means the direct application of an epinephrine auto-injector to the body of an individual.

(b) "Authorized entity" means any entity or organization, other than a school described in s. 118.2925, operating a business, activity, or event at which allergens capable of causing anaphylaxis may be present, including a recreational and educational camp, college, university, day care facility, youth sports league, amusement park, restaurant, place of employment, and sports arena.

(c) "Epinephrine auto-injector" means a device for the automatic injection of epinephrine into the human body to prevent or treat a life-threatening allergic reaction.

(d) "Health care practitioner" means a physician, a physician assistant licensed under s. 448.04 (1) (f), or an advanced practice nurse who is certified to issue prescription orders under s. 441.16.

(2) **PRESCRIBING TO AN AUTHORIZED ENTITY PERMITTED.** A health care practitioner may prescribe an epinephrine auto-injector in the name of an authorized entity for use in accordance with this section.

(3) **AUTHORIZED ENTITIES PERMITTED TO MAINTAIN SUPPLY.** An authorized entity may acquire and maintain a supply of epinephrine auto-injectors pursuant to a prescription issued in accordance with this section. The authorized entity shall store an epinephrine auto-injector in a location readily accessible in an emergency and in accordance with the epinephrine auto-injector's instructions for use. An authorized entity shall designate an employee or agent who has completed the training required in sub. (5) to be responsible for the storage, maintenance, control, and general oversight of epinephrine auto-injectors acquired by the authorized entity.

(4) **USE OF EPINEPHRINE AUTO-INJECTORS.** An employee or agent of an authorized entity, or other individual, who has completed the training required by sub. (5) may use an epinephrine auto-injector prescribed under sub. (2) to do any of the following:

(a) Provide one or more epinephrine auto-injectors to any individual who the employee, agent, or individual believes in good faith is experiencing anaphylaxis, or to the parent, guardian, or caregiver of that individual for immediate administration, regardless of whether the individual has a prescription for an epinephrine auto-injector or has previously been diagnosed with an allergy.

(b) Administer an epinephrine auto-injector to any individual who the employee, agent or other individual believes in good faith is experiencing anaphylaxis, regardless of whether the individual has a prescription for

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an epinephrine auto-injector or has previously been diagnosed with an allergy.

(5) TRAINING. (a) An employee, agent, or other individual described in sub. (3) or (4) shall complete an anaphylaxis training program and at least every 4 years thereafter. The employee, agent, or other individual shall complete a training program conducted by a nationally recognized organization experienced in training laypersons in emergency health treatment or an organization approved by the department. The department may approve an organization to conduct training, either online or in person, that covers, at a minimum, all of the following:

1. How to recognize signs and symptoms of severe allergic reactions, including anaphylaxis.
2. Standards and procedures for the storage and administration of an epinephrine auto-injector.
3. Emergency follow-up procedures after an epinephrine auto-injector is administered, including the necessity of calling the telephone number "911" or another telephone number for an emergency medical service provider.

(b) The organization that conducts the training under par. (a) shall issue a certificate, on a form approved by the department, to each person who successfully completes the anaphylaxis training program.

(6) GOOD SAMARITAN PROTECTIONS; LIABILITY. (a) All of the following are not liable for any injury that results from the administration or failure to administer an epinephrine auto-injector under this section, unless the injury is the result of an act or omission that constitutes gross negligence or willful or wanton misconduct:

1. An authorized entity that possesses and makes available an epinephrine auto-injector and its employees, agents, and other individuals that store, maintain, control, oversee, provide, or use an epinephrine auto-injector.
2. A health care practitioner who prescribes or dispenses an epinephrine auto-injector to an authorized entity.
3. A pharmacist or other person who dispenses an epinephrine auto-injector to an authorized entity.
4. An organization that conducts the training described in sub. (5).

(b) The use of an epinephrine auto-injector under this section does not constitute the practice of medicine or of any other health care profession that requires a credential to practice.

(c) This immunity from liability or defense provided under this subsection is in addition to and not in lieu of that provided under s. 895.48 or any other defense or immunity provided under state law.

(d) A person is not liable for any injuries or related damages that result from providing or administering an epinephrine auto-injector outside of this state if the person satisfies any of the following criteria:

1. The person would not have been liable for injuries or damages if the epinephrine auto-injector was provided or administered in this state.

2. The person is not liable for injuries or damages under the law of the state in which the epinephrine auto-injector was provided or administered.

(e) Nothing in this section creates or imposes any duty, obligation, or basis for liability on any authorized entity, or its employees, agents, or other individuals, to acquire or make available an epinephrine auto-injector.

(7) HEALTH CARE PROVIDERS. Nothing in this section prohibits a health care provider, as defined in s. 146.81 (1) (a) to (hp) and (q) to (s), from acting within the scope of practice of the health care provider's license, certificate, permit, or registration.

SECTION 2. 448.03 (2) (q) of the statutes is amended to read:

448.03 (2) (q) The administration of an epinephrine auto-injector in accordance with s. 118.2925 or 255.07.

SECTION 3. 450.11 (1) of the statutes is amended to read:

450.11 (1) DISPENSING. Except as provided in sub. (1i) (b) 2., no person may dispense any prescribed drug or device except upon the prescription order of a practitioner. All prescription orders shall specify the date of issue, the name and address of the practitioner, the name and quantity of the drug product or device prescribed, directions for the use of the drug product or device, the symptom or purpose for which the drug is being prescribed if required under sub. (4) (a) 8., and, if the order is written by the practitioner, the signature of the practitioner. Except as provided in ss. 118.2925 (3) and 255.07 (2), 441.18 (2), 448.035 (2), and 448.037 (2), all prescription orders shall also specify the name and address of the patient. A prescription order issued under s. 118.2925 (3) shall specify the name and address of the school. A prescription order issued under s. 255.07 (2) shall specify the name and address of the authorized entity. Any oral prescription order shall be immediately reduced to writing by the pharmacist and filed according to sub. (2).

SECTION 4. 450.11 (3) of the statutes, as affected by 2015 Wisconsin Act 3, is amended to read:

450.11 (3) PREPARATION OF PRESCRIPTION DRUGS. Except as provided in sub. (1i) (b) and s. ss. 118.2925 (4), 255.07 (3), and 450.076, no person other than a pharmacist or practitioner or their agents and employees as directed, supervised, and inspected by the pharmacist or practitioner may prepare, compound, dispense, or prepare for delivery for a patient any prescription drug.

SECTION 5. 450.11 (4) (a) 5. a. of the statutes is amended to read:

450.11 (4) (a) 5. a. Except as provided in subd. 5. b. and e. to d., the full name of the patient.

SECTION 6. 450.11 (4) (a) 5. d. of the statutes is created to read:

450.11 (4) (a) 5. d. For an epinephrine auto-injector prescribed under s. 118.2925 (3) or 255.07 (2), the name

of the school, authorized entity, or other person specified under s. 255.07 (3).

State of Wisconsin



2015 Senate Bill 84

Date of enactment: **July 1, 2015**
Date of publication*: **July 2, 2015**

2015 WISCONSIN ACT 40

AN ACT to create 15.145 (6), 301.103 and 450.01 (16) (hr) of the statutes; **relating to:** creating a Corrections System Formulary Board in the Department of Corrections, therapeutic alternate drug selections in the state correctional system, and granting rule-making authority.

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

SECTION 1. 15.145 (6) of the statutes is created to read:

15.145 (6) CORRECTIONS SYSTEM FORMULARY BOARD. There is created in the department of corrections a corrections system formulary board. The board shall consist of the following members appointed to serve at the pleasure of the secretary of corrections:

- (a) Two physicians, as defined in s. 448.01 (5), one of whom specializes in psychiatry.
- (b) A pharmacist, as defined in s. 450.01 (15).
- (c) Any other members appointed by the secretary in his or her discretion.

SECTION 2. 301.103 of the statutes is created to read:

301.103 Prescription drug formulary. The corrections system formulary board shall promulgate rules establishing written guidelines or procedures for making

therapeutic alternate drug selections for the purposes of s. 450.01 (16) (hr). Rules promulgated under this section shall apply uniformly within all state correctional institutions.

SECTION 3. 450.01 (16) (hr) of the statutes is created to read:

450.01 (16) (hr) Making therapeutic alternate drug selections in accordance with written guidelines or procedures previously established in rules promulgated by the corrections system formulary board under s. 301.103, if the use of the therapeutic alternate drug selection has been approved for a prisoner, as defined in s. 301.01 (2), during his or her period of confinement in a state correctional institution, as defined in s. 301.01 (4), by any of the following:

1. A physician.
2. An advanced practice nurse prescriber.
3. A physician assistant.

* Section 991.11, WISCONSIN STATUTES: Effective date of acts. "Every act and every portion of an act enacted by the legislature over the governor's partial veto which does not expressly prescribe the time when it takes effect shall take effect on the day after its date of publication."

PHARMACY EXAMINING BOARD GOALS

Current Rule-making

1. Phar 1, 8, 18 (definitions, misplaced word “emergency”, PDMP revisions): Drafted but new scopes are necessary
2. Phar 2, 3, 4 (Act 114 and 124): Drafting rule
3. Phar 5 (renewal and reinstatement): Drafting rule
4. Phar 6 (temperature/humidity control): Scope at GORC
5. Phar 7 (practice of pharmacy): Obtaining proposals
6. Phar 7.015 (technicians): Scope approved by Governor on 12/4/12, however will be working this into Phar 7 revision rather than separate project. (NOTE: The Governor’s Office cautioned the Board that statutory authority to regulate pharmacy technicians is limited to regulating the distribution and dispensing functions of a pharmacy technician.)
7. Phar 8, 18 (Act 199): New scopes are necessary
8. Phar 15 (compounding): Drafting rule

Potential Rule-making

1. Phar 7.09(1)(b) (Automated Dispensing systems): Different definitions of “Institutional” pharmacy throughout the practice act (see RDS); would like to include jails, prisons, etc. under Phar 7.09(1)(b).
2. Phar 13 (Distributor Requirements): Clean-up
3. Phar 7.02 (Prescription label): § 450.11(4g), Wis. Stats. Brand name permitted on label; issue prescription written for generic.
4. Rules based upon § 450.073(3), Wis. Stats. (electronic track and trace pedigree system) Implementation date of July 1, 2015.
5. Phar 12: Update to include security requirements
6. Update administrative rules (sections or omnibus)
7. Phar 17.02(5) (intern hours from 1500 to 1740) and Phar 17.07(1) (student non-academic internship after second professional year). Change “internship” to “practice experience” IPPE v. APPE. {NOTE: *There is a scope related to this and the Board decided to not move forward*}
8. Phar 1.01 and 1.02; chs. Phar 1 to 16. Phar 17 and Phar 18.

Potential Legislation

1. Pharmacy technician credentialing
2. Recognize other types of pharmacy licenses besides community and institutional ex. licensure of entities that supply oxygen to patients, clinics, RDS, etc.
3. Change § 450.03(1)(f) for interns, Wis. Stats.
4. Update pharmacy statutes (sections or omnibus)
5. Change 450.01(15) to include “pharmacy intern” (track federal language)

Additional Board member ideas

1. Address pharmacists working at home issue
2. Wis. Stats. Chapter 450.02 (3m), option to exceed 90 days
3. Define patient consultation
4. Develop scope of practice statement
5. Monitor Medical Examining Board changes
6. Continuous professional development (CPD) v. continuing education
7. Administrative rules for out-of-state pharmacies
8. USP recommendations on what should be on prescription label
9. Address collaborative practice agreements.