



PHARMACY EXAMINING BOARD
Contact: Dan Williams (608) 266-2112
Room 121A, 1400 East Washington Avenue, Madison, WI 53703
May 25, 2016

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 April 7, 2016 (5-8)**
- 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. Thaddeus Schumacher – 7/1/2019
 - d. Kristi Sullivan – 7/1/2016
 - e. Philip Trapskin – 7/1/2017
 - f. Cathy Winters – 7/1/2017
 - g. Public Member – **Vacancy**
- D. APPEARANCE: St. Vincent de Paul Charitable Pharmacy Request as to Remote Dispensing Deviation (9-19)**
- E. Pilot Programs – Discussion and Consideration (20-32)**
 - 1) Hospital Tech-Check-Tech
 - 2) Pharmacy Technician Ratio
 - 3) Robotic
 - 4) Possible Pilot Programs
 - a. **Community Pharmacy Tech-Check-Tech Pilot Program - Pharmacy Society of Wisconsin (PSW) Application (33-55)**
- F. Legislation/Administrative Rule Matters – Discussion and Consideration(56-76)**
 - 1) Phar 6 Relating to Temperature and Humidity Controls
 - 2) Phar 7.10 Relating to Administration of Drug Products (Act 290)
 - 3) Phar 15 Relating to Compounding
 - 4) Rule Projects List
 - 5) Update on Legislation and Pending or Possible Rulemaking Projects

- G. **Speaking Engagement(s), Travel, or Public Relations Request(s) – Discussion and Consideration**
- 1) 2016 Pharmacy Society of Wisconsin (PSW) Legislative Breakfast – August 26, 2016 **(77)**
 - 2) National Association of Boards of Pharmacy (NABP) 2016 Program Review and Training Session – June 28-29, 2016**(78-79)**
- H. Informational Items
- I. **Items Received After Preparation of the Agenda**
- 1) Introductions, Announcements and Recognition
 - 2) Election of Board Officers
 - 3) Appointment of Board Liaisons
 - 4) Administrative Updates
 - 5) Education and Examination Matters
 - 6) Credentialing Matters
 - 7) Practice Matters
 - 8) Legislation/Administrative Rule Matters
 - 9) Informational Items
 - 10) Disciplinary Matters
 - 11) Presentations of Petitions for Summary Suspension
 - 12) Petitions for Designation of Hearing Examiner
 - 13) Presentation of Proposed Stipulations, Final Decisions and Orders
 - 14) Presentation of Proposed Final Decision and Orders
 - 15) Presentation of Interim Orders
 - 16) Petitions for Re-Hearing
 - 17) Petitions for Assessments
 - 18) Petitions to Vacate Orders
 - 19) Requests for Disciplinary Proceeding Presentations
 - 20) Motions
 - 21) Petitions
 - 22) Appearances from Requests Received or Renewed
 - 23) Speaking Engagement(s), Travel, or Public Relations Request(s)
 - 24) Division of Legal Services and Compliance (DLSC) Matters
 - 25) Prescription Drug Monitoring Program Information
 - 26) Consulting with Legal Counsel
 - 27) **Liaison Report(s)**
 - a. Appointed to Controlled Substances Board per Wis. Stats. §15.405(5g): Franklin LaDien
 - b. Continuing Education (CE) and Education and Examinations Liaison: Terry Maves
 - c. Credentialing Liaison(s): Terry Maves, Cathy Winters
 - d. Digest Liaison: Philip Trapskin
 - e. DLSC Liaison: Thaddeus Schumacher, Cathy Winters
 - f. Legislative Liaison: Philip Trapskin, Thaddeus Schumacher, Terry Maves
 - g. Monitoring Liaison(s): Franklin LaDien, Cathy Winters
 - h. PHARM Rep to State Council on Alcohol and Other Drug Abuse (SCAODA): Kristi Sullivan
 - i. Pharmacy Rules Committee: Thaddeus Schumacher, Franklin LaDien, Philip Trapskin, Kristi Sullivan
 - j. Professional Assistance Procedure (PAP) Liaison: Franklin LaDien
 - k. Screening Panel: Cathy Winters, Kristi Sullivan, Philip Trapskin
 - l. Variance Report Liaison: Philip Trapskin, Cathy Winters
- J. 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.).

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

1) Monitoring

a. **APPEARANCE: Cynthia Hennen, R.Ph. – Requesting Full Licensure (80-97)**

2) Administrative Warnings

a. 14 PHM 128 (J.J.A.) **(98-99)**

b. 15 PHM 105 (Z.D.L.) **(100-101)**

3) Proposed Stipulations, Final Decision and Orders

a. 14 PHM 081 (N.B.P.) **(102-108)**

b. 14 PHM 081 (R.A.S.) **(109-116)**

c. 14 PHM 085 and 14 PHM 136 (W.F.) **(117-122)**

d. 14 PHM 128 (A.M.G.) **(123-128)**

e. 14 PHM 130 (H.P. #8) **(129-134)**

f. 15 PHM 154 (O.M.H.L.) **(135-141)**

g. 15 PHM 212 (W.V.P.) **(142-147)**

4) Case Closings

a. 14 PHM 130 (R.G.) **(148-152)**

b. 15 PHM 105 (Walgreens # 11858) **(153-156)**

c. 15 PHM 192 (C.D.) **(157-158)**

d. 15 PHM 206 (F.C.) **(159-162)**

e. 15 PHM 219 (M.O.W.) **(163-164)**

f. 15 PHM 222 (S.W.T. and M.S.) **(165-167)**

g. 16 PHM 004 (A.W. and G.V.P.) **(168-170)**

h. 16 PHM 007 (M.P.) **(171-172)**

i. 16 PHM 008 (C.A.P.S.) **(173-174)**

j. 16 PHM 044 (A.S.P.) **(175-176)**

k. 16 PHM 045 (V.F.C.) **(177-178)**

l. 16 PHM 047 (C.S.P.) **(179-180)**

L. Deliberation on Order(s) Fixing Costs in the Matter of Disciplinary Proceedings Against:

1) Khushboo S. Modi, R.Ph., Respondent (ORDER0004596)(DHA Case # SPS-15-0042)(DLSC Case # 14 PHM 062) **(181-188)**

M. Deliberation of Items Received After Preparation of Agenda

- 1) Education and Examination Matters
- 2) Credentialing Matters
- 3) Disciplinary Matters
- 4) Monitoring Matters
- 5) Professional Assistance Procedure (PAP) Matters
- 6) Petitions for Summary Suspension
- 7) Petitions for Designation of Hearing Examiner
- 8) Proposed Stipulations, Final Decisions and Orders
- 9) Administrative Warnings
- 10) Review of Administrative Warnings

- 11) Proposed Final Decisions and Orders
- 12) Orders Fixing Costs/Matters Related to Costs
- 13) Case Closings
- 14) Proposed Interim Orders
- 15) Petitions for Assessments and Evaluations
- 16) Petitions to Vacate Orders
- 17) Remedial Education Cases
- 18) Motions
- 19) Petitions for Re-Hearing
- 20) Appearances from Requests Received or Renewed

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 July 21, 2016.

**PHARMACY EXAMINING BOARD
MEETING MINUTES
APRIL 7, 2016**

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

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

CALL TO ORDER

Thaddeus Schumacher, Chair, called the meeting to order at 11:05 a.m. A quorum of six (6) members was confirmed.

ADOPTION OF AGENDA

MOTION: Philip Trapskin moved, seconded by Kristi Sullivan, to adopt the agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF FEBRUARY 24, 2016

MOTION: Philip Trapskin moved, seconded by Kristi Sullivan, to approve the minutes of February 24, 2016 as published. Motion carried unanimously.

LEGISLATIVE AND ADMINISTRATIVE RULE MATTERS

Act 290 Relating to Administration by Injection of Prescribed Drugs by Pharmacists

MOTION: Philip Trapskin moved, seconded by Terry Maves, to approve the Scope Statement on Phar 7.10 relating to Administration of Drug Products and Devices Other Than Vaccines for submission to the Governor's Office and publication, and to authorize the Chair to approve the scope for implementation no less than 10 days after publication. Motion carried unanimously.

Update on Legislation and Pending or Possible Rulemaking Projects

MOTION: Philip Trapskin moved, seconded by Kristi Sullivan, to request DSPS Staff compile a list of all current and potential Board rulemaking projects based upon historical Board discussion and current state and federal legislative activity that could impact the Board's rules for prioritization at a future meeting. Motion carried unanimously.

DISCUSSION AND CONSIDERATION OF PILOT PROGRAM RELATED TO ACT 313

MOTION: Franklin LaDien moved, seconded by Kristi Sullivan, to request DSPS Staff to work with Cathy Winters and Philip Trapskin to develop a proposed Pilot Program for Tech-Check-Tech including any necessary forms and report back at a future Board meeting. Motion carried unanimously.

MOTION: Franklin LaDien moved, seconded by Terry Maves, to request DSPS Staff to work with Cathy Winters and Thaddeus Schumacher to develop a proposed Pilot Program for Technician Ratios including any necessary forms and report back at a future Board meeting. Motion carried unanimously.

MOTION: Franklin LaDien moved, seconded by Terry Maves, to request DSPS Staff to work with Philip Trapskin and Franklin LaDien to develop a proposed Pilot Program for Automation and Robotics including any necessary forms and report back at a future Board meeting. Motion carried unanimously.

CLOSED SESSION

MOTION: Kristi Sullivan moved, seconded by Terry Maves, 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; Thaddeus Schumacher-yes; Kristi Sullivan- yes; Philip Trapskin-yes; Cathy Winters-yes. Motion carried unanimously.

The Board convened into Closed Session at 3:07 p.m.

RECONVENE TO OPEN SESSION

MOTION: Philip Trapskin moved, seconded by Kristi Sullivan, to reconvene into open session. Motion carried unanimously.

The Board reconvened into Open Session at 4:16 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED ON IN CLOSED SESSION

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

DIVISION OF LEGAL SERVICES AND COMPLIANCE (DLSC) MATTERS

Administrative Warning(s)

MOTION: Terry Maves moved, seconded by Cathy Winters, to issue an Administrative Warning following matters:

1. 15 PHM 019 (R.J.D.)
2. 15 PHM 140 (L.P.)
3. 15 PHM 188 (T.H.E.)

Motion carried unanimously.

15 PHM 198 (B.P.)

MOTION: Terry Maves moved, seconded by Cathy Winters, to issue an Administrative Warning in the matter of 15 PHM 198 (B.P.). Motion carried.

Proposed Stipulations, Final Decisions and Orders

MOTION: Franklin LaDien moved, seconded by Philip Trapskin, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against:

1. 14 PHM 093 (B.P.I.)
2. 15 PHM 010 (M.C.H.S.)
3. 15 PHM 069 (C.M.I.)

Motion carried unanimously.

Case Closings

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

1. 14 PHM 146 (J.A.Z.) – No Violation
2. 15 PHM 118 (Z.P.) – Prosecutorial Discretion (P2)
3. 15 PHM 151 (P.H.) - **Prosecutorial Discretion (P2)**
4. 15 PHM 186 (B.T., LLC.) - Prosecutorial Discretion (P2)
5. 15 PHM 188 (H.P.) - Prosecutorial Discretion (P2)
6. 15 PHM 197 (M.S.) - Prosecutorial Discretion (P2)

Motion carried unanimously.

15 PHM 001

MOTION: Franklin LaDien moved, seconded by Terry Maves, to **table** 15 PHM 001 (M.H.) for more information. Motion carried unanimously.

15 PHM 010

MOTION: Kristi Sullivan moved, seconded by Philip Trapskin, to close DLSC case number 15 PHM 010 (T.W.G.) for Prosecutorial Discretion (P3). Motion carried. Recused: Terry Maves

(Terry Maves recused himself and left the room for deliberation and voting in the matter of 15 PHM 010 (T.W.G.))

15 PHM 162

MOTION: Philip Trapskin moved, seconded by Kristi Sullivan, to **not close** DLSC case number 15 PHM 162 (R.K. and S.D., Inc.). Motion carried unanimously.

16 PHM 005

MOTION: Philip Trapskin moved, seconded by Terry Maves, to **not close** DLSC case number 15 PHM 005 (C.P.). Motion carried unanimously.

ADJOURNMENT

MOTION: Philip Trapskin moved, seconded by Kristi Sullivan, to adjourn the meeting.
Motion carried unanimously.

The meeting adjourned at 4:16 p.m.

DRAFT

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Dan Williams		2) Date When Request Submitted: Items will be considered late if submitted after 4:30 p.m. and less than: <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: Wisconsin Pharmacy Examining Board			
4) Meeting Date: May 25, 2016	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? St. Vincent de Paul Charitable Pharmacy request as to Remote Dispensing deviation – Discussion and Consideration	
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? If yes, who is appearing? <input type="checkbox"/> Yes by <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: Dear Chair Schumacher, I would like to request a discussion of our proposed St Vincent De Paul Charitable Pharmacy RDS training program at the upcoming pharmacy board meeting on 5/25/16. I would like to be added to the agenda for that purpose to both discuss and approve (hopefully) our plan. My initial request was indicated on the RDS Notice application originally sent on 4/21/16 and I was not sure how to make the request for appearance formally. If you need anything further from me, please let me know. Thank you in advance for your time and consideration! Sincerely, Yolanda Tolson, RPh Managing Pharmacist St. Vincent de Paul Charitable Pharmacy 2033 Fish Hatchery Road P.O. Box 259686 Madison, WI 53725-9686			

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

REMOTE DISPENSING SITE NOTICE

COMPLETED FORM MUST BE SUBMITTED TO THE BOARD PRIOR TO OPERATING REMOTE SITE. "Remote" means a dispensing site not licensed as a pharmacy, not geographical distance or location, i.e. rural v. urban. The remote dispensing site (RDS) is not licensed as a pharmacy; therefore, the RDS may not use or display the title "pharmacy", "drugstore", "apothecary", or any other title, symbol or insignia having the same or similar meanings, Wis. Stat. § 450.06(1).

Remote Dispensing Site (RDS):

NAME OF CONTACT PERSON <u>Yolanda Tolson / Kelly Christian, RN</u> <u>RPh</u> (please print)		TELEPHONE NO. <u>(608) 268-0355</u>
EMAIL ADDRESS <u>tlc@banc.org</u> <u>yolandatolson@svdphmadison.org</u>		HOURS AVAILABLE <u>10-3 Monday-Thursday</u>
RDS: Name or title under which business is operated. <u>St. Vincent de Paul Community Outreach Dispensary</u> <u>1301 Cheri Blvd, Marinette, WI 54143</u>		TELEPHONE NO. <u>(715) 732-1349</u> FAX NO. <u>(715) 732-1386</u> RDS BUSINESS HOURS <u>Monday & Wednesday 12-3³⁰pm</u>
PHYSICAL ADDRESS (number, street, city, zip code)		

- The RDS shall not open for operation if the supervising pharmacy is closed. The RDS may not dispense in the absence of the ability to communicate with the supervising pharmacist pursuant to Wis. Admin. Code § PHAR 7.01 including visual access of prescription orders, labels and dispensed product apply to the RDS.
- The prescription label attached to the RDS container shall contain the name and address of the supervising pharmacy as the licensed facility from which the prescribed drug or device was dispensed. Wis. Admin. Code § PHAR 7.12(g).
- When closed, a RDS shall have a centrally monitored alarm. For all after hour entries the person entering the RDS will record their name, date, time and purpose for entering the site in a log. All logs will be retained for two (2) years.
- RDS may be "open" to the public provided they are operated as for profit retail. Put another way if the RDS drug inventory is purchased at "preferential" prices, then "own use" laws apply.
- If an RDS dispenses a controlled substance, the RDS must comply with DEA requirements. 21 CFR S 1301.12(a).
- An RDS shall submit written notification to the board 30 days prior to operating the remote dispensing site.

Supervising Pharmacy that is overseeing the Remote site:

- Each RDS must display a sign, easily viewable by customers, that states:
 - Prescriptions may be filled at this location.
 - This store is a Remote Dispensing Site being supervised by a pharmacist located at:
 - Name of store
 - Address of store
 - Telephone number of store
 - The pharmacist is required to talk to you, each time you pick up a prescription.

"Supervising pharmacy" means a licensed pharmacy that oversees the operations and administration of all aspects of the remote dispensing site.

Wisconsin Department of Safety and Professional Services

Type of supervising pharmacy: <input checked="" type="checkbox"/> COMMUNITY <input type="checkbox"/> INSTITUTIONAL	CURRENT LICENSE NUMBER OF SUPERVISING PHARMACY: <div style="text-align: center; font-size: 1.2em;">9183-042</div>
DBA: Name or title under which supervising pharmacy is operated. (This must be the name on the pharmacy label.) <div style="font-size: 1.2em; margin-top: 10px;">St. Vincent de Paul Charitable Pharmacy</div>	TELEPHONE NO. (608) 268-0355 <hr/> FAX NO. (608) 237-1136 <hr/> SUPERVISING PHARMACY STORE HOURS <div style="font-size: 1.2em; margin-top: 5px;">Mondays, Wednesdays 1-4pm + Thursdays 3-6pm</div>
PHARMACY ADDRESS: number, street, city, zip code <div style="font-size: 1.2em; margin-top: 10px;">2033 Fish Hatchery Rd S Madison, WI 53725</div>	

EMAIL ADDRESS

yolanda@svdpmadison.org

Managing RPh responsible for dispensing site: <div style="font-size: 1.2em; margin-top: 10px;">Yolanda Tolson</div>	<div style="font-size: 1.2em; margin-top: 10px;">12500-040</div>
Name (Printed)	Pharmacist License #

The "Managing pharmacist" at the supervising pharmacy is responsible for all remote dispensing sites connected to the supervising pharmacy.

- The managing pharmacist of the RDS shall (refer to Wis. Admin. Code § PHAR 7.09(5)):
 - a. Have written policies and procedures for system operation, safety, security, accuracy and access
 - b. Implement an ongoing quality assurance program that monitors performance, e.g., the number of prescriptions dispensed per month, number of medication errors documented, loss/diversion of inventory, documentation of remedial training to prevent future errors, etc.
 - c. Visit the RDS at least monthly to conduct a controlled substance inventory, to ensure written policies and procedures are being followed, and to ensure the RDS personnel comply with all federal and state laws regulating the practice of pharmacy.
 - d. Retain documentation of the monthly inspection visits at the RDS for two (2) years.
 - e. There is no limit on the number of RDSs a managing pharmacist may manage, however, a pharmacist may supervise no more than one (1) pharmacy intern and four (4) pharmacy technicians engaged in compounding and dispensing activities. Wis. Admin. Code § PHAR 7.01(3).

- RDS pharmacy technician requirements. Pharmacy technicians and interns employed at a remote dispensing site shall satisfy all of the following requirements:
 - a. 18 years of age
 - b. High school graduate or equivalent
 - c. 1,500 hours of working as a technician within the three (3) years prior to the date of employment at the RDS or a training program approved by the Board will present @ PSB meeting 5/25/16

- Interns must meet the qualifications of a technician when working at a RDS and an intern would be considered a technician and not an intern.

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.

Yolanda Tolson
Requester Signature

Managing Pharmacist 04/21/16
Title Date

Yolanda Tolson
Printed Name of person signing above

Mail completed form to:

DSPS
Pharmacy Examining Board
P.O. Box 8935
Madison, WI 53708

Chapter Phar 7

PHARMACY PRACTICE

Phar 7.01	Minimum procedures for compounding and dispensing.	Phar 7.065	Answering machines in pharmacies.
Phar 7.015	Pharmacy technicians.	Phar 7.07	Medication profile record system.
Phar 7.02	Prescription label; name of drug or drug product dispensed.	Phar 7.08	Prescription orders transmitted electronically.
Phar 7.03	Prescription renewal limitations.	Phar 7.09	Automated dispensing systems.
Phar 7.04	Return or exchange of health items.	Phar 7.095	Operation of remote dispensing sites.
Phar 7.05	Prescription records.	Phar 7.10	Administration of drug products and devices other than vaccines.
Phar 7.055	Transfer of prescription order information.	Phar 7.12	Central fill pharmacy.

Phar 7.01 Minimum procedures for compounding and dispensing. (1) Except as provided in sub. (4), a pharmacist or pharmacist–intern who compounds or dispenses according to a prescription order shall follow the procedures described in this rule and other applicable procedures. The pharmacist or pharmacist–intern as directed and supervised by a pharmacist shall:

(a) Receive electronic or oral prescription orders of a prescriber, review all original and renewal prescription orders, whether electronic, written or oral, and determine therapeutic compatibility and legality of the prescription order. The review shall include, when indicated or appropriate, consultation with the prescriber.

(b) Read and interpret a prescriber’s directions for use for the purpose of accurately transferring the instructions to the prescription label.

(c) Select, compound, mix, combine, measure, count and otherwise prepare drugs needed to dispense a prescription except that an agent of the pharmacist may procure, measure or count prefabricated dosage forms if a pharmacist verifies accuracy of the agent’s action.

(d) Make a final check on the accuracy and correctness of the prescription. For all original and renewed prescriptions, the prescription order record shall identify the pharmacist responsible for the prescription.

(e) Give the patient or agent appropriate consultation relative to the prescription except that prescriptions may be delivered by an agent of the pharmacist to a location of the patient’s choice if the delivery is accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist. The consultation requirement applies to original and renewal prescription orders and, except when prescriptions are delivered to a location of the patient’s choice, is not satisfied by only offering to provide consultation.

(em) Transfer the prescription to the patient or agent of the patient.

(f) Receive, when required by law and standard professional practice, permission to renew from authorized prescribers, and note on the prescription order, medication profile record or uniformly maintained and readily retrievable document the following information:

1. Date renewed.
2. Name of practitioner authorizing renewal, if different from the original prescriber.
3. Quantity of drug dispensed.
4. Identification of the pharmacist renewing the prescription.

(2) Subsection (1) (d) and (e) does not prohibit institutional pharmacists or community pharmacists serving institutions from receiving prescription orders, dispensing and returning prescription medications consistent with accepted inpatient institutional drug distribution systems. Subsection (1) applies to any institutional pharmacy dispensing to outpatients, including prescriptions for discharged patients.

(3) A pharmacist may supervise no more than one pharmacy intern and 4 pharmacy technicians engaged in compounding and dispensing activities as described in sub. (1), except a higher ratio may be authorized by the board upon request to and approval by the board of a specific plan describing the manner in which additional interns or pharmacy technicians shall be supervised.

(4) A system for compounding and dispensing not in conformance with subs. (1) to (3) may be used if reviewed and approved by the board.

History: Cr Register, January, 1983, No. 325, eff. 2–1–83; am. (1) (intro.), (d) and (f) (intro.), Register, August, 1991, No. 428, eff. 9–1–91; am. (1) (e), Register, January, 1996, No. 481, eff. 2–1–96; am. (1) (a), (e), (f) (intro.), (3) and cr. (1) (em), Register, December, 1998, No. 516, eff. 1–1–99; am. (1) (a), Register, November, 1999, No. 527, eff. 12–1–99; am. (3), Register, April, 2001, No. 544, eff. 5–1–01; CR 13–018: am. (1) (e) Register October 2013 No. 694, eff. 11–1–13.

Phar 7.015 Pharmacy technicians. (1) As used in this section, “pharmacy technician” means a non–pharmacist or non–pharmacist intern who, under the general supervision of a pharmacist who regularly coordinates, directs and inspects the activities of the pharmacy technician, assists the pharmacist in the technical and nonjudgmental functions related to the practice of pharmacy in the processing of prescription orders and inventory management. “Pharmacy technician” does not include ancillary persons which include, clerks, secretaries, cashiers or delivery persons, who may be present in the pharmacy.

(2) A pharmacist may delegate technical dispensing functions to a pharmacy technician, but only under the general supervision of the pharmacist where the delegated functions are performed. Technical dispensing functions include:

(a) Accepting written or electronic prescription orders of the prescribing practitioner or from the prescribing practitioner’s agent.

(b) Accepting original oral prescription orders from the prescribing practitioner or prescribing practitioner’s agent, if the conversation is recorded and listened to and verified by the pharmacist prior to dispensing.

(c) Requesting authorization for a refill from the prescribing practitioner.

(d) Accepting oral authorization for a refill from the prescribing practitioner or prescribing practitioner’s agent, provided there are no changes to the original prescription order.

(e) Accepting a request from a patient to refill a prescription.

(f) Obtaining and entering patient or prescription data into the patient information system.

(g) Preparing a prescription label.

(h) Retrieving medication from stock, counting or measuring medication, and placing the medication in its final container.

(i) Reconstituting prefabricated dosage forms.

(j) Compounding pharmaceuticals pursuant to written policies and procedures.

(k) Affixing a prescription label to its final container.

(L) Placing ancillary information on the prescription label.

(m) Prepackaging and labeling drugs for dispensing by a pharmacist.

(n) Preparing unit dose carts for final review by a pharmacist.

(o) Retrieving and transporting stock medication to and from pharmacist approved areas.

(p) Other technical functions that do not require the professional judgment of a pharmacist.

(q) Transferring the prescription to the patient or agent of the patient, provided that the pharmacist has first provided a patient consultation.

(3) A pharmacy technician may not do any of the following:

(a) Provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order.

(b) Perform any of the following tasks:

1. Participate in final drug utilization reviews.
2. Make independent therapeutic alternate drug selections.
3. Participate in final drug regimen screening, including screening for therapeutic duplication, drug-to-drug interactions, incorrect dosage, incorrect duration of treatment, drug allergy reactions and clinical abuse or misuse.

4. Perform any act necessary to be a managing pharmacist.

5. Administer any prescribed drug products, devices or vaccines.

(c) Provide patient counseling, consultation, or patient specific judgment, such as interpreting or applying information, including advice relating to therapeutic values, potential hazards and uses.

(4) The pharmacist shall provide the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription prior to the delivery of the prescription to the patient or the patient's representative.

History: Cr. Register, April, 2001, No. 544, eff. 5-1-01; CR 07-099: cr. (2) (q), r. (3) (d) Register May 2008 No. 629, eff. 6-1-08.

Phar 7.02 Prescription label; name of drug or drug product dispensed. No drug product may be dispensed unless the prescription label discloses the brand name and strength, or the generic name, strength, and manufacturer or distributor of the drug product dispensed unless the prescribing practitioner requests omission of the above information. If a pharmacist, pursuant to a prescription order that specifies a drug product by its brand name, dispenses the drug product equivalent of the drug product specified in the prescription order, the prescription label may include both the generic name of the drug product equivalent and the brand name specified in the prescription order, unless the prescribing practitioner requests that the brand name be omitted from the label. If a brand name drug product is dispensed, the prescription label may contain both the brand name and the generic name of the drug product equivalent dispensed unless the prescribing practitioner requests that the generic name of the drug product equivalent be omitted from the label.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; Register, August, 1991, No. 428, eff. 9-1-91; am. Register, January, 1996, No. 481, eff. 2-1-96; CR 07-097: am. Register May 2008 No. 629, eff. 6-1-08.

Phar 7.03 Prescription renewal limitations. A prescription order for any drug other than controlled substances, which bears renewal authorization permitting the pharmacist to renew the prescription as needed (PRN) by the patient, shall not be renewed beyond one year from the date originally prescribed. No prescription order containing either specific or PRN renewal authorization is valid after the patient-physician relationship has ceased.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; Register, August, 1991, No. 428, eff. 9-1-91.

Phar 7.04 Return or exchange of health items. (1) In this section:

(a) "Health item" means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug, medicines, or items of personal hygiene.

(b) "Inpatient health care facility" means any hospital, nursing home, county home, county mental hospital, tuberculosis sanitarium or similar facility, but does not include community-based residential facilities, jails or prison facilities.

(c) "Original container" means the container in which a health item was sold, distributed or dispensed.

(d) "Resident health care patient" means a patient residing in a community-based residential facility that controls a resident's prescribed and over-the-counter medications as specified by s. DHS 83.37

(e) "Secured institutional health care patient" means any of the following:

1. A jail inmate patient whose dispensed health items are maintained under the custody and control of the jail pursuant to an approved policy and procedure manual under s. DOC 350.17, containing policies and procedures for the control and administration of medications complying with s. DOC 350.20.

2. A juvenile patient who resides in a juvenile correctional facility, as defined in s. 938.02 (10p), Stats.; a secured residential care center for children and youth, as defined in s. 938.02 (15g), Stats.; a juvenile detention facility, as defined in s. 938.02 (10r), Stats.; or a juvenile portion of a county jail whose dispensed health items are maintained under the custody and control of the health services staff as defined in s. DOC 316.02 (6) and provided to a juvenile patient under the provisions of s. DOC 316.03.

(f) "Tamper-resistant package" means a container bearing a beyond use date that is sealed so that the contents cannot be used without obvious destruction of the seal.

(2) No health items after taken from a pharmacy where sold, distributed or dispensed, may be returned to that pharmacy, except for any of the following:

(a) From an inpatient health care facility, provided they are in their original containers and the pharmacist determines the contents are not adulterated or misbranded.

(b) Where the health items were dispensed in error, were defective, adulterated, misbranded, or dispensed beyond their beyond use date.

(c) When in the professional judgment of the pharmacist substantial harm could result to the public or a patient if they were to remain in the possession of the patient, patient's family or agent, or other person.

(d) For a secured institutional health care patient or resident health care patient where all of the following apply:

1. The health item was never in the possession and control of the patient.

2. The health item was sold, distributed or dispensed in a tamper-resistant package and, for a drug, includes the beyond use date and manufacturer's lot number.

3. The health item is not commingled with a different health item unless the health item will be repackaged and redispensed to the same patient.

4. The health item is in its original container and the pharmacist determines the contents are not adulterated or misbranded.

(e) A health item that is prepackaged for consumer use and labeled in compliance with all applicable state and federal laws where all of the following apply:

1. The pharmacist determines that the original package is unopened, sealed and intact and that package labeling is unaltered.

2. The pharmacist determines the contents are not adulterated.

(3) Health items returned to a pharmacy pursuant to sub. (2) (b) and (c), may not be sold, resold, or repackaged and sold or resold, given away, or otherwise distributed or dispensed.

Returned health items shall either be destroyed at the pharmacy or delivered for destruction or other disposal by an authorized person or entity.

(3m) Health items returned from a secured institutional health care patient to a pharmacy pursuant to sub. (2) (d), must be segregated in the pharmacy and may not be sold, resold, or repackaged and sold or resold, given away, or otherwise sold, distributed or redispensed other than to a secured institutional health care patient.

(4) It is not a “return” for a patient or agent of a patient to deliver a previously dispensed drug or device to a pharmacy for the purpose of repackaging and relabeling of that previously dispensed drug or device, and subsequent return of the drug or device for the same patient’s use.

Note: The DEA does not permit the return of controlled substances to a pharmacy from a non-DEA registrant under any circumstances.

(5) It is not a “return” for a patient or agent of a patient to deliver a previously dispensed drug or device to a pharmacy for the purpose of destruction at the pharmacy or other disposal by an authorized person or entity.

Note: Cancer and chronic disease drug returns and redispensing pursuant to ch. DHS 148 are allowed provided the pharmacy follows the requirements in ch. DHS 148.

Note: A prescription drug that is returned to a pharmacy that primarily serves patients confined in a state prison is not addressed in this rule. Such a drug may be redispensed to a patient in a state prison provided the requirements of s. 450.09 (7m), Stats., are satisfied.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. Register, August, 1991, No. 428, eff. 9-1-91; r. and recr., Register, December, 1998, No. 516, eff. 1-1-99; CR 05-029: cr. (1) (c) to (f), (2) (d) and (e), (3m) and (5), am. (2) (intro.) and (b) Register December 2005 No. 600, eff. 1-1-06; correction in (1) (d) made under s. 13.92 (4) (b) 7., Stats., Register March 2010 No. 651; CR 13-076: am. (1) (e) 2. Register August 2014 No. 704, eff. 9-1-14.

Phar 7.05 Prescription records. (1) A computerized system may be used for maintaining a record, as required under this section, of prescription dispensing and transfers of prescription order information for the purposes of original or refill dispensing if the system:

(a) Is capable of producing a printout of any prescription data which the user pharmacy is responsible for maintaining. The system shall be designed so that the pharmacy can receive the printout within 48 hours after requesting the printout.

(b) Is equipped with an auxiliary procedure which, during periods of down-time, shall be used for documentation of prescription dispensing. The auxiliary procedure shall ensure that prescription refills are authorized by the original prescription order, that the maximum number of prescription refills has not been exceeded and that all of the appropriate data are retained for on-line entry as soon as the computer system is again available for use.

(1m) A record of all prescriptions dispensed shall be maintained for a period of 5 years after the date of the last refill.

(2) All systems used for maintaining a record of any prescription dispensing shall include:

- (a) Patient’s identification.
- (b) Name, strength and dosage form of the drug product dispensed.
- (c) Quantity dispensed.
- (d) Date of all instances of dispensing.
- (e) Practitioner’s identification.
- (f) Pharmacist’s identification.
- (g) Retrieval designation.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; cr. (5), Register, September, 1987, No. 381, eff. 10-1-87; CR 00-165: am. (3) (a) (intro.), (b) 6., (c), (5) and (6) (intro.), r. (3) (b) 4., cr. (3) (b) 8., Register July 2001, No. 547 eff. 8-1-01; CR 05-078: rn. (1) and (6) to be (1m) and (1) and am. (1) (intro.), (b) and (1m), r. (3) to (5) Register January 2006 No. 601, eff. 2-1-06.

Phar 7.055 Transfer of prescription order information. (1) GENERAL REQUIREMENTS. A pharmacist may transfer prescription order information between pharmacies licensed in

this state or another state, for the purpose of original or refill dispensing, if all of the following conditions are satisfied:

(a) The transfer is communicated directly between 2 pharmacists either by verbal transfer or by a computer system transfer meeting the requirements of sub. (4). Communication by facsimile machine is not allowed unless the prescription order information being transferred is verified verbally between 2 pharmacists.

(b) A computer system used to record a verbal transfer of prescription order information for a non-controlled substance meets the requirements of s. Phar 7.05 (1) (a) and (b).

(c) The pharmacist receiving the verbal transfer of prescription order information for either a controlled or a non-controlled substance records the transferred information in writing unless a computer system transfer meeting the requirements of sub. (4) is used.

(d) All original and transferred prescription orders are maintained for a period of 5 years from the date of the last refill.

(e) A written copy of any prescription order for a prescribed drug provided by a pharmacist is identified in writing as “COPY – FOR INFORMATION ONLY.” No prescribed drug may be dispensed based on an information copy.

(f) A pharmacist making or receiving a transfer of prescription order information is licensed in the state in which he or she performs an act required by this section.

(2) NON-CONTROLLED SUBSTANCES. The transfer of prescription order information for non-controlled substances for the purposes of original or refill dispensing is permissible pursuant to the following requirements:

(a) The pharmacist making the transfer records the following information:

1. The word “VOID” is written on the face of the invalidated prescription order or recorded in a similar manner to “VOID” on a prescription order in a computer system meeting the requirements of s. Phar 7.05 (1) (a) and (b).

2. The name and address of the pharmacy to which it was transferred, the name of the pharmacist receiving the prescription order, the date and the name of the pharmacist transferring the information are recorded on the reverse side of the invalidated prescription order or in a computer system meeting the requirements of s. Phar 7.05 (1) (a) and (b).

3. A transfer of prescription order information for a non-controlled substance for the purposes of refill dispensing is limited to the number of authorized refills.

(b) The pharmacist receiving the transferred prescription order information shall record in writing the following:

1. The word “TRANSFER” on the face of the transferred prescription order.

2. The name and address of the patient, the name and address of the prescribing practitioner, and the name and quantity and dosage form of the drug product or device prescribed and the directions for use.

3. The date of issuance of the original prescription order.

4. The original number of refills authorized on the original prescription order.

5. The date of original dispensing if the prescription order has previously been dispensed.

6. The number of valid refills remaining and the date of the last refill.

7. The pharmacy’s name, address, and the prescription order number from which the prescription order information was transferred.

8. The name of the pharmacist making the transfer.

9. The name, address and telephone number of the pharmacy from which the original prescription order was transferred if different than subd. 7.

(3) CONTROLLED SUBSTANCES. The transfer of prescription order information for controlled substances for the purposes of

refill dispensing is permissible pursuant to the following requirements:

(a) The transfer of prescription order information is permissible only on a one time basis unless a computer system meeting the requirements of sub. (4) is used.

(b) If a computer system meeting the requirements of sub. (4) is used, a transfer of prescription order information for the purposes of refill dispensing is limited to the number of authorized refills.

(c) Unless a computer system meeting the requirements of sub. (4) is used, the pharmacist making the transfer shall record in writing the following information:

1. The word "VOID" is written on the face of the invalidated prescription order.

2. The name, address and DEA registration number of the pharmacy to which it was transferred, the name of the pharmacist receiving the prescription order and the date and the name of the pharmacist transferring the information are recorded on the reverse side of the invalidated prescription order.

(d) Unless a computer system meeting the requirements of sub. (4) is used, the pharmacist receiving the transferred prescription order information shall record in writing the following information:

1. The word "TRANSFER" on the face of the transferred prescription order.

2. The name and address of the patient, the name, address and DEA number of the prescribing practitioner, and the name and quantity and dosage form of the drug product or device prescribed and the directions for use.

3. The date of issuance of the original prescription order.

4. The original number of refills authorized on the original prescription order.

5. The date of original dispensing.

6. The number of valid refills remaining and the dates and locations of previous refills, if applicable.

7. The name, address, telephone number, DEA registration number and prescription order number of the pharmacy from which the prescription order information was transferred if different from the pharmacy from which the prescription order was originally dispensed.

8. The name of the pharmacist making the transfer.

9. The name, address, telephone number, DEA registration number and prescription order number of the pharmacy from which the prescription order was originally dispensed.

(4) USE OF COMPUTER SYSTEM. A computer system used for transferring prescription order information shall, in addition to meeting the requirements of s. Phar 7.05 (1) (a) and (b), contain a common central processing unit electronically sharing a real-time, on-line database to which both the transferring and receiving pharmacy have access.

History: CR 05-078; cr. Register January 2006 No. 601, eff. 2-1-06.

Note: See the table of Appellate Court Citations for Wisconsin appellate cases citing s. Phar 7.055.

Phar 7.065 Answering machines in pharmacies.

Oral prescription orders may be received at a pharmacy via a telephone answering device and dispensed by the pharmacist if the voice of the physician or physician's agent is known to the pharmacist, and provided other requirements of reducing the prescription order to writing, labeling and filing are met.

History: Cr. Register, December, 1998, No. 516, eff. 1-1-99.

Phar 7.07 Medication profile record system. (1) An individual medication profile record system shall be maintained in all pharmacies for persons for whom prescriptions, original or renewal, are dispensed for outpatient use. The system shall be capable of permitting the retrieval of information. The system need not be limited to individual medication profile records.

(2) The following minimum information shall be retrievable:

(a) Patient name, or other identifying information.

(b) Address of the patient.

(c) Birth date of the patient if obtainable.

(d) Name of the drug product dispensed.

(e) Strength of the drug product dispensed.

(f) Dosage form of the drug product dispensed.

(g) Quantity of the drug product dispensed.

(h) Directions for use.

(i) Retrieval designation assigned to the prescription order.

(j) Date of all instances of dispensing, for original and renewal prescriptions.

(k) Practitioner identification.

Note: This subsection incorporates renewal dispensing information required by federal law (21 CFR 1306.22) and state law (s. 450.11 (5), Stats.).

(3) The pharmacist shall be responsible for attempting to ascertain and record any patient allergies, adverse drug reactions, drug idiosyncrasies, and any chronic conditions which may affect drug therapy as communicated by the patient or agent of the patient. If none, this should be indicated.

(4) At the time a prescription order is reviewed by the pharmacist for dispensing, the pharmacist shall review the medication profile record of the patient for the previously dispensed medication history and shall determine whether the prescription order presented should be dispensed.

(5) Medication profile records, if used as the only documentation of renewal dispensing, shall be maintained for a period of not less than 5 years following the date of the last entry. If the profile records are not used as the only documentation of renewal dispensing they shall be maintained for a period of not less than 1 year from the date of the last entry.

History: Cr. Register, January, 1989, No. 397, eff. 2-1-89; renum. from Phar 7.08, Register, August, 1991, No. 428, eff. 9-1-91; am. (1), Register, December, 1998, No. 516, eff. 1-1-99.

Phar 7.08 Prescription orders transmitted electronically. (1) Except as provided in s. 453.068 (1) (c) 4., Stats., and as otherwise prohibited by law, prescription orders may be accepted and dispensed if they have been transmitted electronically from a practitioner or his or her designated agent to a pharmacy via computer modem or other similar electronic device. Prescription orders transmitted by facsimile machine are not considered electronic prescription orders; but rather, written prescription orders.

(2) A pharmacist may dispense a prescription pursuant to a prescription order transmitted electronically, if the pharmacist assures the prescription order does all of the following:

(a) Was sent only to the pharmacy of the patient's choice and only at the option of the patient, with no intervening person or third party having access to the prescription order other than to forward it to the pharmacy.

(b) Identifies the individual sender's name and telephone number for oral confirmation, the time and date of transmission, and the pharmacy intended to receive the transmission.

(c) Is designated "electronically transmitted prescription", or with similar words or abbreviations to that effect.

(d) Contains all other information that is required in a prescription order.

(3) The prescribing practitioner's electronic signature, or other secure method of validation shall be provided with a prescription order electronically transmitted via computer modem or other similar electronic device.

(4) Any visual or electronic document received in connection with an electronically transmitted prescription order shall be accessible only within the professional service area of the pharmacy to protect patient confidentiality and assure security.

(5) A pharmacist who receives a prescription order electronically shall ensure the security, integrity and confidentiality of the

prescription order and any information contained in the order. To maintain the confidentiality of patient records, the electronic system shall have adequate security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. Once the prescription has been dispensed, any alterations in prescription order drug data shall be documented including the identification of the pharmacist responsible for the alteration.

(6) Access to the electronic mail system for the receipt of prescription orders electronically may only be acquired by use of a password or passwords, known only to individuals authorized to access the system.

(7) A pharmacist may not use any electronic device to circumvent his or her responsibilities with regard to documenting, authenticating and verifying prescription orders or in order to circumvent other pharmacy laws.

History: Cr. Register, November, 1999, No. 527, eff. 12-1-99.

Phar 7.09 Automated dispensing systems. (1) In this section:

(a) “Automated dispensing system” means a mechanical system that perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing or distribution of medications, and which collects, controls, and maintains all transaction information.

(b) “Inpatient health care facility” means any hospital, nursing home, county home, county mental hospital, or tuberculosis sanatorium, but does not include community-based residential facilities.

(2) An automated dispensing system may be used in a community pharmacy, as provided in this section.

(3) An automated dispensing system may be used as provided in this section by an institutional pharmacy serving an inpatient health care facility, that has an established program of receiving prescription orders, and dispensing and returning prescription medications consistent with accepted inpatient institutional drug distribution systems. An automated dispensing system used by an institutional pharmacy shall only be located in that institutional pharmacy or within the inpatient health care facility.

(4) The managing pharmacist of a community pharmacy or an institutional pharmacy is responsible for all of the following:

(a) Assuring that the automated dispensing system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed and complying with the recordkeeping and security safeguards pursuant to sub. (5).

(b) Implementing an ongoing quality assurance program that monitors performance of the automated dispensing system, which is evidenced by written policies and procedures.

(c) Providing the board with prior written notice of the installation or removal of an automated dispensing system. The notice provided shall include, but is not limited to the:

1. Name and address of the pharmacy.

2. Initial location of the automated dispensing system. The automated dispensing system may thereafter be relocated within the pharmacy or inpatient health care facility without providing subsequent notification to the board.

3. Identification of the managing pharmacist.

(d) Assigning, discontinuing or changing personnel access to the system.

(e) Assuring that access to the medications comply with state and federal laws.

(f) Assuring that the automated dispensing system is stocked accurately and in accordance with established written policies and procedures.

(5) An automated dispensing system shall comply with the following provisions:

(a) A pharmacy shall maintain on-site the following documentation relating to an automated dispensing system:

1. Name and address of the pharmacy or inpatient health care facility where the system is being used.

2. The system manufacturer’s name, model and serial number.

3. Description of how the system is used.

4. Written quality assurance procedures to determine continued appropriate use of the system.

5. Except as required pursuant to par. (b), written policies and procedures for system operation, safety, security, accuracy, access and malfunction.

(b) All written policies and procedures shall be maintained in the pharmacy responsible for the automated dispensing system.

(c) An automated dispensing system shall have adequate security systems and procedures, evidenced by written policies and procedures to prevent unauthorized access to maintain patient confidentiality and to comply with federal and state laws.

(d) Records and data kept by the automated dispensing system shall meet the following requirements:

1. All events involving the contents of the automated dispensing systems must be recorded electronically.

2. Records shall be maintained by the pharmacy and be available to the board. Records shall include:

a. The time and location of the system accessed.

b. Identification of the individual accessing the system.

c. Type of transaction.

d. Name, strength, dosage form and quantity of the drug accessed.

e. Name of the patient for whom the drug was ordered.

f. Such additional information as the managing pharmacist may deem necessary.

(e) The stocking of all medications in the automated dispensing system shall be accomplished by qualified personnel under no less than the general supervision of a licensed pharmacist; except that when an automated dispensing system is located within a pharmacy the supervision must be direct.

(f) A record of medications stocked into an automated dispensing system shall be maintained for 5 years and shall include identification of the person stocking and pharmacist checking for accuracy.

(g) All containers of medications stored in the automated dispensing system shall be packaged and labeled in accordance with state and federal law.

(h) All aspects of handling controlled substances shall meet the requirements of all state and federal law.

(i) The automated dispensing system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated dispensing system, in accordance with state and federal law.

(j) The automated dispensing system shall provide a mechanism for securing and accounting for medication returned to the system and accounting for wasted medications in accordance with state and federal law.

History: Cr. Register, October, 2000, No. 538, eff. 11-1-00.

Phar 7.095 Operation of remote dispensing sites.

(1) DEFINITIONS. In this section:

(a) “Health care facility” means a facility, as defined in s. 647.01 (4), Stats., or any hospital, nursing home, community-based residential facility, county home, county infirmary, county hospital, county mental health center or other place licensed or approved by the department of health services under s. 49.70, 49.71, 49.72, 50.02, 50.03, 50.35, 51.08 or 51.09, Stats., or a facility under s. 45.50, 51.05, 51.06, 233.40, 233.41, 233.42 or 252.10, Stats.

(b) “Managing pharmacist” means a pharmacist designated by the pharmacy owner to have responsibility for and direct control of pharmaceutical operations in a pharmacy.

(c) “Practitioner” means a person licensed in this state to prescribe and administer drugs or licensed in another state and recognized by this state as a person authorized to prescribe and administer drugs.

(d) “Remote dispensing site” means a dispensing site that is not licensed as a pharmacy. Remote does not mean geographical distance or location.

(e) “Supervising pharmacy” means a licensed pharmacy that oversees the operations and administration of all aspects of the remote dispensing site.

(2) LICENSING REQUIREMENTS AND USE OF TITLES RELATING TO THE OPERATION OF REMOTE DISPENSING SITES. (a) A remote dispensing site shall not be licensed as a pharmacy.

(b) No person may use or display the title “pharmacy,” “drug-store,” “apothecary,” or any other title, symbol or insignia having the same or similar meanings in connection with a remote dispensing site.

(3) LOCATION OF REMOTE DISPENSING SITES. A pharmacist may dispense at the following locations:

(a) A health care facility or a facility identified under s. 980.065, Stats.

(b) The office or clinic of a practitioner.

(c) A county jail, rehabilitation facility under s. 59.53 (8), Stats., state prison under s. 302.01, Stats., or county house of correction under s. 303.16 (1), Stats.

(d) A juvenile correctional facility under s. 938.02 (10p), Stats., juvenile detention facility under s. 938.02 (10r), Stats., residential care center for children and youth under s. 938.02 (15d), Stats., secured residential care center for children and youth under s. 938.02 (15g), Stats., type 1 juvenile correctional facility under s. 938.02 (19), Stats., type 2 residential care center for children and youth under s. 938.02 (19r), Stats., or type 2 juvenile correctional facility under s. 938.02 (20), Stats.

(4) REQUIREMENTS FOR THE OPERATION OF REMOTE DISPENSING SITES. (a) A remote dispensing site shall display a sign, easily viewable by customers, that states all of the following:

1. Prescriptions may be filled at this location.
2. This store is a remote dispensing site being supervised by a pharmacist located at all of the following:

- a. Name of store.
- b. Address of store.
- c. Telephone number of store.

3. The pharmacist is required to talk to you each time you pick up a prescription.

(b) A remote dispensing site shall not open for operation if the supervising pharmacy is closed.

(c) A remote dispensing site shall not dispense a prescribed drug or device in the absence of the ability of a patient to communicate with the pharmacist.

(d) When closed, a remote dispensing site shall have a centrally monitored alarm. For all after hour entries, the personnel entering the site shall record their name, and the date, time and purpose for entering the site in a log. All logs shall be retained for 2 years.

(e) A remote dispensing site shall submit written notification to the board 30 days prior to operating the remote dispensing site.

(5) DISPENSING REQUIREMENTS. A remote dispensing site shall meet all of the following:

(a) Comply with the requirements under s. Phar 7.01 and visually inspect prescription orders, labels and dispensed product.

(b) Comply with the labeling requirements under s. Phar 7.12 (2) (g). The prescription label shall contain the name and address

of the supervising pharmacy as the licensed facility from which the prescribed drug or device was dispensed.

(c) Comply with federal law if a remote dispensing site dispenses controlled substances.

(6) RESPONSIBILITIES OF MANAGING PHARMACISTS. (a) The managing pharmacist of a remote dispensing site shall, in accordance with s. Phar 7.09, do all of the following:

1. Have written policies and procedures for system operation, safety, security, accuracy and access.

2. Implement an on-going quality assurance program that monitors performance that includes the number of prescriptions dispensed per month, number of medication errors documented, loss or diversion of inventory, and documentation of remedial training to prevent future errors.

3. Visit the remote dispensing site at least monthly to conduct controlled substance inventory, to ensure written policies and procedures are being followed, and to ensure that remote dispensing site personnel comply with all federal and state laws regulating the practice of pharmacy.

4. Retain documentation of the monthly inspection visits at the remote dispensing site for 2 years.

(b) The managing pharmacist at the supervising pharmacy is responsible for all remote dispensing sites connected to the supervising pharmacy.

(7) REQUIREMENTS FOR PHARMACY TECHNICIANS AND INTERNS. Pharmacy technicians and interns employed at a remote dispensing site shall satisfy all of the following requirements:

(a) Be 18 years of age or older.

(b) Be a high school graduate or have equivalent education.

(c) Have completed 1500 hours of work as a technician within the 3 years prior to the date of employment at the remote dispensing site or completed a training program approved by the board.

History: CR 09-099; cr. Register March 2010 No. 651, eff. 4-1-10.

Phar 7.10 Administration of drug products and devices other than vaccines. A pharmacist may administer a drug product, as defined in s. 450.01 (11), Stats., or device, as defined in s. 450.01 (6), Stats., in the course of teaching a patient self-administration techniques except a pharmacist may not administer by injection a prescribed drug product or device unless he or she satisfies each of the following:

(1) The pharmacist has successfully completed 12 hours in a course of study and training, approved by the Accreditation Council for Pharmacy Education or the board, in injection techniques, emergency procedures, and record keeping.

(2) The pharmacist has in effect liability insurance against loss, expense and liability resulting from errors, omissions or neglect in the administration by injection of prescribed drug products or devices in an amount that is not less than \$1,000,000 for each occurrence and \$2,000,000 for all occurrences in any one policy year. The pharmacist shall maintain proof that he or she satisfies this requirement and, upon request, shall provide copies of such proof to the department or board.

(3) The pharmacist has written procedures regarding the administration by injection of a prescribed drug product or device in the course of teaching self-administration techniques to a patient.

Note: To administer a vaccine a pharmacist must meet the requirements in s. 450.035, Stats.

History: Cr. Register, December, 1999, No. 528, eff. 1-1-00; CR 14-023; am. (1) Register August 2014 No. 704, eff. 9-1-14.

Phar 7.12 Central fill pharmacy. (1) In this section:

(a) “Central fill pharmacy” means a pharmacy licensed in this state acting as an agent of an originating pharmacy to fill or refill a prescription.

(b) “Originating pharmacy” means a pharmacy licensed in this state that uses a central fill pharmacy to fill or refill a prescription order.

(2) A central fill pharmacy and originating pharmacy may process a request for the filling or refilling of a prescription order received by an originating pharmacy only pursuant to the following requirements:

(a) The central fill pharmacy either has the same owner as the originating pharmacy or has a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state law.

(b) The central fill pharmacy shall maintain a record of all originating pharmacies, including name, address and DEA number, for which it processes a request for the filling or refilling of a prescription order received by the originating pharmacy. The record shall be made available upon request for inspection by the board or its agent.

(c) The central fill pharmacy and originating pharmacy maintain a written filling protocol delineating each pharmacy’s assumption of responsibility for compliance with the prescription drug compounding and dispensing requirements of this chapter and ch. Phar 8.

(d) The originating pharmacy shall remain responsible for compliance with the prescription drug compounding and dispensing requirements of this chapter and ch. Phar 8, and which are not assumed in writing by the central fill pharmacy pursuant to a written filling protocol.

(e) The originating pharmacy shall at all times remain solely responsible to perform and comply with the requirements of s. Phar 7.01 (1) (e) and (em).

(f) Unless the central fill pharmacy shares a common central processing unit with the originating pharmacy, it may not perform processing functions such as the medication profile record review

of the patient, drug utilization review, refill authorizations, interventions and drug interactions.

(g) The prescription label attached to the container shall contain the name and address of the originating pharmacy as the licensed facility from which the prescribed drug or device was dispensed for purposes of s. 450.11 (4) (a) 1., Stats. The date on which the prescription was dispensed for purposes of s. 450.11 (4) (a) 2., Stats., shall be the date on which the central fill pharmacy filled the prescription order.

(h) The originating pharmacy shall maintain the original of all prescription orders received for purposes of filing and recordkeeping as required by state and federal law.

(i) The central fill pharmacy shall maintain all original fill and refill requests received from the originating pharmacy and shall treat them as original and refill prescription orders for purposes of filing and recordkeeping as required by state and federal law.

(j) In addition to meeting the other recordkeeping requirements required by state and federal law, the central fill pharmacy and originating pharmacy shall each maintain records to identify each of its pharmacists responsible for receiving and reviewing prescription orders and compounding and dispensing pursuant to a prescription order and track the prescription order during each step in the dispensing process.

(k) The central fill pharmacy and originating pharmacy shall adopt a written quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, resolve identified problems and insure compliance with this section.

(L) The originating pharmacy shall provide the patient with the name and address of the central fill pharmacy and obtain consent as required by applicable state and federal law.

History: CR 01-075: cr. Register November 2003 No. 575, eff. 12-1-03; CR 09-098: am. (2) (f) Register May 2010 No. 653, eff. 6-1-10.

**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: 13 May 2016	
		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: 25 May 2016	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Pilot Programs – Discussion and Consideration 1. Hospital Tech-Check-Tech 2. Pharmacy Technician Ratio 3. Robotic 4. Possible Pilot Programs	
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:			
11) Authorization			
<i>Sharon Henes</i>		<i>13 May 2016</i>	
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.			

Hospital Tech-Check-Tech Pilot Program

Authority: Pursuant to s. 450.02 (3r) (a), this pilot program is related to the practice of pharmacy or prescription verification and the Board determines that the program will improve the safety, quality or efficiency of the practice of pharmacy in this state.

The Board may modify the parameters of the Hospital Tech-Check-Tech Pilot Program at any time during the Pilot Program duration. Participants remain in the Pilot Program at the discretion of the Board.

Duration: September 1, 2016 to August 31, 2019 (or promulgation of rules whichever is sooner).

Purpose: To evaluate Tech-Check-Tech programs. A tech-check-tech program authorizes validated pharmacy technicians to review the work of other pharmacy technicians in connection with unit dose dispensing systems for hospital [institution] based patients whose orders have previously been reviewed and approved by a licensed pharmacist and will have medications administered by a health care professional. A tech-check-tech program is to increase the availability of the pharmacist for involvement in patient care activities and not to reduce pharmacist staffing levels.

Pharmacy Eligibility:

1. Pharmacy practice involves doses dispensed to hospital patients.
2. [Pharmacy located and licensed in the state of Wisconsin.]

Application:

1. Complete application form
2. Identification of a Tech-Check-Tech Coordinator who is a full-time Wisconsin licensed pharmacist in good standing and is responsible for assuring compliance with Tech-Check-Tech policies and procedures. [The tech-check-tech activities of the validated technicians will be considered delegated acts of the supervising pharmacist.]
3. [Name and email address of the managing pharmacist.]
4. [Name and address of the pharmacy.]
5. [Signed attestation by the Tech-Check-Tech Coordinator and managing pharmacist that they have read, understand, and will comply with the Pilot Program requirements.]

Program Requirements:

General

1. Only validated technicians may perform tech-check-tech activities.
2. Prospective DUR must occur prior to dispensing. [Pharmacist must review the medication order prior to tech-check-tech dispensing.]

Validated Technicians

1. *Eligibility.* A technician shall meet the following eligibility criteria:
 - a. Employment status of full time [greater than or equal to 0.5 full time equivalent].
 - b. A minimum of one year [2080 hours] technician experience at the pharmacy or be a Certified Pharmacy Technician (CpHT).
2. *Training.* A technician shall successfully complete a training curriculum that includes all of the following:
Didactic training:
 - a. Different elements of the label. [Elements of a unit-dose package including medication name, dose, dosage form and expiration date.]
 - b. Common dispensing medication errors and concepts.
 - c. Knowledge of common abbreviations. [Medication and pharmacy abbreviations routinely used in matching ordered medication with dispensed medication]
 - d. Pharmacy Tech-Check-Tech policies and procedures.

- e. Organizational policies and procedures on reporting of medication errors.
- f. Overview of the organization's medication use process including procurement, ordering, dispensing, administration and monitoring..

Practical training:

An one-on-one practical training consisting of [shadowing a validated technician performing tech-check-tech] a minimum of 24 [16] hours.

3. *Validation.* After training, the technician shall complete a validation process which includes all of the following:
 - a. The technician shall check the work of another technician for at least 1000 [2500] consecutive doses over 5 separate days and achieve at least a 99.8% accuracy rate.
 - b. During the validation process the pharmacist shall artificially introduce errors at a minimum rate 0.2% [no percentage]. Artificially introduced errors will include at least one of each of the following: an occurrence of wrong drug, wrong dose, wrong dosage form, extra/insufficient quantity, omitted medications and an expired dose. The pharmacist coordinating the audit will keep a record of the introduced errors and is responsible they are removed prior to distribution [delivery to a patient care area].
 - c. [A pharmacist shall check audit 100% of the doses checked during the validation process.]
 - d. If a technician fails to achieve the required 99.8% accuracy level, the technician shall complete the didactic training and 24 hours of practical training again. If the technician fails on the second attempt, the technician is no longer eligible for tech-check-tech. [omit this paragraph]
 - e. Upon successful completion of the validation with 99.8% accuracy rate, the technician will be recognized as a Validated Technician.

Eligible medications.

1. The medication shall be one of the following:
 - a. Unit dosed from a manufacturer.
 - b. [Medications previously repackaged and relabeled, with the final product checked by a pharmacist.] [If bulk packaged in the pharmacy, checked by a licensed pharmacist, prior to stocking in the pharmacy.]
2. Chemotherapy drugs are prohibited from being checked via tech-check-tech. [A medication is not eligible if defined by the organization as high-alert, chemotherapy, or a medication which requires an independent double check prior to administration.]

Quality Assurance.

1. Each individual Validated Technician's accuracy shall be audited by checking a minimum of 10% and recorded every day, the tech-check-tech duties are performed. [A minimum of 10% of all tech-check-tech doses (each unit-dose package dispensed shall be counted as one dose) shall be audited by a licensed pharmacist each day that tech-check-tech is performed. The accuracy of each validated technician shall be tracked individually.]
2. If the accuracy is less than 99.8% over a six month period or the first 2000 validation doses within a six month period [If a validated technician fails to maintain a rolling accuracy rate of 99.8% for every 2500 doses checked or has not performed tech-check-tech duties in the last 6 months], the Validated Technician is required to be re-trained (didactic and practical) and re-validated (1000 checked doses with 99.8% accuracy).

Records.

The pharmacy shall maintain and make available to the Board upon request all of the following records:

- a. Policies and procedures for the tech-check-tech program.
- b. Complete list of Validated Technicians.
- c. Training materials, assessments and exams.
- d. Training log of all trainings.
- e. Quality Assurance records, including audits and error logs. [Including name of technician, total doses checked, errors identified, type of error]

- f. Log of any errors which reach the patient. [Errors that were identified after the medication left the pharmacy to the patient care unit including type of error, how the error was identified and if patient harm occurred]
- g. Board report forms.
- h. Validation records for each Validated Technician
- i. Name of supervising tech-check-tech pharmacists including start and end date of supervision.
- j. Rolling error rates of Validated Technicians for every 2500 doses checked.

Reporting Requirements: The Tech-Check-Tech Coordinator will submit to the Board twice a year a Board approved report form and appear in person to answer any questions related to the Pilot Program as necessary. [The Tech-Check-Tech Coordinator will submit to the Board annually:

- a. The total number doses checked by validated technicians.
- b. The number of errors identified and type of error.
- c. Errors that were identified after the medication left the pharmacy to the patient care unit including type of error, how the error was identified and if patient harm occurred.
- d. Number of pharmacist hours reallocated to other patient care activities and description of those activities.]

Wisconsin Department of Safety & 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

INSTITUTIONAL TECH-CHECK-TECH PILOT PROGRAM APPLICATION

DBA NAME OF PHARMACY: (This must be the name on the pharmacy license.)	PHARMACY TELEPHONE:	PHARMACY WI LICENSE NUMBER:
PHARMACY ADDRESS (pharmacy location to which the variance applies): number, street, city, zip code		
MANAGING PHARMACIST:	EMAIL:	
TECH-CHECK-TECH SUPERVISING PHARMACIST:	EMAIL:	

Wisconsin Department of Safety and Professional Services

We attest that we have read, understand, and will comply with all requirements of the institutional tech-check-tech pilot program requirements;; the variance applied for covers only the pharmacy indicated above and at the location specified; and that we will comply with the provisions of the Wisconsin Statutes and the Rules of the Pharmacy Examining Board.

Supervising Pharmacist Signature

WI License Number

Date

Printed Name of person signing above

Managing Pharmacist Signature

WI License Number

Date

Printed Name of person signing above

#TBD (6/16)
Ch. 450, Stats.

Committed to Equal Opportunity in Employment and Licensing

Page 1 of 1

Wisconsin Department of Safety & 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

INSTITUTIONAL TECH-CHECK-TECH PILOT PROGRAM REPORT

COMPLETED REPORTS MUST BE SUBMITTED TO THE BOARD ON OR BEFORE JULY 31 OF EACH YEAR AFTER AN INSTITUTIONAL TECH-CHECK-TECH VARIANCE IS GRANTED.

DBA NAME OF PHARMACY: (This must be the name on the pharmacy license.)	PHARMACY TELEPHONE:	PHARMACY WI LICENSE NUMBER:
PHARMACY ADDRESS (pharmacy location to which the variance applies): number, street, city, zip code		
MANAGING PHARMACIST:	EMAIL:	
TECH-CHECK-TECH SUPERVISING PHARMACIST:	EMAIL:	

OVERALL ACCURACY RATES FOR PHARMACY

FOR TIME PERIOD ____/____/____ TO ____/____/____
Month Day Year Month Day Year

Total number of doses checked by Validated Technicians	
Total number of doses checked by pharmacist as part of quality assurance audit	
Errors identified by pharmacist as part of quality assurance audit	
Wrong Drug	Wrong quantity
Wrong Dose	Omitted medication
Wrong Dose Form	Expired Dose
Errors identified after leaving the pharmacy	
Wrong Drug	Wrong quantity
Wrong Dose	Omitted medication
Wrong Dose Form	Expired Dose
Total number of errors that reached the patient and caused harm	
Number of pharmacist hours reallocated to other patient care activities	
Description of reallocated activities	

I/We declare that the foregoing statements and attached corresponding documents are true and correct to the best of my/our knowledge and belief.

Reporter Signature

WI License Number

Date

Printed Name of person signing above

Managing Pharmacist Signature

WI License Number

Date

Printed Name of person signing above

Technician Ratio Pilot Program

Pursuant to 450.02(3r)(a), this pharmacist to technician ratio pilot program is related to the practice of pharmacy or prescription verification and the Board determines that the program will improve the safety, quality or efficiency of the practice of pharmacy in this state.

The Board may modify the parameters of the Pilot Program at any time during the Pilot Program duration. Participants remain in the Pilot Program at the discretion of the Board.

Duration: September 1, 2016 to August 31, 2019 (or promulgation of rules whichever is sooner).

Purpose: To evaluate the pharmacist to technician ratio. This Pilot Project allows the 1 pharmacist to 4 pharmacy technician ratio to be increased within certain parameters.

Pharmacy Eligibility: Pharmacy practice is closed, long term care setting {*Note we do have a current vet pharmacy with a ratio variance*}

Application: The pharmacy shall submit an application to participate in the Pilot Program on a Board approved application.

Policy: The pharmacy may deviate from the one pharmacist to four pharmacy technician ratio, as long as the overall hours in the week maintain a 1 pharmacist to 4 pharmacy technicians ratio. However, the ratio may not exceed 1 pharmacist to 8 pharmacy technicians at any time.

Reporting Requirements: The Managing Pharmacist will submit to the Board twice a year a Board approved report form and appear in person to answer any questions related to the Pilot Program as necessary.

Wisconsin Department of Safety & 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@dsps.wi.gov
Website: http://dsps.wi.gov

PHARMACY EXAMINING BOARD

TECHNICIAN:PHARMACIST RATIO

COMPLETED REPORTS MUST BE SUBMITTED TO THE BOARD ON OR BEFORE JANUARY 31 AND JULY 31 OF EACH YEAR. PLEASE NOTE: ADDITIONAL DETAILS MAY BE REQUESTED BY THE BOARD ON A CASE BY CASE BASIS.

DBA NAME OF PHARMACY: (This must be the name on the pharmacy license)	WI LICENSE NUMBER:	TELEPHONE:
MANAGING PHARMACIST:	EMAIL:	
PHARMACY ADDRESS (actual pharmacy location):		
number, street, city, zip code		

RATIO REPORT TIME PERIOD

January 1-June 30 July 1-December 31

Reporting Period	Reporting Period	Technicians Weekly Average	Pharmacist Weekly Average	Weekly Ratio
January	July			
February	August			
March	September			
April	October			
May	November			
June	December			

I/We declare that the foregoing statements are true and correct to the best of my/our knowledge and belief; for 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.

Managing Pharmacist's Signature

Title

Date

Printed Name of Managing Pharmacist

#3015 (11/12)
Ch. 450, Stats.

Technician:Pharmacist Ratio Report Form

Pharmacy Name: _____ WI License #: _____ Date: ____/____/____

	<input type="checkbox"/> JAN			<input type="checkbox"/> FEB			<input type="checkbox"/> MAR			<input type="checkbox"/> APR			<input type="checkbox"/> MAY			<input type="checkbox"/> JUN		
	<input type="checkbox"/> JUL			<input type="checkbox"/> AUG			<input type="checkbox"/> SEP			<input type="checkbox"/> OCT			<input type="checkbox"/> NOV			<input type="checkbox"/> DEC		
DAY	Techs	R.Ph	Ratio															
1																		
2																		
3																		
4																		
5																		
6																		
7																		
8																		
9																		
10																		
11																		
12																		
13																		
14																		
15																		
16																		
17																		
18																		
19																		
20																		
21																		
22																		
23																		
24																		
25																		
26																		
27																		
28																		
29																		
30																		
31																		

Tech: The number of technician hours for the day
R.Rph: The number of Pharmacist hours for the day
Ratio: Daily ratio

Automated Dispensing Technology Final Check Pilot Program

Pursuant to 450.02(3r)(a), this Automated Dispensing Technology Final Check Pilot Program is related to the practice of pharmacy or prescription verification and the Board determines that the program will improve the safety, quality or efficiency of the practice of pharmacy in this state.

The Board may modify the parameters of the Pilot Program at any time during the Pilot Program duration. Participants remain in the Pilot Program at the discretion of the Board.

Duration: September 1, 2016 to August 31, 2019 (or promulgation of rules whichever is sooner).

Purpose: To evaluate final check by automated dispensing technology programs. An automated dispensing technology program authorizes the use of dispensing technology (e.g. robots) for institutional based patients whose orders have previously been reviewed and approved by a licensed pharmacist and will have medications administered by a health care professional. An automated dispensing technology program is to increase the availability of the pharmacist for involvement in patient care activities and not to reduce pharmacist staffing levels.

Pharmacy Eligibility:

1. Pharmacy practice involves doses dispensed to hospital patients.
2. [Pharmacy located and licensed in the state of Wisconsin.]

Application:

1. Complete application form
2. A supervising pharmacist at each location, licensed in the state of Wisconsin, must be identified to be accountable for operations and outcomes of the Institutional Automated Dispensing Technology Final Check Pilot Program.
3. Name of automated technology and software version.
4. Signed attestation by the supervising and managing pharmacists that they have read, understand, and will comply with the Pilot Program requirements.

Policies and Procedures: The pharmacy shall develop policies and procedures which shall include all of the following:

General

1. The technology shall use barcodes [or machine readable technology to verify the drug, dose, dosage form and expiration date prior to dispensing].
2. A pharmacist shall prospectively review the medication order prior to automated technology dispensing.

Validation of Technology

1. A total of at least 2500 doses must be audited by a pharmacist and achieve at least a 99.8% accuracy rate of correct drug, dose, dosage form, expiration date, and quantity.
2. If the software or any component of the technology responsible for medication dispensing accuracy is upgraded or serviced, the technology must be revalidated.

Eligible medications.

1. The medication shall be one of the following:
 - a. Unit dosed from a manufacturer.
 - b. If bulk packaged in the pharmacy, checked by a licensed pharmacist, prior to stocking in the pharmacy.
2. A medication is not eligible if defined by the organization as high-alert, chemotherapy, or a medication which requires an independent double check prior to administration.

Quality Assurance

The accuracy shall be audited (a minimum of 10%) and recorded every day.

If the accuracy is less than 99.8%, the systems and equipment shall be reviewed and modifications made as necessary to ensure a 99.8% accuracy.

Records: The pharmacy shall maintain and make available to the Board upon request all of the following:

1. Quality Assurance records, including audits and error logs.
2. Log of any errors which reaches the patient.
3. The total number of doses checked by the automated dispensing technology.
4. Number of errors identified and type of error
5. Number of errors that were identified after the medication left the pharmacy to the patient care unit including the type of error, how the error was identified and if patient harm occurred.
6. Number of pharmacist hours reallocated to other patient care activities and description of those activities.
7. Board report forms.

Reporting Requirements: The Managing Pharmacist will submit to the Board twice a year [annually] a Board approved report form and appear in person to answer any questions related to the Pilot Program as necessary.

Wisconsin Department of Safety & 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@dsps.wi.gov
Website: http://dsps.wi.gov

PHARMACY EXAMINING BOARD

INSTITUTIONAL AUTOMATED DISPENSING TECHNOLOGY PILOT PROGRAM APPLICATION

DBA NAME OF PHARMACY: (This must be the name on the pharmacy license.)	PHARMACY TELEPHONE:	PHARMACY WI LICENSE NUMBER:
PHARMACY ADDRESS (pharmacy location to which the variance applies): number, street, city, zip code		
MANAGING PHARMACIST:	EMAIL:	
AUTOMATED DISPENSING TECHNOLOGY SUPERVISING PHARMACIST:	EMAIL:	
TECHNOLOGY NAME: SOFTWARE VERSION: VENDOR:		

Wisconsin Department of Safety and Professional Services

We attest that we have read, understand, and will comply with all requirements of the institutional automated dispensing technology pilot program requirements; the variance applied for covers only the pharmacy indicated above and at the location specified; and that we will comply with the provisions of the Wisconsin Statutes and the Rules of the Pharmacy Examining Board.

Supervising Pharmacist Signature

WI License Number

Date

Printed Name of person signing above

Managing Pharmacist Signature

WI License Number

Date

Printed Name of person signing above

#TBD (6/16)
Ch. 450, Stats.

Committed to Equal Opportunity in Employment and Licensing

Page 1 of 1

Wisconsin Department of Safety & 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

INSTITUTIONAL AUTOMATED DISPENSING TECHNOLOGY PILOT PROGRAM REPORT

COMPLETED REPORTS MUST BE SUBMITTED TO THE BOARD ON OR BEFORE JULY 31 OF EACH YEAR AFTER AN INSTITUTIONAL TECH-CHECK-TECH VARIANCE IS GRANTED.

DBA NAME OF PHARMACY: (This must be the name on the pharmacy license.)	PHARMACY TELEPHONE:	PHARMACY WI LICENSE NUMBER:
PHARMACY ADDRESS (pharmacy location to which the variance applies): number, street, city, zip code		
MANAGING PHARMACIST:	EMAIL:	
AUTOMATED DISPENSING TECHNOLOGY SUPERVISING PHARMACIST:	EMAIL:	

OVERALL ACCURACY RATES FOR PHARMACY

FOR TIME PERIOD ____/____/____ TO ____/____/____
Month Day Year Month Day Year

Total number of doses checked by the automated dispensing technology				
Total number of doses checked by pharmacist as part of quality assurance audit				
Errors identified by prior to leaving the pharmacy				
	Wrong Drug		Wrong quantity	
	Wrong Dose		Omitted medication	
	Wrong Dose Form		Expired Dose	
Errors identified after leaving the pharmacy				
	Wrong Drug		Wrong quantity	
	Wrong Dose		Omitted medication	
	Wrong Dose Form		Expired Dose	
Total number of errors that reached the patient and caused harm				
Number of pharmacist hours reallocated to other patient care activities				
Description of reallocated activities				

I/We declare that the foregoing statements and attached corresponding documents are true and correct to the best of my/our knowledge and belief.

Reporter Signature

WI License Number

Date

Printed Name of person signing above

Managing Pharmacist Signature

WI License Number

Date

Printed Name of person signing above



Wednesday, May 11, 2016

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,

Pursuant to the allowances granted by 2015 Wisconsin Act 313, the Pharmacy Society of Wisconsin (PSW) is seeking approval of a pilot proposal entitled "Advancing Community Pharmacy Quality – A Wisconsin Statewide Research Pilot Project." The intent of the project is to implement tech-check-tech (TCT) programs in a variety of community pharmacy practices across the state and assess the impact of the program on patient safety measures and pharmacist patient care service expansion. This research pilot project is similar to efforts in Iowa to evaluate a new practice model for community pharmacy designed to facilitate community pharmacist delivery of patient care services. It is also founded upon the principles of the inpatient pharmacy-based TCT programs that have promoted patient safety and workflow efficiencies in Wisconsin hospitals for over a decade.

The pharmacy practices eligible for inclusion in this pilot project include independent, chain, and health-system community-based pharmacies. A community pharmacy-based TCT program would allow pharmacists to dedicate more time to clinical activities and improving patient care such as medication therapy management services, immunization services, and point of care testing. At the same time, safeguards would be in place to ensure that the accuracy of filling medications is not compromised. As a prerequisite to participating in this research program, community pharmacies would be required to: 1. be WPQC-accredited; 2. utilize nationally-certified pharmacy technicians or meet other prespecified technician eligibility grandfathering requirements; 3. support the completion of pharmacy staff training; 4. comply with TCT accuracy validation requirements; 5. perform show-and-tell at each dispensing or have prescription label or monograph that denote a description of the medication; 6. utilize technology to support dispensing activities (e.g. barcode scanning or automated dispensing); 7. implement and follow a quality assurance protocol and process; and 8. comply with research pilot project deliverables and reporting requirements.

We request a variance to the State of Wisconsin pharmacy regulations that limit a pharmacy technician from providing final verification of a non-delivered, non-compounded, non-Schedule II controlled substance medication. Specifically, we seek a waiver of Phar 7.01(1)(c) and (d), 7.01(1)-(3), 7.015(3)(a), and 7.015(4) to allow the implementation of a community pharmacy-

based TCT program. We also request the appointment of a PEB liaison to the pilot project leadership team.

Upon approval of this request, PSW will engage community pharmacy leaders, the research consultant, and the PEB liaison to develop TCT pilot program policies and procedures, training materials, and research methods. The community pharmacy-based TCT program will align with the components in the PSW TCT Toolkit. PSW will provide the board with a progress report every six months. This report will include information on validated pharmacy technicians' accuracy rates during both the training period and throughout the program as well as patient care service advancements and expansion for the pilot pharmacy group overall.

Thank you for your consideration of this request. I would like to request an appearance at the Wednesday, May 25, 2016 Pharmacy Examining Board meeting to discuss this pilot program proposal. I look forward to meeting with you and discussing this program further.

Sincerely,



Anna Legreid Dopp, PharmD
Vice President of Public Affairs
Pharmacy Society of Wisconsin

Enclosures: Pharmacy Pilot Application, Pilot Project Key Steps, Community Pharmacy Letters of Support

Wisconsin Department of Safety and Professional Services
Pharmacy Examining Board
Pharmacy Pilot Application
Advancing Community Pharmacy Quality
A Wisconsin Statewide Research Pilot Project

Leveraging Tech-Check-Tech to Expand Patient Care Services in Community Pharmacies

Pharmacy Society of Wisconsin

Primary contact:
Sarah Sorum, PharmD
Vice President of Professional Affairs
Pharmacy Society of Wisconsin
sarabs@pswi.org
608-827-9200

Secondary contact:
Anna Legreid Dopp, PharmD
Vice President of Public Affairs
Pharmacy Society of Wisconsin
annad@pswi.org
608-827-9200

Acknowledgements: PSW would like to thank Rachael Fleagle, PGY2 Administrative Resident, UW Health, Casey Spitzer, 2016 PharmD Candidate, University of Wisconsin School of Pharmacy and Lauren Putterman, 2016 PharmD Candidate, University of Wisconsin School of Pharmacy for their assistance in preparing this application

Submitted to the Wisconsin Pharmacy Examining Board
May 11, 2016

BACKGROUND

Medication-related spending and costs are rising at an unprecedented rate, demanding that medication use processes, such as medication preparation, verification, and dispensing, must be of high quality and efficiency. In addition, demand for pharmacist involvement in optimizing patient medication regimens promises to improve the value of medication use while minimizing waste. Studies demonstrate that when pharmacists are engaged in patient care in the ambulatory setting, patient access to care is improved, physician time is saved, and clinical and economic outcomes are enhanced.¹ Therefore, positioning pharmacists in direct patient care roles while implementing streamlined and cost effective processes for medication dispensing is an essential step for the profession of pharmacy.

In the current community pharmacy model, pharmacists consistently report a lack of time to focus on patient care activities and services. A 2009 survey of community pharmacists found that the majority would like to at least double the amount of time they are able to dedicate to such tasks.² A recent study performed in Iowa by Kjos and Andreski found that lack of availability of pharmacists' time, insufficient staffing levels, and high levels of dispensing activities were the most frequently reported barriers to provision of medication therapy management (MTM) services.³ Additionally, workflow and time limitations were the most prevalent barrier to Wisconsin Pharmacy Quality Collaborative (WPQC) service provision in the 3-year Centers for Medicare and Medicaid Services-funded evaluation led by the Pharmacy Society of Wisconsin (PSW).

A solution to the barriers listed above is increased utilization of pharmacy technicians. Expansion of technician responsibilities is correlated with increased pharmacist time for patient care tasks. For example, tech-check-tech (TCT) programs have demonstrated greater deployment of pharmacist time for clinical services, enabling them to improve patient clinical outcomes.⁴ In addition, this model elevates technician practice and augments a technician career development platform in the community setting.

A growing number of states have either adopted permissive language in state laws and regulations allowing technicians to provide final verification of prepared medications when administered by another health professional or have granted variance requests legally authorizing the expanded roles of pharmacy technicians in the medication distribution processes at specific institutions. In numerous health-systems across Wisconsin, pharmacy technicians are delegated more dispensing functions which has allowed growth of clinical pharmacy services in institutionalized settings. Studies dating back to the 1970s have demonstrated that technicians are at least as accurate as pharmacists in performing the technical work of checking medications in unit dose carts.⁵ Pharmacist-reported time savings ranges from 10 hours per pharmacist per month to 1 hour per pharmacist per day (more than 30 hours per pharmacist per month). It has been documented that a pharmacist's focus on clinically-oriented activities reduces medication errors and associated consequences such as increased length of stay, mortality, drug costs, and overall health care costs.⁶ Indeed, TCT programs have provided a framework to expand these activities in the inpatient setting and have potential to do so in the community pharmacy setting.

To incorporate a TCT practice in the community setting, patient safety must be ensured. The same safety checks found in the inpatient medication distribution process are in place within the community pharmacy dispensing workflow. The community pharmacist is primarily responsible for ensuring prescription transcription accuracy before technicians perform the prescription filling activities. The community pharmacist reviews clinical appropriateness of prescriptions either before or after the step

of filling the medications. Also frequently used in the inpatient setting, medication barcode scanning technology and dispensing machines are available to community pharmacy practices and provide safeguards to ensure the correct medication is dispensed. With pharmacists maintaining a clinical judgment function and access to dispensing accuracy tools, the technical work of product checking is an ideal task to delegate to pharmacy technicians. Then, instead of the pharmacist performing the final product check in the medication distribution process, a TCT program grants specially-trained pharmacy technicians the authority to check the accuracy of medications filled by another pharmacy technician for dispensing to the patient.

Community pharmacy-based TCT programs are being implemented and evaluated elsewhere. In Iowa, the Iowa Pharmacy Association and Drake University College of Pharmacy and Health Sciences partnered to evaluate the effect of implementing TCT programs in community pharmacies across the state with the goal of increasing pharmacist provision of MTM services while maintaining patient safety. To date, there has been no statistical difference in error rates between TCT and the traditional pharmacist-check model (Table 1.)

Table 1. Iowa Community TCT Data over 18 Months

	Pharmacist- Checked (Baseline)	Technician- Checked (Overall Pilot)
Total Rx Refills	5565	5950
Wrong Drug	1	1
Wrong Strength	0	2
Safety Cap Error	8	19
Wrong Quantity	2	3
Other Error	4	8
Total Errors	15	33
Accuracy Rate	99.73%	99.445%*

*Rate difference was not statistically significant (p=0.484)

The Iowa pilot demonstrated that patient safety was not compromised with implementation of community pharmacy-based TCT programs. As the pilot program progressed, technician accuracy was statistically significantly better (p=0.02) than that of the pharmacist in the last quarter of the follow up period. Safety cap errors accounted for 58% of the errors reported. As such, further analysis compared the accuracy rates by patient-safety errors (wrong drug; wrong dose), administrative errors (safety cap error; wrong quantity), and other errors (determined on a case-by-case basis). This subgroup analysis revealed error rates of 0.07% (p=0.808 compared to pharmacist-checked) and 0.49% (p=0.443 compared to pharmacist-checked) for patient safety and administrative errors, respectively, indicating that patient safety errors occurred infrequently and at a similar rate as that of the pharmacist-checked prescriptions.

In addition to accuracy, a time study was conducted. In the Iowa pharmacies, the amount of time pharmacists spent on dispensing decreased with a corresponding increase in patient care activities. There was a statistically significant increase in the amount of pharmacist time spent in patient care, increasing from 15.9% to 35.08% (p=0.002). There was also a statistically significant decrease in the amount of pharmacist time spent in dispensing, decreasing from 67.3% to 48.58% (p=0.004). When comparing percentages of time spent in activities, the ratio of dispensing to patient care at baseline was

3.70:1, and at the end of the pilot the ratio shifted to 1.14:1. This is an important change in the composition of the pharmacist workday.

Additionally, 95% of the time gained from the decrease in dispensing activities was converted to patient care activities with the other 5% being spent on practice development. No time was shifted to management or administrative activities. Indeed, TCT effectively allowed pharmacists in these pharmacies to transition from primarily dispensing roles to a balance between medication dispensing and patient care activities.

The purpose of this application to the PEB is to evaluate the effects of a new community pharmacy practice model designed to afford community pharmacists with more time to deliver patient care services across the state of Wisconsin. Implementation of a TCT program is not intended to reduce pharmacist staffing levels, but is intended to increase the availability of the pharmacist for involvement in patient care activities.

Specific aims of this study are to:

1. Implement and assess the impact of a TCT program in community pharmacies in Wisconsin on patient safety measures, and
2. Implement and assess the impact of a TCT program in community pharmacies in Wisconsin in facilitating the provision of community pharmacist-provided services.

LEADERSHIP TEAM MEMBERS

PSW Vice President of Professional & Educational Affairs—will oversee the research pilot project, assure its completion, and serve as the NACDS liaison for the project

PSW Vice President of Public Affairs—will lead the regulatory and legislative work, as necessary, to allow tech-check-tech programs in community pharmacies in the state

PSW Vice President of Health Care Quality Initiatives—will provide program assistance and coordinate the research pilot project and its participants together with other related PSW practice advancement initiatives, including collaborative practice agreement development, MTM services, and point of care testing

PSW TCT Project Coordinator—will manage the project details, work directly with pharmacy participants, coordinate the study activities, and chair the regular team meetings

Research Consultant—will participate in regular team meetings, analyze the research pilot project data, and lead the writing of the study report

Community Pharmacy Leadership—will provide a pharmacy management perspective for coordinating the community pharmacy care services and tech-check-tech programs within the community pharmacy sites. They will participate in regular team meetings.

PSW Executive Vice President & CEO—will be available to all project team members and provide direction as necessary

Program Facilitator (National Association of Chain Drug Stores)—will oversee completion of program milestones and provide guidance aligned with allocation of funds

Wisconsin Pharmacy Examining Board Liaison—will participate in the development of program components and monitor the progress of the community pharmacy-based TCT program pursuant to regulations

PHARMACY SITE-SPECIFIC INFORMATION

A limited number of community pharmacies (n=15-20) will participate in the study by transforming their current patient care delivery model to allow for a TCT program to engage pharmacists in clinical programs that improve patient safety and provide enhanced patient care. As a prerequisite to participating in this research program, pharmacies would be required to: 1. be WPQC-accredited; 2. utilize nationally-certified pharmacy technicians or meet technician eligibility grandfathering requirements; 3. support the completion of pharmacy staff training; 4. comply with TCT accuracy validation requirements; 5. perform show-and-tell at each dispensing or have prescription label or monograph that denote a description of the medication; 6. utilize technology to support dispensing activities (e.g. barcode scanning or automated dispensing); 7. implement and follow a quality assurance protocol and process; and 8. comply with research pilot project deliverables and reporting requirements.

PROJECT SUMMARY

Community pharmacies will implement TCT programs to increase the availability of the community pharmacist for direct patient care. The pharmacists' time will be concentrated on those aspects of dispensing that require the expertise of the pharmacist to assure safe and accurate dispensing. Pharmacists will continue to have ultimate authority over the dispensing process in this model and to provide patient consultation at the final point of the dispensing process, providing a safeguard prior to the patient receiving the medication. A workflow for community pharmacy-based TCT is provided in Appendix A.

Following is a brief description of the components of a community pharmacy-based TCT program:

- A pharmacist will be physically located on the premises of the pharmacy in an environment and location that is close in proximity and efficient for direct patient interaction. Pharmacist staffing will be adequate to ensure safe and consistent deployment of the TCT program.
- Each enrolled pharmacy will select a designated pharmacist to oversee TCT program implementation and will be the person ultimately responsible for meeting the TCT program requirements such as training and record keeping.
- All prescription transcription accuracy and clinical review must be completed by a pharmacist prior to availability for patient dispensing.
- Compounded medications, Schedule II Controlled Substances, and prescriptions that are to be mailed or delivered are excluded from the TCT workflow and will follow the traditional dispensing and verification workflow.
- The technician performing the final check in the TCT workflow must be a Verified Pharmacy Technician (VPT). To become a VPT, a technician must be Pharmacy Technician Certification

Board (PTCB)-certified OR meet the following requirements: (a) be 18 years of age or older, (b) be a high school graduate or have equivalent education, (c) have completed 1500 hours of work as a technician within the 3 years prior to the date working as a VPT. In addition, to be a VPT, one must complete additional practice-specific training developed for the purpose of this pilot program. This training will be modeled after the inpatient TCT training, with site-specific modifications as appropriate. Training will include didactic and experiential education, successful completion of a written competency test, and completion of a validation period. The VPT must maintain an accuracy rate during the validation period and throughout the pilot of greater than or equal to the pharmacists' baseline accuracy rate.

- The pharmacy must maintain a continuous quality improvement system to monitor the accuracy of the final product. This includes monitoring and recording of any errors discovered during patient consultation. The responsible pharmacist shall also conduct continuous monitoring and evaluation of each VPT authorized to participate in the TCT program in order to ensure the continued competency of the VPT, safety of patients, and compliance with the research protocol.
- The pharmacy will maintain records documenting VPT requirements, training completion, and accuracy rates.
- Consistent with Wisconsin pharmacy practice statutes and code, patient consultation and response to patient questions must be completed in association with the dispensing of the medication to the patient, but it may also occur outside of dispensing. Included in the consultation parameters, using procedures like show and tell or depicting an image and description of the medication on the printed label or monograph will afford the pharmacist an additional final check of the medication before it is dispensed to the patient.
- Examples of expanded pharmacist provided patient care services include: MTM, immunization services, clinical screenings and disease state monitoring, and comprehensive patient counseling.

Pharmacy Examining Board Rules Needed to be Waived for the Purpose of the Pilot

Currently, the state of Wisconsin does not allow technicians to provide a final check of patient-specific medications. Thus, a variance is needed for the following Phar Administrative Rules:

- Phar 7.01 (c) and (d), which outlines a separate process for providing safe and accurate medications to patients;
- Phar 7.01 (1)-(3), relating to minimum procedures for compounding and distribution;
- Phar 7.015(3)(a) which limits a pharmacy technician from providing a final verification of a filled prescription or medication order; and
- Phar 7.015(4) which requires the pharmacist to provide the final verification

METHODS

The specifics of the research methods will be determined upon consultation with the pilot Research Consultant, Community Pharmacy Leadership, and the PEB liaison pending approval of the Community Tech Check Tech Pilot Program Application from the PEB (Appendix B). A summary of the approach is provided below.

Subjects

Select community pharmacies throughout the state of Wisconsin will be asked to participate in this study. The pharmacy practices eligible for inclusion in this pilot project include independent, chain, and health-system community-based pharmacies. Interested pharmacies must be willing to meet the requirements listed earlier and participate in all phases of the project, from design to final assessment, as well as to complete all required documentation.

Measures

Aim 1: Implement and assess the impact of a TCT program in community pharmacies in Wisconsin on patient safety measures.

The baseline accuracy of a pharmacist will be determined prior to initiating a TCT program. The sample size will be determined proportionally based on the prescription volume of the pharmacy. Data will be continually gathered to ensure dispensing accuracy. An accuracy rate of the VPT will be determined and, if that accuracy rate is not maintained over a 6-month period, they will be required to undergo retraining and must repeat the validation requirements. Data will be continually gathered to ensure dispensing accuracy. The research consultant will review these results on an ongoing basis. Data will be compiled to evaluate patient safety and administrative errors.

Aim 2: Implement and assess the impact of a TCT program in community pharmacies in Wisconsin in facilitating the provision of community pharmacist-provided services.

For the assessment of this aim, information will be gathered regarding the amount of pharmacist time that is made available for other duties as a result of the TCT program. The primary data sources will be self-reported pharmacist daily activity logs and numbers of both compensated and identified opportunities for patient care services development.

Design & Analysis

Each pharmacy will act as its own control, with baseline measurement of dispensing errors being determined for 50 refills per day for 15 weekdays before initiation of the TCT procedures. For the first week after the new procedures have been initiated, the pharmacist will continue to check refill prescriptions to ensure accuracy and to gather information on the efficacy of the procedures. If the error rate is equal to or less than the baseline measurement, 50 refills per month for the remainder of the project will be double-checked for errors and those measurements recorded. If the error rate is greater than baseline measurement, additional training will be provided and procedures reviewed, after which time a second weeklong assessment will be performed. The research consultant will review these results on an ongoing basis and bi-annual reports will be provided to the PEB as necessary during the 12-month study period.

Error rates during the study period will be analyzed. Specific errors tracked will include patient safety errors (wrong drug; wrong strength) and administrative errors (wrong quantity; wrong cap). Comparisons of pharmacist task composition will be compared at baseline and 12 months using Chi-squared testing.

STUDY PARTNERS

- Pharmacy Society of Wisconsin

- Concordia University Wisconsin School of Pharmacy
- Community pharmacy leadership and enrolled pharmacies
- Wisconsin Pharmacy Examining Board

PROJECT TIMELINE

Months 1-6

- Project start-up
- Determine regulatory allowance for TCT in Wisconsin
- Submit proposal to Wisconsin PEB for pilot/demonstration project
- Engage university partner
- Gather resources and training materials for pharmacists' service provision
- Conduct educational needs assessment

Month 6-8

- Develop procedures for data collection with university partner
- Recruit community pharmacies to participate
- Begin program training development

Month 8-12

- Deploy educational training
- Community pharmacies implement tech-check-tech programs

Month 12-24

- Pharmacists engage in patient care service development opportunities
- Data collection
- Ongoing reporting to Wisconsin PEB

Month 22-24

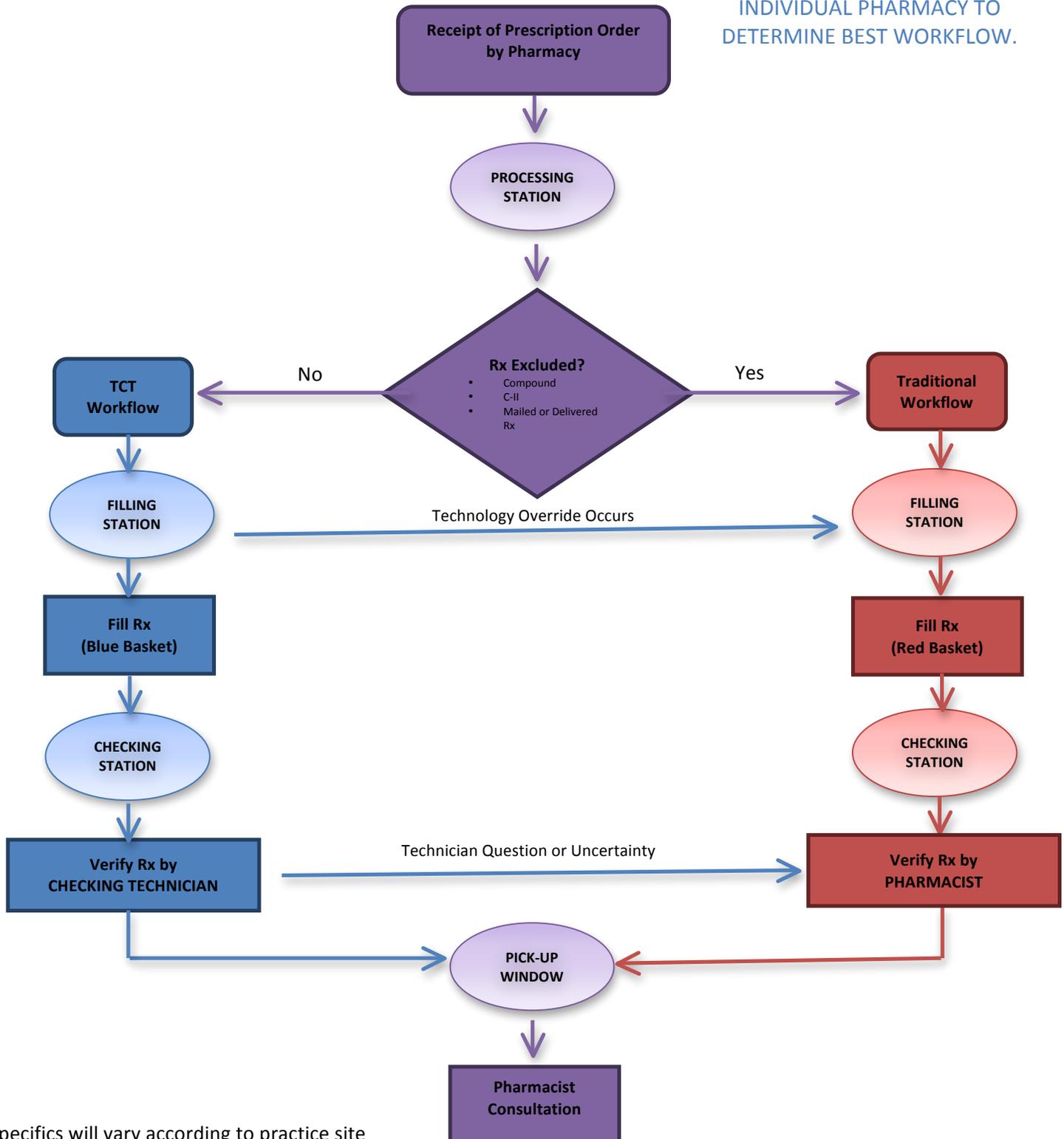
- Data analyses and report writing to inform future pilot projects and future rule-making

REFERENCES

1. Helling DK and Johnson SG. Defining and advancing ambulatory care pharmacy practice: it is time to lengthen our stride. *ASHP Ambulatory Care Conference and Summit*. Presented March 2014.
2. Schommer JC, Doucette WR, Gaither CA, et al. Final report of the 2009 National Pharmacist Workforce Summary. Presented November 2009. Accessible at http://www.aacp.org/resources/research/pharmacy_manpower/Pages/default.aspx
3. American Pharmacists Association. Medication Therapy Management Digest: Pharmacists Emerging as Interdisciplinary Health Care Team Members. Washington, DC: American Pharmacists Association; March 2013.
4. Shane R. Advancing technician roles: an essential step in pharmacy practice model reform. *American Journal of Health-System Pharmacy*. 2011; 68:1834-1835.

5. Grogan JE, Hannan JA, Haight RA. A study of accuracy of pharmacy technicians working in a unit dose system. *Hospital Pharmacy*. 1978;13:194-199.
6. Reed M, Thomley S, Ludwig B, Rough S. Experience with a “tech-check-tech” program in an academic medical center. *American Journal of Health-System Pharmacy*. 2011; 68:1820-23.

CLINICAL REVIEW OF A PRESCRIPTION MUST BE COMPLETED BY A PHARMACIST PRIOR TO THE DISPENSING OF THE PRESCRIPTION TO THE PATIENT. THIS WILL BE DETERMINED WITHIN EACH INDIVIDUAL PHARMACY TO DETERMINE BEST WORKFLOW.



*Specifics will vary according to practice site

Appendix B - Community Tech Check Tech Pilot Program

Pursuant to 450.02(3r)(a), this Community Tech Check Tech Pilot Program is related to the practice of pharmacy or prescription verification and the Board determines that the program will improve the safety, quality or efficiency of the practice of pharmacy in this state.

The Board may modify the parameters of the Pilot Program at any time during the Pilot Program duration. Participants remain in the Pilot Program at the discretion of the Board.

Duration: June 1, 2016 to May 31, 2019 (or promulgation of rules whichever is sooner).

Purpose: To evaluate the effects of a new community pharmacy practice model designed to afford community pharmacists with more time to deliver patient care services across the state of Wisconsin. Implementation of a TCT program is not intended to reduce pharmacist staffing levels, but is intended to increase the availability of the pharmacist for involvement in patient care services.

Pharmacy Eligibility: PSW will invite select pharmacies throughout the state of Wisconsin to participate in this study. The pharmacy practices eligible for inclusion in this pilot project include independent, chain, and health-system community-based pharmacies. As a prerequisite to participating in this research program, community pharmacies would be required to: 1. be WPQC-accredited; 2. utilize nationally-certified pharmacy technicians or meet technician eligibility grandfathering requirements; 3. support the completion of pharmacy staff training; 4. comply with TCT accuracy validation requirements; 5. perform show-and-tell at each dispensing or have prescription label or monograph that denote a description of the medication; 6. utilize technology to support dispensing activities (e.g. barcode scanning or automated dispensing); 7. implement and follow a quality assurance protocol and process; and 8. comply with research pilot project deliverables and reporting requirements.

TCT Policies and Procedures: The pharmacy shall develop policies and procedures which shall include all of the following:

General

1. A pharmacist will be physically located on the premises of the pharmacy in an environment and location that is close in proximity and efficient for direct patient interaction. Pharmacist staffing will be adequate to ensure safe and consistent deployment of the TCT program.
2. Each enrolled pharmacy will select a designated pharmacist to oversee TCT program implementation and will be the person ultimately responsible for meeting the TCT program requirements such as training and record keeping.
3. All prescription transcription accuracy and clinical review must be completed by a pharmacist prior to availability for patient dispensing.
4. Compounded medications, Schedule II Controlled Substances, and prescriptions that are to be mailed or delivered are excluded from the TCT workflow and will follow the traditional dispensing and verification workflow.
5. The technician performing the final check in the TCT workflow must be a Verified Pharmacy Technician (VPT). To become a VPT, a technician must be Pharmacy Technician Certification Board (PTCB)-certified OR meet the following requirements: (a) be 18 years of age or older, (b) be a high school graduate or have equivalent education, (c) have completed 1500 hours of work as a technician within the 3 years prior to the date working as a VPT. In addition, to be a VPT, one must complete additional practice-specific training developed for the purpose of this pilot program. This training will be modeled after the inpatient TCT training, with site-specific modifications as appropriate. Training will include didactic and experiential education, successful completion of a written competency test, and

completion of a validation period. The VPT must maintain an accuracy rate during the validation period and throughout the pilot of greater than or equal to the pharmacists' baseline accuracy rate.

6. The pharmacy must maintain a continuous quality improvement system to monitor the accuracy of the final product. This includes monitoring and recording of any errors discovered during patient consultation. The responsible pharmacist shall also conduct continuous monitoring and evaluation of each VPT authorized to participate in the TCT program in order to ensure the continued competency of the VPT, safety of patients, and compliance with the research protocol.
7. The pharmacy will maintain records documenting VPT requirements, training completion, and accuracy rates.
8. Consistent with Wisconsin pharmacy practice statutes and code, patient consultation and response to patient questions must be completed in association with the dispensing of the medication to the patient, but it may also occur outside of dispensing. Included in the consultation parameters, using procedures like show and tell or depicting an image and description of the medication on the printed label or monograph will afford the pharmacist an additional final check of the medication before it is dispensed to the patient.

Validated Pharmacy Technician Eligibility and Training

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

1. To become a VPT, a technician must be Pharmacy Technician Certification Board (PTCB)-certified OR meet the following requirements: (a) be 18 years of age or older, (b) be a high school graduate or have equivalent education, (c) have completed 1500 hours of work as a technician within the 3 years prior to the date working as a VPT.
2. In addition to be a VPT, one must complete additional practice-specific training developed for the purpose of this pilot program. This training will be modeled after the inpatient TCT training, with site-specific modifications as appropriate. Training will include didactic and experiential education, successful completion of a written competency test, and completion of a validation period.
 - a. Fundamentals of TCT
 - b. Medication safety and prevention of medication errors
 - c. Dosage forms review
 - d. Pharmaceutical calculations
 - e. Review of top 200 medications
 - f. Organizational TCT policies and procedures
3. The VPT must maintain an accuracy rate during the validation period and throughout the pilot of greater than or equal to the pharmacists' baseline accuracy rate.

Quality Assurance

Each pharmacy will act as its own control, with baseline measurement of dispensing errors being determined for 50 refills per day for 15 weekdays before initiation of the TCT procedures. For the first week after the new procedures have been initiated, the pharmacist will continue to check refill prescriptions to ensure accuracy and to gather information on the efficacy of the procedures. If the error rate is equal to or less than the baseline measurement, 50 refills per month for the remainder of the project will be double-checked for errors and those measurements recorded. If the error rate is greater than baseline measurement, additional training will be provided and procedures reviewed, after which time a second weeklong assessment will be performed. The research consultant will review these results on an ongoing basis and bi-annual reports will be provided to the PEB as necessary during the 12-month study period.

Records: The pharmacy shall maintain and make available to the Board upon request all of the following:

1. Complete list of VPTs (completed training and are in good standing)
2. Training materials, assessments and exams
3. Training log of all trainings
4. Validation records
5. Quality Assurance records, including audits and error logs
6. Log of any errors which are discovered during patient consultation or which reach the patient
7. Board report forms

Reporting Requirements: The Pharmacy Society of Wisconsin's TCT Coordinator will submit aggregate data relating to the specific aims of the research pilot program to the Board twice a year and appear in person to answer any questions related to the Pilot Program as necessary.

Advancing Community Pharmacy Quality

A Wisconsin Statewide Research Pilot Project

Key Pilot Project Steps

- Enact legislation enabling the Wisconsin Pharmacy Examining Board (PEB) to grant pilot programs related to the practice of pharmacy and prescription verification
- Submit pilot proposal to the PEB requesting approval of the pilot program (providing applicable variances to rule) and appointment of PEB liaison to the project
- Create policies, procedures, and training materials to ensure the program’s adherence to legislative statute, regulatory allowances, patient safety assurances, and best practice standards
- Recruit and enroll 15-20 pilot sites having capabilities to expand clinical services, meeting pilot program criteria
- Train participants and support implementation of workflow changes and clinical service expansion
- Provide regular reports to the PEB
- Collect and analyze data to assess achievement of specific aims

Pilot Project Timeline

Months 1-6	Months 6-8	Months 8-12	Months 12-24	Months 22-24
<ul style="list-style-type: none"> ▪ Project start-up ▪ Determine regulatory allowance for TCT in Wisconsin ▪ Submit proposal to Wisconsin PEB for pilot/demonstration project ▪ Engage university partner ▪ Gather resources and training materials for pharmacists’ service provision ▪ Conduct educational needs assessment 	<ul style="list-style-type: none"> ▪ Develop procedures for data collection with university partner ▪ Recruit community pharmacies to participate ▪ Begin program training development 	<ul style="list-style-type: none"> ▪ Deploy educational training ▪ Community pharmacies implement TCT programs 	<ul style="list-style-type: none"> ▪ Pharmacists engage in patient care service development opportunities ▪ Data collection ▪ Ongoing reporting to Wisconsin PEB 	<ul style="list-style-type: none"> ▪ Data analyses and report writing to inform future pilot projects and future rule-making

May 2, 2016

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,

With this letter, our organization would like to express our support of the Pharmacy Society of Wisconsin (PSW) proposal titled "Advancing Community Pharmacy Quality – A Wisconsin Statewide Research Pilot Project" which seeks to study how "tech-check-tech" workflow adaptations can be leveraged in a community pharmacy setting to expand pharmacist-provided patient care services.

With the Pharmacy Examining Board's approval, our organization and our staff will engage with PSW in the implementation of this project to streamline workflow, improve patient care, and maintain patient safety statewide.

This pilot proposal is important to the advancement of pharmacy practice and is important to our organization. It will allow us to utilize trained and validated pharmacy technicians to perform technical tasks that are currently being performed by pharmacists. In addition to providing advanced roles for technicians, it will allow us to focus pharmacist resources on value-added clinical activities to improve accessibility to patients in the community. Due to the success of tech-check-tech within hospital settings with regard to verification accuracy, we believe that we can build upon these frameworks to safely integrate tech-check-tech procedures within community pharmacies.

We look forward to working closely with PSW and other pilot pharmacies in adapting our policies and procedures to align with pilot approval. In addition, we are excited to expand pharmacist-provided service offerings.

Sincerely,

A handwritten signature in black ink, appearing to read "Joe Cesarz".

Joe Cesarz, PharmD, MS
Manager, Ambulatory Pharmacy Services
UW Health
Madison, WI

A handwritten signature in black ink, appearing to read "Steve Rough".

Steve Rough, MS, RPh, FASHP
Director of Pharmacy
UW Health
Madison, WI



There's a way™

May 3, 2016

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,

With this letter, our organization would like to express our support of the Pharmacy Society of Wisconsin (PSW) proposal titled "Advancing Community Pharmacy Quality – A Wisconsin Statewide Research Pilot Project" which seeks to study how "tech-check-tech" workflow adaptations can be leveraged in a community pharmacy setting to expand pharmacist-provided patient care services.

With the Pharmacy Examining Board's approval, our organization and our staff will engage with PSW in the implementation of this project to streamline workflow, improve patient care, and maintain patient safety statewide.

This pilot proposal is important to the advancement of pharmacy practice and is important to our organization because it will allow our pharmacists to dedicate more time towards patient centric services like medication adherence, immunizations, and medication therapy management.

We look forward to working closely with PSW and other pilot pharmacies in adapting our policies and procedures to align with pilot approval. In addition, we are excited to expand pharmacist-provided service offerings.

Sincerely,

Tony Fields PharmD
Regional Healthcare Director
Walgreens

Brennan Beck PharmD
Area Healthcare Supervisor
Milwaukee



May 2, 2016

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,

With this letter, our organization would like to express our support of the Pharmacy Society of Wisconsin (PSW) proposal titled “Advancing Community Pharmacy Quality – A Wisconsin Statewide Research Pilot Project” which seeks to study how “tech-check-tech” workflow adaptations can be leveraged in a community pharmacy setting to expand pharmacist-provided patient care services

With the Pharmacy Examining Board’s approval, our organization and our staff will engage with PSW in the implementation of this project to streamline workflow, improve patient care, and maintain patient safety statewide.

This pilot proposal is important to the advancement of pharmacy practice and is important to our organization as it will help pharmacist to get more involved in clinical roles.

We look forward to working closely with PSW and other pilot pharmacies in adapting our policies and procedures to align with pilot approval. In addition, we are excited to expand pharmacist-provided service offerings.

Sincerely,

Hashim Zaibak

Hashim Zaibak
President
Hayat Pharmacy. Milwaukee
(414) 931-0000
zaibak@hayatrx.com

GUNDERSEN HEALTH SYSTEM®

May 2, 2016

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,

With this letter, our organization would like to express our support of the Pharmacy Society of Wisconsin (PSW) proposal titled “Advancing Community Pharmacy Quality – A Wisconsin Statewide Research Pilot Project” which seeks to study how “tech-check-tech” workflow adaptations can be leveraged in a community pharmacy setting to expand pharmacist-provided patient care services.

Gundersen Health System is in full support of this innovative project. This work will streamline workflow and improve patient care. The initiative, if passed, will allow Pharmacists to increase their clinical and consultative time with patients.

Sincerely,

Ryan Holte, RPH
Administrative Director of Ambulatory Pharmacy
Gundersen Health Systems
La Crosse, WI



Boscobel Pharmacy, Inc.

1028 Wisconsin Avenue
(608) 375-4466

Boscobel, WI 53805
Fax (608) 375-2383

www.boscobelpharmacy.com

May 2, 2016

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,

With this letter, our organization would like to express our support of the Pharmacy Society of Wisconsin (PSW) proposal titled "Advancing Community Pharmacy Quality – A Wisconsin Statewide Research Pilot Project" which seeks to study how "tech-check-tech" workflow adaptations can be leveraged in a community pharmacy setting to expand pharmacist-provided patient care services.

With the Pharmacy Examining Board's approval, our organization and our staff will engage with PSW in the implementation of this project to streamline workflow, improve patient care, and maintain patient safety statewide.

This pilot proposal is important to the advancement of pharmacy practice and is important to our organization because it will free our pharmacists to pursue clinical care activities including comprehensive medication reviews and provide clinical care recommendations.

We look forward to working closely with PSW and other pilot pharmacies in adapting our policies and procedures to align with pilot approval. In addition, we are excited to expand pharmacist-provided service offerings.

Sincerely,

Michelle Farrell, PharmD, BCACP
Owner, Managing Pharmacist
Boscobel Pharmacy

April 22, 2016

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,

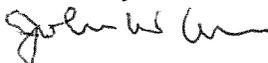
With this letter, our organization would like to express our support of the Pharmacy Society of Wisconsin (PSW) proposal titled "Advancing Community Pharmacy Quality – A Wisconsin Statewide Research Pilot Project" which seeks to study how "tech-check-tech" workflow adaptations can be leveraged in a community pharmacy setting to expand pharmacist-provided patient care services.

With the Pharmacy Examining Board's approval, our organization and our staff will engage with PSW in the implementation of this project to streamline workflow, improve patient care, and maintain patient safety statewide.

This pilot proposal is important to the advancement of pharmacy practice and is important to our organization because it allows pharmacists the ability to optimize clinical quality and patient care.

We look forward to working closely with PSW and other pilot pharmacies in adapting our policies and procedures to align with pilot approval. In addition, we are excited to expand pharmacist-provided service offerings.

Sincerely,



John Gates, R.Ph.
Vice President Retail Pharmacy Operations
Aurora Health Care



May 10, 2016

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,

With this letter, our organization would like to express our support of the Pharmacy Society of Wisconsin (PSW) proposal titled "Advancing Community Pharmacy Quality – A Wisconsin Statewide Research Pilot Project" which seeks to study how "tech-check-tech" workflow adaptations can be leveraged in a community pharmacy setting to expand pharmacist-provided patient care services.

With the Pharmacy Examining Board's approval, our organization and our staff will engage with PSW in the implementation of this project to streamline workflow, improve patient care, and maintain patient safety statewide.

This pilot proposal is important to the advancement of pharmacy practice and is important to our organization because of the opportunity to shift pharmacist time from product tasks to providing professional service that advances our practice of pharmacy at Shopko.

We look forward to working closely with PSW and other pilot pharmacies in adapting our policies and procedures to align with pilot approval. In addition, we are excited to expand pharmacist-provided service offerings.

Sincerely,

Ken Walker
Regional Pharmacy Supervisor
Shopko Stores

**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: 13 May 2016 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: 25 May 2016	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. Phar 6 Relating to Temperature and Humidity Controls 2. Phar 7.10 Relating to Administration of Drug Products (Act 290) 3. Phar 15 Relating to Compounding 4. Rule Projects List 5. Update on Pending and Possible Rulemaking Products	
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:			
11) Authorization			
<i>Sharon Henes</i>		<i>13 May 2016</i>	
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.			

TEXT OF RULE

SECTION 1. Phar 6.075 is created to read:

Phar 6.075 Temperature. (1) DEFINITIONS. In this section:

- (a) Business day is a day the pharmacy is open for business.
- (b) Dry place means a place that does not exceed 40% average relative humidity at 68 degree Fahrenheit or the equivalent water vapor pressure at other temperatures.
- (c) Freezer means a place in which the temperature is maintained between -13 and 14 degrees Fahrenheit.
- (d) Mean kinetic temperature means the calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures.
- (e) Refrigerator means a place in which the temperature is maintained between 36 and 46 degrees Fahrenheit.

(2) STORAGE. Drugs shall be stored at appropriate temperature and under appropriate conditions, including in a dry place, according to the manufacturer recommendation or an official pharmaceutical compendium.

(3) RECORDING DEVICES. Manual, electromechanical or electronic temperature and humidity recording devices shall be placed within the storage space to accurately determine the area's temperature and humidity.

(4) FREQUENCY. The temperature of the refrigerator, freezer and pharmacy shall be monitored at least once during each business day. A minimum and maximum temperature over the course of the time a pharmacy is closed shall be obtained.

(5) RECORDS. Temperature and humidity records shall be maintained for a minimum of 5 years.

(6) DISPENSING OF SAFE DRUGS. The pharmacist shall use professional judgement, including consideration of the mean kinetic temperature, to determine whether a drug is safe to be dispensed.

SECTION 2. **EFFECTIVE DATE.** The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

TEXT OF RULE

SECTION 1. Phar 7.10 is amended to read:

Phar 7.10 Administration of drug products and devices other than vaccines. A pharmacist may administer a drug product, as defined in s. 450.01 (11), Stats., or device, as defined in s. 450.01 (6), Stats., ~~in the course of teaching a patient self-administration techniques except a pharmacist may not administer by injection a prescribed drug product or device unless~~ if he or she satisfies each of the following:

- (1) The pharmacist has successfully completed 12 hours in a course of study and training, approved by the Accreditation Council for Pharmacy Education, or the board, ~~in injection administration techniques,~~ emergency procedures, and record keeping.
- (2) The pharmacist has in effect liability insurance against loss, expense and liability resulting from errors, omissions or neglect in the administration ~~by injection~~ of prescribed drug products or devices in an amount that is not less than \$1,000,000 for each occurrence and \$2,000,000 for all occurrences in any one policy year. The pharmacist shall maintain proof that he or she satisfies this requirement and, upon request, shall provide copies of such proof to the department or board.
- (3) The pharmacist has written procedures regarding the administration ~~by injection~~ of a prescribed drug product or device ~~in the course of teaching self-administration techniques to a patient.~~
- (4) After the pharmacist administers a prescribed drug product or device, the pharmacist shall notify the prescribing practitioner or enter the information in a patient record system shared by the prescribing practitioner.

SECTION 2. EFFECTIVE DATE. Pursuant to s. 227.24 (1) (c), Stats., these rules shall take effect upon publication in the official state newspaper.

(END OF TEXT OF RULE)

TEXT OF RULE

SECTION 1. Repeals and recreates ch Phar 15 to read:

15.01 Definitions. In this chapter:

- (1) Active pharmaceutical ingredient (API) means any substance or mixture of substances intended to be used in the compounding of a drug preparation and that, when used in the compounding of a drug preparation, becomes an active ingredient in the preparation intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease in humans and animals or affecting the structure and function of the body.
- (2) Added substances means ingredients that are necessary to compound a drug preparation that are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation.
- (3) Adverse Drug Event means an injury resulting from the use of a drug.
- (4) Beyond Use Date (BUD) means one of the following:
- (a) The date after which a non-sterile compounded preparation shall not be used.
 - (b) The date and time after which a sterile compounded sterile preparation shall not be used.
- (5) Certificate of analysis means a report from the supplier of a component, container or closure that accompanies the component, container or closure and contains the specifications and results of all analyses and a description.
- (6) Classified area means a space that maintains an air cleanliness classification based on the International Organization for Standardization (ISO).
- (7) Component means any, active pharmaceutical ingredient, or added substances used in the compounding of a drug preparation.
- (8) Compounding means the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug delivery device, or a device in accordance with a prescription, or medication order. Compounding does not include repackaging. Compounding includes any of the following:
- (a) Preparation of drug dosage forms for both human and animal patients.
 - (b) Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.
 - (c) Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients. Notwithstanding this paragraph, the reconstitution or mixing that is performed in accordance with the directions contained in approved labeling provided by the manufacturer is not compounding.
 - (d) Preparation of drugs or devices for the purposes of, or as an incident to, research, teaching or chemical analysis.
- (9) Container-closure system is the sum of packaging components that together contain and protect a dosage form including primary packaging components and secondary packaging components.
- (10) Controlled room temperature means a temperature maintained thermostatically that encompasses the usual and customary working environment of 68 degrees to 77 degrees Fahrenheit.

- (11) Freezer means a place in which the temperature is maintained between -13 degrees and 14 degrees Fahrenheit
- (12) NF means the National Formulary.
- (13) Refrigerator means a cold place in which the temperature is maintained between 36 degrees and 46 degrees Fahrenheit
- (14) Stability means the extent to which a compounded preparation retains, within specified limits and throughout its beyond use date, the same properties and characteristics that it possessed at the time of compounding.
- (a) Chemical stability means each active pharmaceutical ingredient retains its chemical integrity and labeled potency, within specified limits.
 - (b) Physical stability means the original physical properties, including appearance, palatability, uniformity, dissolution, and suspendability, are retained.
 - (c) Microbiological stability means sterility or resistance to microbial growth is retained according to specified requirements and antimicrobial agents that are present retain effectiveness within specified limits.
 - (d) Therapeutic stability means the therapeutic effect remains unchanged.
 - (e) Toxicological stability means no significant increase in toxicity occurs.
- (15) USP means the United States Pharmacopeia.

SUBCHAPTER I – General

15.10 Facilities. A pharmacist engaged in compounding shall ensure all of the following:

- (1) An area designated for compounding.
- (2) Orderly placement of compounding equipment, materials, and components in order to minimize the potential for compounding errors.
- (4) The compounding area is maintained in a clean and sanitary condition.
- (5) The compounding area is easily accessible to all of the following:
 - (a) Hot and cold running water, exclusive of the bathroom sink.
 - (b) Soap or detergent.
 - (c) Single-use towels.
- (6) All compounding equipment, materials and components shall be stored off the floor and in a manner to prevent contamination and permit inspection and cleaning of the compounding and storage areas

15.11 Equipment and Drug Preparation Containers.

- (1) A pharmacy shall possess equipment and drug preparation containers or packaging appropriate to the type of compounding performed at the pharmacy.
- (2) Equipment and drug preparation containers or packaging used in compounding shall be of appropriate design and capacity, and shall be suitably stored in a manner to facilitate use, cleaning, maintenance, and protect it from contamination.
- (3) Equipment and drug preparation containers/packaging used in compounding drug products shall be of suitable composition. Equipment surfaces that contact components may not be reactive, additive, adsorptive or absorptive so as to alter the stability of the compounded preparation.

- (4) Equipment used in compounding shall be thoroughly cleaned and sanitized after each use, and when necessary, prior to use, according to written policies and procedures, in order to reduce bioburden and reduce the opportunity for cross-contamination.
- (5) All equipment utilized in compounding preparations shall be inspected, maintained, calibrated and validated at appropriate intervals, consistent with manufacturer's recommendations, to ensure the accuracy and reliability of equipment performance. Records shall be kept indicating the equipment was inspected, maintained, calibrated and validated.

15.12 Records. The managing pharmacist shall ensure written or electronic compounding documentation to systematically trace, evaluate, and replicate the compounding steps throughout the process of a preparation. The compounding documentation shall be maintained for a period of 5 years after the date of the last refill. The compounding documentation shall include all of the following:

- (1) Official or assigned name, strength, and dosage form of the preparation.
- (2) List of all APIs and added substances and their quantities.
- (3) Vendor or manufacturer, lot number and expiration date of each APIs and added substances.
- (4) Equipment and supplies needed to prepare the preparation.
- (5) Mixing instructions including all of the following:
 - (a) Order of mixing.
 - (b) Mixing temperatures or other environmental controls.
 - (c) Duration of mixing.
 - (d) Other factors pertinent to the replication of the preparation as compounded.
- (6) Compatibility and stability information, including references or laboratory testing.
- (7) Container or container-closure system used in dispensing.
- (8) Packaging and storage requirements.
- (9) Quality control procedures and expected results.
- (10) Sterilization method when using non sterile ingredients to make a sterile preparation.
- (11) Total quantity compounded.
- (12) Name of the person who prepared the preparation.
- (13) Name of the person who performed the quality control procedures.
- (14) Name of the person who approved the preparation.
- (15) Date of preparation.
- (16) Assigned control or prescription number.
- (17) Assigned BUD.
- (18) Copy of the label to dispense final product.
- (19) Documentation of any adverse reactions or preparation problems reported by the patient or caregiver.

15.13 Quality control.

- (1) A pharmacist shall complete a final check which shall include verification of all the following:
 - (a) Written procedures were followed in the compounding process.
 - (b) Preparation instructions were followed.
 - (c) Finished preparation appears as expected.
 - (d) Label includes all required elements.
 - (e) Quality control procedures were completed.

- (f) Compounding records are complete
- (2) A pharmacist shall investigate any discrepancies and take appropriate corrective action before the prescription is dispensed.

15.14 Training, Policies and Procedures. (1) TRAINING. All personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations shall be properly trained and competency is assessed for the type of compounding conducted. It is the responsibility of the managing pharmacist to ensure personnel training and competency assessments are completed and documented.

(2) POLICIES AND PROCEDURES. The pharmacy and managing pharmacist shall establish written policies and procedures governing all of the following:

- (a) Personnel qualifications and training, responsibilities, and competencies.
- (b) Personal hygiene, garb, garbing, and personal protective gear.
- (c) Use and maintenance of compounding facilities and equipment, including applicable certifications.
- (d) Environmental monitoring including storage, handling, packaging and transport.
- (e) Cleaning and disinfection of compounding area.
- (f) Component selection.
- (g) Sterilization and depyrogenation, if pharmacy does sterile compounding.
- (h) Documentation requirements.
- (i) Establishing BUD.
- (j) Reporting of adverse drug events.
- (k) A risk management program, including documentation of incidents, adverse drug reactions and product contamination.
- (L) Quality assurance program.
- (m) Maintaining the integrity of the classified work area of the laminar airflow workbenches, compounding aseptic isolators, compounding aseptic containment isolators and biological safety cabinets.
- (n) Handling small and large spills of antineoplastic agents and other hazardous substances.

(3) REVIEW OF POLICIES AND PROCEDURES The policy and procedures shall be reviewed at least once every 36 months and shall be updated, on a continuous basis, to reflect current practice. Documentation of the review shall be made available to the board upon request.

15.15 Labeling. The label of a compounded preparation shall include all of the following:

- (1) Labeling requirements in s. Phar 7.02 and 8.08.
- (2) Storage conditions if other than controlled room temperature.
- (3) BUD.
- (4) Special handling instructions.

15.16 Component Selection. (1) Active pharmaceutical ingredients or added substances used in compounding shall be manufactured by an FDA registered facility or accompanied by a certificate of analysis.

(2) APIs and added substances shall meet USP or NF monograph specifications when monographs are available.

- (3) All components shall be stored and handled consistent with the manufacturer's labeling or USP-NF monographs and in a manner that prevents contamination and deterioration.
- (4) A pharmacist compounding for human use may not use components that have been withdrawn or removed from the market for safety or efficacy reasons by the FDA. A pharmacist compounding for food producing animal use may not use components prohibited for use in food producing animals.

15.17 Non-patient specific compounding. Compounded preparations dispensed or distributed directly to a practitioner to be administered to an individual patient without a patient specific prescription shall meet all of the following:

- (1) The prescription order shall include the name, address, drug, quantity and the purpose of the compounded preparation.
- (2) The label shall include the practitioner's name in place of the patient's name and state "For Practitioner Use Only – Not for Dispensing or Distribution". If the sterility or integrity of the compounded preparation is not maintained after the initial opening of the container, the label shall state "Single-Dose Only".
- (3) The pharmacist shall record the name and address of the location the compounded preparation was dispensed or distributed, and the lot number and BUD of all preparations dispensed or distributed to the practitioner.
- (4) There shall be a procedure for immediate notification to all practitioners of a preparation which is recalled.

SUBCHAPTER II – Non-sterile Compounding

15.20 Component Selection. (1) Components with an expiration date from the manufacturer or distributor may be used before the expiration date provided all of the following:

- (a) The component is stored in its original container under conditions to avoid decomposition
 - (b) There is minimal exposure of the remaining component each time component is withdrawn from the container.
 - (c) When any withdrawals from the container are performed by those trained in the proper handling of the component.
- (2) Components without an expiration date assigned by the manufacturer or supplier, shall be labeled with the date of receipt and assigned a conservative expiration date, not to exceed three years after receipt, based upon the nature of the component and its degradation mechanism, the container in which it is packaged and the storage conditions.
- (3) Components transferred to another container which shall provide integrity that is minimally equivalent to the original container and shall be identified with all of the following:
- (a) Component name.
 - (b) Original supplier.
 - (c) Lot or control number.
 - (d) Transfer date.
 - (e) Expiration date.

15.21 Assigning BUD. (1) The BUD shall not be later than the expiration date on the container of any component.

(2) In the absence of stability information that is applicable to a specific drug product and preparation, the maximum BUD for a non-sterile compounded drug preparation that is packaged in a tight, light-resistant container is as follows:

(a) For nonaqueous formulations stored at controlled room temperature, the BUD shall not be later than the time remaining until the earliest expiration date of any active pharmaceutical ingredient or 6 months, whichever is earlier.

(b) For water-containing oral formulations, the BUD shall not be later than 14 days when stored in a refrigerator

(c) For water-containing semisolid, mucosal liquid, topical or dermal formulations, stored at controlled room temperature, the BUD shall not be later than 30 days.

(3) Assignment of BUD shall include an assessment of the need for antimicrobial agents and or storage in a refrigerator to protect against bacteria, yeast, and mold contamination introduced during or after the compounding process.

SUBCHAPTER III – Sterile Compounding

15.30 Definitions. In this subchapter:

(1) Ante area means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, labeling and other high particulate generating activities are performed. The ante-area is the transition area between the unclassified area of the facility and the buffer area.

(2) Buffer area means an ISO Class 7 or ISO Class 8 if using an isolator or cleaner area where the PEC that generates and maintains an ISO Class 5 environment is physically located.

(3) Category 1 means a compounded sterile preparation compounded with a primary engineering control in a segregated compounding area.

(4) Category 2 means a compounded sterile preparation compounded with a primary engineering control in a classified area.

(5) Compounded sterile preparation means a compounded final preparation intended to be sterile through the BUD.

(6) Compounded stock solution means a compounded solution to be used in the preparation of multiple units of a finished compounded sterile preparation.

(7) Critical site means a location that includes any component or fluid pathway surfaces or openings that are exposed and at risk of direct contact with air, moisture or touch contamination.

(8) HEPA means high-efficiency particulate air.

(9) ISO Class 5 air quality conditions means conditions in which the air particle count is no greater than a total of 3,520 particles of 0.5 micrometers and larger per cubic meter of air that is supplied by HEPA or HEPA-filtered air.

(10) ISO Class 7 air quality conditions means conditions in which the air particle count is no greater than a total of 352,000 particles of 0.5 micrometers and larger per cubic meter of air that is supplied by HEPA or HEPA-filtered air.

(11) ISO Class 8 air quality conditions means conditions in which the air particle count is no greater than a total of 3,520,000 particles of 0.5 micrometers and larger per cubic meter of air that is supplied by HEPA or HEPA-filtered air.

(12) Isolator means an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is

decontaminated using an automated system. An isolator uses only decontaminated interfaces or rapid transfer ports for materials transfer.

(13) Primary engineering control means a device or zone that provides an ISO Class 5 environment for sterile compounding.

(14) Restricted access barrier system (RABS) means an enclosure that provides HEPA filtered ISO Class 5 unidirectional air that allows for the ingress or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. RABS include compounding aseptic isolators and compounding aseptic containment isolators.

(15) Sterility assurance level of 10^{-6} means an equivalent to a probability that 1 unit in a million is nonsterile.

(16) Segregated compounding area means a designated, unclassified space, area, or room that contains a primary engineering control.

(17) Urgent use compounded sterile preparation means a preparation needed urgently for a single patient and preparation of the compounded sterile preparation under Category 1 or Category 2 requirements would subject the patient to additional risk due to delays.

15.31 Facility design and environmental controls. (1) GENERAL. Facilities shall meet all of the following requirements:

- (a) Be physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites.
- (b) Be accessible only to designated personnel.
- (c) Have a heating, ventilation, and air conditioning system controlling the temperature and humidity.

(2) SEGREGATED COMPOUNDING AREA. A segregated compounding area shall meet all of the following requirements:

- (a) Be located in an area away from unsealed windows and doors that connect to the outdoors, or significant traffic flow.
- (b) Be located in an area which is not adjacent to construction sites, warehouses and food preparation areas.
- (c) Have a defined perimeter.
- (d) Locate the primary engineering control at least 1 meter from any sink.

(3) CLASSIFIED AREA. A classified area shall meet all of the following:

- (a) The surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets shall be smooth, impervious, free from cracks and crevices and nonshedding.
- (b) Work surfaces shall be constructed of smooth, impervious materials. All work surfaces shall be resistant to damage from cleaning and sanitizing agents.
- (c) Junctures where ceilings meet walls shall be covered, caulked, or sealed to avoid cracks and crevices in which microorganisms and other contaminate can accumulate. All areas in ceilings and walls where the surface has been penetrated shall be sealed.
- (d) Ceilings that consist of inlaid panels shall be impregnated with a polymer to render them impervious and hydrophobic and shall either be caulked or weighted and clipped.
- (e) Walls shall be constructed of a durable material, panels locked together and sealed or of epoxy-coated gypsum board.
- (f) Floors shall have a covering that shall be seamless or have heat-welded seams and coving to the sidewall. There shall be no floor drains.

- (g) All sprinkler heads shall be flush with the ceiling.
- (h) Ceiling lighting fixtures shall have exterior lens surfaces which are smooth, mounted flush and sealed.
- (i) Carts shall be constructed of stainless steel wire, nonporous plastic or sheet metal with cleanable casters.
- (j) Tacky mats may not be used in a classified area.
- (k) HEPA filters and unidirectional airflow shall be used to maintain the appropriate airborne particulate classification.
- (L) The classified area shall measure not less than 30 air changes per hour of which at least half shall be HEPA-filtered fresh air.
- (m) A minimum differential positive pressure of 0.02-inch water column is required to separate each classified area. A pressure gauge or velocity meter shall be used to monitor the pressure differential or airflow between classified areas with results documented at least daily.
- (n) Devices and objects essential to compounding shall be located at an appropriate distance from the primary engineering control.
- (o) The ante area and buffer area shall be separate rooms, with walls and doors between them and controls to prevent the flow of lower quality air into the higher ISO class areas. If a pass through is used, only one door shall be opened at a time.
- (p) The ante area shall meet all of the following requirements:
 1. Be capable of maintaining an ISO class 8 air or higher.
 2. Have a sink with running hot and cold running water.
- (q) The buffer area shall meet all of the following requirements:
 1. Be capable of maintaining an ISO class 7 air or better.
 2. Only contain any of the following:
 - a. Items, including furniture, equipment, and supplies, that are required for the tasks to be performed in the buffer area.
 - b. Items that are smooth, impervious, free from cracks and crevices, nonshedding, and easily cleaned and disinfected.
 - c. Items that have been cleaned and disinfected immediately prior to their being placed in the buffer area.
 3. Does not contain any sinks.
 4. Does not contain any course cardboard, external shipping containers and nonessential paper.

(4) PRIMARY ENGINEERING CONTROL. The primary engineering control shall be certified by an independent, qualified individual prior to initial use and then every six months. It shall also be certified when any of the following occurs:

- (a) Redesign of the facility.
- (b) Replacement of the primary engineering control.
- (c) Relocation of the primary engineering control.

15.32 Personnel hygiene, garbing and protective gear. (1) Personnel suffering from rashes, sunburn, oozing tattoos or sores, conjunctivitis, active respiratory infection, or other active communicable disease shall be excluded from working in compounding areas until the condition is resolved.

- (2) All personnel who engage in compounding sterile preparations shall comply with all of the following requirements before entering the compounding area:
- (a) Remove personal outer garments, all cosmetics, exposed jewelry and piercings, headphones, ear buds, and cell phones.
 - (b) Abstain from eating, chewing gum or drinking in the compounding area or bringing food, gum or drink into the compounding area.
 - (c) Artificial nails, nail extenders or nail polish may not be worn while working in the compounding area. Nails shall be neat and trim.
 - (d) Personnel protective equipment shall be put on in the following order:
 - 1. Low-lint, disposable shoe covers.
 - 2. Low-lint, disposable covers for head and facial hair that cover the ears and forehead.
 - 3. Face masks if compounding Category 2 compounded sterile preparations using laminar airflow system and biological safety cabinet.
 - 4. Eye shields, if required due to working with irritants or hazardous drugs.
 - (e) A hand hygiene procedure shall be performed after performing the protective equipment in par (d). The hand hygiene procedure includes all of the following:
 - 1. Wash hands and forearms up to the elbows with unscented soap and water for at least 30 seconds.
 - 2. Hands and forearms to the elbows shall be completely dried using either lint-free disposable towels or wipes.
 - 3. Prior to donning sterile gloves hand antisepsis shall be performed using an alcohol-based hand rub with sustained antimicrobial activity following the manufacturers labeled instructions and application times.
 - (f) Personnel shall wear one of the following:
 - 1. Non-cotton, low-lint sterile gown and sterile gloves.
 - 2. Non-cotton, low-lint gown, sterile sleeves and sterile gloves.
- (3) Gloves on hands and gauntlet sleeves on RABS shall be routinely inspected for holes, punctures, or tears and shall be replaced immediately if any are detected.
- (4) Disinfection of contaminated gloved hands shall be accomplished by wiping or rubbing sterile 70% isopropyl alcohol on all contact surface areas of the gloves and letting the gloved hands dry thoroughly. Routine application of sterile 70% isopropyl alcohol shall occur throughout the compounding process and whenever non-sterile surfaces, including vials, counter tops, chairs and carts, are touched.
- (5) When compounding personnel exit the buffer or segregated compounding area during a work shift, a nonsterile gown may be removed and retained in the ante area or segregated compounding area if not visibly soiled, to be worn again during the same work shift. Coveralls, sterile gowns, shoe covers, hair and facial hair covers, face masks, eye shields, gloves and sleeves shall be replaced with new ones before re-entering the compounding area.
- (6) Garbing items, including gowns, shall be segregated and stored before use in an enclosure to prevent contamination.
- (7) Coveralls and sterile gowns shall not be reused. Visibly soiled gowns shall be changed immediately.
- (8) Gloves shall be sterile and powder free and tested by the manufacturer for compatibility with alcohol disinfection.

15.33 Cleaning and Disinfecting the Compounding Area. (1) Compounding personnel are responsible determining the cleaning and disinfecting products to be used and for ensuring that the frequency of cleaning and disinfecting compounding area is done in accordance with the following minimum frequency:

- (a) Primary engineering control work surfaces, excluding isolators, at the beginning of each shift, end of each shift and before each batch, but not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring.
 - (b) Counters and work surfaces outside the primary engineering control in the buffer area, ante room and segregated compounding areas daily.
 - (c) Floors daily.
 - (d) Walls, ceilings and storage shelving monthly.
- (2) An isolator shall be cleaned each time it is opened and decontaminated once it is closed after each time it is opened. If cleaning occurs without opening, decontaminate after each cleaning cycle.
- (3) Cleaning and disinfecting sterile compounding areas shall occur on a regular basis at the intervals in sub. (1) or when any of the following occurs:
- (a) Spills occur.
 - (b) The surface is visibly soiled.
 - (c) Microbial contamination is known to have been or is suspected of having been introduced into the compounding area.
- (4) All cleaning and disinfecting practices and policies for the compounding area shall be included in written standard operating procedures and shall be followed by all compounding and environmental services personnel.
- (5) Cleaning, detergents and disinfection agents shall be selected and used with consideration of compatibilities, effectiveness and inappropriate or toxic residues. The selection and use of disinfectants shall be guided by microbicidal activities, inactivation by organic matter, residue, and shelf life. Disinfectants shall have antifungal, antibacterial and antiviral activity. Sporicidal agents shall be used at least weekly to clean compounding areas.
- (6) Storage sites for compounding ingredients and supplies shall remain free from dust and debris.
- (7) Floors, walls, ceiling and shelving in the classified and segregated compounding areas are cleaned when no aseptic operations are in progress. Cleaning shall be performed in the direction from cleanest to dirtiest areas.
- (8) All cleaning tools and materials shall be sterile, low-lint and dedicated for use in the buffer room, ante room and segregated compounding areas. If cleaning tools and materials are reused, procedures shall be developed based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bioburden of the area being cleaned.
- (9) Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent delivered from a spray bottle or other suitable delivery method. After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used for compounding purposes.
- (10) Entry points on bags and vials shall be wiped with small sterile 70% isopropyl alcohol swabs or comparable method for disinfecting, allowing the isopropyl alcohol to dry before piercing stoppers with sterile needles and breaking necks of ampuls. The surface of the sterile

70% isopropyl alcohol swabs used for disinfecting entry points of sterile package and devices may not contact any other object before contacting the surface of the entry point. Particle generating material may not be used to disinfect the sterile entry points of packages and devices. (11) When sterile supplies are received in sealed pouches designed to keep them sterile until opening, the sterile supplies may be removed from the covering pouches as the supplies are introduced into the ISO Class 5 primary engineering control without the need to disinfect the individual sterile supply items.

15.34 Urgent use compounded sterile preparations.

- (1) The compounding process shall be a continuous process that does not exceed one hour, unless required for the preparation.
- (2) Administration shall begin within one hour of preparation of the completion of the preparation.
- (3) Aseptic technique shall be followed during preparation, and procedures shall be used to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other compounded sterile products.
- (4) Unless immediately and completely administered by the person who prepared the compounded sterile preparation or immediate and complete administration is witnessed by the preparer, the compounded sterile preparation shall have a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation and the 1 hour BUD and time.

15.35 Sterilization methods.

- (1) Sterilization methods employed shall sterilize while maintaining its physical and chemical stability and the packaging integrity of the compounding sterile preparations. The efficacy of sterilization and depyrogenation of container closure systems performed in the pharmacy shall be established, documented, and reproducible.
- (2) Pre-sterilization requirements shall meet all of the following:
 - (a) During all compounding activities that precede terminal sterilization, including weighing and mixing, compounding personnel shall be garbed and gloved in the same manner as when performing compounding in an ISO Class 5 environment. All pre-sterilization procedures shall be completed in an ISO Class 8 or better environment.
 - (b) Immediately before use, all nonsterile measuring, mixing, and purifying devices used in the compounding process shall be thoroughly rinsed with sterile, pyrogen-free water and then thoroughly drained or dried.
- (3) Sterilization shall be performed utilizing one of the following methods:
 - (a) *Sterilization by filtration.* Sterilization by filtration involves the passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent. Filtration may not be used when compounding a suspension when the suspended particles are removed by the filter being used. This method shall meet all of the following:
 1. Sterile filters used to sterile filter preparations shall meet all of the following requirements:
 - a. Be pyrogen-free and have a nominal pore size of 0.22 microns.
 - b. Be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of *Brevundimonas diminuta* per square centimeter of upstream

filter surface area under conditions similar to those in which the compounded sterile preparations will be filtered.

c. Be chemically and physically stable at the compounding pressure and temperature conditions.

d. Have sufficient capacity to filter the required volumes.

e. Yield a sterile filtrate while maintaining pre-filtration pharmaceutical quality, including strength of ingredients of the specific compounded sterile preparations

2. The filter dimensions and liquid material to be sterile filtered shall permit the sterilization process to be completed rapidly without the replacement of the filter during the filtering process.

3. When compounded sterile preparations are known to contain excessive particulate matter, one of the following shall occur:

a. A pre-filtration step using a filter of larger nominal pore size.

b. A separate filter of larger nominal pore size placed upstream of the sterilizing filter to remove gross particulate contaminants before the compounding sterile compound is passed through the sterilizing grade filter.

4. Sterilization by filtration shall be performed entirely within an ISO Class 5 or better air quality environment.

5. Filter units used to sterilize compounded sterile preparations shall be subjected to the manufacturers' recommended post-use integrity test.

(b) *Sterilization by steam heat.* The process of thermal sterilization using saturated steam under pressure shall be the method for terminal sterilization of aqueous preparations in their final, sealed container closure system. The effectiveness of steam sterilization shall be established and verified with each sterilization run or load by using biological indicators, physicochemical indicators and integrators. This method shall meet all of the following:

1. All materials shall be directly exposed to steam under adequate pressure for the length of time necessary, as determined by use of appropriate biological indicators, to render the items sterile. The duration of the exposure period shall include sufficient time for the compounded sterile preparation to reach the sterilizing temperature.

2. The compounded sterile preparation and other items shall remain at the sterilizing temperature for the duration of the sterilization period. The sterilization cycle shall be designed to achieve a SAL of 10^{-6} .

3. Compounded sterile preparations shall be placed in trays which allow steam to reach the compounded sterile preparations without entrapment of air. Paper, glass and metal devices or items shall be wrapped in low lint protective fabric, paper or sealed in envelopes that will permit steam penetration and prevent post sterilization microbial contamination.

4. Immediately before filling ampules and vials, solutions shall be passed through a filter having a nominal pore size of not larger than 1.2 microns for removal of particulate matter.

5. Sealed containers shall be able to generate steam internally. Stoppered and crimped empty vials shall contain a small amount of moisture to generate steam.

Deep containers, including beakers and graduated cylinders, shall be placed on their sides to prevent air entrapment or have a small amount of water placed in them.

6. Porous materials and items with occluded pathways shall only be sterilized by steam if the autoclave chamber has cycles for dry goods.

7. The steam supplied shall be free of contaminants and generated using clean water.

8. The seals on the doors of autoclave chambers shall be examined visually every day they are used for cracks or damage and the seal surfaces shall be kept clean.

9. A data recorder or chart shall be used to monitor each cycle and the data shall be reviewed to identify cycle irregularities in temperature or exposure time.

10. Materials in direct contact with the compounded sterile preparation shall undergo a depyrogenation process before being sterilized using steam heat unless the materials used are certified to be pyrogen-free.

(c) *Sterilization by dry heat.* Dry heat sterilization shall be used only for those materials that cannot be sterilized by steam or filtration. The effectiveness of dry heat sterilization shall be verified using appropriate biological indicators and temperature sensing devices. This method shall meet all of the following:

1. The duration of the exposure period shall include sufficient time for the compounding sterile preparation or items to reach the sterilizing temperature. The compounded sterile preparation and items shall remain at the sterilizing temperature for the duration of the sterilization period.

2. Heated air shall be evenly distributed throughout the chamber.

3. Sufficient space shall be left between materials to allow for good circulation of the hot air.

4. The oven shall be equipped with temperature controls and a timer.

5. A data recorder or chart shall be used to monitor each cycle and the data shall be reviewed to identify cycle irregularities in temperature or exposure time.

6. Materials shall first undergo a depyrogenation process before being sterilized using dry heat, unless the materials used are certified to be pyrogen-free.

(4) Dry heat depyrogenation shall be used to render glassware and other thermostable containers pyrogen free. The duration of the exposure period shall include sufficient time for the items to reach the depyrogenation temperature. The items shall remain at the depyrogenation temperature for the duration of the depyrogenation period. The effectiveness of the dry heat depyrogenation cycle shall be established and verified annually using endotoxin challenge vials to demonstrate that the cycle is capable of achieving at least a 3-log reduction in endotoxins.

15.36 Inspection, sterility testing and antimicrobial effectiveness.

(1) PHYSICAL INSPECTION. (a) At the completion of compounding, the compounded sterile preparation shall be inspected by performing all of the following:

1. Visually inspect the container closure for leakage, cracks in the container or improper seals.

2. Visually check the compounded sterile preparation for phase separation.

3. Each individual injectable unit shall be inspected against a lighted white background and a black background for evidence of visible particulates or other foreign matter or discoloration.

(b) For compounded sterile preparations which will not be dispensed promptly after preparation, an inspection shall be conducted immediately before it is dispensed for any defects, including precipitation, cloudiness or leakage, which may develop during storage.

(c) Compounded sterile preparations with any observed defects shall be immediately discarded or marked and segregated from acceptable units in a manner that prevents them from being dispensed.

(2) STERILITY TESTING.

(a) The membrane filtration method shall be used for sterility testing unless it is not possible due to the compounded sterile preparation formulation. The direct inoculation of the culture method shall be used when the membrane filtration method is not possible.

(b) If a preparation may be needed before the results of sterility testing have been received, the pharmacy shall daily observe the incubating test specimens and immediately recall the dispensed preparations when there is any evidence of microbial growth in the test specimens. The patient and the prescriber to whom a potentially contaminated compounded sterile preparation was administered shall be notified immediately of the potential risk.

(c) Positive sterility test results shall prompt a rapid and systematic investigation into the causes of the sterility failure, including identification of the contaminating organism and any aspects of the facility, process or personnel that may have contributed to the sterility failure. The investigation and resulting corrective actions shall be documented.

(d) All Category 2 compounded sterile preparations made from one or more nonsterile ingredients, except those for inhalation and ophthalmic administration, shall be tested to ensure that they do not contain excessive bacterial endotoxins.

(e) Notwithstanding par. (d), a compounded sterile preparation does not need to be tested for bacterial endotoxins if the material is stored under cool and dry conditions and one of the following:

1. The certificate of analysis for the nonsterile ingredient lists the endotoxins burden, and that burden is found acceptable.
2. The pharmacy has predetermined the endotoxins burden of the nonsterile ingredient and that burden is found acceptable.

(3) ANTIMICROBIAL EFFECTIVENESS. Compounded sterile preparations containing a preservative shall pass an antimicrobial effectiveness testing with the results obtained on the specific formulation before any of the compounded sterile preparation is dispensed. The test may be conducted only once on each formulation in the particular container-closure system in which it will be stored or dispensed. The antimicrobial effectiveness test shall occur at one of the following times:

(a) At the completion of the sterility test.

(b) At the time of preparation for compounded sterile preparations which have not undergone a sterility testing.

15.37 Beyond Use Dating.

(1) Sterility and stability considerations shall be taken into account when establishing a BUD. The following dates and times for storage and initiation of administration of the compounded sterile preparations shall apply:

(a) For compounded sterile preparations including components from conventionally manufactured products, the BUD shall not exceed the shortest expiration of any of the starting components. If the compounded sterile preparation includes non-conventionally manufactured products, the BUD may not exceed the shortest BUD of any of the starting components.

(b) For Category I compounded sterile preparations, one of the following:

1. May not exceed 12 hours when the preparation is stored at controlled room temperature.
2. May not exceed 24 hours when the preparation is stored in a refrigerator.

(c) For aseptically prepared Category 2 compounded sterile preparations, one of the following:

1. Prepared with one or more nonsterile ingredients, no preservative added and no sterility testing performed, one of the following:
 - a. Within 4 days when the preparation is stored at controlled room temperature.
 - b. Within 7 days when the preparation is stored in a refrigerator.
 - c. Within 45 days when the preparation is stored in a freezer.
2. Prepared only with sterile ingredients, no preservative added and no sterility testing performed, one of the following:
 - a. Within 6 days when the preparation is stored at controlled room temperature.
 - b. Within 9 days when the preparation is stored in a refrigerator.
 - c. Within 45 days when the preparation is stored in a freezer.
3. Prepared with sterile ingredients, no preservative added and sterility testing performed, one of the following:
 - a. Within 28 days when the preparation is stored at controlled room temperature.
 - b. Within 42 days when the preparation is stored in a refrigerator.
 - c. Within 45 days when the preparation is stored in a freezer.
4. Prepared with sterile ingredients, preservative added and no sterility testing, one of the following:
 - a. Within 28 days when the preparation is stored at controlled room temperature.
 - b. Within 42 days when the preparation is stored in a refrigerator.
 - c. Within 45 days when the preparation is stored in a freezer.
5. Prepared with sterile ingredients, preservative added and sterility testing, one of the following:
 - a. Within 42 days when the preparation is stored at controlled room temperature.
 - b. Within 42 days when the preparation is stored in a refrigerator.
 - c. Within 45 days when the preparation is stored in a freezer.

(d) For terminally sterilized Category 2 compounded sterile preparations, one of the following:

1. Prepared with no preservative added and no sterility testing performed, one of the following:

- a. Within 14 days when the preparation is stored at controlled room temperature.
 - b. Within 28 days when the preparation is stored in a refrigerator.
 - c. Within 45 days when the preparation is stored in a freezer.
2. Prepared with no preservative added and sterility testing performed, one of the following:
- a. Within 28 days when the preparation is stored at controlled room temperature.
 - b. Within 42 days when the preparation is stored in a refrigerator.
 - c. Within 45 days when the preparation is stored in a freezer.
3. Prepared with preservative added and no sterility testing performed, one of the following:
- a. Within 28 days when the preparation is stored at controlled room temperature.
 - b. Within 42 days when the preparation is stored in a refrigerator.
 - c. Within 45 days when the preparation is stored in a freezer.
4. Prepared with preservative added and sterility testing performed, one of the following:
- a. Within 42 days when the preparation is stored at controlled room temperature.
 - b. Within 42 days when the preparation is stored in a refrigerator.
 - c. Within 45 days when the preparation is stored in a freezer.

(2) The administration dates and times established in sub. (1) may not be exceeded or extended for compounded sterile preparations without verifiable supporting valid scientific sterility and stability information that is directly applicable to the specific preparation or compound.

(3) For compounded sterile preparations which have been assigned a BUD based upon storage in a freezer, the integrity of the container closure system with the specific compounded sterile preparation in it shall have been demonstrated for 45 days at frozen storage. The container closure integrity test may be conducted only once on each formulation in the specific container closure system in which it will be stored or dispensed.

15.38 Training and evaluation. (1) GENERAL. The managing pharmacist, all pharmacists, pharmacy technicians, pharmacy interns and pharmacy externs involved in compounding sterile preparations shall successfully complete didactic and practical training. The didactic and practical training shall be done before any compounding personnel initially prepares compounded sterile preparations and annually thereafter and shall include all of the following:

- (a) Hand hygiene and garbing.
- (b) Cleaning and disinfection.
- (c) Measuring and mixing.
- (d) Aseptic manipulation.
- (e) Cleanroom behavior.
- (f) Sterilization and depyrogenation.
- (g) Use of equipment.
- (h) Documentation.
- (i) Use of primary engineering controls.

(2) EVALUATION. Compounding personnel shall successfully complete an initial and annual evaluation which includes all of the following:

- (a) Visual observation of hand hygiene and garbing.
- (b) Visual observation of aseptic technique.
- (c) Gloved fingertip and thumb sampling.
- (d) Media-fill tests.

(3) GLOVED FINGERTIP. Successfully gloved and thumb sampling is measured by samplings resulting in zero colony-forming units no fewer than three times. Sampling shall be performed on sterile gloves inside of an ISO Class 5 primary engineering control. Gloved fingertip and thumb sampling in a RABS or an isolator shall be taken from the sterile gloves placed over the gauntlet gloves. When gloved fingertip sample results exceed action levels defined by the pharmacy, a review of hand hygiene and garbing procedures, glove and surface disinfection procedures and work practices shall be performed and documented.

(5) RECORDS. The pharmacy shall maintain written policies and procedures for the initial and ongoing training and evaluation of persons involved in compounding sterile preparations. Documentation of all training, assessments, gloved fingertip tests and media-fill simulations shall be maintained by the pharmacy for 5 years and made available to the Board upon request.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

PHARMACY RULES LIST

Current Rule Projects

Legislative Review (Will be presented to Board for adoption in July)

Phar 1, 8 (definitions; misplaced word “emergency”)
Phar 2, 4 (application and examinations)
Phar 5 (renewal/reinstatement)
Phar 8 (Act 199)

Drafting

Phar 6 (Temperature/Humidity) – Anticipate holding Public Hearing in the fall
Phar 7.10 (Act 290) – Anticipate holding Public Hearing in the fall
Phar 14 (Medical Oxygen) – Anticipate holding Public Hearing in the fall
Phar 15 (Compounding) – Anticipate holding Public Hearing in the fall
Phar 7 (Practice of Pharmacy)

Projects identified on previous Goals Lists which fall under this chapter

7.015 Technicians
7.09 (1) (b) Automated Dispensing Systems (include jails, prisons, etc)
7.02 Prescription Labels
Pharmacists working from home
Patient consultation
Collaborative Practice Agreements

Potential Rule Projects

Required rules pursuant to 450.073 (3), Wis. Stats. (Electronic track and trace)
Compliance with Drug Supply Chain Security Act

- Third Party Logistics Providers
- Wholesale Distributor Requirements
- Product Tracing Requirements

Phar 12 Update (including security requirements)
Phar 13 Clean-Up
Phar 17.02 (Intern)
Phar 1 (add definitions apply to chapter 17)
Out of state pharmacies



Wednesday, May 11, 2016

Thaddeus Schumacher, Chair
Wisconsin Pharmacy Examining Board
P.O. Box 8935
Madison, Wisconsin 53708-8935

Dear Dr. Schumacher,

RE: PSW Legislative Breakfast, Friday, August 26, 2016

The Pharmacy Society of Wisconsin (PSW) is hosting an annual Legislative Breakfast from 7 am to 8 am on Friday, August 26, 2016 in the Wisconsin Dells. This breakfast is part of our 2016 Annual Meeting. We anticipate an attendance of over 150 pharmacists, pharmacy technicians, and pharmacy students. The agenda will include a discussion of several pharmacy-related legislative and regulatory priorities.

On behalf of the Board of Directors and staff of the Pharmacy Society of Wisconsin, I would like to extend an invitation to you to attend this event and address our members. They would appreciate an update from the Pharmacy Examining Board on the recent rule revisions being considered for Phar 7 and Phar 15.

A summary of the breakfast is provided below.

Date: Friday, August 26, 2016

Location: Kalahari Resort and Convention Center, 1305 Kalahari Drive, Wisconsin Dells

Time: 7:00 am to 8:00 am

Annual Meeting Agenda: <http://www.pswi.org/Education/2016-Annual-Meeting>

Thank you for your consideration of our request to attend the 2016 PSW Legislative Breakfast.

Sincerely,

A handwritten signature in cursive script that reads "Anna Legreid Dopp".

Anna Legreid Dopp, PharmD
Vice President of Public Affairs
Pharmacy Society of Wisconsin



National Association of Boards of Pharmacy

1600 Feehanville Drive • Mount Prospect, IL 60056-6014
Tel: 847/391-4406 • Fax: 847/391-4502
Web Site: www.nabp.net

nabp

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY
FROM: Carmen A. Catizone, Executive Director/Secretary
DATE: April 28, 2016
RE: 2016 NABP Program Review and Training Session - *Reminder to Register Now!*

The National Association of Boards of Pharmacy® (NABP®) is pleased to announce that we will be hosting our Annual Program Review and Training session for board staff members who are new or seeking a refresher course on NABP programs and services.

The Program Review and Training session will be held at NABP Headquarters in Mount Prospect, IL, on June 28-29, 2016, beginning with a group dinner on Tuesday, June 28, 2016, at 6 PM and following with the training session on Wednesday, June 29, 2016, from 8:30 AM to 4 PM.

The interactive sessions between NABP staff and board representatives will provide an overview of the following NABP programs and services:

- Electronic Licensure Transfer Program® (e-LTP™) and license verification
- NABP Clearinghouse/National Practitioner Data Bank reporting
- Competency Assessment Programs and Services
 - North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®)
 - Pharmacist Assessment for Remediation Evaluation® (PARE®)
 - NABP e-Profile Connect: NAPLEX/MPJE eligibility; score reporting and Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification; and online reporting to candidates
 - FPGEC Certification Program including the application, examination, and certification process
 - Pharmacy Curriculum Outcomes Assessment® (PCOA®) program
- Accreditation Programs and Services
 - Verified Pharmacy Program® (VPP®) and inspection sharing network
 - Verified Internet Pharmacy Practice Sites® (VIPPS®); Veterinary-Verified Internet Pharmacy Practice Sites® (Vet-VIPPS®); Verified-Accredited Wholesale Distributors® (VAWD®); durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation; and the NABP e-Advertiser Approval^{CM} Program
 - Community pharmacy practice accreditation
- Internet Drug Outlet Identification program and the .Pharmacy Top-Level Domain Program
- AWA_R_XE® Prescription Drug Safety Program
- CPE Monitor® service and the continuing pharmacy education (CPE) reporting tool for the boards
- NABP PMP InterConnect®
- Member Relations and Government Affairs
- Professional Affairs
- Communications

We can accommodate a total of 20 participants, so please contact us at your earliest convenience to ensure we can hold a place for your staff member. Currently, NABP plans to pay for reasonable transportation costs, one night's hotel accommodation, and three meals for one participant per board. If a member from your board is attending the training session, please have the participant complete and submit the attached hotel reservation form so that we may confirm his or her attendance and reserve a room at the Hilton Chicago/Northbrook hotel in Northbrook, IL.

Hotel Information/Reservations

Following receipt of the hotel reservation form, NABP will reserve rooms for participants at:

**Hilton Chicago/Northbrook
2855 N Milwaukee Ave
Northbrook, IL 60062
Phone: 847/480-7500**

NABP's master account at the hotel includes only room and room tax. Therefore, if you wish to charge meals or other expenses during your stay, please be sure to bring a personal credit card that can be imprinted for the hotel's use. Should you decide to stay in the Chicago area for additional nights, NABP will reserve a room for you if you supply a credit card guarantee. However, all charges for additional nights are the responsibility of the individual and will not be paid by NABP.

Travel Arrangements

NABP has engaged the services of **Options Travel, located in Des Plaines, IL**, to handle the airline reservations for all Association meetings. **Association policy requires that all NABP-related travel arrangements be made through this designated agent. Tickets booked elsewhere will not be reimbursed.** We ask that you plan to arrive in Chicago by 4 PM the evening of Tuesday, June 28, 2016, and plan your departure for any time after 5 PM on Wednesday, June 29, 2016. When you are ready to make your airline reservations to attend the training session, please contact:

**Options Travel
800/544-8785
Meeting Code 0401**

(Please mention the meeting code when making your flight arrangements.)

All Options Travel agents are aware that you will be contacting them for airline reservations to Chicago O'Hare International Airport and can help you book your tickets. Your airfare will be charged directly to the NABP master account and you may, of course, keep all frequent flyer mileage earned during your trip. Please note that airfare exceeding \$600 must be pre-approved by NABP.

We look forward to seeing a member from your state board and anticipate a productive meeting in June! Please feel free to call Julie Burstyn, human resources coordinator, at 800/774-6227 or directly at 847/391-4542 if you have any questions or need additional information.

Thank you for your time. We look forward to hearing from you.

Attachment

cc: NABP Executive Committee