Wisconsin Department of Safety and Professional Services
Division of Policy Development
4822 Madison Yards Way, 2nd Floor
PO Box 8366
Madison WI 53708-8366

Phone: 608-266-2112
Web: http://dsps.wi.gov
Email: dsps@wisconsin.gov

**Scott Walker, Governor**
**Laura Gutiérrez, Secretary**

# PHARMACY RULES COMMITTEE
# of the
# PHARMACY EXAMINING BOARD

**Room N208, 4822 Madison Yards Way, 2nd Floor, Madison, WI 53705**
**Contact: Tom Ryan (608) 266-2112**
**September 27, 2018**

*Notice: The following agenda describes the issues that the Committee plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda.* ***A quorum of the Board may be present during any committee meetings.***

## AGENDA

## 8:30 A.M.

**OPEN SESSION – CALL TO ORDER**

**A. Approval of Agenda (1)**

**B. Legislation and Rule Matters – Discussion and Consideration (2-21)**

1) Sterile Product Tech-Check-Tech
2) Phar 7
   a. Automated Dispensing Systems that Dispense to Authorized Individuals in an Inpatient Health Care Facility
   b. Automated Dispensing Systems that Dispense Directly to Patients
3) Pilot Projects

C. Public Comments

**ADJOURNMENT**

**********

MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held at 4822 Madison Yards Way, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112.

# State of Wisconsin
# Department of Safety & Professional Services

## AGENDA REQUEST FORM

| 1) Name and Title of Person Submitting the Request: | 2) Date When Request Submitted: |
|---|---|
| **Sharon Henes**<br>**Administrative Rules Coordinator** | **18 September 2018**<br>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 Rules Committee**

| 4) Meeting Date: | 5) Attachments: | 6) How should the item be titled on the agenda page? |
|---|---|---|
| **27 September 2018** | ☐ Yes<br>☐ No | **Legislation and Rule Matters – Discussion and Consideration**<br>**1. Sterile Product Tech-Check-Tech**<br>**2. Phar 7**<br>**a. Automated dispensing systems that dispense to authorized individuals in an inpatient health care facility.**<br>**b. Automated dispensing systems that dispense directly to patients**<br>**3. Pilot Projects** |

| 7) Place Item in: | 8) Is an appearance before the Board being scheduled? | 9) Name of Case Advisor(s), if required: |
|---|---|---|
| ☒ Open Session<br>☐ Closed Session | ☐ Yes<br>☐ No | |

**10) Describe the issue and action that should be addressed:**

**11) Authorization**

*Sharon Henes*

**Signature of person making this request** **Date**

**Supervisor (if required)** **Date**

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

**Directions for including supporting documents:**

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

May 10th, 2018

Aurora West Allis Medical Center
8901 W Lincoln Ave.
West Allis, WI 53227

Dear Pharmacy Examining Board,

Wisconsin law mandates that a pharmacist perform the final product verification for all medication products prior to the medication being dispensed or administered to the patient.[1] Tech-check-tech pilot programs are variances granted by the Wisconsin Pharmacy Examining Board (PEB) that allow for a trained pharmacy technician to perform the final product verification check, instead of a pharmacist.[2] Currently, tech-check-tech (TCT) pilot programs exist for the community setting and institutional setting. However, neither of these programs include tech-check-tech for sterile products.[3]

Last month, Aurora Health Care presented to the PEB a proposed new pilot program for sterile products. During the meeting there was good discussion regarding the proposed new pilot program. A few of the main areas of discussion were on technician training requirements, eligible medications, and automation mechanisms. The revised document now includes required technician certification and a minimum of 1,000 hours of experience in the sterile products area. The document also now excludes medications for any patients under the age of 18 years old and antineoplastic agents for all patients. Lastly, multiple automation mechanisms should be used; however a minimum of bar-code scanning must be utilized for all eligible medications.

Please see my attached PEB pilot program for sterile products document for further details on this new pilot program. The layout of the document is very similar to the current PEB institutional tech-check-tech pilot program document. I would welcome the opportunity to discuss more details about this potential new pilot program at a future PEB meeting.

Sincerely,

Rachel Miller, PharmD

Reference:


1. Pharmacy Examining Board: Chapter Phar 7.01.
2. Pharmacy Examining Board: Chapter 450.02 (3r).
3. Pharmacy Examining Board: Institutional Tech-Check-Tech Pilot Program Information.

# Pharmacy Examining Board

**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: DSPSCredPharmacy@wisconsin.gov
Website: http://dsps.wi.gov

Sterile Products Tech-Check-Tech Pilot Program
Information

**Authority:**
Pursuant to Wisconsin Stat. § 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 Pilot Program at any time and participants shall remain in the Pilot Program at the discretion of the Board.**

**Purpose:** The purpose of institutional tech-check-tech (TCT) pilot program is to study the safety, quality, and efficiency of a pharmacy technician to make a final check of another pharmacy technician on the accuracy and correctness of the final dispensed medication. Implementation of a tech-check-tech program is not intended to reduce pharmacist staffing levels but is intended to increase the availability of a pharmacist for involvement for other patient care activities.

**Waives:** Phar 7.01(1)(c) and (d), and 7.015(3) (a) and (4), Phar 15.09 (5), Wis. Admin. Code

**Pilot Duration**: TBD

**Pharmacy Eligibility:**
1. The pharmacy shall be located and licensed in the state of Wisconsin.
2. A supervising pharmacist, licensed in the state of Wisconsin, shall be identified for each pharmacy to be accountable for the operations and outcomes of the TCT program. The final checks made by the validated technicians will be considered delegated acts of the supervising pharmacist. In the event of change of the supervising pharmacist, the managing pharmacy shall notify the Board of change within 5 days on a Board approved form.

**Program Requirements:**
1. Validated Technicians
   a. Initial Validation: In order to become a validated technician, the following requirements must be met and maintained:
      i. Employment averaging at least 20 hours per week at the pilot pharmacy
      ii. A minimum of 2000 hours of experience as a pharmacy technician and at least 6 months of employment at the pilot pharmacy
      iii. A minimum of 1000 hours of experience as a pharmacy technician working in the sterile products area
      iv. Certified pharmacy technician (CPhT) or equivalent
      v. Completion of a didactic and practical training curriculum that includes the following:
         1. Elements of a package label (i.e. drug name, dose, dosage form, control or lot number and expiration date)
         2. Medication and pharmacy abbreviations needed to match ordered medication with dispensed medication (e.g., mg, mEq, ER, IR, tab, cap)
         3. Calculations review specific to sterile products.
         4. Common dispensing medication errors and concepts (i.e. wrong medication, wrong dose, wrong dosage form, expired medication, wrong beyond use date, wrong product labeling, look-alike sound-alike errors, high-alert medications).
         5. Organizational policies and procedures on reporting of medication errors
         6. Overview of the organizations medication use process (i.e. procurement, ordering, dispensing, administration, and monitoring).
         7. A practical training designed to assess the competency of the technician prior to starting the validation process.
      vi. Completion of the following validation process:
         1. The technician being validated shall make a final check on the work of another technician for accuracy and correctness of a minimum of 250 final checks over a minimum of 10 separate days and achieve an accuracy rate of 99.8% or greater.

2. At least one occurrence each of wrong drug, wrong dose, wrong dosage form, wrong product labeling, wrong beyond use date and, expired dose shall be artificially introduced by a pharmacist who will ensure they are removed prior to delivery to a patient care area.
3. A pharmacist shall audit 100% of the final checks made by the technician during the validation process.

b. Re-validation:

i. An assessment of validated technician accuracy shall be completed quarterly of the previous 12 months of TCT final checks. A technician shall be revalidated if a validated technician fails to maintain a final check accuracy rate of 99.8% or has not performed TCT final checks within the last 6 months.

2. Eligible Medications
   a. Medications are to be sterile products, which may include compounded, packaged or manufactured medications with the following exceptions:
      i. Medications for patients less than 18 years old
      ii. Antineoplastic
   b. Preferably, multiple automation mechanisms should be utilized, however at a minimum all medications must be prepared utilizing bar-code scanning
   c. The supervising pharmacist shall ensure a process is in place for a pharmacist to prospectively review the clinical appropriateness of the medication order prior to leaving the pharmacy.
   d. The medication shall be administered by an individual authorized to administer medications at the institution where the medication is administered.
3. Quality Assurance

   a. A minimum of 5% of all TCT final checks shall be audited by a licensed pharmacist each day that TCT is performed.

   b. The accuracy of each validated technician shall be tracked individually.
4. Policies and Procedures

   a. Each pharmacy shall maintain policies, procedures, and training materials for the TCT program that will be made available to the Board upon request.
5. Records

   a. Each pharmacy shall maintain records for 5 years, available to the Board upon request, of the following:
      i. All initial validation and revalidation records of each validated technician that include the dates that the validation occurred, the number of final checks performed, the number of final check errors, and overall accuracy rate.
      ii. Names the supervising TCT pharmacist including start date and end date of supervision responsibilities.
      iii. Daily quality assurance logs of the 5% pharmacist TCT audit including the name of technician, total number of final checks performed, number of final checks audited by the pharmacist, percentage of final checks audited by pharmacist, number of final check errors identified, and type of error (i.e., wrong drug, wrong dose, wrong dosage form, wrong product labeling, wrong beyond use date and, expired dose)
6. Reporting Requirements
   a. The supervising pharmacist of the tech-check-tech program shall annually submit to the Board, on a form approved by the Board, all of the following:
      i. Total number of TCT final checks
      ii. Total number TCT final checks audited by a pharmacist
      iii. Total number of errors identified in the TCT final check pharmacist audit that were of the type of wrong drug, wrong dose, wrong dosage form, wrong product labeling, wrong beyond use date and, expired dose
      iv. Total number of pharmacist hours reallocated to other patient care activities and description of those activities

**Application:** The managing pharmacist shall submit a Board approved application and receive approval of the Board to participate in the Pilot Program.

## Automated Dispensing Systems

Commented [l1]: Core principles…
Accountability for everything (integrity, stability, correct drugs, etc.)
A pharmacist

**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 sanitorium, 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.

NABP Model Rules

**Section 9. Automated Pharmacy Systems.**

(a) Automated Pharmacy Systems can be utilized in licensed pharmacies and Shared Pharmacy Services Pharmacies located within an Institutional Facility or clinic. A Pharmacist is not required to be physically present at the site of the Automated Pharmacy System if the system is supervised electronically by a Pharmacist. Automated Pharmacy Systems shall comply with the following provisions.

(1) Documentation as to type of equipment, serial numbers, content, policies and procedures, and Shared Pharmacy Services Pharmacy location shall be maintained in the Pharmacy for review . Such documentation shall include, but is not limited to:
   (i) name and address of the Pharmacy and the Shared Pharmacy Services Pharmacy where the Automated Pharmacy System(s) is being used;
   (ii) Manufacturer's name and model;
   (iii) description of how the Automated Pharmacy System is used;
   (iv) quality assurance procedures to determine continued appropriate use of the Automated Pharmacy System;
   (v) policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, and malfunction; and
   (vi) documentation evidencing that the Automated Pharmacy System has been tested prior to initial use and on a periodic basis at each location to ensure that the Automated Pharmacy System is operating properly.

(2) Automated Pharmacy Systems should be used only in settings where there is an established program of Pharmacist Care that ensures medication orders or Prescription Drug Orders are reviewed by a Pharmacist in accordance with established policies and procedures and good Pharmacist Care. [1]
   (i) A Pharmacist shall be accessible to respond to inquiries or requests pertaining to Drugs Dispensed from the Automated Pharmacy System.[2]

(ii) Any Pharmacy that maintains an Automated Pharmacy System for the purposes of remote Dispensing to outpatients[3] shall maintain a video/auditory communication system to provide for effective communication between the patient and the Pharmacist; the video/auditory communication system shall allow for the appropriate exchange of oral and written communication and Patient Counseling; if the video/auditory communication system malfunctions, then all operations of the Automated Pharmacy System shall cease until the system is fully functional.

(3) All policies and procedures must be maintained in the Pharmacy responsible for the Automated Pharmacy System and , if the Automated Pharmacy System is being used at a different location, at that location as well.

(4) Automated Pharmacy Systems shall have adequate security systems and procedures, evidenced by written policies and procedures[4], to:

---

[1] Each state should determine whether or not the Dispensing of a "first dose" or an "emergency dose" may take place without prior order review by a Pharmacist but with appropriate security and patient medication management controls in place.

[2] In order to facilitate communication between the Pharmacy and the site where the Automated Pharmacy System is located, a Pharmacy should provide a toll-free telephone number so that the Pharmacist is accessible at all times the Automated Pharmacy System is operational.

[3] Although an "outpatient" generally refers to a Person who receives Drugs for use outside of an Institutional Facility, the definition of "outpatient" must be defined by each state. For example, although the *Model Act* classifies penal institutions as a type of Institutional Facility and therefore its inmates as inpatients, the Pharmacist is exempt from providing Patient Counseling. However, some states may consider inmates of penal institutions as outpatients and therefore should decide if a video/audio communication system is required in such facilities so that the Pharmacist is able to provide Patient Counseling.

[4] The use of Automated Pharmacy Systems requires written policies and procedures in place prior to installation to ensure safety, accuracy, security, and patient confidentiality and to define access and limits to access to equipment and medications.

(i) prevent unauthorized access;
(ii) comply with federal and state regulations; and
(iii) prevent the illegal use or disclosure of Protected Health Information.

(5) Records and/or electronic data kept by Automated Pharmacy Systems shall meet the following requirements.
(i) All events involving the contents of the Automated Pharmacy System must be recorded electronically.
(ii) Records must be maintained by the Pharmacy and must be readily available to the Board. Such records shall include:
(A) identity of 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; and
(F) such additional information as the Pharmacist-in-Charge may deem necessary.

(6) Access to and limits on access (eg, security levels) to the Automated Pharmacy System must be defined by policy and procedures and must comply with state and federal regulations. [5]

(7) The Pharmacist-in-Charge shall have the responsibility to:
(i) assign, discontinue, or change access to the system;
(ii) ensure that access to the medications comply with state and federal regulations;
(iii) ensure that the Automated Pharmacy System is filled/stocked accurately and in accordance with established, written policies and procedures.

(8) The filling/stocking of all medications in the Automated Pharmacy System shall be accomplished by qualified personnel under the supervision of a licensed Pharmacist.

(9) A record of medications filled/stocked into an Automated Pharmacy System shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.[6]

(10) All containers of medications stored in the Automated Pharmacy System shall be packaged and labeled in accordance with federal and state laws and regulations.

(11) All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.

(12) The Automated Pharmacy System shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the

---

[5] This section anticipates that decisions regarding which health care professionals may access the Automated Pharmacy System and the level of access allowed (eg, access to medications, access to patient profiles for viewing only, access to patient profiles for modification) will be left up to the individual(s) responsible for the Automated Pharmacy System; however, states may decide to take on this responsibility and define those who may have access to the system and the levels of access allowed.

[6] This section anticipates that states will allow non-Pharmacist personnel to fill/stock Automated Pharmacy Systems under a Pharmacist's supervision; however, the state may decide to only allow a Pharmacist to perform this function. Should the State allow non-Pharmacist personnel to perform this function, it should define the level of Pharmacist supervision necessary (eg, immediate, direct, or general).

Automated Pharmacy System, all in accordance with existing state and federal law.[7]

(13) The Automated Pharmacy System shall provide a mechanism for securing and accounting for wasted medications or discarded medications in accordance with existing state and federal law.

**"Vending" Dispensing Systems**

Iowa Rule

**7.12(4) Use of InstyMeds dispensing system.** A hospital located in an area of the state where 24-hour outpatient pharmacy services are not available within 15 miles of the hospital may implement the InstyMeds dispensing system in the hospital emergency department only as provided by this subrule.

a. Persons with access to the dispensing machine for the purposes of stocking, inventory, and monitoring shall be limited to pharmacists, pharmacy technicians, and pharmacist-interns.

b. The InstyMeds dispensing system shall be used only in the hospital emergency department for the benefit of patients examined or treated in the emergency department.

c. The dispensing machine shall be located in a secure and professionally appropriate environment.

d. The stock of drugs maintained and dispensed utilizing the InstyMeds dispensing system shall be limited to acute care drugs provided in appropriate quantities for a 72-hour supply or the minimum commercially available package size, except that antimicrobials may be dispensed in a quantity to provide the full course of therapy.

e. Drugs dispensed utilizing the InstyMeds dispensing system shall be appropriately labeled as provided in 657—subrule 6.10(1), paragraphs "a" through "g."

f. Prior to authorizing the dispensing of a drug utilizing the InstyMeds dispensing system, the prescriber shall offer the patient the option of being provided a prescription that may be filled at the pharmacy of the patient's choice.

g. When appropriate for an acute condition, the prescriber shall provide to the patient or the patient's caregiver a prescription for the remainder of drug therapy beyond the supply available utilizing the InstyMeds dispensing system. During consultation with the patient or the patient's caregiver, the prescriber shall clearly explain the appropriate use of the drug supplied, the need to have a prescription for any additional supply of the drug filled at a pharmacy of the patient's choice, and the need to complete the full course of drug therapy.

h. The pharmacy shall, in conjunction with the hospital emergency department, implement policies and procedures to ensure that a patient utilizing the InstyMeds dispensing system has been positively identified.

i. The hospital pharmacist shall review the printout of drugs provided utilizing the InstyMeds dispensing system within 24 hours unless the pharmacy is closed, in which case the printout shall be reviewed during the first day the pharmacy is open following the provision of the drugs. The purpose of the review is to identify any dispensing errors, to determine dosage appropriateness, and to complete a retrospective drug use review of any antimicrobials dispensed in a quantity

[7] The State may require that each licensed Pharmacy or facility have in place written policies and procedures to address situations in which medications removed from the system remain unused and must be secured and accounted for.

greater than a 72-hour supply. Any discrepancies found shall be addressed by the pharmacy's continuous quality improvement program.

# Pharmacy Examining Board


**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@dsps.wi.gov
Website: http://dsps.wi.gov


## Automated Technology Final Check Pilot Program Information

**Authority:**
Pursuant to Wisconsin Stat. § 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 Pilot Program at any time and participants shall remain in the Pilot Program at the discretion of the Board.**

**Purpose:** The purpose of the Automated Technology Final Check Pilot Program (ATFC) is to study the safety, quality, and efficiency of automated technology to make the final check on the accuracy and correctness of the final dispensed medication. Implementation of an Automated Technology Final Check Pilot Program is not intended to reduce pharmacist staffing levels but is intended to increase the availability of the pharmacist for involvement for other patient care activities.

**Waives:** Phar 7.01(1)(c) and (d), Wis. Admin. Code

**Pilot Duration**: October 1, 2016 to September 30, 2019 (or promulgation of rules whichever is sooner).

**Pharmacy Eligibility:**

1. The pharmacy shall be located and licensed in the state of Wisconsin.
2. A supervising pharmacist, licensed in the state of Wisconsin, shall be identified for each pharmacy to be accountable for the operations and outcomes of the ATFC program. The final checks made by the automated technology will be considered delegated acts of the supervising pharmacist. In the event of change of the supervising pharmacist, the managing pharmacy shall notify the Board of change within 5 days on a Board approved form.
3. The automated technology shall be located within the licensed pharmacy.

**Program Requirements:**

1. Automated Technology Validation
    a. Initial Validation: In order to become a validated automated technology, the following requirements must be met and maintained:
        i. The automated technology must use barcodes or machine readable technology to complete the final check.
        ii. The automated technology shall make a final check on the accuracy and correctness of at least 2500 final checks and achieve an accuracy rate of 99.8% or greater.
        iii. A pharmacist shall audit 100% of the final checks made by the automated technology during the validation process.
    b. Re-validation:
        i. The automated technology shall be revalidated if the software is upgraded or any component of the automated technology responsible for the accuracy of the final check is replaced, or serviced outside of the manufacturer's standard maintenance recommendations.
2. Eligible Medications
    a. Medications shall be contained in a final package from a manufacturer or if packaged in the pharmacy a licensed pharmacist has ensured that the packaging process results in a final package that is labeled with the correct drug name, dose, strength, form, control or lot number, and beyond use date.
    b. The supervising pharmacist shall ensure a process is in place for a pharmacist to prospectively review the clinical appropriateness of the medication order prior to leaving the pharmacy.
    c. The medication shall be administered by an individual authorized to administer medications at the institution where the medication is administered.

3. Policies and Procedures
    a. Each pharmacy shall maintain policies, procedures, and training materials for ATFC program that will be made available to the Board upon request. These policies and procedures shall include a plan for completing the manufacturer's recommended maintenance and quality assurance measures.
4. Records
    a. Each pharmacy shall maintain records for 5 years, available to the Board upon request, of the following:
        i. All initial validation and revalidation records of each automated technology that include the dates that the validation occurred, the number of final checks performed, the number of final check errors, and overall accuracy rate.
        ii. Names the supervising ATFC pharmacist including start date and end date of supervision responsibilities.
        iii. Documentation of the completion of the manufacturer's recommended maintenance and quality assurance measures
        iv. Documentation of the dates of all software upgrades
        v. Documentation of all service performed outside of the manufacture's standard maintenance recommendations
5. Reporting Requirements
    a. The supervising pharmacist of the ATFC program shall annually submit to the Board, on a form approved by the Board, all of the following:
        i. Total number of automated technology final checks
        ii. Total number of automated technology final checks audited by a pharmacist
        iii. Total number of errors identified in the automated final check pharmacist audit that were of the type of wrong drug, wrong dose, or wrong dosage form
        iv. Total number of pharmacist hours reallocated to other patient care activities and description of those activities

**Application:** The managing pharmacist shall submit a Board approved application and receive approval of the Board to participate in the Pilot Program.

# Pharmacy Examining Board

**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: DSPSCredPharmacy@dsps.wi.gov
Website: http://dsps.wi.gov

## Community Tech-Check-Tech Pilot Program Information

**Authority:**
Pursuant to Wisconsin Stat. § 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 Pilot Program at any time and participants shall remain in the Pilot Program at the discretion of the Board.**

**Purpose:** Wisconsin Administrative Rule 7.01 stipulates that a pharmacist or pharmacist-intern as directed and supervised by the pharmacist shall make a final check on the accuracy and correctness of the prescription. The purpose of community Tech-Check-Tech (cTCT) pilot program is to study the safety, quality, and efficiency of a pharmacy technician to make a final check of another pharmacy technician on the accuracy and correctness of the final dispensed medication. Implementation of a Tech-Check-Tech program is not intended to reduce pharmacist staffing levels but is intended to increase the availability of a pharmacist for involvement in other patient care activities.

**Pilot Duration**: November 1, 2016 – October 31, 2019 (or promulgation of rules, whichever is sooner).

**Pharmacy Eligibility:**

1. Licensed and located in the state of Wisconsin (independent, chain, or health-system)
2. Have a continuous quality improvement program, which means a system of standards and procedures to identify and evaluate quality related events, and to constantly enhance the efficiency and effectiveness of the structures and process of a pharmacy system that determine the outcomes of medication use.
3. Willingness to participate in the research studies of Community Tech-Check-Tech approved by the PEB
4. Patient consultation will include a procedure like "show and tell", which affords the pharmacist and patient a visual check of the medication before it is dispensed or inclusion of a description (i.e. color, shape, imprints) on the prescription label for the patient to visually check the medication after it is dispensed.

**Program Requirements:**

1. Validated Pharmacy Technicians
    a. Initial Validation: In order to become a validated pharmacy technician, the following requirements must be met and maintained:
        i. Age of 18 years or older
        ii. Employment status of greater than or equal to an average of 20 hours per week as a pharmacy technician at any pharmacy within the organization
        iii. A minimum of 2000 hours of experience as a pharmacy technician or completion of an accredited technician training program and at least 6 months of employment as a pharmacy technician at any pharmacy within the organization
        iv. Completion of a didactic and practical training curriculum that includes the following:
            1. Elements of a package label (i.e., drug name, dose, dosage form, control or lot number, and expiration date)
            2. Medication and pharmacy abbreviations needed to match ordered medication with dispensed medication (e.g., mg, mEq, ER, IR, tab, cap)
            3. Common dispensing medication errors and concepts (i.e., wrong medication, wrong dose, wrong dosage form, extra/insufficient quantity, omitted medications, expired medication, look-alike sound-alike errors, high-alert medications)
            4. Organizational policies and procedures on reporting of medication errors
            5. Overview of the organization's medication use process (i.e., procurement, ordering, dispensing, administration, and monitoring)
            6. A practical training designed to assess the competency of the technician prior to starting the validation process

v. Completion of the following validation process:
    1. The technician being validated shall make a final check on the work of another technician for accuracy and correctness of a minimum of 1000 final checks over a minimum of 5 separate days and achieve an accuracy rate of 99.8% or greater.
    2. A pharmacist shall audit 100% of the final checks made by the technician during the validation process.

b. Re-validation:
    i. An assessment of a validated pharmacy technician accuracy shall be completed quarterly of the previous 12 months of cTCT final checks. A technician shall be revalidated if a validated pharmacy technician fails to maintain a final check accuracy rate of 99.8% or has not performed cTCT final checks within the last 6 months.

2. Eligible Medications
    a. Non-compounded, non-reconstituted, non-mailed, non-delivered medications dispensed to a patient using a method to ensure the right patient is receiving the right drug, dose, and dosage form at the time of dispensing
    b. Medications following the pharmacy workflow assisted by technology which has not been overridden
    c. The supervising pharmacist shall ensure a process is in place for a pharmacist to prospectively review the clinical appropriateness of the prescription prior to leaving the pharmacy.
3. Quality Assurance
    a. A minimum of 5% of all cTCT final checks per VPT shall be audited by a licensed pharmacist each day that cTCT is performed.
    b. The accuracy of each validated pharmacy technician shall be tracked individually.
4. Policies and Procedures
    a. Each pharmacy shall maintain policies, procedures, and training materials for the cTCT program that will be made available to the Board upon request.
5. Records
    a. Each pharmacy shall maintain records for 5 years, available to the Board upon request, of the following:
        i. All initial validation and revalidation records of each validated pharmacy technician that include the dates that the validation occurred, the number of final checks performed, the number of final check errors, and overall accuracy rate.
        ii. Names the supervising cTCT pharmacist including start date and end date of supervision responsibilities.
        iii. Daily quality assurance logs of the 5% pharmacist cTCT audit including the name of technician, total number of final checks performed, number of final checks audited by the pharmacist, percentage of final checks audited by pharmacist, number of final check errors identified, and type of error (i.e., wrong drug, wrong dose, wrong dosage form, extra/insufficient quantity).
6. Reporting Requirements
    a. The supervising pharmacist shall annually submit, in aggregate, to the Board, on a form approved by the Board, all of the following:
        i. Total number of cTCT final checks
        ii. Total number cTCT final checks audited by a pharmacist
        iii. Total number of errors identified in the cTCT final check pharmacist audit that were of the type of wrong drug, wrong dose, or wrong dosage form
        iv. Total number of pharmacist hours reallocated to other patient care activities and description of those activities

**Application:** The managing pharmacist shall submit a Board approved application and receive approval of the Board to participate in the Pilot Program.

# Pharmacy Examining Board

**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: DSPSCredPharmacy@dsps.wi.gov
Website: http://dsps.wi.gov

## COMMUNITY PHARMACY TECH-CHECK-TECH (cTCT) 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 pilot 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 community Tech-Check-Tech pilot program; the community Tech-Check-Tech pilot program will be utilized to provide direct patient care services and is not intended to reduce staffing levels; pharmacist to technician ratio will be maintained according to the Rules of the Pharmacy Examining Board; the application 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

**Committed to Equal Opportunity in Employment and Licensing**

# Pharmacy Examining Board

**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: DSPSCredPharmacy@dsps.wi.gov
Website: http://dsps.wi.gov

## COMMUNITY PHARMACY TECH-CHECK-TECH (cTCT) PILOT PROGRAM REPORT

| **DBA NAME OF PHARMACY: (This must be the name on the pharmacy license.)** | **PHARMACY TELEPHONE:** | **PHARMACY WI LICENSE NUMBER:** |
|---|---|---|
| **PHARMACY ADDRESS** (pharmacy location waiver 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 cTCT final checks | |
| Total number of cTCT final checks audited by a pharmacist | |
| Total number of errors identified in the cTCT final check pharmacist audit that were wrong drug, wrong dose, or wrong dosage form | |
| Total number of pharmacist hours reallocated to other patient care activities | |
| Description of patient care activities from reallocated pharmacist hours | |

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

_____ _____ _____
Supervising Pharmacist Signature WI License Number Date

_____
Printed Name of person signing above

# Pharmacy Examining Board

**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@dsps.wi.gov
Website: http://dsps.wi.gov

## Institutional Tech-Check-Tech Pilot Program Information

**Authority:**
Pursuant to Wisconsin Stat. § 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 Pilot Program at any time and participants shall remain in the Pilot Program at the discretion of the Board.**

**Purpose:** The purpose of institutional tech-check-tech (TCT) pilot program is to study the safety, quality, and efficiency of a pharmacy technician to make a final check of another pharmacy technician on the accuracy and correctness of the final dispensed medication. Implementation of a tech-check-tech program is not intended to reduce pharmacist staffing levels but is intended to increase the availability of a pharmacist for involvement for other patient care activities.

**Waives:** Phar 7.01(1)(c) and (d), and 7.015(3) (a) and (4), Wis. Admin. Code

**Pilot Duration**: October 1, 2016 to September 30, 2019 (or promulgation of rules whichever is sooner).

**Pharmacy Eligibility:**
1. The pharmacy shall be located and licensed in the state of Wisconsin.
2. A supervising pharmacist, licensed in the state of Wisconsin, shall be identified for each pharmacy to be accountable for the operations and outcomes of the TCT program. The final checks made by the validated technicians will be considered delegated acts of the supervising pharmacist. In the event of change of the supervising pharmacist, the managing pharmacy shall notify the Board of change within 5 days on a Board approved form.

**Program Requirements:**
1. Validated Technicians
    a. Initial Validation: In order to become a validated technician, the following requirements must be met and maintained:
        i. Employment averaging at least 20 hours per week at the pilot pharmacy
        ii. A minimum of 2000 hours of experience as a pharmacy technician and at least 6 months of employment at the pilot pharmacy
        iii. Completion of a didactic and practical training curriculum that includes the following:
            1. Elements of a package label (i.e. drug name, dose, dosage form, control or lot number and expiration date)
            2. Medication and pharmacy abbreviations needed to match ordered medication with dispensed medication (e.g., mg, mEq, ER, IR, tab, cap)
            3. Common dispensing medication errors and concepts (i.e. wrong medication, wrong dose, wrong dosage form, extra/insufficient quantity, omitted medications, expired medication, look-alike sound-alike errors, high-alert medications)
            4. Organizational policies and procedures on reporting of medication errors
            5. Overview of the organizations medication use process (i.e. procurement, ordering, dispensing, administration, and monitoring).
            6. A practical training designed to assess the competency of the technician prior to starting the validation process.
        iv. Completion of the following validation process:
            1. The technician being validated shall make a final check on the work of another technician for accuracy and correctness of a minimum of 1000 final checks over a minimum of 5 separate days and achieve an accuracy rate of 99.8% or greater.

2. At least one occurrence each of wrong drug, wrong dose, wrong dosage form, extra/insufficient quantity, omitted medication and, expired dose shall be artificially introduced by a pharmacist who will ensure they are removed prior to delivery to a patient care area.
3. A pharmacist shall audit 100% of the final checks made by the technician during the validation process.

b. Re-validation:
   i. An assessment of validated technician accuracy shall be completed quarterly of the previous 12 months of ITCT final checks. A technician shall be revalidated if a validated technician fails to maintain a final check accuracy rate of 99.8% or has not performed TCT final checks within the last 6 months.

2. Eligible Medications
   a. Medications shall be contained in a final package from a manufacturer or if packaged in the pharmacy a licensed pharmacist has ensured that the packaging process results in a final package that is labeled with the correct drug name, dose, strength, form, control or lot number, and beyond use date.
   b. The supervising pharmacist shall ensure a process is in place for a pharmacist to prospectively review the clinical appropriateness of the medication order prior to leaving the pharmacy.
   c. The medication shall be administered by an individual authorized to administer medications at the institution where the medication is administered.
3. Quality Assurance
   a. A minimum of 5% of all TCT final checks shall be audited by a licensed pharmacist each day that TCT is performed.
   b. The accuracy of each validated technician shall be tracked individually.
4. Policies and Procedures
   a. Each pharmacy shall maintain policies, procedures, and training materials for the TCT program that will be made available to the Board upon request.
5. Records
   a. Each pharmacy shall maintain records for 5 years, available to the Board upon request, of the following:
      i. All initial validation and revalidation records of each validated technician that include the dates that the validation occurred, the number of final checks performed, the number of final check errors, and overall accuracy rate.
      ii. Names the supervising TCT pharmacist including start date and end date of supervision responsibilities.
      iii. Daily quality assurance logs of the 5% pharmacist TCT audit including the name of technician, total number of final checks performed, number of final checks audited by the pharmacist, percentage of final checks audited by pharmacist, number of final check errors identified, and type of error (i.e., wrong drug, wrong dose, wrong dosage form, extra/insufficient quantity, omitted medications and, expired dose)
6. Reporting Requirements
   a. The supervising pharmacist of the tech-check-tech program shall annually submit to the Board, on a form approved by the Board, all of the following:
      i. Total number of TCT final checks
      ii. Total number TCT final checks audited by a pharmacist
      iii. Total number of errors identified in the TCT final check pharmacist audit that were of the type of wrong drug, wrong dose, or wrong dosage form
      iv. Total number of pharmacist hours reallocated to other patient care activities and description of those activities

**Application:** The managing pharmacist shall submit a Board approved application and receive approval of the Board to participate in the Pilot Program.

# Pharmacy Examining Board


| | | | |
|---|---|---|---|
| **Mail To:** | **P.O. Box 8935**<br>**Madison, WI 53708-8935** | 1400 E. Washington Avenue<br>Madison, WI 53703 | |
| FAX #: | (608) 261-7083 | E-Mail: | web@dsps.wi.gov |
| **Phone #:** | **(608) 266-2112** | Website: | http://dsps.wi.gov |


## Pharmacist to Pharmacy Technician or Intern Ratio Pilot Program Information

**Authority:**
Pursuant to Wisconsin Stat. § 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 Pilot Program at any time and participants shall remain in the Pilot Program at the discretion of the Board.**

**Purpose:** The purpose of the Pharmacist to Pharmacy Technician or Intern Ratio Program is to study the safety, quality, and efficiency of waiving the ratio if a pharmacy meets eligibility requirements.

**Waives:** Phar 7.01 (3), Wis. Admin. Code

**Pilot Duration**: October 1, 2016 to September 30, 2019 (or promulgation of rules whichever is sooner).

**Pharmacy Eligibility:**

1. The pharmacy shall be located and licensed in the state of Wisconsin.
2. The managing pharmacist shall coordinate a continuous quality improvement (CQI) program that includes:
    a. Written CQI policies and procedures
    b. Pharmacy personnel training on medication errors and CQI principles
    c. Ability for pharmacy personnel to document and report quality related events

**Records**

1. Each pharmacy shall maintain records for 5 years, available to the Board upon request, of the following:
    a. The date and number of hours worked by a pharmacy technician that day
    b. The date and number of hours worked by a pharmacist that day
    c. The date and the pharmacist to pharmacy technician hours worked ratio that day.

2. Each pharmacy shall maintain records for 5 years, available to the Board upon requrest, of the following:
    a. The date and number of hours worked by a pharmacy intern that day.
    b. The date and number of hours worked by a pharmacist that day.
    c. The date and the pharmacist to intern hours worked ratio that day.

**Reporting Requirements**

1. The managing pharmacist shall annually submit to the Board, on a form approved by the Board, all of the following:
    a. The total number of hours worked by a pharmacy technician each month.
    b. The total number of hours worked by a pharmacist each month.
    c. The pharmacist to pharmacy technician hours worked ratio each month.
    d. The total number of hours worked by an intern each month.
    ~~c.~~e. The pharmacist to intern hours worked ratio each month.

**Application:** The managing pharmacist shall submit a Board approved application and receive approval of the Board to participate in the Pilot Program.

**Formatted:** Font: (Default) Times New Roman, 10 pt

**Formatted:** List Paragraph, Line spacing: single, Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.25" + Indent at: 0.5"

**Formatted:** List Paragraph, Line spacing: single, Numbered + Level: 1 + Numbering Style: a, b, c, … + Start at: 1 + Alignment: Left + Aligned at: 0.75" + Indent at: 1"

**Formatted:** Font: (Default) Times New Roman, 10 pt

**Formatted:** Font: (Default) Times New Roman, 10 pt

**Formatted:** Line spacing: single