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**PHARMACY RULES COMMITTEE  
of the  
PHARMACY EXAMINING BOARD**

**Room 121A, 1400 East Washington Avenue, Madison, WI 53703**  
**Contact: Dan Williams (608) 266-2112**  
**March 25, 2015**

*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**

**8:00 A.M.**

**OPEN SESSION – CALL TO ORDER**

- A. Approval of Agenda (1)**
- B. Legislation and Rule Matters – Discussion and Consideration (2-34)**
  - 1) Proposals for Phar 2 and 4 Relating to Application and Examination (3-6)**
  - 2) Review Partial Draft of Phar 15 Relating to Compounding (7-11)**
  - 3) Proposals for Phar 7 Relating to Practice of Pharmacy (12-34)**
- C. Public Comments**

**ADJOURNMENT**

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

**AGENDA REQUEST FORM**

1) Name and Title of Person Submitting the Request:  <b>Sharon Henes Administrative Rules Coordinator</b>		2) Date When Request Submitted:  <b>18 March 2015</b>	
		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:  <b>Pharmacy Rules Committee</b>			
4) Meeting Date:  <b>25 March 2015</b>	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? <b>A. Approval of the Agenda</b> <b>B. Legislation and Rules Matters – Discussion and Consideration</b> <b>1. Proposals for Phar 2 and 4 Relating to Application and Examination</b> <b>2. Review Partial Draft of Phar 15 Relating to Compounding</b> <b>3. Proposals for Phar 7 Relating to Practice of Pharmacy</b> <b>C. Public Comments</b>	
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 ( <a href="#">Fill out Board Appearance Request</a> ) <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><b>Sharon Henes</b></i>		<i><b>18 March 2015</b></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.			

## Chapter Phar 2

### APPLICATION FOR PHARMACIST LICENSE

Phar 2.01	Qualifications for original licensure.
Phar 2.02	Application procedure for original licensure.
Phar 2.03	Examinations for original licensure.

Phar 2.04	Qualifications for persons licensed in another state.
Phar 2.05	Application procedure for persons licensed in another state.
Phar 2.06	Examinations for persons licensed in another state.

**Note:** Chapter Phar 2 as it existed on January 31, 1983, was repealed and a new chapter Phar 2 was created effective February 1, 1983.

**Phar 2.01 Qualifications for original licensure.** An applicant for original licensure as a pharmacist may be admitted to examination under ch. 450, Stats., if the applicant:

(1) Has been graduated from a school or college of pharmacy approved by the board or has obtained certification by the foreign pharmacy graduate examination committee.

(2) Has completed an internship in the practice of pharmacy.

**History:** Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. (2), Register, August, 1991, No. 428, eff. 9-1-91; am. (1), Register, January, 1996, No. 481, eff. 2-1-96; am. (intro.), Register, December, 1998, No. 516, eff. 1-1-99; emerg. am. (2), eff. 1-1-02; CR 01-091: am. (1), Register January 2002 No. 553, eff. 2-1-02; CR 01-134: am. (2), Register July 2002 No. 559, eff. 8-1-02.

**Phar 2.02 Application procedure for original licensure.** (1) Each applicant for original licensure as a pharmacist shall submit a completed notarized application prior to the examination date on forms provided by the board. The application shall include all of the following:

(a) The signature of the applicant.

(b) A statement from the dean of the school of pharmacy or the academic records office of the respective educational institution that the applicant has graduated from the pharmacy school.

(c) If the applicant intends to engage in a foreign graduate internship under s. Phar 17.04, evidence satisfactory to the board that the applicant has obtained certification by the foreign pharmacy graduate examination committee and disclosure of the applicant's supervising pharmacist. Any change of a supervising pharmacist shall be disclosed to the board by filing an amendment to the application prior to further performing duties constituting the practice of pharmacy as a foreign graduate intern.

(d) Evidence of having completed an internship in the practice of pharmacy which shall consist of one or more of the following:

1. A statement from the dean of the school of pharmacy or the academic records office of the respective educational institution certifying the number of hours that the applicant has successfully completed in a practical experience program described in ch. Phar 17.

2. A statement from a supervising pharmacist certifying the number of hours that the applicant was supervised by that supervising pharmacist in an internship in the practice of pharmacy described in ch. Phar 17.

3. Verification of practical experience acquired by the applicant in another state as described in ch. Phar 17, which is approved and verified by the board or by the agency which is the equivalent of the board in the state in which the practical experience was acquired.

(e) The fees required under s. 440.05 (1), Stats.

**Note:** Applications are available upon request to the board office located at 1400 East Washington Avenue, P. O. Box 8935, Madison, WI 53708.

(2) Any change of name made prior to admission to examination shall be supported by an affidavit satisfactory to the board.

**History:** Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. (1) (intro.) and (d), Register, December, 1998, No. 516, eff. 1-1-99; emerg. renum. (1) (d) to be (1) (e), cr. (1) (d), eff. 1-1-02; CR 01-134: renum. (1) (d) to be (1) (e), cr. (1) (d), Register July 2002 No. 559, eff. 8-1-02; CR 02-140: am. (1) (intro.) Register May 2003 No. 569, eff. 6-1-03; CR 02-150: r. (1) (c) Register May 2003 No. 569, eff. 6-1-03; CR

06-050: cr. (1) (c) Register October 2006 No. 610, eff. 11-1-06; CR 09-019: am. (1) (intro.) Register October 2009 No. 646, eff. 11-1-09.

**Phar 2.03 Examinations for original licensure.**

(1) An applicant for original licensure as a pharmacist is required to pass the examinations identified in s. Phar 4.02 (1) and (3).

(2) The coverage and conduct of examinations administered by the board are specified in ch. Phar 4.

(4) An applicant for licensure as a pharmacist shall not be eligible to be admitted to NAPLEX or the multi-state pharmacy jurisprudence examination prior to completing an internship in the practice of pharmacy and either obtaining certification by the foreign pharmacy graduate examination committee or graduating from a school or college of pharmacy approved by the board.

**History:** Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. (1) and (3), cr. (4) and (5), Register, August, 1991, No. 428, eff. 9-1-91; am. (1), (4) and (5) and r. (3), Register, December, 1998, No. 516, eff. 1-1-99; CR 00-157: am. (1) Register May 2002 No. 557 eff. 6-1-02; CR 01-134: am. (4), r. (5), Register July 2002 No. 559, eff. 8-1-02; CR 03-005: am. (4) Register May 2003 No. 569, eff. 6-1-03; CR 04-002: am. (4) Register June 2004 No. 582, eff. 7-1-04; CR 09-019: am. (1) and (4) Register October 2009 No. 646, eff. 11-1-09.

**Phar 2.04 Qualifications for persons licensed in another state.** A pharmacist holding a license to practice pharmacy in another state may become licensed in Wisconsin if the applicant:

(1) Has been graduated from a school or college of pharmacy approved by the board, or has obtained certification by the foreign pharmacy graduate examination committee.

(2) Has passed the required examinations administered by the board.

**History:** Renum. from Phar 3.01, Register, December, 1998, No. 516, eff. 1-1-99; CR 01-091: am. (1), Register January 2002 No. 553, eff. 2-1-02.

**Phar 2.05 Application procedure for persons licensed in another state.** (1) Each applicant licensed as a pharmacist in another state shall file with the board, prior to the examinations, the following:

(a) Completed application form.

(b) The fee specified under s. 440.05 (2), Stats.

(2) Verification of license shall be forwarded from the original state of licensure by examination.

(3) Credentials received in a name other than that on the original application shall be supported by a change of name affidavit satisfactory to the board.

**History:** Renum. from Phar 3.02 and am. (1) (intro.), Register, December, 1998, No. 516, eff. 1-1-99; CR 09-019: am. (1) (intro.) Register October 2009 No. 646, eff. 11-1-09.

**Phar 2.06 Examinations for persons licensed in another state.** (1) An applicant licensed as a pharmacist in another state who is engaged in the active practice of pharmacy, shall take the multi-state pharmacy jurisprudence examination described in s. Phar 4.02 (1). The applicant shall submit, on forms furnished by the board, information describing his or her practice experience preceding the filing of the application. The board may review requests for reciprocity.

(2) DEFINITION. In this section, "active practice of pharmacy" means having engaged in at least 2,000 hours of the practice of pharmacy within the 12 months preceding application for licensure in Wisconsin or at least 2,000 hours of the practice of phar-

macy comprised of no less than 500 hours in each of 3 of the 4, 12-month periods preceding application for licensure in Wisconsin.

**(3) EQUIVALENCY EXAMINATION.** Any applicant who has not engaged in the active practice of pharmacy shall take and pass each of the following examinations:

(b) Multi-state pharmacy jurisprudence.

(c) Any other examination, as determined by the board.

**(4) COVERAGE AND CONDUCT.** The coverage and conduct of examinations administered by the board are specified in ch. Phar 4.

**History:** Renum. from Phar 3.04 and am. (1), (3) (intro.), (a),(b), and (c), [Register, December, 1998, No. 516](#), eff. 1-1-99; [CR 00-157](#): am. (1), r. (3) (a), renum. and am. (3) (b) to be (3) (a), and renum. (3) (c) to be (3) (b) [Register May 2002 No. 557](#), eff. 6-1-02; [CR 09-019](#): r. (3) (a), cr. (3) (c) [Register October 2009 No. 646](#), eff. 11-1-09.

## Chapter Phar 4

### EXAMINATIONS

Phar 4.01	Administration.
Phar 4.02	Competencies tested.
Phar 4.03	Passing scores.
Phar 4.035	Unauthorized assistance.

Phar 4.04	Scoring.
Phar 4.045	Examination review.
Phar 4.046	Claim of examination error.
Phar 4.05	Failure and reexamination.

**Phar 4.01 Administration.** (1) Examinations may be written, oral, or practical.

(2) Examinations are conducted in the English language only.

(3) At least 10 days prior to the examination, the applicant shall be mailed an admission card and that card shall be presented at the door of the examination room, with a driver's license or passport photograph.

(4) A number shall be assigned to each applicant. Rules of conduct shall be provided at the beginning of the examination.

(5) An applicant found by the board to have violated rules of the examination may be denied licensure by the board.

**History:** Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. (3), Register, December, 1998, No. 516, eff. 1-1-99.

**Phar 4.02 Competencies tested.** Competencies are tested by examination as follows:

(1) The multi-state pharmacy jurisprudence examination shall determine an applicant's competence to practice within federal laws and regulations and Wisconsin laws and rules governing the practice of pharmacy.

(3) NAPLEX shall determine an applicant's competence in the basic principles and professional areas within the practice of pharmacy.

(4) An otherwise qualified applicant shall be provided with reasonable accommodations, as required by the Americans with disabilities act.

**History:** Cr. Register, January, 1983, No. 325, eff. 2-1-83; emerg. r. and recr. eff. 5-21-85; r. and recr. Register, November, 1985, No. 359, eff. 12-1-85; am. (1) and (2), Register, August, 1991, No. 428, eff. 9-1-91; am. (4), Register, January, 1996, No. 481, eff. 2-1-96; am. (1) and (5), r. (2), cr. (6), Register, December, 1998, No. 516, eff. 1-1-99; CR 00-157; r. (3), renun. and am. (4) to be (2) and renun. (5) and (6) to be (3) and (4) Register May 2002 No. 557, eff. 6-1-02; EmR0903: emerg. r. (2), eff. 2-28-09; CR 09-019; r. (2) Register October 2009 No. 646, eff. 11-1-09.

**Phar 4.03 Passing scores.** (1) The passing scores set by the board represent the minimum competency required to protect public health and safety.

(2) Each examination specified in s. Phar 4.02 is scored separately. An applicant shall achieve a passing score on each required examination to qualify for licensure.

(3) The score required to pass an examination shall be based on the board's determination of the level of examination performance required for minimum acceptable competence in the profession. The board shall make the determination after consultation with experts in the subject matter of the examination who have reviewed a representative sample of the examination questions and available candidate performance statistics, and shall set the passing score for the examination at that point which represents minimum acceptable competence in the profession.

**History:** Cr. Register, January, 1983, No. 325, eff. 2-1-83; emerg. am. (2), r. and recr. (3) and (4), r. (5) and (6), eff. 5-21-85; am. (2), r. and recr. (3) and (4), r. (5) and (6), Register, November, 1985, No. 359, eff. 12-1-85; r. (3), renun. (4) to be (3) and am. Register, May, 1986, No. 365, eff. 6-1-86; r. and recr. (3), Register, December, 1998, No. 516, eff. 1-1-99.

**Phar 4.035 Unauthorized assistance.** An applicant may not give or receive unauthorized assistance during the examination. The action taken by the board when unauthorized assistance occurs shall be related to the seriousness of the offense.

These actions may include withholding the scope of the applicant, entering a failing grade for the applicant, and suspending the ability of the applicant to sit for the next scheduled examination after the examination in which the unauthorized assistance occurred.

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

**Phar 4.04 Scoring.** (1) The board shall send written notification of results to applicants.

(2) An applicant shall be offered the opportunity to make written comments and objections within 30 days after notification of the examination results.

(3) Any unsuccessful applicant may request in writing that his or her answer sheet be rescored by hand to verify the accuracy of scoring.

(4) The cost of rescoring shall be paid by the applicant.

**History:** Cr. Register, January, 1983, No. 325, eff. 2-1-83.

**Phar 4.045 Examination review.** (1) An applicant who fails an examination administered by the board may request a review by the applicant of that examination by filing a written request to the board within 45 days after the date on which the examination results were mailed to the applicant.

(2) An examination review shall be conducted under the following conditions:

(a) The time for review shall be limited to one hour.

(b) The examination shall be reviewed only by the applicant and in the presence of a proctor.

(c) The proctor may not respond to inquiries by the applicant regarding allegations of examination error.

(d) An applicant shall be permitted only one review of the failed examination each time it is taken and failed.

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

**Phar 4.046 Claim of examination error.** (1) An applicant wishing to claim an error regarding specific questions or procedures on an examination administered by the board shall file a written request on a form provided for this purpose in the board office within 30 days after the date the examination was reviewed. The request shall include:

(a) The applicant's name and address.

(b) The type of registration applied for.

(c) A description of the alleged error, including reference text citations or other supporting evidence for the applicant's claim.

(2) The request shall be reviewed by the board in consultation with an expert in the subject matter of the examination. The applicant shall be notified in writing of the board's decision.

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

**Phar 4.05 Failure and reexamination.** (2) An applicant who fails to achieve a passing score on any examination specified in s. Phar 4.02 is eligible for reexamination. An applicant who twice fails any licensing examination specified in s. Phar 4.02 is not eligible for further examination until the applicant has satisfactorily completed additional preparation as directed and approved by the board. This condition on eligibility also applies to each third and subsequent failure.

(3) An application for reexamination shall be made on forms provided by the board. An applicant shall remit the reexamination fee.

**Note:** A list of all current examination fees may be obtained at no charge from the Office of Education and Examinations, Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8366, Madison, WI 53708.

**Note:** An application form may be obtained upon request to the board office located at 1400 East Washington Avenue, Madison, Wisconsin 53702.

**History:** Cr. [Register, January, 1983, No. 325](#), eff. 2-1-83; emerg. r. and recr. eff. 5-21-85; r. and recr. [Register, November, 1985, No. 359](#), eff. 12-1-85; r. and recr. (1), r. (2) to (4), renum. (5) to (7) to be (2) to (4), [Register, May, 1986, No. 365](#), eff. 6-1-86; am. (2), [Register, August, 1991, No. 428](#), eff. 9-1-91; am. (3), [Register, June, 1994, No. 462](#), eff. 7-1-94; r. (1) and (4), [Register, December, 1998, No. 516](#), eff. 1-1-99.

**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, thereby becoming the active ingredient in the preparation and furnishing 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) Beyond Use Date (BUD) means the date after which a compounded preparation should not be used.
- (3) Component means any ingredient used in the compounding of a drug preparation.
- (4) Compounding means the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug delivery device, or a device in accordance with a prescription, medication order or initiative. 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 pursuant to the directions contained in approved labeling provided by the manufacturer of a commercially available product is not compounding.
  - (d) Preparation of drugs or devices for the purposes of, or as an incident it, research, teaching or chemical analysis.{NOTE: Unresolved - Preparation of drugs and devices for prescriber's office use}
- (5) Stability means the extent to which a preparation retains, within specified limits and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of compounding.

**SUBCHAPTER I – General**

- 15.10 Facilities.** (1) A pharmacy engaged in compounding shall ensure all of the following:
- (a) An area shall provide for safe and orderly compounding of drug products.
  - (b) An area shall provide for the orderly placement of equipment and materials in order to minimize the potential for errors.
  - (c) The area is well-lighted and ventilated.
  - (d) The area is maintained in a clean and sanitary condition.
  - (e) Heating and air conditioning systems are controlled to avoid decomposition and contamination of chemicals.
  - (f) Sewage, trash and other refuse in and from the pharmacy and immediate drug compounding area are maintained, and disposed of, in a timely, safe and sanitary manner.
  - (g) The area is easily accessible to all of the following:
    1. Hot and cold running water, exclusive of the bathroom sink.
    2. Soap or detergent.

3. Air dryers or single source towels.
- (h) Areas for sterile preparations shall be separated and distinct from non-sterile compounding areas.

**15.11 Equipment.** (1) A pharmacy shall possess equipment appropriate to the type of compounding performed at the pharmacy.

(2) Equipment used in compounding drug products shall be of appropriate design and capacity, and shall be suitably located to facilitate operations for the intended use, cleaning and maintenance of the equipment.

(3) Equipment used in compounding drug products shall be of suitable composition. Equipment surfaces that contact components shall be reactive, additive or adsorptive so as to alter the safety, identity, strength, quality and purity of the compounded product.

(4) Equipment used in compounding drug products shall be thoroughly cleaned and sanitized after each use, and when necessary, prior to use, in order to prevent cross-contamination of ingredients and preparations.

(5) Equipment used in compounding drug products shall be stored in a manner to prevent cross-contamination of ingredients and preparations.

(6) Automated, mechanical or electronic equipment may be used in compounding non-sterile preparations. All equipment utilized in compounding preparations shall be inspected, maintained and validated at appropriate intervals, consistent with manufacturer's recommendations, to ensure the accuracy and reliability of equipment performance.

**15.12 Records.** A pharmacist shall maintain written or electronic documentation to systematically trace, evaluate, and replicate the steps throughout the process of a compounded preparation. The records shall include all of the following:

- (1) Master Formulation Record shall include all of the following:
  - (a) Official or assigned name, strength, and dosage form on the preparation.
  - (b) Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients.
  - (c) Description of all ingredients and their quantities.
  - (d) Equipment needed to prepare the preparation.
  - (e) Mixing instructions including all of the following:
    1. Order of mixing.
    2. Mixing temperatures or other environmental controls.
    3. Duration of mixing.
    4. Other factors pertinent to the replication of the preparation as compounded.
  - (f) Sample labeling information, including all of the following:
    1. Name and quantity of concentration of each active ingredient.
    2. Assigned BUD.
    3. Storage conditions.
    4. Prescription or control number.

- (g) Container used in dispensing.
- (h) Packaging and storage requirements.
- (i) Description of final preparation.
- (j) Quality control procedures and expected results.

(2) Compounding Record shall include all of the following:

- (a) Official or assigned name, strength, and dosage of the preparation.
- (b) Master Formulation Record reference for the preparation.
- (c) Names and quantities of all components.
- (d) Sources, lot numbers and expiration dates of all components.
- (e) Total quantity compounded.
- (f) Name of the person who prepared the preparation.
- (g) Name of the person who performed the quality control procedures.
- (h) Name of the person who approved the preparation.
- (i) Date of preparation.
- (j) Assigned control or prescription number.
- (k) Assigned BUD.
- (L) Duplicate label as described in the Master Formulation Record.
- (m) Description of the final product.
- (n) Results of quality control procedures.
- (o) Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver.

**15.13 Quality control.** (1) The pharmacist shall do a final check and review each procedure in the compounding process. A final check shall include verification of all the following:

- (a) The master formulation record, compounding record and written procedures were followed in the execution of the compounding process. Any deviation in procedures shall be documented.
- (b) There was a check and recheck of each procedure at each stage of the process.
- (c) The tests or examinations conducted on the compounded preparation to ensure their uniformity and integrity followed established written procedures.
- (d) The performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations.

(2) The pharmacist shall observe the finished preparation to ensure that it appears as expected.

(3) The pharmacist shall investigate any discrepancies and take appropriate corrective action before the prescription is dispensed to the patient.

**15.14 Training.** All personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations shall be properly trained for the type of compounding conducted. It is the responsibility of the pharmacist to ensure and document that a training program has been implemented and that it is ongoing.

**15.15 Adverse Event Reporting.** A pharmacy or pharmacist that becomes aware of an adverse event attributed to the integrity of the product of a compounded pharmaceutical shall report the

adverse event to the department not later than 10 calendar days after becoming aware of the adverse event. For purposes of this section, an adverse event does not include an isolated allergic reaction to a substance included in the compound.

## SUBCHAPTER II – Non-sterile Compounding

**15.20 Component Selection.** (1) A pharmacist shall use components manufactured in a FDA registered facility. If a component is unavailable from a FDA registered facility, the pharmacist may utilize a component that has been tested by a FDA approved vendor and the component has been determined to be pure and safe documented by a Certificate of Analysis.

(2) Components with an expiration date from the manufacture or distribute may be used before the expiration date provided all of the following:

- (a) The material is stored in its original container under conditions to avoid decomposition of the chemicals.
- (b) There is minimal exposure of the remaining material each time material is withdrawn from the container.
- (c) When any withdrawals from the container are performed by those trained in the proper handling of the material.

(3) Components without an expiration date assigned by the manufacturer or supplier, shall be labeled with the date of receipt and assigned an 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.

(4) 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.

(5) Manufactured drug products utilized as the source of active ingredients shall be manufactured in an FDA registered facility and the manufacturer's product container shall be labeled with a lot number and expiration date.

(6) 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.

(7) All components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first.

**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 and stored at controlled room temperature is one of the following:

(a) For nonaqueous liquids and solid formulations, 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 at cold temperatures {NOTE: Define “cold temperatures”}

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

## Chapter Phar 7 – Pharmacy Practice: Priority Topic Areas Identified by PSW Members February 2015

**Prepared by:**  
PSW Members

**Disclosure:**  
Recommendations and/or points for consideration that are outlined below are meant for the purposes of generating discussion only. They are not final positions of the Pharmacy Society of Wisconsin.

**Summary of Methods:**

In the Statement of Scope for revising Phar 7, the Pharmacy Examining Board (PEB) intends to revise Phar 7 to reflect the current practice of pharmacy and support pharmacy practice advancement. The following table lists topic areas identified by PSW members for consideration by the PEB during the Phar 7 rule revision process. They represent areas that PSW members feel should be researched and evaluated for potential revision of, inclusion in, or exclusion from the rule. Pharmacy rules from several states and the NABP Model Practice Act were compared against Wisconsin’s Pharmacy Administrative Code (Chapter Phar 7) to identify areas of opportunity in order to promote patient health and safety and modernize current pharmacy practice rules.

Topic Area	Recommended Change(s)	Explanation / Background / State Examples
Tech-check-tech (TCT)	<ul style="list-style-type: none"> <li>▪ Recommend streamlining TCT variance approval and eliminating reporting requirements</li> <li>▪ Recommend that the PEB to evaluate pros and cons for expanding TCT beyond institutional practice sites.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Reference PSW TCT Toolkit for requirements (Appendix A)</li> <li>▪ Other states have a broader scope for TCT and regulate technicians through TCT. For example, ND Chapter 61 allows “any licensed pharmacy” to implement TCT after meeting certain criteria and Iowa allows for TCT specifically in hospital and long-term care settings.</li> <li>▪ State examples: ND, IA, SC</li> </ul>
Delegation by pharmacists	<ul style="list-style-type: none"> <li>▪ Recommend that PEB consider the topic of delegation of technical and non-technical functions by pharmacists. Suggest review of other states and rules for other professions in WI (e.g. medicine &amp; nursing delegation)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Technicians (and possibly MAs) perform duties related to dispensing medications, but they are also capable of performing duties that may not directly relate to dispensing medications, such as the collection of medication lists/histories from patients in health system settings.</li> <li>▪ Changes may require revisions to Ch. 450 (e.g. 450.01(16): Definition of Practice of Pharmacy)</li> <li>▪ State examples: MI, PA, IA, WA, MN</li> </ul>
Automated kiosks	<ul style="list-style-type: none"> <li>▪ Add specific information to define automated kiosks and outline conditions of use:               <ol style="list-style-type: none"> <li>1) Automated dispensing systems are defined as equipment used to fill and dispense medications within the physical pharmacy</li> <li>2) Identify location of the kiosk (in a pharmacy with a permit from the board)</li> </ol> </li> </ul>	<ul style="list-style-type: none"> <li>▪ Guidance and regulations should also be included for use of self-service kiosks.</li> <li>▪ State examples: IL, ME, MS, RI, and MT</li> </ul>

	<ul style="list-style-type: none"> <li>3) Adequate security to prevent the unauthorized removal of the system or unauthorized access to medications and to maintain patient confidentiality</li> <li>4) Keep records of all individuals with access to the kiosk, and transactions, quality assurance documents (kept for 5 years or same amount of time as other records)</li> <li>5) Filling of the kiosk should be limited to technicians or pharmacists</li> <li>6) Equipped with a camera and audio system for troubleshooting with a healthcare professional</li> </ul>	
Chart order	<ul style="list-style-type: none"> <li>▪ Recommend PEB consideration to add as a definition due to increased access to and use of electronic health records</li> </ul>	<ul style="list-style-type: none"> <li>▪ NABP Definition: “Chart Order” means a lawful order entered on the chart or a medical record of an inpatient or resident of an Institutional Facility by a Practitioner or his or her designated agent for a Drug or Device and shall be considered a Prescription Drug Order provided that it contains: <ul style="list-style-type: none"> <li>(1) the full name of the patient;</li> <li>(2) date of issuance;</li> <li>(3) name, strength, and dosage form of the Drug prescribed;</li> <li>(4) directions for use; and</li> <li>(5) if written, the prescribing Practitioner’s signature or the signature of the Practitioner’s agent (including the name of the prescribing Practitioner); or if electronically submitted, the prescribing Practitioner’s electronic or digital signature.</li> </ul> </li> </ul>
Classes of licenses for practice settings	<ul style="list-style-type: none"> <li>▪ Recommend PEB consider pros and cons of different types of licenses for practice settings.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Opportunity to capture information on those facilities that are compounding.</li> </ul>
Counseling requirements based on practice setting	<ul style="list-style-type: none"> <li>▪ Recommend PEB review other states’ counseling requirements</li> </ul>	<ul style="list-style-type: none"> <li>▪ See Appendix C</li> <li>▪ State examples: MN, IL, IA</li> </ul>
Labeling based on USP Standards	<ul style="list-style-type: none"> <li>▪ While considering economic and logistic burden on pharmacies consider including language similar to the NABP Model Practice Act (with some changes to be consistent with changes to Chapter 450)</li> <li>▪ Language listed in Appendix D.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Based on research on medication errors and medication misuse it is important to implement regulations that address these issues but it is also important not to make the language too specific that it makes pharmacy implementation unreasonable. It is also important that the language is not so vague rendering it unenforceable.</li> <li>▪ USP has recommended Chapter 17 be adopted by state boards for labeling.</li> <li>▪ NAPB has worked closely with the USP to incorporate the USP recommendations into the Model Practice Act language.</li> <li>▪ State Example: CA</li> </ul>
Labeling for multiple medications in a	<ul style="list-style-type: none"> <li>▪ Recommend PEB consider options for labeling multiple medications</li> </ul>	<ul style="list-style-type: none"> <li>▪ USP 661 standards available for customized patient medication packets</li> <li>▪ See Appendix E</li> </ul>

package		<ul style="list-style-type: none"> <li>▪ State examples: MN, OR, IA</li> </ul>
Answering machines / voice recognition	<ul style="list-style-type: none"> <li>▪ Phar 7.065. Suggest deleting “if the voice of the physician or physician’s agent is known to the pharmacist.”</li> </ul>	<ul style="list-style-type: none"> <li>▪ Current wording may be too restrictive</li> <li>▪ No comment of “voice of the physician or physician’s agent is known” in NABP Model State Pharmacy Act.</li> <li>▪ State examples: Twenty other states’ (including all Midwestern states) statutory and regulatory laws were also reviewed (AL, AZ, CA, CO, CT, FL, GA, HI, ID, IL, IN, IA, KS, MI, MN, MO, NE, ND, OH, SD) for mention of answering machines, voicemail, or telephone/verbal/oral orders. <ul style="list-style-type: none"> <li>○ Only CO, MN, and OH law mention answering machines. All require that a pharmacist or intern must receive such messages; none require voice recognition. The other 17 states’ laws do not mention of answering machines or voice recognition.</li> <li>○ AZ requires a practitioner’s phone number for oral prescriptions.</li> <li>○ IA, KS, OH require the first and last name of the transmitting agent (if other than the prescriber) be included in oral prescriptions.</li> <li>○ Multiple states stipulate that only a pharmacist or pharmacist intern may accept oral prescriptions.</li> </ul> </li> </ul>
Transferring of prescriptions	<ul style="list-style-type: none"> <li>▪ Consider removing or revising the following: “Communication by facsimile machine is not allowed unless the prescription order information being transferred is verified verbally between 2 pharmacists</li> </ul>	<ul style="list-style-type: none"> <li>▪ Most states are very similar to WI as far as requirements to what goes on the prescription and who can transfer, etc. Some states specified who could take the transfers (pharmacists versus interns). Iowa and North Carolina require that the person receiving the transferred prescription add the date of transfer to the prescription. WI only requires that the person sending the transfer has to date it.</li> </ul>
Quantity changing authority	<ul style="list-style-type: none"> <li>▪ At the pharmacist’s discretion and without requiring approval by the provider, a non-controlled prescription ordered for a quantity of a 30 day supply with refills can be changed to a 90 day supply with refills adjusted accordingly so as the total quantity of the prescription remains the same.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Eliminates pharmacists having to make phone calls or send faxes to providers to ask for permission to change a prescription to a 90 day supply when the prescription that was approved by the provider allowed for the same quantity total to be dispensed, just in a different quantity at a time. Patient care will no longer be delayed in order to secure a 90 day prescription. Providers will not be interrupted by phone calls or faxes to address a trivial issue.</li> </ul>
Scanning of hard copies/Electronic storage of hard copies	<ul style="list-style-type: none"> <li>▪ Recommend PEB consideration</li> </ul>	<ul style="list-style-type: none"> <li>▪ Support allowances for maintaining records in alternative data retention systems (eg data processing system or direct imaging system) provided requirements are met</li> <li>▪ State examples: NM, AZ</li> </ul>

# Wisconsin Tech-Check-Tech

FEBRUARY 2013

*Helping members advance pharmacy practice across the state*



Pharmacy Society  
of Wisconsin

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## Tech-Check-Tech Overview

### Introduction & Background

The American Society of Health-System Pharmacists' Pharmacy Practice Model Initiative (PPMI) focuses on improving patient care by advancing pharmacists' roles in direct patient care. PPMI advocates a practice model in which pharmacists devote significantly more time to drug therapy management services and promotes expanded roles for pharmacy technicians in drug distribution services to help pharmacists focus on activities requiring their clinical judgment. The PPMI recommendations come at a time when hospitals and health systems are facing new and broader challenges than ever before. Increasing financial pressures have forced hospitals and health systems to evaluate operational expenses and opportunities for more cost-efficient care, such as redistribution of traditional tasks and skill mix changes.<sup>1</sup> Additionally, millions of Americans are expected to gain health insurance coverage as result of the Patient Protection and Affordable Care Act (PPACA), creating pressures to expand capacity through enhanced efficiency to meet increased access-to-care needs without adding additional expense. While some provisions of PPACA, in conjunction with recommendations from PPMI, offer an opportunity to expand pharmacists' responsibilities to include additional direct patient care activities, health care reform efforts and the current economic climate together pose a challenge for advancing pharmacy services.<sup>2</sup>

To address such challenges and support the expanding role of the pharmacist in direct patient care, it is imperative hospitals and health systems expand the roles of their pharmacy technicians. PPMI recommends utilizing technicians to carry out all distributive roles not requiring a pharmacist's clinical judgement.<sup>1</sup> A growing number of states have either adopted permissive language in state laws and regulations for 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 drug distribution processes at specific institutions. However, approximately 79% of pharmacy department respondents from Wisconsin hospitals do not recognize these technician programs exist and can be legally implemented.<sup>1,3-4</sup>

This toolkit, whose development was coordinated through the Pharmacy Society of Wisconsin, is intended to assist hospitals with the implementation of Tech-Check-Tech (TCT) programs, wherein trained and validated pharmacy technicians are permitted to perform the final verification of dispensed products. The toolkit is designed to provide an overview of the steps for acquiring a variance, recommended program elements for obtaining a variance under Wisconsin law, policy and procedure templates for submitting a variance request and tools for implementing a successful TCT program. Templates are based on existing Wisconsin TCT programs and include customizable language for easy adaptation to site-specific needs. With the use of these tools, the Pharmacy Society of Wisconsin aims to expand the number of pharmacy sites successfully deploying pharmacy technicians in advanced drug distribution roles to allow pharmacists a broader opportunity to provide direct patient care services.

### Organizational Impact

Facing economic and quality-based incentives to improve the effective and efficient delivery of care, health care organizations must be cognizant of opportunities to re-define traditional pharmacist and technician roles to allow pharmacists to utilize their advanced training to for direct patient care or advanced medication therapy management. TCT offers a means of redistributing traditional dispensing workload performed by pharmacists to capably-trained technical staff to allow pharmacists to focus on activities which demand their level of expertise.

Commonly, pharmacists perform the "final check" in the drug distribution process, confirming the accuracy of products prepared by pharmacy technicians. TCT programs grant specially-trained pharmacy technicians the authority to check the accuracy of medications prepared or filled by another pharmacy technician for dispensing.<sup>1</sup>

As a result of TCT, pharmacy technicians will:

- Provide the "final check" on medications prior to dispensing
- Control workflow and drug distribution with greater autonomy (less dependence on pharmacists' final verification)

Additionally, TCT will:

- Reduce the need for pharmacists to perform final verification functions
- Improve efficiencies in the preparation and delivery of medications
- Allow for redeployment of pharmacists' time to the provision of clinical services and participation in direct patient care activities

### Literature Review

Eleven studies comparing the accuracy of technicians and pharmacists in performing final dispensing checks published from 1978 to present are summarized in **Appendix A**.

#### Technician Accuracy Rates

Studies evaluating the product-verification and error-detection capabilities of pharmacy technicians compared to pharmacists consistently illustrate that specially-trained pharmacy technicians provide the “final check” in unit-dose medication distribution systems as accurately as pharmacists (mean ± S.D., 99.6% ± 0.55% versus 99.3% ± 0.68%, respectively).<sup>1,3,5-14</sup> Five studies demonstrated increased accuracy with TCT compared to pharmacist verification, although significant heterogeneity with regards to sample sizes for technicians and pharmacists existed.<sup>6,8-9,11,13</sup> Table 1 summarizes the studies with results showing greater dispensing accuracy with TCT over pharmacist final verification.

**Table 1: Summary of studies favoring TCT**<sup>6,8-9,11,13</sup>

Ref	Setting	TCT application	Sample size	Accuracy rate (%)		Error-detection rate (%)		p
				Technician	Pharmacist	Technician	Pharmacist	
6	Teaching hospital	Checking unit dose cart fill	--	99.1	98.2	--	--	--
8	Tertiary care institution	Checking unit dose envelopes	15,252	99.9	99.8	97	94.3	< 0.01
9	Tertiary care institution	Checking unit dose carts	7,571 technicians 3,116 pharmacists	99.8	98.9	--	--	< 0.01
11	--	Checking unit dose and parenteral medications	--	99.7	99	--	--	< 0.01 <sup>a</sup>
13	Tertiary care institutions (2)	Checking unit dose medication cassettes	161,740 technicians 35,829 pharmacists	99.9	99.5	--	--	<0.0001

<sup>a</sup> No significant statistical difference in checking parenteral admixtures

#### Pharmacist Opportunities

The implementation of TCT will assist hospitals and health systems in further expanding pharmacy clinical services. The clinical role of the pharmacist is an increasingly important requirement for providing quality patient care and optimal patient safety. However, the time required for distributive functions often limits pharmacist involvement in activities shown to improve patient outcomes and safety. Four studies reported time savings, including up to a 94.5% reduction in pharmacist time spent checking per day, and/or an increase in clinical activities as result of TCT programs. Pharmacists reported more time for direct communication with health care professionals, therapeutic drug monitoring and processing, participating in interdisciplinary rounds, medication reconciliation, and discharge counseling.<sup>3,7,12-13</sup> These studies are summarized in Table 2 below.

**Table 2: Summary of studies reporting pharmacist time savings as a result of TCT** <sup>7,12-13</sup>

Ref	Setting (# of sites)	Reporting method	Time savings	Clinical activities (as result of time savings)
3	Academic medical center	Self-reported	94.5% reduction in pharmacist time per day avg prior to TCT program: 6 hrs, 5 min avg after TCT: 20 min	<ul style="list-style-type: none"> <li>• Interviewing and discharge counseling</li> <li>• Medication reconciliation</li> <li>• Patient education</li> <li>• Rounding with patient care teams</li> <li>• Therapeutic drug monitoring and documentation</li> <li>• Electronic medication processing</li> </ul>
7	Tertiary care institutions (3)	Self-reported	--	<ul style="list-style-type: none"> <li>• Direct communication with professionals</li> <li>• Therapeutic drug monitoring/intervening</li> <li>• Evaluating drug use</li> <li>• Discharge counseling</li> </ul>
12	Specialty pharmacy	Estimation	3 hours pharmacist time per day	--
13	Tertiary care institutions (2)	Estimation	1 hour pharmacist time per day	<ul style="list-style-type: none"> <li>• Direct communication with professionals</li> <li>• Respond to drug therapy questions</li> </ul>

The PPMI Hospital Self-Assessment Survey distributed in 2011 gathered data from pharmacy departments in nearly seventy Wisconsin hospitals. In both small and large hospitals, medication reconciliation, discharge education, and medication-related continuity of care were documented as potential areas of improvement. Pharmacist involvement in patient care plan development and medication reconciliation has been shown to reduce adverse drug events, adverse drug reactions, and medication errors.<sup>4</sup>

Overall, the reallocation of pharmacist time will be dependent upon the scope of pharmacy services offered at the time of reallocation. Each individual institution must assess their needs and determine where additional pharmacist time will be best utilized. In addition to the areas for improvement listed above, other potential opportunities for pharmacists identified in the literature include:

- Development of a pharmacy residency program
- Development of ambulatory clinical services, such as smoking cessation, anticoagulation, and medication therapy management
- Development of hospital stewardship programs, such as antimicrobial stewardship
- Development of technology-related medication use safety standards

#### **Starting a Tech-Check-Tech Program**

A TCT program, verification of unit-dose medications for cart fill and automated dispensing cabinet (ADC) restock, allows for specially-trained technicians to provide the “final check” on medications prepared by another pharmacy technician. TCT helps address the workload constraints and financial pressures placed on hospitals and health system pharmacists by providing safe and effective drug distribution services and allowing for expansion of clinical pharmacy services by reallocating pharmacist time.

#### *Expectations*

- All pharmacy technicians participating in a TCT program will receive appropriate training
- All pharmacy technicians participating in a TCT program will comply with standards outlined in variances granted by the state board of pharmacy
- All pharmacy technicians participating in a TCT program will comply with the standards outlined within the policies and procedures of their institution

- Pharmacy department leaders will provide necessary financial and personnel support for successful program implementation

## Obtaining a Variance for Tech-Check-Tech<sup>†</sup>

<sup>†</sup>Information in this section of the toolkit applies to organizations requesting a variance to perform Tech-Check-Tech in Wisconsin.

### Variance Overview

#### *What is a variance?*

A variance is permission granted by the Wisconsin Pharmacy Examining Board (PEB) to perform pharmacy operations differently than expressed in the current state rules and regulations. Variances may only be requested and granted if explicitly allowed in state statute and rules. According to Phar 7.01 (4), institutions may request a variance from the PEB for rules 7.01 (1)-(3), relating to minimum procedures for compounding and distribution. TCT is allowed at a specific site through an approved variance to Phar 7.01 (1) (c) and (d). The current version of Phar 7 can be accessed [online](#).

#### *Why is a variance needed?*

Currently, the state of Wisconsin does not allow technicians to provide a final check of patient specific medications. Thus, a variance to Phar 7.01 (c) and (d), which outlines a separate process for providing safe and accurate medications to patients, can be submitted for review for institutional settings.

#### *What types of dispensing activities are eligible for a TCT variance?*

Any dispensing area can be considered. To date, variances have been approved for automated dispensing cabinets, cart fill, and packaging/repackaging of unit dose products. When submitting a variance request, all documents listed in “Steps to Complete a Variance Request” below must be submitted for review by the PEB.

#### *Are there dispensing activities which do not require a TCT variance?*

Previous institutions requesting TCT variances for ADC restock have been advised by the PEB that a variance for this activity is not necessary because restocking of ADCs is considered a normal part of the technicians’ duties and falls under the general supervision requirement of a pharmacist as the medications are not stored as patient-specific doses. Although a variance is not required for ADC restock, it is advised that institutions develop and maintain policies, procedures, and quality assurance methods surrounding these TCT activities to assist with meeting the requirement for pharmacist general supervision. This toolkit has the necessary components to adequately develop these policies, procedures, and quality assurance metrics.

### Steps to Complete a Variance Request

- Write a cover letter addressed to the PEB Chair (**Appendix B**)
- Complete the Variance Request Form (**Appendix C**)
- Submit institution-specific policies & procedures (see examples in **Appendices D, E, F**)
- Submit training (**Appendices G, H, I, J and K**), validation (**Appendices L and M**), and quality assurance documents (**Appendix N and O**)
- Documents must be submitted 15 business days prior to PEB meeting to appear on the agenda (click [here](#) for PEB meeting dates)
- Site representation is highly recommended at the PEB meeting to clarify any questions or concerns the Board may have

The variance request should address why the variance is necessary. Specifically, identify how the proposed variance will meet professional standards for patient safety and confidentiality, including how each step in the prescription order handling/dispensing process will address security, work flow delineation, accountability and pharmacist supervision.

Of note, if the variance is not suitable or needs clarification, the PEB may request the institution representative change elements of the variance request at the Board meeting. The variance is still able to be approved at that PEB meeting as amended if minor modifications are made. However, if the Board requires extensive changes from the institution, the Board will allow the institution to withdraw the request and re-submit at a later date.

**Reasons Variances are Denied or Delayed**

- Site does not submit materials 15 business days prior to the PEB meeting to make it on the agenda
- Site does not provide all documents necessary for PEB review
- Site is not present at the PEB meeting to answer questions, thus delaying approval

**Reporting Requirements**

Reporting requirements are outlined in a site’s variance. Typically, the TCT Variance Report (**Appendix P**) must be completed and sent to the PEB every six months; on or before January 31<sup>st</sup> and July 31<sup>st</sup> of each calendar year. This document serves as an official report to the PEB of the total doses checked and accuracy of each Validated Pharmacy Technician (VPT) during that six month period. The TCT Variance Report is subject to change and the most recent report form can be found [online](#).

**Tech-Check-Tech Program Structure**

All previously granted variances in the state of Wisconsin have three core elements: technician training, skill validation and ongoing quality assurance. After the successful completion of training and skill validation, these technicians are known as Validated Pharmacy Technicians (VPTs) and can perform TCT activities provided they meet established quality assurance thresholds for accuracy.

**Training**

Comprehensive technician training should confer a detailed understanding of drug distribution processes, generic and brand name product recognition, product labeling requirements, commonly encountered abbreviations, basic pharmaceutical calculations, medication errors, look-alike/sound-alike medications, and dosage form recognition. This understanding is typically accomplished through the use of self-study packets (**Appendix J**) in combination with one-on-one practical experience. Understanding of the focus areas should be assessed and documented via training checklists (**Appendices G and H**) and a formal competency exam (**Appendix K**).

**Skill Validation**

Once this training is completed, the skills and accuracy of the technician must be validated by pharmacist review (**Appendix L**). For Wisconsin institutions who have PEB-granted variances, the required number of doses for cart fill or line items for ADCs to accomplish the validation process varies as noted in Table 3. Most sites utilize a 99.8% accuracy rate based on historical studies comparing the error rates of pharmacists and technicians. This accuracy rate equates to 0 to 1 error per 500 checked doses. As described in the Literature Review section above, studies have found technician accuracy rates meet or exceed those of pharmacists.

**Table 3: Examples of PEB-approved TCT validation requirements**

	UW Hospital and Clinics	Aurora Health Care	Froedtert Hospital	Froedtert Community Memorial	St. Mary’s Hospital	Amery Regional Medical Center <sup>‡</sup>	Minnesota Board of Pharmacy <sup>15</sup>
<b>Cart Fill Validation</b>	2500 doses	2500 doses	3500 doses*	2500 doses	2500 doses	1000 doses	1500 doses
<b>ADC Validation</b>	-	-	3500 doses*	-	-	-	500 line items
<b># of Validation Sessions</b>	≥5	≥5	≥5	≥5	≥5	≥5	≥5
<b>Required Accuracy Rate</b>	98.8%	98.8%	98.8%	98.8%	98.8%	98.8%	98.8%

\*Completion of a combination of 3500 items confers ability to TCT both cart fill and ADC

<sup>‡</sup>Critical access hospital

The majority of PEB granted variances for cart fill are based on 2500 validated doses. The institutions with these variances are large in size, typically >400 beds. In December 2012, Amery Regional Medical Center, a critical access hospital, was granted a cart fill variance with 1000 validated doses.

The contributors to this toolkit feel a reasonable approach for smaller institutions is to vary the required validated doses based on the average number of doses checked per five days at that institution in an effort to lessen the burden of the cart fill TCT validation process. Table 4 below provides recommendations for this approach. The standard error of 0 to 1 errors per 500 doses checked, or 99.8% accuracy, is still maintained using this methodology. Additionally, this also maintains the standard of at least five days of technician validation that has previously been set. At the time of toolkit publication, this approach had not been considered by the PEB.

**Table 4: Recommendations for required number of validated doses (based on avg # of doses checked in five day period)**

Average Number of Doses Checked in 5 Days	Number of Doses Required for Validation	Errors Allowed	Required Accuracy Rate	Required Number of Independent Checking Days
≥ 2500	2500	5	99.8 %	5
1500 to 2499	2000	4	99.8 %	5
1000 to 1499	1500	3	99.8 %	5
500 to 999	1000	2	99.8 %	5
<500	500	1	99.8 %	5

#### Ongoing Quality Assurance

Once a technician becomes a Validated Pharmacy Technician (VPT), quality assurance protocols and documentation must be put in place to ensure the integrity of the program. Throughout Wisconsin, each program has utilized at least a 10% check of accuracy by the supervising pharmacist; whereby the pharmacist verifies at least 10% of the total doses checked by the VPT. In order to document accuracy, these results must be recorded in a Quality Assurance Error Log (**Appendix O**) every time a technician participates in TCT. Results must be maintained for each individual technician and reported to the PEB on or before January 31 and July 31 of each year (**Appendix P**). Within their quality assurance documents, sites must specify what technician accuracy rate must be achieved and maintained (**Appendix N**).

#### Policies and Procedures Related to Tech-Check-Tech

To submit a variance request to the PEB, the institution must have a specific policy and procedure in place for TCT, outlining the requirements and framework with which TCT will be performed. **Appendix D** is a generic sample policy and procedure which outlines the elements included in this toolkit. This policy and procedure should be modified prior to use based on the specifics of the institution and the TCT program that will be implemented. **Appendices E** and **F** are actual policies and procedures from specific Wisconsin institutions with TCT variances and are available for reference purposes.

#### Toolkit Instructions

The appendices within this toolkit were designed to be turn-key for easy use by each institution wishing to implement TCT programs. However, some modifications will be necessary. Each site should edit the necessary documents, policies, and procedures to include their site- and program-specific materials prior to submission to the PEB and prior to the implementation of any TCT program. Specific pieces of information which necessitate review and potential modifications are highlighted within each appendix, however additional modifications may be necessary based on the needs of the individual institution and the program being implemented. For convenience, a TCT Development and Implementation Checklist is included (**Appendix V**) as a general guide for institutions in the preparation and implementation of a TCT program.

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## Appendix B: State Comparison - Delegation by Pharmacists

### Michigan:

In order for delegation to occur:

- 1) The pharmacist must determine what knowledge and training is needed to safely complete the task
- 2) The pharmacist must evaluate that the delegate has the appropriate knowledge and training to safely complete the task
- 3) there must be a written policy and procedure for each task to be delegated
- 4) the delegated task requires pharmacist supervision
- 5) the delegating pharmacist has responsibility for the performance of delegated tasks

### Pennsylvania:

Delegation: A pharmacist may delegate aspects of the practice of pharmacy to a pharmacy intern or pharmacy technician subject to the following conditions:

- 1) The pharmacist shall review every prescription or drug order prior to its being dispensed to determine the name of the drug, strength, dosage, quantity, permissible refills and other information required under 27.18 (relating to standards of practice) to verify the accuracy of the preparation
- 2) the pharmacist shall provide direct, immediate, and personal supervision to pharmacy interns and pharmacy technicians working with the pharmacist. Direct, immediate, and personal supervision means that the supervising pharmacist has reviewed the prescription or drug order prior to its being dispensed, has verified the final product and is immediately available on the premises to direct the work of interns and technicians and respond to questions or problems
- 3) the pharmacist shall ensure that the label of the container in which a nonproprietary drug is dispensed or sold pursuant to a prescription complies with the labeling requirements of 27.18(d).

### Iowa:

155A.33 Delegation of technical functions

A pharmacist may delegate technical dispensing functions to pharmacy technicians but only if the pharmacist is physically present to verify the accuracy and completeness of the patient's prescription prior to the delivery of the prescription to the patient or the patient's representative. However, the physical presence requirement does not apply when a pharmacist is utilizing an automated dispensing system or a tech-check-tech program. When using an automated dispensing system or a tech-check-tech program, the pharmacist shall utilize an internal quality control assurance plan that ensures accuracy for dispensing. Verification of automated dispensing and tech-check-tech accuracy and completeness remains the responsibility of the pharmacist and shall be determined in accordance with rules adopted by the board.

657—3.21 (155A) Delegation of functions.

3.21(1) Technical dispensing functions. A pharmacist may delegate technical dispensing functions to an appropriately trained and registered pharmacy technician, but only if the

pharmacist is on site and available to supervise the pharmacy technician when delegated functions are performed, except as provided in 657—subrule 6.7(2) or 657—subrule 7.6(2), as appropriate, or as provided for telepharmacy in 657—Chapter 9. Except as provided for an approved tech-check-tech program pursuant to 657—Chapter 40, the pharmacist shall provide and document the final verification for the accuracy, validity, completeness, and appropriateness of the patient’s prescription or medication order prior to the delivery of the medication to the patient or the patient’s representative. A pharmacy technician shall not delegate technical functions to a pharmacy support person.

3.21(2) Nontechnical functions. A pharmacist may delegate nontechnical functions to a pharmacy technician or a pharmacy support person only if the pharmacist is present to supervise the pharmacy technician or pharmacy support person when delegated nontechnical functions are performed, except as provided in 657—subrule 6.7(2) or 657—subrule 7.6(2), as appropriate, or as provided for telepharmacy in 657—Chapter 9.

**Washington:**

Instead gives a list of professional responsibilities that a pharmacist shall NOT delegate.

**Minnesota:**

Subp. 2. Permissible duties. Pharmacy technicians may perform pharmacy tasks not specifically reserved in this chapter to a licensed pharmacist or pharmacist-intern and that do not involve the use of professional judgment.

Subp. 3. Certifying. Pharmaceutical products prepared or processed, in whole or in part, by a pharmacy technician must be certified for accuracy by a licensed pharmacist, practitioner, or pharmacist-intern as provided for in part 6800.3100, subpart 1, item F, prior to release for patient use.

Subp. 4. Written procedures. Written procedures for the use of pharmacy technicians in a pharmacy shall be prepared by the pharmacist-in-charge. A copy of the procedures must be given to each technician and a copy must be kept on file in the pharmacy. The written procedures must be made available for inspection by the board upon request. These procedures must comply with the standards in this chapter and will be reviewed for compliance on that basis.

These procedures must indicate in detail the tasks performed by the pharmacy technician; the name, address, and registration number of the pharmacy technician; and the certification steps performed by the licensed pharmacist in verifying the technician's work. Procedures must be updated at least every five years and whenever a significant change in the way in which pharmacy technicians are utilized occurs. The pharmacist-in-charge shall ensure that each technician has reviewed the procedures when the technician is first employed by the pharmacy as a technician and when any substantial changes to the procedures have been made. The pharmacist-in-charge must ensure that proper documentation of training is maintained in the pharmacy for a period of at least two years after the training occurs.

Subp. 5. Supervision. Pharmacy technicians shall be supervised by a licensed pharmacist stationed within the same work area who has the ability to control and is responsible for the action of the pharmacy technician. The ultimate responsibility for the actions of a pharmacy

technician working under a licensed pharmacist's supervision shall remain with the licensed pharmacist.

Subp. 9. Unprofessional conduct. The use of pharmacy technicians in the performance of delegated tasks not included in written procedures may be considered unprofessional conduct on the part of the pharmacist supervising the technician, the pharmacist-in-charge, and the pharmacy technician. Falsification of any documents pertaining to the training of pharmacy technicians shall be considered unprofessional conduct on the part of any pharmacist or pharmacy technician involved in such act.

## Appendix C: State Comparison – Pharmacy Patient Counseling

**Minnesota:** <https://www.revisor.mn.gov/rules/?id=6800.0910>

Policy and procedure required

New Rx – consultation required

Refill Rx – discretion of RPh

Delivery/mail – consultation can be accomplished with written info and phone #

Pt refusal – allowed with pharmacy documentation

**Illinois:** <http://www.ilga.gov/commission/jcar/admincode/068/068013300G07000R.html>

### **Section 1330.700 Patient Counseling**

New and refill Rx – offer to counsel

Pt refusal – allowed with pharmacy documentation

**Iowa:** <http://www.iowa.gov/pages/search?q=patient+counseling&=Search>

New Rx – counseling required

Refill Rx – not required

Pt refusal – allowed with pharmacy documentation

## Appendix D: Labeling Standards

### NABP Model Practice Act (with some changes made to be consistent with changes to Chapter 450)

- (i) Critical Information for Patients – Critical information must appear on the label with emphasis (highlighted or bolded), in a sans serif typeface (such as “arial”), minimum 12-point size, and in “sentence case.” Field size and font size may be increased in the best interest of patient care. Critical information text should never be truncated and shall include:
  - (A) patient name
    - (-a-) legal name of the patient; or
    - (-b-) if patient is an animal, include the last name of the owner, name of the animal, and animal species.
  - (B) directions for use
    - (-a-) directions for use as indicated by the prescriber and medication purpose/indication if included on prescription drug order; and
    - (-b-) language should be simplified, avoiding unfamiliar words and medical jargon; when applicable, use numeric instead of alphabetic characters.
  - (C) drug name
    - (-a-) if written for a brand name and a generic drug is dispensed, include phrase “Generic for [brand name];”and
    - (-b-) include drug name suffixes, such as CD, SR, XL, XR, etc.
  - (D) drug strength, expressed in the metric system whenever possible
  - (E) “use by” date
    - (-a-) date after which medication should be used; not expiration date of medication or expiration date of prescription; and
    - (-b-) format as – “Use by: MM/DD/YY.”
- (ii) Important information for patients – Must appear on the label but should not supersede critical information for patients and shall include:
  - (A) pharmacy name or dispensing practitioner’s entity name;
  - (B) pharmacy telephone number;
  - (C) prescriber name;
    - (-a-) format as – “Prescriber: [prescriber name].”
  - (D) “fill date;”
    - (-a-) format as – “Date filled: MM/DD/YY.”
  - (E) prescription number;
  - (F) drug quantity;
    - (-a-) format as – “Qty: [number].”
  - (G) number of remaining refills;
    - (-a-) format as – “Refills: [number remaining]” or “No refills,” using whole numbers only and managing partial fills through the pharmacy record keeping system;
  - (H) written or graphic product description;
  - (I) auxiliary information;
  - (J) any cautions and other provisions which may be required by federal or state law.
- (iii) The following additional information for Patients – may appear on the label:
  - (A) bar codes;

- (B) pharmacy address; and
- (C) store number.

**EXPLANATION:**

The USP has recommended Chapter 17 be adopted by state boards similar to what is happening with 797.

The NAPB has worked closely with the USP to incorporate the USP recommendations into the Model Practice Act language.

The only state I could find that had addressed this issue in their regulations was the State of California (links included in the references). The proposed language was very detailed. The comment period recently ended and some suggested the regulations were going to be very expensive to implement because of computer system changes. Others commented about how the regulations would be enforced.

Based on research on medication errors and medication misuse it is important to implement regulations that address these issues but it is also important not to make the language too specific that it makes pharmacy implementation unreasonable. It is also important that the language is not so vague rendering it unenforceable. I felt the NABP language was the best mix of these.

**REFERENCES:**

**USP Chapter 17 General Info**

Enforcement of the standard will be the decision of individual state boards of pharmacy, which may choose to adopt it into their regulations—similar to USP standards for sterile and nonsterile pharmaceutical compounding, both of which are widely recognized by states. At its 2012 annual meeting, the National Association of Boards of Pharmacy passed a resolution supporting state boards in requiring a standardized prescription container label.

Key areas covered in General Chapter <17> include organizing the label in a patient-friendly way, using explicit language to describe dosages and intervals, improving readability with clear formatting, including “purpose for use” (e.g., “for high blood pressure”) and addressing those with visual impairments and those with limited English comprehension.

**NABP Model Practice Act**

**Labeling**

- (1) All Drugs Dispensed for use by inpatients of a hospital or other health care facility, whereby the Drug is not in the possession of the ultimate user prior to Administration, shall meet the following requirements:

- (i) The label of a single-unit package of an individual-dose or unit-dose system of packaging of Drugs shall include:
  - (A) the nonproprietary or proprietary name of the Drug;
  - (B) the route of Administration, if other than oral;
  - (C) the strength and volume, where appropriate, expressed in the metric system whenever possible;
  - (D) the control number and expiration date;
  - (E) identification of the repackager by name or by license number shall be clearly distinguishable from the rest of the label; and
  - (F) special storage conditions, if required.
- (ii) When a multiple-dose Drug Distribution system is utilized, including Dispensing of single unit packages, the Drugs shall be Dispensed in a container to which is affixed a label containing the following information:
  - (A) identification of the Dispensing Pharmacy;
  - (B) the patient's name;
  - (C) the date of Dispensing;
  - (D) the nonproprietary and/or proprietary name of the Drug Dispensed; and
  - (E) the strength, expressed in the metric system whenever possible.
- (2) All Drugs Dispensed to inpatients for self-administration shall be Labeled in accordance with Subparagraph 4 of this Section (e).
- (3) Whenever any Drugs are added to parenteral solutions, such admixtures shall bear a distinctive label indicating:
  - (i) name of solution, lot number, and volume of solution;
  - (ii) patient's name;
  - (iii) infusion rate;
  - (iv) bottle sequence number or other system control number;
  - (v) name and quantity of each additive;
  - (vi) date of preparation;
  - (vii) Beyond-Use Date and time of parenteral admixture; and
  - (viii) ancillary precaution labels.
- (4) All Drugs Dispensed to ambulatory or outpatients, including Drugs Dispensed by Practitioners shall contain a label affixed to the container in which such Drug is Dispensed including:
  - (i) Critical Information for Patients – Critical information must appear on the label with emphasis (highlighted or bolded), in a sans serif typeface (such as "arial"), minimum 12-point size, and in "sentence case." Field size and font size may be increased in the best interest of patient care. Critical information text should never be truncated and shall include:
    - (A) patient name
      - (-a-) legal name of the patient; or
      - (-b-) if patient is an animal, include the last name of the owner, name of the animal, and animal species.
    - (B) directions for use
      - (-a-) directions for use as indicated by the prescriber and medication purpose/indication if included on prescription drug order; and
      - (-b-) language should be simplified, avoiding unfamiliar words and medical jargon; when applicable, use numeric instead of alphabetic characters.
    - (C) drug name

- (-a-) if written for a brand name and a generic drug is dispensed, include phrase “Generic for [brand name];”and
      - (-b-) include drug name suffixes, such as CD, SR, XL, XR, etc.
    - (D) drug strength, expressed in the metric system whenever possible
    - (E) “use by” date
      - (-a-) date after which medication should be used; not expiration date of medication or expiration date of prescription; and
      - (-b-) format as – “Use by: MM/DD/YY.”
  - (ii) Important information for patients – Must appear on the label but should not supersede critical information for patients and shall include:
    - (A) pharmacy name or dispensing practitioner’s entity name;
    - (B) pharmacy telephone number;
    - (C) prescriber name;
      - (-a-) format as – “Prescriber: [prescriber name].”
    - (D) “fill date;”
      - (-a-) format as – “Date filled: MM/DD/YY.”
    - (E) prescription number;
    - (F) drug quantity;
      - (-a-) format as – “Qty: [number].”
    - (G) number of remaining refills;
      - (-a-) format as – “Refills: [number remaining]” or “No refills,” using whole numbers only and managing partial fills through the pharmacy record keeping system;
    - (H) written or graphic product description;
    - (I) auxiliary information;
    - (J) any cautions and other provisions which may be required by federal or state law.
  - (iii) The following additional information for Patients – may appear on the label:
    - (A) bar codes;
    - (B) pharmacy address; and
    - (C) store number.
- (5) No radiopharmaceutical may be Dispensed unless a label is affixed to the immediate container bearing the following information:
- (i) the standard radiation symbol;
  - (ii) the words “Caution – Radioactive Material”; and
  - (iii) the prescription number.
- (6) No radiopharmaceutical may be Dispensed unless a label is affixed to the outer or Delivery container bearing the following information:
- (i) the standard radiation symbol;
  - (ii) the words “Caution – Radioactive Material”;
  - (iii) the radionuclide and chemical form;
  - (iv) the activity and date and time of assay;
  - (v) the volume, if in liquid form;
  - (vi) the requested activity and the calibrated activity;
  - (vii) the prescription number;
  - (viii) patient name or space for patient name. Where the patient’s name is not available at the time of Dispensing, a 72-hour exemption is allowed to obtain the name of the patient. No later than 72 hours after Dispensing the radiopharmaceutical, the

patient's name shall become a part of the Prescription Drug Order to be retained for a period of three years;

- (ix) the name and address of the nuclear Pharmacy;
- (x) the name of the Practitioner; and
- (xi) the lot number of the prescription.

### California Proposed Regulations

[http://www.pharmacy.ca.gov/laws\\_regs/1707\\_5\\_isor.pdf](http://www.pharmacy.ca.gov/laws_regs/1707_5_isor.pdf)

[http://www.pharmacy.ca.gov/laws\\_regs/1707\\_5\\_proposed.pdf](http://www.pharmacy.ca.gov/laws_regs/1707_5_proposed.pdf)

### WI Chapter 450

#### 4) LABEL REQUIRED.

(a) Except as provided under par. (b), no prescribed drug or device may be dispensed unless there is a label attached to the container disclosing all of the following:

1. The name and address of the dispensing practitioner or licensed facility from which the prescribed drug or device was dispensed.

1m. The telephone number of the pharmacy, if the prescribed drug or device is dispensed by an out-of-state pharmacy licensed under s. 450.065.

2. The date on which the prescription was dispensed.

3. The number of the prescription order as recorded in the prescription order file of the facility from which the prescription was dispensed.

4. The name of the practitioner who prescribed the drug or device.

5.

a. Except as provided in subd. 5. b. and c., the full name of the patient.

b. For an antimicrobial drug dispensed under sub. (1g), the full name of the patient, if known, or the words, "expedited partner therapy" or the letters "EPT."

c. For an opioid antagonist when delivered under sub. (1i) (a), the name of the person to whom the opioid antagonist will be delivered as specified in s. 441.18 (2) (a) or 448.037 (2) (a).

6. Directions for use of the prescribed drug or device as contained in the prescription order.

7. The name and strength of the prescribed drug dispensed, unless the prescribing practitioner requests omission of the name and strength of the drug dispensed.

8. The symptom or purpose for which the drug is being prescribed if the prescription order specifies the symptom or purpose under sub. (4m).

(b) Paragraph (a) does not apply to complimentary samples of drug products or devices dispensed by a practitioner to his or her patients.

#### (4g) BRAND NAME PERMITTED ON LABEL.

(a) In this subsection:

1. "Brand name" has the meaning given in s. 450.12 (1) (a).

2. "Drug product equivalent" has the meaning given in s. 450.13 (1).

3. "Generic name" has the meaning given in s. 450.12 (1) (b).

- (b)** 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 label required under sub. (4) (a) 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.
- (4m)** LABEL OPTIONS. If a patient indicates in writing to a practitioner who makes a prescription order for the patient that the patient wants the symptom or purpose for the prescription to be disclosed on the label, the practitioner shall specify the symptom or purpose in the prescription order.

## Appendix E: State Comparisons - Labeling Standards for Multiple Medications in a Package

- **Minnesota:** Customized patient medication packages. In lieu of dispensing two or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or the prescriber, provide a customized patient medication package as defined in the United States Pharmacopeia (USP), chapter 661, standards.
- **Oregon:** Labeling: The patient med pak shall be accompanied by a patient package insert, in the event that any medication therein is required to be dispensed with such insert as accompanying labeling.

Alternatively, such required information may be incorporated into a single, overall educational insert provided by the pharmacist for the total patient med pak.

### Iowa:

- 22.5(6) Alternate labeling. If the patient med pak container is not of sufficient size to accommodate the label information as required in subrule 22.5(5) in a legible font, a patient med pak;  
The patient package insert shall contain all label information required in subrule 22.5(5). In such case, the label affixed to the patient med pak shall minimally include:
  - a. The name of the patient;
  - b. A statement directing the patient or patient's caregiver to the patient package insert; and
  - c. The beyond-use date assigned to the patient med pak;
  - d. The name and telephone number of the dispensing pharmacy.