



PHARMACY RULES COMMITTEE
of the
PHARMACY EXAMINING BOARD

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

- 1) **Phar 2, 4 Relating to Application and Examination (2-6)**
- 2) **Phar 5 Relating to Renewal and Reinstatement (7-9)**
- 3) **Phar 6 Relating to Temperature and Humidity Controls**
- 4) **Phar 14 Relating to Home Medical Oxygen Providers (10-13)**
- 5) **Phar 7 Relating to Practice of Pharmacy (13-26)**
 - a) **Types of Pharmacies**
 - b) **Technicians**
 - c) **Counseling**
- 6) **Update on Legislation and Pending or Possible Rulemaking Projects**

C. Public Comments

ADJOURNMENT

TEXT OF RULE

SECTION 1. Phar 1.02(6m) is created to read:

Phar 1.02(6m) “NABP” means the National Association of Boards of Pharmacy.

SECTION 2. Phar 2.01 is repealed.

SECTION 3. Phar 2.02 (1) (intro) and (a) are amended to read:

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~~ Completed application form with the signature of the applicant.

SECTION 4. Phar 2.02 (f) and (g) are created to read:

Phar 2.02 (f) Evidence of having passed the NAPLEX.

(g) Evidence of having passed the multi-state pharmacy jurisprudence examination.

SECTION 5. Phar 2.03 and 2.04 is repealed.

SECTION 6. Phar 2.05 repealed and recreated:

Phar 2.05 Application procedure for persons licensed in another state. Each applicant licensed as a pharmacist in another state shall submit all of the following:

- (1) Completed application and fee as determined by the department under s. 440.05, Stats.
- (2) NABP Clearinghouse license transfer application.
- (3) Evidence of having passed the multi-state pharmacy jurisprudence examination.

SECTION 7. Phar 4.01 is repealed.

SECTION 8. Phar 4.03 is amended to read:

Phar 4.03 Passing scores. (1) The passing scores set by the board represent the minimum competency required to protect public health and safety. The board may adopt the recommended passing score of the examination provider.

SECTION 9. Phar 4.03(3) is repealed.

SECTION 10. Phar 4.04, 4.045 and 4.046 are repealed.

SECTION 11. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

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), renum. and am. (4) to be (2) and renum. (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), renum. (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.

TEXT OF RULE

SECTION 1. Phar 5.01 (1) is amended to read:

Phar 5.01 Requirements. (1) Pharmacists, pharmacies, manufacturers, ~~and~~ distributors and home medical oxygen providers licensed under ch. 450, Stats., and otherwise qualified for renewal, may continue to be licensed biennially by applying for renewal and paying the fee ~~specified in s. 440.08(2), Stats.~~ as determined by the department under s. 440.03(9)(a), Stats..

SECTION 2. Phar 5.01 (3) is amended to read:

Phar 5.01(3) No pharmacy, manufacturer, ~~or~~ distributor or home medical oxygen provider may operate without a current license.

SECTION 3. Phar 5.04 is amended to read:

Phar 5.04 Renewal prohibited; relicensure. Any person whose license is currently suspended or revoked may not renew his or her license. ~~A person whose license has been suspended or revoked and subsequently reinstated by the board, and who is otherwise qualified for renewal, may renew his or her license upon completion of a renewal form and filing of the required renewal fee.~~

SECTION 4. Phar 5.05 is repealed and recreated to read:

Phar 5.05 Renewal. (1) GENERAL. A person with an expired credential may not reapply for a credential using the initial application process.

(2) RENEWAL WITHIN 5 YEARS. A person renewing the license within 5 years shall do all of the following:

(a) Pay the renewal fee as determined by the department under s. 440.03(9)(a), Stats. and any applicable late renewal fee.

(b) Certify the completion of 30 hours of continuing education during the last biennium.

(3) RENEWAL AFTER EXPIRATION DATE. Notwithstanding par. (2), if a pharmacist fails to obtain renewal on or before the applicable renewal date, the board may suspend the pharmacist's license and may require the pharmacist to pass an examination to the satisfaction of the board to restore that license.

{NOTE: Need to discuss this section}

(4) RENEWAL AFTER 5 YEARS. This subsection does not apply to license holders who have unmet disciplinary requirements or whose license has been surrendered or revoke. A person renewing the credential after 5 years shall do all of the following:

(a) Pay the renewal fee as determined by the department under s. 440.03(9)(a), Stats. and the renewal late fee.

(b)

SECTION 5. Phar 5.06 is created to read:

Phar 5.06 Reinstatement. A licensee who has unmet disciplinary requirements and failed to renew the license within 5 years or whose license has been surrendered or revoked may apply to have the license reinstated in accordance with all of the following:

- (1) Evidence of completion of the requirements in Phar 5.05(4) if the license has not been active within 5 years.
- (2) Evidence of completion of the disciplinary requirements, if applicable.
- (3) Evidence of rehabilitation or change in circumstances warranting reinstatement.

SECTION X.

SECTION X.

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

(END OF TEXT OF RULE)

Chapter Phar 5

LICENSE RENEWAL

Phar 5.01 Requirements.
Phar 5.02 Change of name or address.
Phar 5.03 Display of licenses.

Phar 5.04 Renewal prohibited; relicensure.
Phar 5.05 Requirements for late renewal; reinstatement.

Phar 5.01 Requirements. (1) Pharmacists, pharmacies, manufacturers and distributors licensed under ch. 450, Stats., and otherwise qualified for renewal, may continue to be licensed biennially by applying for renewal and paying the fee specified in s. 440.08 (2), Stats.

(2) No one without a current renewal certificate may engage in the practice of pharmacy, nor hold himself or herself out to be a pharmacist nor use the title or letters “Pharmacist” or “Registered Pharmacist” or “R.Ph.”

(3) No pharmacy, manufacturer or distributor may operate without a current license.

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

Phar 5.02 Change of name or address. (1) A pharmacist shall notify the board in writing when his or her name has been legally changed, within 30 days of the change.

(2) A pharmacist shall notify the board in writing when his or her address has been changed, within 30 days of the change.

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

Phar 5.03 Display of licenses. A pharmacist who engages in the practice of pharmacy shall display his or her license in a manner conspicuous to the public view. Biennial renewal cards shall be displayed with the license when received. Only current renewal cards may be displayed. A pharmacist may not display his or her license in any place other than the pharmacy where he or she engages in the practice of pharmacy. A pharmacist who engages in the practice of pharmacy at more than one pharmacy shall display his or her license and renewal card in the pharmacy at which he or she practices most.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. Register, January, 1996, No. 481, eff. 2-1-96.

Phar 5.04 Renewal prohibited; relicensure. Any person whose license is currently suspended or revoked may not renew his or her license. A person whose license has been suspended or revoked and subsequently reinstated by the board, and who is otherwise qualified for renewal, may renew his or her license upon completion of a renewal form and filing of the required renewal fee.

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

Phar 5.05 Requirements for late renewal; reinstatement. (1) An individual who files an application for renewal of a license within 5 years after the renewal date may be reinstated by filing with the board all of the following:

(a) An application for renewal on a form prescribed by the department.

(b) The fee required under s. 440.08 (2), Stats., plus the applicable late renewal fee required under s. 440.08 (3), Stats.

(2) An individual who files an application for renewal of a license 5 years or more after the renewal date may be reinstated by filing with the board all of the following:

(a) An application for renewal on a form prescribed by the department.

(b) The fee required under s. 440.08 (2), Stats., plus the applicable late renewal fee required under s. 440.08 (3), Stats.

(c) Verification of successful completion of examinations or educational requirements, or both, as the board may prescribe, provided that the examination or education requirements may not be more extensive than those required to obtain an initial license.

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

Chapter Phar 14

HOME MEDICAL OXYGEN PROVIDERS

Phar 14.01 Application. Each applicant for licensure as a home medical oxygen provider shall submit all of the following:

- (1) Submits an application for licensure on a form provided by the board.
- (2) Pays the fee specified in s. 440.05(1).
- (3) Evidence of accreditation by an organization deemed an accreditation organization for suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) by the United States department of health and human services, centers for medicare and medicaid services.

Phar 14.02 Standards of Professional Conduct. Licensed home medical oxygen providers and their employees and agents shall do all of the following:

- (1) Comply with all transportation rules and regulations while transporting oxygen in cylinder or liquid form.
- (2) Comply with food and drug administration regarding transporting medical oxygen systems.
- (3) Demonstrate that oxygen provided to cylinder or liquid form meets purity standards for medical grade oxygen.
- (4) Meet safety inspection requirements including all of the following:
 - (a) Demonstrate that each piece of oxygen or respiratory equipment has been checked, is free of defect and operates within the manufacturer's specifications.
 - (b) Equipment shall not be modified to the extent that the modification may reasonably cause harms.
 - (c) Maintain all electrical components so that they do not present a fire or shock hazard.
 - (d) Ensure that all appropriate warning labels, including tags, are present on the equipment provided.
- (5) Maintain recall procedures including all of the following:
 - (a) Ensure that lot numbers and expiration dates are affixed to each cylinder delivered.
 - (b) Maintain a tracking system for all medical oxygen and gas delivered.
 - (c) Document all equipment serial numbers and model numbers to ensure that equipment can be retrieved if a recall is initiated.
 - (d) Maintain records for equipment that requires food and drug administration tracking.
- (6) Comply with the all of the following maintenance and cleaning requirements:
 - (a) Maintain documentation demonstrating that a function and safety check of equipment was performed prior to set up.
 - (b) Maintain an established protocol for cleaning and disinfecting equipment which address both aerobic and anaerobic pathogens.
 - (c) Maintain a material safety data sheet on file for solutions and products used in cleaning and disinfecting procedures.
 - (d) Maintain segregated areas on the premises and in delivery vehicles for clean, dirty and contaminated equipment.

- (e) Clean and disinfect equipment according to manufacturers' specifications.
 - (f) Instruct the patient on proper cleaning techniques as specified by the manufacturer.
- (7) Implement a comprehensive preventative maintenance program which includes all of the following
- (a) Procedures for problem reporting, tracking, recall and resolution.
 - (b) Performance of service as specified by the manufacturer and the documentation of such performance in the service records.
 - (c) Routine inspection, service, and maintenance of equipment located in the patient's or customer's home according to manufacturers' specifications.
- (8) Maintain repair logs to document repair and maintenance of equipment, including oxygen concentrators, infant monitors and mechanical ventilators. The repair log shall include all of the following:
- (a) Type of equipment.
 - (b) Manufacturer.
 - (c) Model.
 - (d) Serial number.
 - (e) Date of repair.
 - (f) Specific repair made.
 - (g) Name of person or company performing the repair.
- (9) Maintain testing equipment to ensure accurate calibration. Testing equipment shall be appropriate for the level of service offered. Scales used to weigh liquid oxygen reservoirs shall be properly maintained to ensure accuracy.
- (10) Provide counseling including all of the following:
- (a) Utilize orientation checklists for review all of the following:
 1. Instructions for use of the equipment.
 2. Safety precautions.
 3. Cleaning procedures.
 4. Maintenance procedures.
 5. Return demonstrations on back up oxygen systems delivered.
 - (b) Instruct the patient about emergency and routine contact procedures.
 - (c) Deliver and review written instruction materials to ensure that the patient receives information regarding the operation of the equipment.
- (11) Develop, implement and document a written plan of services in the patient record, including an assessment of the safety of the home environment, the caregiver or patient ability to comply with the prescription and the caregiver or patient ability to operate and clean the equipment as instructed.

State of Wisconsin



2015 Senate Bill 13

Date of enactment: **March 23, 2015**
Date of publication*: **March 24, 2015**

2015 WISCONSIN ACT 3

AN ACT *to amend* 450.03 (1) (e), 450.08 (2) (b) and 450.11 (3); and *to create* 440.08 (2) (a) 38h. and 450.076 of the statutes; **relating to:** licensure of home medical oxygen providers, providing an exemption from emergency rule procedures, and granting rule-making authority.

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

SECTION 1. 440.08 (2) (a) 38h. of the statutes is created to read:

440.08 (2) (a) 38h. Home medical oxygen provider:
June 1 of each even-numbered year.

SECTION 2. 450.03 (1) (e) of the statutes is amended to read:

450.03 (1) (e) Any person lawfully practicing within the scope of a license, permit, registration, certificate, or certification granted to provide home medical oxygen under s. 450.076, to practice professional or practical nursing or nurse-midwifery under ch. 441, to practice dentistry or dental hygiene under ch. 447, to practice medicine and surgery under ch. 448, to practice optometry under ch. 449 or to practice veterinary medicine under ch. 453, or as otherwise provided by statute.

SECTION 3. 450.076 of the statutes is created to read:

450.076 Home medical oxygen providers; licensure. (1) DEFINITIONS. In this section:

(a) "Home medical oxygen provider" means a person that provides medical oxygen directly to a consumer or patient in this state for that consumer's or patient's own use.

(b) "Licensed provider" means a home medical oxygen provider licensed under this section.

(c) "Medical oxygen" means oxygen that is a prescription drug.

(2) LICENSE REQUIRED. (a) Except as provided in par. (b), no person may operate as a home medical oxygen provider, use the title "home medical oxygen provider" or any similar title, or hold itself out as a home medical oxygen provider unless the person is a licensed provider.

(b) No license under this section is required for any of the following:

1. A person that holds a current credential, as defined in s. 440.01 (2) (a), and is acting within the scope of that credential.

2. A hospital, excluding any home medical oxygen provider that is owned or operated by a hospital.

3. An employee or agent of a licensed provider acting within the scope of his or her employment or agency.

(3) LICENSURE. The board may grant a license to act as a home medical oxygen provider to a person that does all of the following:

(a) Submits an application for licensure on a form provided by the board.

(b) Pays the fee specified in s. 440.05 (1).

(c) Satisfies any other requirements established by the board by rule.

(4) RULES. The board shall promulgate rules implementing this section. The rules shall include rules gov-

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

erning the professional conduct of licensed providers and their employees and agents.

SECTION 4. 450.08 (2) (b) of the statutes is amended to read:

450.08 (2) (b) A pharmacy, manufacturer's or distributor's, or home medical oxygen provider's license may be renewed by paying the applicable fee determined by the department under s. 440.03 (9) (a) on or before the applicable renewal date specified under s. 440.08 (2) (a).

SECTION 5. 450.11 (3) of the statutes is amended to read:

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

SECTION 6. Nonstatutory provisions.

(1) EMERGENCY RULES. The pharmacy examining board may promulgate emergency rules under section 227.24 of the statutes implementing section 450.076 of

the statutes, as created by this act. Notwithstanding section 227.24 (1) (c) and (2) of the statutes, emergency rules promulgated under this subsection remain in effect until June 30, 2017, or the date on which permanent rules take effect, whichever is sooner. Notwithstanding section 227.24 (1) (a) and (3) of the statutes, the board is not required to provide evidence that promulgating a rule under this subsection as an emergency rule is necessary for the preservation of the public peace, health, safety, or welfare and is not required to provide a finding of emergency for a rule promulgated under this subsection.

(2) REGULATION OF HOME MEDICAL OXYGEN PROVIDERS. The pharmacy examining board shall administer section 450.076 of the statutes, as created by this act, on a case-by-case basis prior to the effective date of the rules promulgated under section 450.076 (4) of the statutes.

SECTION 7. Effective date.

(1) The treatment of section 450.076 (2) (a) of the statutes takes effect on May 1, 2015, or on the day after publication, whichever is later.

Chapter Phar 7 – Pharmacy Practice Revisions: Pharmacist Delegation Topic Area

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 or its members.

Background:

Phar 7.015 allows pharmacists to delegate technical dispensing functions to a pharmacy technician. However, it does not explicitly address pharmacist delegation of technical non-dispensing functions. While technicians perform duties related to dispensing medications, they also perform duties not directly related to dispensing medications, such as the collection of medication lists/histories from patients in health system settings. In addition, another aspect that is not addressed is if pharmacists can delegate technical functions to another healthcare colleague such as a medical assistant. Both of the issues outlined earlier would need to fall within the scope of pharmacy practice and therefore any revisions to encompass pharmacist delegation opportunities may be limited by statutory authority.

Summary of Methods:

The NABP Model Practice Act and pharmacy administrative rules were reviewed from Michigan, Pennsylvania, Iowa, Washington and Minnesota.

Summary of Recommendations:

Based on a review of the pharmacist delegation policies in other states, we request that the PEB consider options for revising existing pharmacist delegation balancing statutory authority for doing so.

State Example Language:

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.

Chapter Phar 7 – Pharmacy Practice Revisions: Tech-Check-Tech Topic Area

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 or its members.

Background:

Tech-check-tech (TCT), the checking of a technician's order-filling by another technician rather than a pharmacist, is a process that has demonstrated accuracy rates similar to that of a pharmacist and has yielded efficiencies in the medication filling process in institutional settings. TCT has been identified as a process that promises to elevate technician roles and enable pharmacist practice advancement, shifting responsibilities from medication distribution to medication utilization management. Over a dozen states (AZ, LA, MI, MO, NC, ND, RI, SC, and TN) permit technicians to check the work of other technicians in the institutional setting and five states (CO, IA, MI, ND, SC) allow it in the community setting. States that have enabling laws for TCT have consistent requirements for technicians with TCT responsibilities. They are: 1) credentialing requirements for technicians; 2) training, documentation, monitoring, and remediation policies; and 3) establishing that the pharmacist is ultimately responsible.

Summary of Methods:

For the purposes of this discussion, laws and rules for TCT were reviewed for the states of Iowa and North Dakota.

Summary of Recommendations

Based on a review of the TCT policies in other states, we request that the PEB consider the following: 1) adopt a vision for elevating and expanding privileges of technicians. For example, Iowa states clearly their purpose and scope for as "TCT is not intended to reduce pharmacist staffing levels but is intended to increase the availability of the pharmacist for involvement in cognitive and patient care activities;" 2) identify statutory limitations for authorizing expanded technician opportunities and solutions for resolving them; 3) streamline existing TCT variance approval and reporting requirements for institutional settings; and 4) evaluate the opportunity to expand TCT beyond institutional practice sites (e.g. long term care or community/ambulatory settings).

State Example Model Language

Iowa Tech-Check-Tech Language

CHAPTER 40 TECH-CHECK-TECH PROGRAMS

657—40.1(155A) Purpose and scope. The board may authorize a hospital pharmacy to participate in a tech-check-tech program. The board may authorize a general pharmacy providing pharmaceutical services to patients in a long-term care facility as defined herein to

participate in a tech-check-tech (TCT) program for dispensing only to patients in the long-term care facility. The purpose of the tech-check-tech program is to authorize certified pharmacy technicians to review the work of other certified pharmacy technicians in connection with the filling of floor stock, including automated medication distribution systems (AMDS) and unit dose dispensing systems for institutionalized patients whose orders have previously been reviewed and approved by a licensed pharmacist, for the purpose of redirecting and optimizing pharmacist patient care services. Implementation of a tech-check-tech program is not intended to reduce pharmacist staffing levels but is intended to increase the availability of the pharmacist for involvement in cognitive and patient care activities.

657—40.2(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

“Automated medication distribution system” or “AMDS” includes, but is not limited to, an automated device or series of devices operated by an electronic interface with one or more computers that is used to prepare, package, or dispense specified dosage units of drugs for administration or dispensing to a patient or the ultimate user. “AMDS” includes a device that prepares and packages a drug for unit dose dispensing, that prepares and packages a drug into outpatient prescription vials, and that dispenses prepackaged drugs.

“Board” means the board of pharmacy.

“Certified medication aide” means an individual who has successfully completed a medication aide course approved by the Iowa department of inspections and appeals or who has passed a medication aide challenge examination approved by the Iowa department of inspections and appeals and administered by an area community college. A “certified medication aide” is not a “licensed health care professional” as that term is used herein.

“Certified pharmacy technician” means an individual who holds a valid current national certification and who has registered with the board as a certified pharmacy technician pursuant to 657—Chapter 3.

“Checking technician” means a certified pharmacy technician who has been authorized by the pharmacist in charge to participate in a TCT program by checking the work of other certified pharmacy technicians.

“Component” means any single physical or electronic storage or access device that, in combination with other devices, makes up an AMDS.

“Drug bin” means a compartment in an AMDS component that is designed to contain one specific drug.

“Floor stock” means a supply of drugs consisting of emergency drugs and controlled substances that are routinely maintained on patient care units and accessible by nursing staff for patient administration.

“Hospital pharmacy” means a pharmacy licensed by the board pursuant to 657—Chapter 7 and located within a facility which is primarily engaged in providing, by or under the supervision of physicians, concentrated medical and nursing care on a 24-hour basis to inpatients and which

maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses.

“Long-term care facility” means a nursing home, retirement care, mental care, or other facility or institution which provides extended health care to resident patients and which is registered by the board for controlled substances under Iowa Code chapter 124.

“Medication order” means a written or electronic order from a practitioner or an oral order from a practitioner or the practitioner’s authorized agent for administration of a drug or device and, for purposes of this chapter, includes a prescription drug order.

“TCT program” means a board-approved tech-check-tech program implemented and formally established pursuant to these rules by the pharmacist in charge who has determined that one or more certified pharmacy technicians are qualified to safely check the work of other certified pharmacy technicians and thereby provide final verification of drugs which are dispensed for subsequent administration to patients in an institutional setting.

“Unit dose dispensing system” means a drug distribution system utilizing single unit, unit dose, or unit of issue packaging in a manner that helps reduce or remove traditional drug stocks from patient care areas, enables the selection and distribution of drugs to be pharmacy-based and controlled, and improves accountability and accuracy.

657—40.3(155A) General requirements. To participate in a TCT program, a hospital pharmacy shall be located in Iowa and provide pharmaceutical services to patients receiving treatment in a hospital located in Iowa. To participate in a TCT program, a general pharmacy shall be located in Iowa, and a TCT program shall only be implemented to provide pharmaceutical services to patients in a long-term care facility located in Iowa.

40.3(1) Site-specific. A TCT program shall be specific to the site at which implementation of the program is proposed and shall include a site-specific training program tailored to the patient population and the drug distribution system utilized.

40.3(2) Plan approval. At least 90 days prior to anticipated implementation of a TCT program, the pharmacist in charge shall submit the program plan, consistent with the requirements of these rules, for board approval. A pharmacy shall not implement a TCT program prior to receipt of notification that the board has approved the submitted TCT program plan.

40.3(3) Technician utilization plan. The pharmacy technician utilization plan shall specifically identify the individual certified pharmacy technicians authorized to participate in the TCT program and shall identify in detail the types of work that the certified pharmacy technicians may perform and check. The pharmacy shall include participation in the TCT program in the defined duties of any certified pharmacy technician authorized to participate in the TCT program, and if the certified pharmacy technician is authorized to check the work of other certified pharmacy technicians, that function shall be clearly identified in the checking technician’s duties.

40.3(4) Certified pharmacy technician participation. All of the following shall apply to a certified pharmacy technician authorized to participate in a TCT program.

- a. National certification. The certified pharmacy technician's national certification shall be current and in good standing.
- b. Iowa registration. The certified pharmacy technician's registration with the board shall be current, in good standing, and not currently subject to disciplinary charges or sanctions.
- c. Prior experience. The checking technician shall be working at the pharmacy full- or part-time and shall have met the experience requirement for a checking technician as specified in policies and procedures and in the TCT program plan.
- d. Training. The certified pharmacy technician shall complete site-specific training in the TCT program and the functions to be performed by the certified pharmacy technician as part of the TCT program.
- e. Specialized training for checking technician. A certified pharmacy technician who is a checking technician shall receive specialized and advanced training as provided in policies and procedures, including training in the prevention, identification, and classification of medication errors. The training program for a checking technician shall be didactic in nature and shall include successful completion of a competency test.

40.3(5) Responsible individuals. The pharmacist in charge may designate one pharmacist to be responsible for meeting TCT program training and validation requirements and may designate one or more pharmacists to supervise the activities of certified pharmacy technicians authorized to participate in the TCT program. A pharmacist supervising TCT program activities shall provide program plan evaluation information to the responsible pharmacist or the pharmacist in charge for collection and analysis. Each individual involved in the TCT program shall be responsible for the activities performed by that individual and for ensuring that those activities adhere to the TCT program policies and procedures and comply with board rules. The pharmacist in charge shall be ultimately responsible for TCT program activities and for development and implementation of TCT program policies and procedures.

40.3(6) Policies and procedures. Parameters for supervising the activities of certified pharmacy technicians participating in the TCT program, including but not limited to specialized and advanced training for checking technicians, shall be specified in policies and procedures regarding the utilization of pharmacy technicians. Policies and procedures shall provide for continuous evaluation of certified pharmacy technicians authorized to participate in the TCT program, shall identify benchmarks and sentinel events, shall define an excessive overall error rate, shall address certified pharmacy technician retraining procedures, and shall address pharmacy staffing.

40.3(7) Staffing. Pharmacy staffing shall be adequate to ensure consistent and safe implementation of the TCT program and to optimize pharmacist patient care services.

40.3(8) Pharmacist review. Except in an emergency, when the pharmacy is closed, or when the prescriber is directly supervising and overseeing the administration of the drug to the patient, a pharmacist shall review all orders against a medication profile as required by rule 657—8.21(155A). A pharmacist shall be on site and available to certified pharmacy technicians during any period that TCT functions are being performed.

40.3(9) Additional drug check prior to administration. The drug distribution system shall be structured so that at least one additional check of dispensed drugs, following dispensing and

checking by a checking technician, is completed by a licensed health care professional in the facility prior to administration of the drug to the patient. A licensed health care professional or certified medication aide shall administer the drug to the patient. The TCT program plan shall identify the individuals authorized to administer the drug to the patient. The identification of these individuals may consist of a description of the classification of the authorized individuals, such as “registered nurse,” “licensed practical nurse,” or “certified medication aide,” or the identification may specifically identify the authorized individuals by name and title. Alternatively, the identification may reference an existing facility policy or procedure that identifies or specifies the individuals authorized to administer a drug to a patient.

40.3(10) Program evaluation. Implementation of a TCT program shall result in the redirection of the pharmacist from distributive tasks to cognitive and patient care activities. As part of an ongoing program review and evaluation as provided in subrule 40.4(5), the pharmacist in charge or designee shall document the specific cognitive and patient care activities, and a summary of the approximate amount of time pharmacists spend on those activities, as a result of implementation of the TCT program. Program review and evaluation records shall be available for inspection and copying by the board or its representatives and any other authorized agencies for two years following the date of the record.

657—40.4(155A) TCT program requirements. A TCT program shall be conducted in compliance with the following requirements.

40.4(1) Training of checking technician. No certified pharmacy technician shall be designated or authorized by the pharmacist in charge or responsible pharmacist to perform, nor shall a certified pharmacy technician perform, the function of checking the work of another certified pharmacy technician without having received and satisfactorily completed the specialized and advanced training provided for in the pharmacy’s policies and procedures. The specialized training shall include the prevention, identification, and classification of medication errors. Training requirements shall include provisions for retraining of a checking technician who fails to maintain the level of competence necessary for the performance of authorized duties as demonstrated by the technician’s failure to satisfactorily meet ongoing evaluation and competency audits.

40.4(2) Authorized checking functions. A certified pharmacy technician authorized by the pharmacist in charge or responsible pharmacist to check the work of another certified pharmacy technician may check activities relating to the filling of floor stock, unit dose distribution systems, proprietary bag and vial systems or manufactured premix intravenous products, and AMDS components for hospital and long-term care facility patients. Medication orders shall have previously been reviewed by a licensed pharmacist against the patient’s medication profile, and the prepared drugs shall be checked by at least one additional licensed health care professional in the facility at the time the drugs are administered to a patient. The checking function performed by the checking technician shall be limited to those types of drugs identified in the written TCT program plan, and the TCT program plan shall specifically describe the method for verifying cassette or drug bin fills.

40.4(3) Certified pharmacy technician evaluation. The responsible pharmacist shall conduct continuous monitoring and evaluation of each certified pharmacy technician authorized to participate in the TCT program in order to ensure the continued competency of the certified

pharmacy technicians and the safety of patients. As a component of the pharmacy's continuous quality improvement program and except as otherwise specifically provided by these rules, errors shall be identified and records maintained as provided in rule 657—8.26(155A).

- a. Periodic review and pharmacist check. Evaluation shall include periodic review and checking by the pharmacist of work checked by the checking technician and identification and documentation of all errors not identified and corrected by the checking technician.
- b. Review of errors identified by pharmacist or checking technician. The responsible pharmacist shall review with all certified pharmacy technicians involved any errors identified during the evaluation and shall discuss procedures to ensure the errors are not repeated.
- c. Review of errors identified following release by checking technician. The responsible pharmacist shall receive, evaluate, and review with all certified pharmacy technicians involved any errors identified by a health care professional, a certified medication aide, a patient, or any other individual following release of a drug by the checking technician.

40.4(4) Records. The pharmacist in charge shall maintain in the pharmacy department a record for each certified pharmacy technician authorized by the pharmacist in charge or responsible pharmacist to participate in the TCT program. The record shall be available for inspection and copying by the board or its representatives and any other authorized agencies for two years beyond the term of the certified pharmacy technician's employment. The record shall include:

1. The name of the certified pharmacy technician.
2. The date on which the certified pharmacy technician completed the site-specific training for participation in the TCT program.
3. c. The date on which the certified pharmacy technician was authorized to participate in the TCT program and the specific TCT program functions and tasks the certified pharmacy technician is authorized to perform.
4. d. If the certified pharmacy technician is authorized to check the work of other certified pharmacy technicians, the date on which the checking technician completed the specialized and advanced training as provided in policies and procedures.
5. The dates and results of all competency evaluations.
6. The dates of and reasons for any suspension or revocation of the certified pharmacy technician's TCT program authorization, identification of corrective action or retraining completed, and the date of the subsequent reinstatement of the certified pharmacy technician's TCT program authorization.
7. g. The dates of and reasons for any disciplinary action taken against the certified pharmacy technician in connection with the certified pharmacy technician's performance of duties relating to the TCT program.

40.4(5) TCT program evaluation. The pharmacist in charge shall maintain in the pharmacy department program evaluation records that demonstrate the redirection of pharmacist activities from distributive tasks to cognitive and patient care activities. The approximate amount of time each pharmacist spent on specific distributive tasks and on specific cognitive and patient care activities prior to implementation of the TCT program shall be documented in the program evaluation records and shall be maintained for the duration of the TCT program. Program evaluation records shall identify the specific cognitive and patient care activities and a summary of the approximate amount of time pharmacists spend on those activities as a result of implementation of the TCT program. TCT program evaluation records shall be updated at least

semiannually and shall be available for inspection and copying by the board or its representatives and any other authorized agencies for two years following the date of the record.

North Dakota Tech-Check-Tech Language

61-02-07.1-12. Technicians checking technicians.

Activities allowed by law to be performed within a licensed pharmacy by a registered pharmacy technician in the preparation of a prescription or order for dispensing or administration may be performed by one registered pharmacy technician and verified by another registered pharmacy technician working in the same licensed pharmacy, under the following conditions:

1. The licensed pharmacy where the work is being conducted has policies and procedures specifically describing the scope of the activities to be verified through this practice, included in the policy and procedure manual required under section 61-02-01-18.*
 - a. Training for the specific activity is reflected in a written policy
 - b. A record of the individuals trained is maintained in the pharmacy for two years.
2. The pharmacy has a continuous quality improvement system in place to periodically verify the accuracy of the final product, including:
 - a. Recording any quality related events leading up to the final dispensing or administration of the drug prepared.
 - b. Recording any errors which actually reach the patient as a result of these activities.
 - c. Specific limits of acceptable quality related event levels before reassessment is required.
 - d. Consideration must be made for high-risk medications on the institute for safe medication practices (ISMP) list and specific monitoring, review, and quality assurance parameters must be instituted if any of these products are included in the pharmacy's technicians-checking-technicians program.
3. Any error must trigger pharmacist review of the process. This review and subsequent recommendations must be documented.
4. The pharmacy has a system in place to review all quality related events and errors recorded and takes corrective action based on the information to reduce quality related events and eliminate errors reaching the patient.
5. As always, the pharmacist-in-charge and the permit holder are jointly responsible for the final product dispensed or released for administration from the pharmacy.

*61-02-01-18. Policy and procedure manual required. Each pharmacy must have a written or electronic and easily accessible policy and procedure manual to address all aspects of the pharmacy's operations. The policy and procedure manual must be available for inspection. The policy and procedure manual must set forth in detail the objectives and operational guidelines of the pharmacy. The policy and procedure manual must be reviewed and revised or reaffirmed on an annual basis.

Inspection procedures, including:

1. Location of controlled substance records, including:
 - a. Location of current biennial inventory;
 - b. Wholesale records of receipt and sale of controlled substances;
 - c. DEA 222 forms, both paper and electronic, executed or not;
 - d. Information for running reports from the pharmacy computer system relative to dispensing of specific controlled substances; and
 - e. Power of attorney forms if granted and termination forms if executed.

2. Location of most recent inspection forms by the state board of pharmacy, accreditation agencies, or the food and drug administration, if applicable.

Chapter Phar 7 – Pharmacy Practice Revisions: Patient Consultation Topic Area

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 or its members.

Background:

Patient medication consultation is an important part of the prescription dispensing process. Counseling provides an opportunity for pharmacists to build relationships, to demonstrate empathy, ensure adherence, and to establish themselves as a trusted source of medication information. It can also result in last-minute findings that may lead to interventions or that prevent errors from reaching the patient. Requiring this consultation also negates the possibility of patients missing out on consultation due to lack of awareness of a need for counseling. On the other hand, some pharmacists report that counseling on every prescription can be time-consuming, particularly with regard to counseling on refill prescriptions. Some argue that the time spent counseling on refill prescriptions may detract from other patient care activities, including providing sufficient consultation on new prescriptions, and may preclude meaningful participation in practice-advancing services like provision of medication therapy management services. Lastly, in some circumstances, multiple interruptions to a pharmacist's work, caused by consulting on every prescription, may increase the risk for error.

Wisconsin pharmacy rules require consultation for both new and refilled prescriptions. Current rules waive the requirement for an in-person verbal consultation for mailed or delivered prescriptions and requires that the prescription be accompanied by appropriate directions for use and a notice that consultation is available by contacting the pharmacist. Wisconsin's rules do not specifically address medication orders administered in institutional settings, to include hospitals, skilled nursing or assisted living facilities, or correctional facilities. Finally, Wisconsin's rules do not provide any waiver to these requirements in the event that a patient refuses consultation.

Summary of Methods:

The NABP Model Practice Act (Table 1.) and pharmacy administrative rules from 13 states (CA, ND, SD, MN, IA, SC, IL, MI, IN, PA, MO, NE, and KS) were reviewed for the following key elements of pharmacist medication consultation requirements: new prescriptions, refill prescriptions, mailed or delivered prescriptions, institutional dispensing, and patient refusal.

Table 1. NABP Model Practice Act Patient Counseling Recommendations
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- A Pharmacist shall personally initiate discussion of matters which will enhance or optimize drug therapy with each patient or caregiver of such patient. Such discussion shall be in person, whenever practicable, or by telephone and shall include appropriate elements of patient counseling.
- Alternative forms of patient information shall be used to supplement patient counseling when appropriate.
- Patient counseling shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s).
- A Pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.
- Legal Commentary: The intent of this Section is to require that the Pharmacist personally initiate counseling for all new Prescriptions and to exercise his or her professional judgment for refills.

Summary of Recommendations:

It is recommended that the PEB consider the following recommendations: 1) discuss and consider alternatives to mandatory counseling on every prescription while balancing goals to ensure patient safety with optimizing pharmacist workflow efficiencies and practice advancement.

Draft Revisions for Consideration

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

- (a) Provide patient or agent with appropriate consultation to optimize drug therapy:
 1. for medications representing a change in therapy
 2. upon acceptance of an offer to provide consultation to a patient or agent for renewal medications, or
 3. whenever the pharmacist or pharmacist-intern deems it warranted in the exercise of his or her professional judgment.
- (2) An offer to counsel shall not fulfill the requirements of this rule for a change in medication therapy.
- (3) Patients must be made aware of the option of consultation for renewal medications.
- (4) Patient counseling, as described in this rule, shall not be required (a) for inpatients of a hospital, skilled nursing facility, institution or other setting where licensed or certified health care professionals are authorized to administer medications; or (b) for inmates of an adult correctional facility or a juvenile detention facility.