Wis. Admin. Code Ch. Phar 1, Refs & Annos

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 1. Authority and Definitions

Note: Chapter Phar 1 as it existed on January 31, 1983 was repealed and a new chapter Phar 1 was created effective February 1, 1983.

Wis. Adm. Code Ch. Phar 1, Refs & Annos, WI ADC Ch. Phar 1, Refs & Annos

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Wis. Admin. Code s Phar 1.01

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 1. Authority and Definitions (Refs & Annos)
Phar 1.01 Authority.

Rules in chs. Phar 1 to 16 are adopted under authority of ss. 15.08 (5) (b), 227.11 (2), Stats., and ch. 450, Stats.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. Register, August, 1991, No. 428, eff. 9-1-91; am., Register, December, 1998, No. 516, eff. 1-1-99; am., Register, March, 2000, No. 531, eff. 4-1-00;correction made under s. 13.93 (2m) (b) 7., Stats., Register January 2002 No. 553.

Wis. Adm. Code s Phar 1.01, WI ADC s Phar 1.01

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Wis. Admin. Code s Phar 1.02

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 1. Authority and Definitions (Refs & Annos)
Phar 1.02 Definitions.

As used in chs. Phar 1 to 16:

(1) “Board” means the pharmacy examining board.

Note: The board office is located at 1400 East Washington Avenue, Madison, Wisconsin 53702, telephone (608) 266-8794.

(2) “Community pharmacy” means practice in a licensed pharmacy providing pharmaceutical services primarily on an outpatient basis.

(3) “DEA” means the drug enforcement administration.

(4) “Institutional pharmacy” means practice in a licensed pharmacy providing pharmaceutical services primarily on an inpatient basis.

(4m) “Long term care facility” means a facility for the developmentally disabled or other nursing home.

(5) “LTCF” means a long term care facility.

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

(7) “NAPLEX” means the north American pharmacy licensing examination.

(8) “Pharmacist” has the meaning given in s. 450.01 (15), Stats.

(9) “Pharmacist-in-charge” means a pharmacist who is physically present in the licensed facility and responsible for the routine operation of a pharmacy for the period of time specified by the managing pharmacist.

Wis. Admin. Code s Phar 1.02

(10) “Pharmacy” means any place of practice licensed by the board under s. 450.06, Stats.

(11) “Pharmacy owner” means a person or entity to whom a pharmacy license is issued.

(12) “Practice of pharmacy” has the meaning under s. 450.01 (16), Stats.

(13) “PRN” means renew as needed.

(14) “Professional service area” means the area of a pharmacy in which prescriptions are compounded or dispensed, hypodermic needles, syringes, poisons and schedule V controlled substances as listed in s. 961.22, Stats., and ch. CSB 2 are available, or where patients are consulted.

(15) “Terminal illness” means an incurable condition caused by injury or illness that reasonable medical judgment finds would cause death.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. (intro.), renum. (2) to (9) to be (6) to (12) and (14) and am. (8), (10) and (12), cr. (2) to (5) and (13), Register, August, 1991, No. 428, eff. 9-1-91; cr. (4m) and (15), Register, September, 1994, No. 465, eff. 10-1-94; am. (7), (8), (11) and (14), Register, December, 1998, No. 516, eff. 1-1-99; am. (intro.), Register, March, 2000, No. 531, eff. 4-1-00; emerg. cr. (3c), (4c), (4e), and (14m), eff. 1-1-02; correction in (intro.) made under s. 13.93 (2m) (b)7, Stats., Register January 2002 No. 553.

Wis. Adm. Code s Phar 1.02, WI ADC s Phar 1.02

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Wis. Admin. Code Ch. Phar 2, Refs & Annos

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 2. Application for Pharmacist License

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.

Wis. Adm. Code Ch. Phar 2, Refs & Annos, WI ADC Ch. Phar 2, Refs & Annos

Current through Wisconsin Register 696, published December, 2013

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Wis. Admin. Code s Phar 2.01

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 2. Application for Pharmacist License (Refs & Annos)
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.

Wis. Adm. Code s Phar 2.01, WI ADC s Phar 2.01

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Wis. Admin. Code s Phar 2.02

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 2. Application for Pharmacist License (Refs & Annos)
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.

Wis. Admin. Code s Phar 2.02

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.**

Wis. Adm. Code s Phar 2.02, WI ADC s Phar 2.02

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Wis. Admin. Code s Phar 2.03

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 2. Application for Pharmacist License (Refs & Annos)
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.**

Wis. Adm. Code s Phar 2.03, WI ADC s Phar 2.03

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Wis. Admin. Code s Phar 2.04

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 2. Application for Pharmacist License (Refs & Annos)
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.

Wis. Adm. Code s Phar 2.04, WI ADC s Phar 2.04

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Wis. Admin. Code s Phar 2.05

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 2. Application for Pharmacist License (Refs & Annos)
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.**

Wis. Adm. Code s Phar 2.05, WI ADC s Phar 2.05

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Wis. Admin. Code s Phar 2.06

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 2. Application for Pharmacist License (Refs & Annos)
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 pharmacy 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.**

Wis. Adm. Code s Phar 2.06, WI ADC s Phar 2.06

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Wis. Admin. Code s Phar 4.01

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 4 Examinations
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.

Wis. Adm. Code s Phar 4.01, WI ADC s Phar 4.01

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Wis. Admin. Code s Phar 4.02

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 4 Examinations
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.

Wis. Adm. Code s Phar 4.02, WI ADC s Phar 4.02

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Wis. Admin. Code s Phar 4.03

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 4 Examinations
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.

Wis. Adm. Code s Phar 4.03, WI ADC s Phar 4.03

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Wis. Admin. Code s Phar 4.035

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 4 Examinations
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.

Wis. Adm. Code s Phar 4.035, WI ADC s Phar 4.035

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Wis. Admin. Code s Phar 4.04

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 4 Examinations
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.

Wis. Adm. Code s Phar 4.04, WI ADC s Phar 4.04

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Wis. Admin. Code s Phar 4.045

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 4 Examinations
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.

Wis. Adm. Code s Phar 4.045, WI ADC s Phar 4.045

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Wis. Admin. Code s Phar 4.046

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 4 Examinations
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.

Wis. Adm. Code s Phar 4.046, WI ADC s Phar 4.046

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Wis. Admin. Code s Phar 4.05

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 4 Examinations
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 Examinations, Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, 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.

Wis. Adm. Code s Phar 4.05, WI ADC s Phar 4.05

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Wis. Admin. Code s Phar 5.01

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 5. License Renewal
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.

Wis. Adm. Code s Phar 5.01, WI ADC s Phar 5.01

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Wis. Admin. Code s Phar 5.02

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 5. License Renewal
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.

Wis. Adm. Code s Phar 5.02, WI ADC s Phar 5.02

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Wis. Admin. Code s Phar 5.03

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 5. License Renewal
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.

Wis. Adm. Code s Phar 5.03, WI ADC s Phar 5.03

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Wis. Admin. Code s Phar 5.04

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 5. License Renewal
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.

Wis. Adm. Code s Phar 5.04, WI ADC s Phar 5.04

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Wis. Admin. Code s Phar 5.05

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 5. License Renewal
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.

Wis. Adm. Code s Phar 5.05, WI ADC s Phar 5.05

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Wis. Admin. Code Ch. Phar 6, Refs & Annos

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 6. **Pharmacy** Licenses and Equipment

Note: Chapter Phar 6 as it existed on January 31, 1983, was repealed and a new chapter Phar 6 was created effective February 1, 1983.

Wis. Adm. Code Ch. Phar 6, Refs & Annos, WI ADC Ch. Phar 6, Refs & Annos

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Wis. Admin. Code s Phar 6.01

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 6. **Pharmacy** Licenses and Equipment (Refs & Annos)
Phar 6.01 Licenses; application.

Requirements and procedures for applying for a pharmacy license are specified in s. 450.06, Stats. Approved application forms are available from the board. Appointments for the required pharmacy inspection may be made by contacting the board office. A license application and fee shall be on file with the board at least 30 days prior to the granting of the pharmacy license. A pharmacy may not operate unless a pharmacy license has been granted. Board action shall be taken within 60 business days of receipt of a completed pharmacy application, as provided in s. SPS 4.03.

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

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; correction made under s. 13.93 (2m) (b) 7., Stats., Register, January, 1989, No. 397; am. Register, August, 1991, No. 428, eff. 9-1-91; am., Register, December, 1998, No. 516, eff. 1-1-99; **correction made under s. 13.92 (4) (b) 7., Stats., Register November 2011 No. 671.**

Wis. Adm. Code s Phar 6.01, WI ADC s Phar 6.01

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Wis. Admin. Code s Phar 6.02

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 6. **Pharmacy** Licenses and Equipment (Refs & Annos)
Phar 6.02 Licenses; change of location or ownership.

(1) A pharmacy license authorizes a pharmacy to operate only at the location designated on the license. Licenses may not be transferred to another location.

(1m) A hospital which has a pharmacy area providing outpatient pharmacy services which is physically separate from, and not contiguous to the area from which inpatient pharmacy services are provided, shall have a pharmacy license for the outpatient pharmacy in addition to a license for the inpatient pharmacy.

(2) Any change in pharmacy ownership shall be reported to the board office and the pharmacy license of the former owner returned. A pharmacy license shall be granted to the new pharmacy owner before the pharmacy may operate.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. Register, August, 1991, No. 428, eff. 9-1-91; cr. (1m), Register, February, 1996, No. 482, eff. 3-1-96.

Wis. Adm. Code s Phar 6.02, WI ADC s Phar 6.02

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Wis. Admin. Code s Phar 6.03

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 6. **Pharmacy** Licenses and Equipment (Refs & Annos)
Phar 6.03 Changes in managing pharmacist.

The pharmacy owner shall report to the board any change of managing pharmacist within 5 days following the change.

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

Wis. Adm. Code s Phar 6.03, WI ADC s Phar 6.03

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Wis. Admin. Code s Phar 6.04

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 6. **Pharmacy** Licenses and Equipment (Refs & Annos)
Phar 6.04 Floor design.

(1) Professional service area. The professional service area of a pharmacy shall not be less than 250 sq. ft. No more than 20% of the space may be used for storage of bulk pharmaceuticals. If the pharmacy is open at any time solely as a non-prescription or sundry outlet, without a pharmacist present, the professional service area shall be secured as specified in sub. (3). A variance to the 250 sq. ft. professional service area requirement may be authorized by the board upon submission of a specific plan describing the manner in which the proposed professional service area plan varies from the requirement.

(2) Prescription counter space. A pharmacy shall have a prescription counter with a free working surface of 18 or more inches in width and at least 12 square feet in area. This free-working surface must be used only for the compounding and dispensing of prescriptions.

(3) Professional service area requirements where pharmacist is absent. (a) Except as provided in par. (c), if no pharmacist is present in the professional service area, a pharmacy may convert to a non-prescription or sundry outlet if the following requirements are met:

1. A secured, physical barrier surrounds the professional service area of the pharmacy and precludes access to the area by unlicensed personnel. A secured barrier may be constructed of other than a solid material with a continuous surface. If constructed of other than a solid material, the openings or interstices in the material shall not be large enough to permit removal of items from the professional service area by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated or bent. The plans and specifications of the barrier shall be submitted to the board for approval.

2. The barrier is locked in the absence of the pharmacist.

3. A patient's telephone request to renew a certain prescription may be accepted, but a telephone message from a practitioner giving a new prescription order or renewal authority may not be accepted.

5. Signs of reasonable size are posted at the entrance of the building and the professional service area prominently displaying the hours the pharmacist will be on duty.

6. The manner in which the telephone is answered does not imply that the location is, at that time, operating as a

pharmacy.

7. The pharmacy examining board office is notified of the hours during which the establishment is operated as a sundry outlet.

(b) The managing pharmacist is responsible for compliance with all professional service area security requirements.

(c) Where no pharmacist is present in the professional service area a pharmacy is not required to convert to a non-prescription or sundry outlet if the following requirements are met:

1. The pharmacist is absent for a time period of one half hour or less.

2. The pharmacist must be accessible for communication with the remaining pharmacy staff by phone, pager or other device.

3. The pharmacy must indicate that the pharmacist is not available in the professional service area and indicate the period of absence and the time of the pharmacist's return.

4. Pharmacy technicians may only perform duties allowed by s. Phar 7.015 (2).

(4) Professional service area remodeling. Any modifications of the approved floor plan shall be submitted to and approved by the board or its designee. Board action must be taken within 60 days.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; cr. (4), Register, August, 1991, No. 428, eff. 9-1-91; r. (3) (a) 4., Register, January, 1996, No. 481, eff. 2-1-96; CR 03-096: am. (3) (a) (intro.), cr. (3) (c) Register May 2004 No. 581, eff. 6-1-04.

Wis. Adm. Code s Phar 6.04, WI ADC s Phar 6.04

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Wis. Admin. Code s Phar 6.05

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 6. **Pharmacy** Licenses and Equipment (Refs & Annos)
Phar 6.05 Sanitation.

The professional service area of a pharmacy shall have a sink convenient and suitable for cleaning pharmaceutical equipment and supplied with hot and cold running water. Detergent and a waste disposal container also shall be provided in the professional service area.

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

Wis. Adm. Code s Phar 6.05, WI ADC s Phar 6.05

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Wis. Admin. Code s Phar 6.06

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 6. **Pharmacy** Licenses and Equipment (Refs & Annos)
Phar 6.06 Minimum equipment.

(1) The professional service area of a pharmacy shall have equipment of appropriate design and size for the intended pharmacy practice consisting of at least the following equipment:

(a) An electronic balance that has a sensitivity of 1 milligram, or a mechanical torsion prescription balance that has a sensitivity reciprocal of 6 milligrams.

(b) One set of accurate weights appropriate for any mechanical torsion prescription balance being used for the purpose of compounding.

(c) A supply of transparent glass graduates in single metric scale capable of measuring 5 ml. to 100 ml.

(d) An accurate device to measure less than 5 ml.

(e) A supply of Wedgewood and glass mortars and pestles.

(f) A supply of stainless steel spatulas and at least one hard rubber spatula.

(g) A supply of acid, base and solvent-resistant funnels.

(h) A heating device for any preparation that requires heat for compounding.

(i) Ointment slab or ointment paper.

(j) The latest available or immediately accessible version of federal and state pharmacy laws consisting of:

1. Drug enforcement administration regulations, 21 CFR 1300 to end.

2. Wisconsin pharmacy laws, ch. 450, Stats.

3. Wisconsin controlled substances act, ch. 961, Stats.

4. Wisconsin administrative code, rules of the pharmacy examining board.

(k) References appropriate to the individual pharmacy practice. These references should include, but are not limited to, the following topics: drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution.

(L) The telephone number of a poison center. This number shall be conspicuously posted in the prescription department.

(2) Any person may apply for a variance to the application of any provisions in sub. (1) (a) through (i) by filing a written request with the board at P.O. Box 8935, Madison, Wisconsin 53708 stating the reasons for the variance.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; r. and recr. Register, January, 1989, No. 397, eff. 2-1-89; correction in (2) made under 13.93 (2m) (b) 6., Stats., Register, January, 1989, No. 397; am. (1) (j) 3., Register, December, 1998, No. 516, eff. 1-1-99; CR 01-023: am. (1) (intro.) and (a) to (c), (j) (intro.) and (k), Register, August 2001 No. 548 eff. 9-1-01.

Wis. Adm. Code s Phar 6.06, WI ADC s Phar 6.06

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Wis. Admin. Code s Phar 6.07

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 6. **Pharmacy** Licenses and Equipment (Refs & Annos)
Phar 6.07 Storage.

(1) The professional service area shall have a refrigerator adequate for the storage of biological and other drugs requiring refrigeration.

(2) The professional service area shall have sufficient shelf, drawer or cabinet space for the proper storage of a representative stock of prescription labels, an assorted stock of prescription containers, and an adequate stock of prescription drugs, chemicals and required pharmacy equipment.

(3) Controlled substances shall be stored in a securely locked, substantially-constructed cabinet or dispersed throughout the inventory of non-controlled substances in a manner that obstructs theft.

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

Wis. Adm. Code s Phar 6.07, WI ADC s Phar 6.07

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Wis. Admin. Code s Phar 6.08

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 6. **Pharmacy** Licenses and Equipment (Refs & Annos)
Phar 6.08 Security.

A pharmacy shall have a centrally monitored alarm system in the pharmacy. A security system or plan that does not utilize a centrally monitored alarm system may be used if reviewed by and prior approval is obtained from the board.

History: Cr. Register, December, 1998, No. 516, eff. 1-1-99; CR 05-001: am. Register August 2005 No. 596, eff. 9-1-05; CR 09-098: am. Register May 2010 No. 653, eff. 6-1-10.

Wis. Adm. Code s Phar 6.08, WI ADC s Phar 6.08

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Wis. Admin. Code s Phar 7.01

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 7. **Pharmacy** Practice
Phar 7.01 Minimum procedures for compounding and dispensing.

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

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

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

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

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

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

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

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

Wis. Admin. Code s Phar 7.01

1. Date renewed.

2. Name of practitioner authorizing renewal, if different from the original prescriber.

3. Quantity of drug dispensed.

4. Identification of the pharmacist renewing the prescription.

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

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

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

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

Wis. Adm. Code s Phar 7.01, WI ADC s Phar 7.01

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Wis. Admin. Code s Phar 7.015

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 7. **Pharmacy** Practice
Phar 7.015 Pharmacy technicians.

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

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

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

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

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

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

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

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

(g) Preparing a prescription label.

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

(i) Reconstituting prefabricated dosage forms.

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

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

(L) Placing ancillary information on the prescription label.

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

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

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

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

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

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

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

(b) Perform any of the following tasks:

1. Participate in final drug utilization reviews.

2. Make independent therapeutic alternate drug selections.

3. Participate in final drug regimen screening, including screening for therapeutic duplication, drug-to-drug interactions, incorrect dosage, incorrect duration of treatment, drug allergy reactions and clinical abuse or misuse.

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

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

Wis. Admin. Code s Phar 7.015

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

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

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

Wis. Adm. Code s Phar 7.015, WI ADC s Phar 7.015

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Wis. Admin. Code s Phar 7.02

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 7. **Pharmacy** Practice
Phar 7.02 Prescription label; name of drug or drug product dispensed.

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

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

Wis. Adm. Code s Phar 7.02, WI ADC s Phar 7.02

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Wis. Admin. Code s Phar 7.03

Wisconsin Administrative Code Currentness
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Chapter Phar 7. **Pharmacy** Practice
Phar 7.03 Prescription renewal limitations.

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

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

Wis. Adm. Code s Phar 7.03, WI ADC s Phar 7.03

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Wis. Admin. Code s Phar 7.04

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 7. **Pharmacy** Practice
Phar 7.04 Return or exchange of health items.

(1) In this section:

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

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

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

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

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

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

2. A juvenile patient who resides in a secured correctional facility, as defined in s. 938.02 (15m), Stats.; a secured child caring institution, as defined in s. 938.02 (15g), Stats.; a secured group home, as defined in s. 938.02 (15p), Stats.; a secured detention facility, as defined in s. 938.02 (16), Stats.; or a juvenile portion of a county jail whose dispensed health items are maintained under the custody and control of the health services staff as defined in s. DOC 316.02 (6) and provided to a juvenile patient under the provisions of s. DOC 316.03.

Note: Section 938.02 (15m), Stats., was renumbered to s. 938.02 (10p), Stats., by 2005 Wis. Act 344 and the term “secured correctional facility” was changed to “juvenile correctional facility”.Section 938.02 (15p), Stats., was repealed by 2005 Wis. Act 344. Section 938.02 (16), Stats., was renumbered to s. 938.02 (10r), Stats., and “secure detention facility” ws changed to “juvenile detention facility” by 2005 Wis. Act 344.

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

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

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

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

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

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

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

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

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

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

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

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

2. The pharmacist determines the contents are not adulterated.

Wis. Admin. Code s Phar 7.04

(3) Health items returned to a pharmacy pursuant to sub. (2) (b) and (c), may not be sold, resold, or repackaged and sold or resold, given away, or otherwise distributed or dispensed. Returned health items shall either be destroyed at the pharmacy or delivered for destruction or other disposal by an authorized person or entity.

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

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

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

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

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

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

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

Wis. Adm. Code s Phar 7.04, WI ADC s Phar 7.04

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Wis. Admin. Code s Phar 7.05

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 7. **Pharmacy** Practice
Phar 7.05 Prescription records.

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

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

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

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

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

(a) Patient's identification.

(b) Name, strength and dosage form of the drug product dispensed.

(c) Quantity dispensed.

(d) Date of all instances of dispensing.

(e) Practitioner's identification.

(f) Pharmacist's identification.

Wis. Admin. Code s Phar 7.05

(g) Retrieval designation.

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

Wis. Adm. Code s Phar 7.05, WI ADC s Phar 7.05

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Wis. Admin. Code s Phar 7.055

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 7. **Pharmacy** Practice
Phar 7.055 Transfer of prescription order information.

(1) GENERAL REQUIREMENTS. A pharmacist may transfer prescription order information between pharmacies licensed in this state or another state, for the purpose of original or refill dispensing, if all of the following conditions are satisfied:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8. The name of the pharmacist making the transfer.

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

(3) CONTROLLED SUBSTANCES. The transfer of prescription order information for controlled substances for the purposes of refill dispensing is permissible pursuant to the following requirements:

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

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

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

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

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

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

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

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

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

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

5. The date of original dispensing.

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

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

8. The name of the pharmacist making the transfer.

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

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

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

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

Wis. Adm. Code s Phar 7.055, WI ADC s Phar 7.055

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END OF DOCUMENT

Wis. Admin. Code s Phar 7.065

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 7. **Pharmacy** Practice
Phar 7.065 Answering machines in pharmacies.

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

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

Wis. Adm. Code s Phar 7.065, WI ADC s Phar 7.065

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Wis. Admin. Code s Phar 7.07

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 7. **Pharmacy** Practice
Phar 7.07 Medication profile record system.

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

(2) The following minimum information shall be retrievable:

(a) Patient name, or other identifying information.

(b) Address of the patient.

(c) Birth date of the patient if obtainable.

(d) Name of the drug product dispensed.

(e) Strength of the drug product dispensed.

(f) Dosage form of the drug product dispensed.

(g) Quantity of the drug product dispensed.

(h) Directions for use.

(i) Retrieval designation assigned to the prescription order.

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

(k) Practitioner identification.

Wis. Admin. Code s Phar 7.07

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

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

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

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

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

Wis. Adm. Code s Phar 7.07, WI ADC s Phar 7.07

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Wis. Admin. Code s Phar 7.08

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 7. **Pharmacy** Practice
Phar 7.08 Prescription orders transmitted electronically.

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

Note: Prescription orders for schedule II controlled substances may not be transmitted electronically except as emergency orders, subject to the same requirements for oral emergency orders for schedule II controlled substances. See s. 961.38 (1r) and (2), Stats., and s. Phar 8.09.

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

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

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

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

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

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

(4) Any visual or electronic document received in connection with an electronically transmitted prescription

order shall be accessible only within the professional service area of the pharmacy to protect patient confidentiality and assure security.

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

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

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

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

Wis. Adm. Code s Phar 7.08, WI ADC s Phar 7.08

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Wis. Admin. Code s Phar 7.09

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 7. **Pharmacy** Practice
Phar 7.09 Automated dispensing systems.

(1) In this section:

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

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

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

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

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

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

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

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

1. Name and address of the pharmacy.

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

3. Identification of the managing pharmacist.

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

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

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

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

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

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

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

3. Description of how the system is used.

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

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

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

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

Wis. Admin. Code s Phar 7.09

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

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

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

a. The time and location of the system accessed.

b. Identification of the individual accessing the system.

c. Type of transaction.

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

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

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

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

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

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

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

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

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

Wis. Admin. Code s Phar 7.09

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

Wis. Adm. Code s Phar 7.09, WI ADC s Phar 7.09

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Wis. Admin. Code s Phar 7.095

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 7. **Pharmacy** Practice
Phar 7.095 Operation of remote dispensing sites.

(1) Definitions. In this section:

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

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

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

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

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

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

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

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

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

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(b) The office or clinic of a practitioner.

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

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

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

1. Prescriptions may be filled at this location.

2. This store is a remote dispensing site being supervised by a pharmacist located at all of the following:

a. Name of store.

b. Address of store.

c. Telephone number of store.

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

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

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

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

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

Wis. Admin. Code s Phar 7.095

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

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

(b) Comply with the labeling requirements under s. Phar 7.12 (2) (g). The prescription label shall contain the name and address of the supervising pharmacy as the licensed facility from which the prescribed drug or device was dispensed.

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

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

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

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

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

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

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

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

(a) Be 18 years of age or older.

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

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

Wis. Admin. Code s Phar 7.095

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

Wis. Adm. Code s Phar 7.095, WI ADC s Phar 7.095

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Wis. Admin. Code s Phar 7.10

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 7. **Pharmacy** Practice
Phar 7.10 Administration of drug products and devices other than vaccines.

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

(1) The pharmacist has successfully completed 12 hours in a course of study and training, approved by the American council on pharmaceutical education or the board, in injection techniques, emergency procedures and record keeping.

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

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

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

History: Cr. Register, December, 1999, No. 528, eff. 1-1-00.

Wis. Adm. Code s Phar 7.10, WI ADC s Phar 7.10

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Wis. Admin. Code s Phar 7.12

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 7. **Pharmacy** Practice
Phar 7.12 Central fill pharmacy.

(1) In this section:

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

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

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

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

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

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

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

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

(f) Unless the central fill pharmacy shares a common central processing unit with the originating pharmacy, it may not perform processing functions such as the medication profile record review of the patient, drug utilization review, refill authorizations, interventions and drug interactions.

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

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

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

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

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

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

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

Wis. Adm. Code s Phar 7.12, WI ADC s Phar 7.12

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Wis. Admin. Code s Phar 8.01

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 8 Requirements for Controlled Substances
Phar 8.01 Scope.

Procedures governing the manufacture, distribution and dispensing of controlled substances pursuant to ch. 961, Stats., are set forth generally by that chapter and specifically by sections of this chapter and chs. Phar 12 and 13.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. Register, August,1991, No. 428, eff. 9-1-91; am. Register, December, 1998, No. 516, eff. 1-1-99.

Wis. Adm. Code s Phar 8.01, WI ADC s Phar 8.01

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Wis. Admin. Code s Phar 8.02

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 8 Requirements for Controlled Substances
Phar 8.02 Records.

(1) Any pharmacy, practitioner, or other federal drug enforcement administration registrant, as referenced in ch. 961, Stats., shall maintain complete and accurate records of each controlled substance received, manufactured, distributed, dispensed or disposed of in any other manner.

(2) Records required by the federal controlled substances act and ch. 961, Stats., shall be maintained at the location where the drug is received, manufactured, distributed or dispensed, and be available for inspection by authorized persons for at least 5 years from the date of such record. Financial and shipping records such as invoices and packing slips, but not executed order forms, may be kept at a central location. A complete and accurate biennial physical inventory of all schedule II, III, IV and V controlled substances pursuant to ss. 961.16, 961.18, 961.20 and 961.22, Stats.,and ch. CSB 2 on hand shall be made in conformance with all applicable federal and state laws.

(3) Required records shall be maintained as follows:

(a) Records of schedule II controlled substances, other than prescription orders, shall be maintained separately from all other records.

(b) Records of schedule III, IV and V controlled substances shall be maintained either separately or in such form that the information required is readily retrievable from the registrant's ordinary records.

(c) The official drug enforcement administration order forms, DEA form 222, used in the procurement and distribution of schedule II substances shall be maintained at the locations from which the drug was distributed and where it is received.

(d) Any person authorized to manufacture, distribute or dispense controlled substances shall maintain complete and accurate records with the following information:

1. The name of the substance.

2. The dosage form, strength and quantity of the substance.

3. The quantity and date of distribution as well as the name, address and DEA registration number of the person to whom distributed.

4. The number of units and date of receipt as well as the name, address and DEA registration number of the person from whom received.

5. The name and address of the person for whom dispensed, date of dispensing, quantity dispensed and name or initials of the individual who dispensed the substance.

(e) Records for dispensed schedule V substances shall be maintained as follows:

1. If a schedule V drug is dispensed pursuant to the prescription order of a practitioner, the prescription shall be labeled properly and the order filed in accordance with the requirements for schedule III and IV orders.

2. If a schedule V drug is dispensed other than pursuant to a prescription order, the dispenser shall make the record required by s. 961.23, Stats., in a bound controlled substance V register at the time of the transaction.

(f) In any instance that a pharmacy, practitioner or other DEA registrant authorized to possess controlled substances is required to file with the DEA a report of theft or loss of controlled substances, the pharmacy, practitioner or other DEA registrant shall also send a copy to the board within 2 weeks of filing with the DEA.

Note: The Drug Enforcement Administration regional office is at 1800 Dirksen Federal Building, 219 S. Dearborn, Chicago, Illinois 60604.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. (3) (f), r. (4) (a) and (b), Register, August, 1991, No. 428, eff. 9-1-91; am. (1), (2) and (3) (e) 2., Register, December, 1998, No. 516, eff. 1-1-99; CR 06-052: am. (3) (f) Register October 2006 No. 610, eff. 11-1-06.

Wis. Adm. Code s Phar 8.02, WI ADC s Phar 8.02

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Wis. Admin. Code s Phar 8.03

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 8 Requirements for Controlled Substances
Phar 8.03 Filing prescription orders.

(1) All controlled substance prescription orders shall be maintained on file, in chronological order, for a period of at least 5 years. The orders shall be readily accessible to enforcement personnel authorized by s. 961.51, Stats.

(2) Schedule II prescription orders may be filed separately from all other orders or they may be filed with those for schedule III, IV and V drugs provided all orders in the file for schedule III, IV and V drugs are stamped in red ink with the letter “C” one inch in height, in the lower right hand corner of the order. Under no circumstances may schedule II orders be filed together with those for non-controlled drugs.

(3) Schedule III, IV and V prescription orders may be filed with those for non-controlled drugs provided that orders for schedule III, IV and V drugs are stamped in red ink with the letter “C” one inch in height in the lower right hand corner of the order or orders for schedule III, IV and V substances may be filed separately. However, if a pharmacy employs an automated data processing system or other electronic recordkeeping system for prescription orders which permits identification by prescription order number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription order with a red “C” is waived.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. (2) and (3), Register, August, 1991, No. 428, eff. 9-1-91; am. (1) and (3), Register, December, 1998, No. 516, eff. 1-1-99.

Wis. Adm. Code s Phar 8.03, WI ADC s Phar 8.03

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Wis. Admin. Code s Phar 8.04

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 8 Requirements for Controlled Substances
Phar 8.04 Purpose of issue of prescription order.

(1) Prescription orders for controlled substances shall be issued for a legitimate medical purpose by individual practitioners acting in the usual course of professional practice. Responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription order not issued in the usual course of professional treatment or in legitimate and authorized research is not a prescription order within the meaning and intent of ss. 450.01 (21) and 961.38, Stats. The person knowingly dispensing pursuant to such a purported order, as well as the person issuing it, shall be subject to the penalties provided for violation of the provision of law relating to controlled substances.

(2) A prescription order issued by a practitioner to obtain controlled substances for the purpose of general dispensing or administration to patients by the practitioner is not valid.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. Register, August, 1991, No. 428, eff. 9-1-91; am. (1), Register, December, 1998, No. 516, eff. 1-1-99.

Wis. Adm. Code s Phar 8.04, WI ADC s Phar 8.04

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Wis. Admin. Code s Phar 8.05

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 8 Requirements for Controlled Substances
Phar 8.05 Dispensing.

(1) All controlled substance prescription orders shall be dated as of, and signed on, the day issued and shall contain the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. Prescription orders shall be written with ink or indelible pencil or be typewritten and shall be signed by the practitioner. Orders for controlled substances may be issued only by individual practitioners who are authorized to prescribe controlled substances by the jurisdiction in which he or she is licensed to practice and registered or exempt from registration under the federal controlled substances act.

(2) A pharmacist may dispense a controlled substance listed in schedule II, III or IV only pursuant to a prescription order issued by an individual practitioner. The order shall be initialed and dated by the dispensing pharmacist as of the date the prescription is dispensed. If the person accepting the medication pursuant to any prescription order for a schedule II controlled substance, specified in s. 961.16, Stats., is not personally known to the pharmacist, there shall be written in ink, on the reverse side, the printed name, signature and address of the person.

(3) An individual practitioner may dispense directly a controlled substance listed in schedule II, III or IV provided that the prescription container is labeled and records are maintained in accordance with the requirements of this code.

(4) A prescription containing a controlled substance listed in schedule II may be dispensed only pursuant to a written order signed by the prescribing individual practitioner, except in emergency situations. A prescription for a controlled substance listed in schedule II may not be dispensed more than 60 days after the date of issue on the prescription order.

(7) A prescription order for a controlled substance may not be dispensed unless the prescription order contains all of the information required in sub. (1). For any controlled substance prescription order, a pharmacist may not add, modify or clarify the patient's name, the controlled substance prescribed, except for generic substitution as permitted by law, and the prescribing practitioner's signature. After consultation with the prescribing practitioner, a pharmacist may add, modify or clarify the strength, dosage form, quantity prescribed, date of issuance and directions for use for a schedule II controlled substance prescription order. For a schedule II controlled substance prescription order, a pharmacist may add, modify or clarify the registration number of the practitioner, and the address of the practitioner and the patient if that information is verifiable and retrievable from information maintained by the pharmacist or is obtained through consultation

with the practitioner. A pharmacist may add, modify or clarify any information allowed in this subsection missing from a prescription order for a schedule III, IV or V controlled substance that is verifiable and retrievable from information maintained by the pharmacist or that is obtained through consultation with a practitioner. A patient may only provide information to a pharmacist to add, modify or clarify the patient's address. The prescription order shall be initialed and dated by the pharmacist and shall indicate the addition, modification or clarification of information and the manner by which the pharmacist obtained that information.

History: Cr. Register, January. 1983. No. 325. eff. 2-1-83; am. (1), (2), (3) and (5), cr. (6), Register, August, 1991, No. 428, eff. 9-1-91; cr. (7), Register, January,1996, No. 481, eff. 2-1-96; am. (4), Register, February, 1996 No. 482, eff. 3-1-96; am. (2), Register, December, 1998, No. 516, eff. 1-1-99; am. (1) and (7), r. (6), Register, February, 2001, No. 542, eff. 3-1-01; CR 01-154: am. (4), r. (5), Register 2002 No. 559, eff. 8-1-02.

Wis. Adm. Code s Phar 8.05, WI ADC s Phar 8.05

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Wis. Admin. Code s Phar 8.06

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 8 Requirements for Controlled Substances
Phar 8.06 Renewing prescriptions.

(1) No prescription containing a schedule II substance may be renewed.

(2) The prescribing practitioner may authorize renewals of schedule III or IV controlled substances on the original prescription order or through an electronic or oral renewal authorization transmitted to the pharmacist. The following conditions must be met:

(a) The pharmacist obtaining the electronic or oral authorization shall note on the prescription order, medication profile record or readily retrievable and uniformly maintained document the following information:

1. Date authorization is received.

2. Quantity of drug authorized.

3. Number of renewals.

4. Identification of practitioner authorizing the renewals if different from the original prescriber.

5. Identification of the pharmacist who received the authorization.

(b) The quantity of each renewal authorized is equal to or less than the quantity authorized for the initial dispensing of the original prescription.

(3) No prescription containing a controlled substance listed in schedule III or IV may be dispensed or renewed more than 6 months after the date on which the prescription order was issued and no prescription authorized to be renewed may be renewed more than 5 times.

(4) A prescription containing a drug listed in schedule V may be renewed only as expressly authorized by the practitioner.

Wis. Admin. Code s Phar 8.06

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; renum. (2) and (3) to be (3) and (4) and am. (3), cr. (2), Register, August, 1991, No. 428, eff. 9-1-91; am. (2) (intro.) and (a) (intro.), Register, November, 1999, No. 527, eff. 12-1-99.

Wis. Adm. Code s Phar 8.06, WI ADC s Phar 8.06

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Wis. Admin. Code s Phar 8.07

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 8 Requirements for Controlled Substances
Phar 8.07 Partial dispensing.

(1) A pharmacist may partially dispense a prescription containing a controlled substance listed in schedule III, IV and V.

(2) The partial dispensing of a prescription containing a controlled substance listed in schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency electronic or oral prescription order, and the pharmacist makes a notation of the quantity supplied on the face of the written prescription order or written record of the emergency electronic or oral prescription order. The remaining portion of the prescription may be dispensed within 72 hours of the first partial dispensing. If the remaining portion is not dispensed within the 72 hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond the 72 hours without a new prescription order.

(3) Prescription orders for schedule II controlled substances written for patients in long term care facilities (LTCF) or for patients with a medical diagnosis documenting a terminal illness may be dispensed in partial quantities to include individual dosage units. The prescribing practitioner may document a terminal illness by writing upon the face of the prescription order the phrase “terminal illness” or words of similar meaning. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the prescribing practitioner prior to partially dispensing the prescription. Documentation of a terminal illness, whether substantiated by the presence of an appropriate phrase written upon the face of the prescription order or through pharmacist contact with the prescribing practitioner, shall be placed within the individual medication profile record maintained under s. Phar 7.07. The pharmacist shall record on the prescription order whether the patient is“terminally ill” or an “LTCF patient.” A prescription order that is partially dispensed and does not contain the notation “terminally ill” or“LTCF patient” shall be deemed to have been dispensed in violation of this section. For each partial dispensing, the dispensing pharmacist shall record on the back of the prescription order or on another appropriate record, uniformly maintained and readily retrievable,the date of the partial dispensing, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist. Subsequent partial dispensing is not permitted under this section if the patient becomes deceased, or is no longer diagnosed as terminally ill, or no longer resides within an LTCF. The total quantity of a schedule II controlled substance dispensed by partial dispensing may not exceed the total quantity prescribed. Prescription orders for schedule II controlled substances for patients in an LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless terminated earlier by the discontinuance of medication.

(4) Information pertaining to current prescription orders for schedule II controlled substances for patients in an

Wis. Admin. Code s Phar 8.07

LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if the system has the capability to permit:

(a) Display or printout of: the original prescription order designation; date of issue; identification of prescribing practitioner; identification of patient; name and address of the LTCF or name and address of the hospital or residence of the patient; identification of medication authorized, including dosage form, strength and quantity; listing of partial quantities that have been dispensed under each prescription order and the information required in sub. (3).

(b) Immediate (real time) updating of the prescription order record each time there is partial dispensing of the prescription.

(c) Retrieval of partially dispensed schedule II prescription information identical to that required by s. Phar 7.05 (2) for all prescription renewal information.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; r. and recr. Register, August, 1991, No. 428, eff. 9-1-91; am. (3), (4) (intro.) and (a), r. (5), Register, September, 1994, No. 465, eff. 10-1-94; am. (2), Register, November, 1999, No. 527, eff. 12-1-99.

Wis. Adm. Code s Phar 8.07, WI ADC s Phar 8.07

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Wis. Admin. Code s Phar 8.08

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 8 Requirements for Controlled Substances
Phar 8.08 Labeling prescriptions.

(1) The pharmacist dispensing a prescription containing a controlled substance shall affix to the immediate container a label showing the date of dispensing; the pharmacy name and address; serial number of the prescription; full name of the patient; name of the prescribing practitioner; directions for use; and cautionary statements, contained in the prescription order or required by law.

(2) Practitioners who personally dispense any controlled substance to patients in the course of their professional practice other than by prescribing or administering shall conform to ch. Med 17, standards for dispensing drugs.

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

Wis. Adm. Code s Phar 8.08, WI ADC s Phar 8.08

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Wis. Admin. Code s Phar 8.09

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 8 Requirements for Controlled Substances
Phar 8.09 Emergency dispensing.

(1) For the purpose of authorizing an electronic or oral prescription order for a schedule II controlled substance, the term “emergency” means those situations in which the prescribing practitioner determines that:

(a) Immediate administration of the controlled substance is necessary for proper treatment of the patient.

(b) No appropriate alternative treatment is available, including the administration of a drug which is not a schedule II controlled substance.

(c) It is not reasonably possible for the prescribing practitioner to provide a written prescription order to be presented to the pharmacist prior to dispensing.

(2) In an emergency a pharmacist may dispense a controlled substance listed in schedule II upon receiving electronic or oral authorization of a practitioner if:

(a) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period.

(b) The prescription order is immediately reduced to writing by the pharmacist and contains all information required in s. Phar 8.05, except for the signature of the practitioner.

(3) If the practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the electronic or oral authorization came from an authorized practitioner, which may include a call back to the prescribing practitioner using the practitioner's phone number as listed in the telephone directory and other good faith efforts to insure the practitioner's identity.

(4) Within 7 days after authorizing an emergency electronic or oral prescription order, the practitioner shall cause a written order for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of s. Phar 8.05, the order shall contain on its face “authorization for emergency dispensing” and the date of the electronic or oral order. The written order may be delivered to the pharmacist in person or by mail, but if delivered by mail it shall be postmarked within the 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription order to the electronic or oral emergency order

reduced to writing under sub. (2) (b). The pharmacist shall notify the board or department of safety and professional services if the practitioner fails to deliver the written order. Failure of the pharmacist to provide notification shall void the authority conferred by this section to dispense without a written order of a practitioner.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. Register, August, 1991, No. 428, eff. 9-1-91; am. (4), Register, December, 1998, No. 516, eff. 1-1-99, am. (1) (intro.), (2) (intro.), (3) and (4), Register, November, 1999. No. 527. eff. 12-1-99;**correction in (4) made under s. 13.92 (4) (b) 6., Stats., Register February 2012 No. 674.**

Wis. Adm. Code s Phar 8.09, WI ADC s Phar 8.09

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Wis. Admin. Code s Phar 8.10

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 8 Requirements for Controlled Substances
Phar 8.10 Disclosure of suspicious orders of controlled substances.

Manufacturers and distributors of controlled substances shall disclose suspicious orders of controlled substances. Suspicious orders include, without limitation because of enumeration, orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency. The licensee shall notify the regional office of the DEA and the board of all suspicious orders.

History: Cr. Register, August, 1991, No. 428, eff. 9-1-91.

Wis. Adm. Code s Phar 8.10, WI ADC s Phar 8.10

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Wis. Admin. Code s Phar 8.11

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 8 Requirements for Controlled Substances
Phar 8.11 Controlled substances in emergency kits for long term care facilities.

Long term care facilities which are not registered with the DEA shall meet all of the following requirements regarding emergency kits containing controlled substances:

(1) The source of supply must be a DEA registered hospital, pharmacy or practitioner.

(2) The pharmaceutical services committee of the facility shall establish security safeguards for each emergency kit stored in the LTCF which shall include the designation of individuals who may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit.

(3) A pharmacist shall be responsible for proper control and accountability for such emergency kits within the LTCF which includes the requirement that the LTCF and the providing DEA registered hospital, pharmacy or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kits, the disposition of those controlled substances, plus the requirement to take at least monthly physical inventories.

(4) The pharmaceutical services committee will establish the emergency medical conditions under which the controlled substances may be administered to patients in the LTCF which shall include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual DEA registered practitioner and in compliance with all applicable federal and state laws.

(5) Noncompliance with this rule may result in revocation, denial or suspension of the privilege of having or placing emergency kits, containing controlled substances, in LTCF.

History: Cr. Register, August, 1991, No. 428, eff. 9-1-91.

Wis. Adm. Code s Phar 8.11, WI ADC s Phar 8.11

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Wis. Admin. Code s Phar 8.12

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 8 Requirements for Controlled Substances
Phar 8.12 Prescription orders transmitted by facsimile machine.

(1) Prescription drugs other than schedule II controlled substances. A pharmacist may dispense a prescription drug, other than a schedule II controlled substance, pursuant to a prescription order transmitted by a facsimile machine from the practitioner or the practitioner's agent to the dispensing pharmacy if all of the following conditions are met:

(a) The transmitted facsimile prescription order shall contain all of the information required for a valid written prescription order. The order shall also contain the time and date of the transmission, as well as the telephone number and name of the transmitter.

(b) Unless the facsimile paper is non-fading, the facsimile prescription order received shall be duplicated by copy machine or other similar device and the copy must be physically attached to the order received.

(2) Schedule II controlled substances. A pharmacist may not dispense a schedule II controlled substance pursuant to a prescription order transmitted by a facsimile machine unless all of the conditions stated in sub. (1) are satisfied, and any of the following conditions are met:

(a) The prescription order is written for a schedule II controlled substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, and is transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.

(b) The prescription order is written for a schedule II controlled substance for a patient who resides in a long term care facility, or who meets the eligibility requirements for placement in a long term care facility but elects to reside at home, and is transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.

(c) The prescription order is written for a schedule II controlled substance for a patient enrolled in a hospice certified by medicare under Title XVIII or licensed by this state, and is transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.

(3) Prescription orders transmitted by facsimile considered written orders. For all purposes under chs. 450 and 961, Stats., and the rules of the board, a prescription order transmitted by facsimile machine shall be considered

Wis. Admin. Code s Phar 8.12

the original written prescription order.

History: Cr. Register, December, 1998, No. 516, eff. 1-1-99; CR 09-098: am. (2) (b) Register May 2010 No. 653, eff. 6-1-10.

Wis. Adm. Code s Phar 8.12, WI ADC s Phar 8.12

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Wis. Admin. Code s Phar 9.01

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 9. Pharmaceutical Services Requirements in Nursing Homes
Phar 9.01 Pharmaceutical services requirements in nursing homes.

Requirements for pharmaceutical services provided in nursing homes are specified in ch. DHS 132.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; correction made under s. 13.93 (2m) (b) 7., Stats., Register, June, 1994, No. 462; correction made under s. 13.93 (2m) (b) 7., Stats., Register, November, 1999, No. 527; **correction made under s. 13.92 (4) (b) 7., Stats., Register November 2011 No. 671.**

Wis. Adm. Code s Phar 9.01, WI ADC s Phar 9.01

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Wis. Admin. Code s Phar 10.01

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 10 Standards of Professional Conduct
Phar 10.01 Authority.

The rules in this chapter are adopted pursuant to the authority in ss. 15.08, 227.11 and 450.02, Stats.

History: Cr. Register, January, 1980, No. 289, eff. 2-1-80; renum. from Phar 5.01, Register, January, 1983, No. 325, eff. 2-1-83; correction made under s. 13.93 (2m) (b) 7., Stats., Register, July, 1993, No. 451.

Wis. Adm. Code s Phar 10.01, WI ADC s Phar 10.01

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Wis. Admin. Code s Phar 10.02

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 10 Standards of Professional Conduct
Phar 10.02 Definitions.

In this chapter:

(1) "Dispense" has the meaning given in s. 450.01 (7), Stats.

(2) "Drug" has the meaning given in s. 450.01 (10), Stats.

(3) "Patient" has the meaning given in s. 450.01 (14), Stats.

History: Cr. Register, January, 1980, No. 289, eff. 2-1-80; renum. from Phar 5.02 and r. (4), Register, January, 1983, No. 325, eff. 2-1-83; am. (1), (2) and (3), Register, December, 1998, No. 516, eff. 1-1-99.

Wis. Adm. Code s Phar 10.02, WI ADC s Phar 10.02

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Wis. Admin. Code s Phar 10.03

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 10 Standards of Professional Conduct
Phar 10.03 Unprofessional conduct.

The following, without limitation because of enumeration, are violations of standards of professional conduct and constitute unprofessional conduct in addition to those grounds specified under s. 450.10 (1), Stats.:

(1) Administering, dispensing, supplying or obtaining a drug other than in legitimate practice, or as prohibited by law;

(2) Engaging in any pharmacy practice which constitutes a danger to the health, welfare, or safety of patient or public, including but not limited to, practicing in a manner which substantially departs from the standard of care ordinarily exercised by a pharmacist which harmed or could have harmed a patient;

(3) Dispensing a drug which the pharmacist should have known would harm the patient for whom the medication was prescribed;

(4) Dispensing or causing to be dispensed a drug which is outdated or contaminated or known by the pharmacist to be unsafe for consumption;

(5) Falsifying patient records;

(6) Disclosing to the public information concerning a patient without the consent of the patient unless the information is requested by the pharmacy examining board or the department of safety and professional services or unless release is otherwise authorized by law;

(7) Failing to report to the pharmacy examining board any pharmacy practice which constitutes a danger to the health, safety or welfare of patient or public;

(7m) Failing to report to the board information that reasonably suggests there is a probability that a prescription drug or device dispensed by a pharmacist has caused or contributed to the substantial bodily injury or death of a customer or patient.

(8) Providing false information to the pharmacy examining board or its agent;

Wis. Admin. Code s Phar 10.03

(9) Refusing to render professional services to a person because of race, color, sex, religion, or age;

(10) Aiding or abetting the unlicensed practice of pharmacy;

(11) Advertising in a manner which is false, deceptive or misleading;

(12) Dispensing sample drug products for any financial consideration;

(13) Exercising undue influence on or taking unfair advantage of a patient in the promotion or sale of services, drugs or other products for the financial gain of the pharmacist or a third party;

(14) Participating in rebate or fee-splitting arrangements with health practitioners or with health care facilities;

(15) Furnishing a prescriber with any prescription order blanks imprinted with the name of a specific pharmacist or pharmacy;

(16) Using secret formula or code in connection with prescription orders;

(17) Having a pharmacist license revoked or suspended in another state or United States jurisdiction or having been subject to other disciplinary action by the licensing authority thereof;

(18) Violating or attempting to violate any formal disciplinary order of the board.

(19) Practicing without a current license.

History: Cr. Register, January, 1980, No. 289, eff. 2-1-80; renum. from Phar 5.03, Register, January, 1983, No. 325, eff. 2-1-83; am. (intro.), r. (1), (2), (7), (13) and (22), renum. (3) to (6), (8) to (12), (14) to (21) to be (1) to (17), Register, August, 1991, No. 428, eff. 9-1-91; am. (17), cr. (18), Register, July, 1993, No. 451, eff. 8-1-93;cr. (7m) and (19), Register, December, 1998, No. 516, eff. 1-1-99; **correction in (6) made under s. 13.92 (4) (b) 6., Stats., Register February 2012 No. 674.**

Wis. Adm. Code s Phar 10.03, WI ADC s Phar 10.03

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Wis. Admin. Code s Phar 11.01

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 11. Procedure for Hearings
Phar 11.01 Procedure for disciplinary proceedings.

Procedures for disciplinary proceedings before the board are set forth in ch. SPS 2.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; **correction made under s. 13.92 (4) (b) 7., Stats., Register November 2011 No. 671.**

Wis. Adm. Code s Phar 11.01, WI ADC s Phar 11.01

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Wis. Admin. Code s Phar 12.01

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 12. Manufacturer Requirements
Phar 12.01 Authority.

The rules in this chapter are adopted under authority in ss. 15.08 (5) (b), 227.11 (2) (a) and 450.07 (4), Stats.

History: Cr. Register, August, 1987, No. 380, eff. 9-1-87.

Wis. Adm. Code s Phar 12.01, WI ADC s Phar 12.01

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Wis. Admin. Code s Phar 12.02

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 12. Manufacturer Requirements
Phar 12.02 Definitions.

In this chapter:

(1) "Device" has the meaning set forth in s. 450.01 (6), Stats.

(2) "Drug" has the meaning set forth in s. 450.01 (10), Stats.

(3) "Establishment" means a place of business under one management at one general physical location.

(4) "Manufacturer" means a person licensed by the board under this chapter.

(5) "Manufacturing" has the meaning set forth in s. 450.01 (13), Stats.

(6) "Prescription drug" has the meaning set forth in s. 450.01 (20), Stats.

History: Cr. Register, August, 1987, No. 380, eff. 9-1-87; am. (3), Register, August, 1991, No. 428, eff. 9-1-91.

Wis. Adm. Code s Phar 12.02, WI ADC s Phar 12.02

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Wis. Admin. Code s Phar 12.03

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 12. Manufacturer Requirements
Phar 12.03 License; application.

(1) No person may engage in the manufacturing of any drug or device in this state unless a license is granted to the person by the board under this chapter.

(2) To obtain a license a person shall do all of the following:

(a) Submit an application on a form provided by the board.

(b) Pay the fee specified in s. 440.05 (1), Stats.

(c) Meet the inspection requirement under s. Phar 12.04.

(d) Register with the food and drug administration and comply with all applicable requirements of 21 CFR 200, 201, 202, 207, 210 and 211.

(e) If applicable, register with the drug enforcement administration and comply with all appropriate requirements of 21 CFR 1301, 1302, 1303, 1304, 1305, 1307, 1311 and 1312.

Note: An application form may be obtained from the board office, 1400 East Washington Avenue, Madison, Wisconsin 53702. Copies of federal applications, laws and regulations may be obtained from the Food and Drug Administration, 5600 Fischers Lane, Rockville, Maryland 20857 and the Drug Enforcement Administration, 500 Dirksen Federal Building, 219 Dearborn, Chicago, Illinois 60604.

(3) A manufacturer license may not be transferred from one establishment to another nor from one person to another. Each establishment requires a separate license.

(4) If the license is denied, the applicant may request a hearing before the board on the denial.

(5) The board shall act on the application for a license within 60 business days after receiving the completed application, as provided in s. SPS 4.03.

Wis. Admin. Code s Phar 12.03

History: Cr. Register, August, 1987, No. 380, eff. 9-1-87; am. (2) (intro.), (a), (b), (c), (d) and (5), Register, December, 1998, No. 516, eff. 1-1-99; CR 00-157: am. (2) (d) and (e) Register May 2002 No. 557, eff. 6-1-02; **correction in (5) made under s. 13.92 (4) (b) 7., Stats., Register November 2011 No. 671.**

Wis. Adm. Code s Phar 12.03, WI ADC s Phar 12.03

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Wis. Admin. Code s Phar 12.04

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 12. Manufacturer Requirements
Phar 12.04 Inspections.

Before a license is granted, an inspection of the establishment shall be conducted by the board or its representative to determine if the location meets the standards in 21 USC 351 and 352 (1984) and 21 CFR 210 and 211 (1985).

History: Cr. Register, August, 1987, No. 380, eff. 9-1-87.

Wis. Adm. Code s Phar 12.04, WI ADC s Phar 12.04

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Wis. Admin. Code s Phar 12.05

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 12. Manufacturer Requirements
Phar 12.05 Compliance.

Failure to comply with all applicable federal and state laws and regulations shall be subject to disciplinary action by the board under s. 450.10, Stats.

History: Cr. Register, August, 1987, No. 380, eff. 9-1-87.

Wis. Adm. Code s Phar 12.05, WI ADC s Phar 12.05

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Wis. Admin. Code s Phar 12.06

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 12. Manufacturer Requirements
Phar 12.06 Authorized distributors of record.

A manufacturer shall maintain and update at least once per month a list of the manufacturer's authorized distributors of record.

History: EmR0815: emerg. cr. eff. 6-1-08; CR 08-051: cr. Register November 2008 No. 635, eff. 12-1-08.

Wis. Adm. Code s Phar 12.06, WI ADC s Phar 12.06

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Wis. Admin. Code Ch. Phar 13, Refs & Annos

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 13. Distributor Requirements

Note: Chapter Phar 13 as it existed on July 31, 1992 was repealed and a new chapter Phar 13 was created effective August 1, 1992.

Wis. Adm. Code Ch. Phar 13, Refs & Annos, WI ADC Ch. Phar 13, Refs & Annos

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Wis. Admin. Code s Phar 13.01

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 13. Distributor Requirements (Refs & Annos)
Phar 13.01 Authority.

The rules in this chapter are adopted under authority in ss. 15.08 (5) (b), 227.11 (2) (a), 450.02 (3) (a) and 450.07 (4), Stats.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92.

Wis. Adm. Code s Phar 13.01, WI ADC s Phar 13.01

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Wis. Admin. Code s Phar 13.02

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 13. Distributor Requirements (Refs & Annos)
Phar 13.02 Definitions.

In this chapter:

(1) “Blood” means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(2) “Blood component” means that part of blood separated by physical or mechanical means.

(3) “Controlled substance” has the meaning set forth in s.961.01 (4), Stats.

(3m) “Department” means the department of safety and professional services.

(4) “Device” has the meaning set forth in s. 450.01 (6), Stats.

(5) “Distribute” has the meaning set forth in s. 450.01 (8), Stats.

(7) “Drug sample” means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(8) “Facility” means a location where a wholesale distributor stores, handles, repackages, or offers for sale prescription drugs.

(9) “Manufacturer” means a person licensed or approved by the federal food and drug administration to engage in the manufacture of drugs or devices, consistent with the definition of “manufacturer” under the federal food and drug administration's regulations and interpreted guidance implementing the federal prescription drug marketing act.

(10) “Prescription drug” has the meaning set forth in s. 450.01 (20), Stats.

(11) “Wholesale distribution” means distribution of a prescription drug to a person other than a consumer or

patient, but does not include any of the following:

(a) Intracompany sales of prescription drugs which include any transaction or transfer between any division, subsidiary, parent, affiliated or related company under common ownership or control of a corporate entity or any transaction between co-licensees or a co-licensed product.

(b) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons.

(c) The distribution of prescription drug samples, if the distribution is permitted under 21 CFR 353 (d).

(d) Drug returns, when conducted by a hospital, health care entity, or charitable institution as provided in 21 CFR 203.23.

(e) Distributions to a practitioner for the purpose of general dispensing by the practitioner to his or her patients if all of the following apply:

1. The total number of dosage units of all prescription drugs distributed to practitioners by the pharmacy during each calendar year in which the pharmacy is licensed does not exceed 5% of the total number of dosage units of all prescription drugs distributed and dispensed by the pharmacy during the same calendar year.

2. The total number of dosage units of all controlled substances distributed to practitioners by the pharmacy during each calendar year in which the pharmacy is licensed does not exceed 5% of the total number of dosage units of all controlled substances distributed and dispensed by the pharmacy during the same calendar year.

(f) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.

(g) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets.

(h) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record, if the manufacturer states in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the drug and the supplying authorized distributor of record states in writing that the drug has previously been exclusively in the normal distribution channel.

(i) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, if the common carrier does not store,

warehouse, or take legal ownership of the drug.

(j) A transaction excluded from the definition of “wholesale distribution” under 21 CFR 203.3 (cc).

(k) The donation or distribution of a prescription drug under s. 255.056, Stats.

(L) The transfer from a retail pharmacy or pharmacy warehouse of an expired, damaged, returned, or recalled prescription drug to the original manufacturer or original wholesale distributor or to a 3rd-party returns processor or reverse distributor.

(m) The return of a prescription drug, if the return is authorized by the law of this state.

(12) “Wholesale distributor” means a person engaged in the wholesale distribution of prescription drugs, including manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; manufacturers' exclusive distributors; manufacturers' authorized distributors of record; prescription drug wholesalers and distributors; independent wholesale prescription drug traders; 3rd-party logistics providers; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; cr. (11) (f), Register, February, 1996, No. 482, eff. 3-1-96; am. (3), Register, December, 1998, No. 516, eff. 1-1-99; EmR0815: emerg. cr. (3m), (11) (b) to (d) and (f) to (m), renum. (6) and (11) (f) to be (12) and (11) (e) and am. (12), am. (8), (9), (11) (intro.) and (a), r. (11) (b) to (e), eff. 6-1-08; CR 08-051: cr. (3m), (11) (b) to (d) and (f) to (m), renum. (6) and (11) (f) to be (12) and (11) (e) and am. (12), am. (8), (9), (11) (intro.) and (a), r. (11) (b) to (e) Register November 2008 No. 635, eff. 12-1-08; **correction in (3m) made under s. 13.92 (4) (b) 6., Stats., Register November 2011 No. 671.**

Wis. Adm. Code s Phar 13.02, WI ADC s Phar 13.02

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Wis. Admin. Code s Phar 13.05

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 13. Distributor Requirements (Refs & Annos)
Phar 13.05 License; other requirements.

In addition to providing the application information, to obtain a license a person shall:

(1) Pay the fee specified in s. 440.05 (1), Stats.

(2) Pass an inspection of the facility conducted by the board or its representative in the 3-year period immediately preceding the date of the application by the board, a pharmacy examining board of another state, the National Association of Boards of Pharmacy, or another accrediting body recognized by the board, with the date of each inspection to determine if the location meets standards specified in ss. Phar 13.08 to 13.11.

(3) Register with the drug enforcement administration, if intending to distribute controlled substances.

Note: Copies of federal applications may be obtained from the Drug Enforcement Administration, Suite 500, Dirksen Federal Building, 219 South Dearborn Street, Chicago, Illinois 60604. Copies of federal statutes and rules may be obtained from the Superintendent of Documents, Government Printing Office, Washington DC 20402-9325.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; CR 00-157: am. (2) Register May 2002 No. 557, eff. 6-1-02; EmR0815: emerg. am. (2), eff. 6-1-08; CR 08-051: am. (2) Register November 2008 No. 635, eff. 12-1-08.

Wis. Adm. Code s Phar 13.05, WI ADC s Phar 13.05

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Wis. Admin. Code s Phar 13.055

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 13. Distributor Requirements (Refs & Annos)
Phar 13.055 Surety bond, irrevocable letter of credit.

The applicant shall supply a surety bond or irrevocable letter of credit in the amount of $5,000.00, which is issued by a company authorized to do business in Wisconsin. The form of the bond or letter of credit shall be approved by the department and conditioned so that the state shall be fully compensated or reimbursed for, and shall be used to, secure payment of fees or costs that relate to the issuance of a wholesale distributor's license that have not been paid within 30 days after the fees or costs have become final. The bond or letter shall be valid for the entire period of an unexpired license issued to the applicant. No claim may be made against a bond or other security under this section more than one year after the date on which the applicant's wholesale distributor's license expires.

History: EmR0815: emerg. cr. eff. 6-1-08; CR 08-051: cr. Register November 2008 No. 635, eff. 12-1-08.

Wis. Adm. Code s Phar 13.055, WI ADC s Phar 13.055

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Wis. Admin. Code s Phar 13.06

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 13. Distributor Requirements (Refs & Annos)
➡➡ Phar 13.06 License; factors considered.

In determining eligibility for a distributor's license, the board shall consider the following factors:

(1) Any convictions of the applicant under any federal, state,or local laws relating to drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;

(2) Any felony convictions of the applicant under federal, state, or local laws, the circumstances of which are substantially related to the practice of a distributor;

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any devices or drugs, including controlled substances;

(6) Compliance with licensing requirements under previously granted licenses, if any;

(7) Compliance with the requirements to maintain or make available to a state licensing authority or to federal, state, or local law enforcement officials those records required to be maintained by wholesale drug or device distributors; and

(8) Any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; EmR0815: emerg. r. (3), eff. 6-1-08; CR 08-051: r. (3) Register November 2008 No. 635, eff. 12-1-08.

Wis. Adm. Code s Phar 13.06, WI ADC s Phar 13.06

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Wis. Admin. Code s Phar 13.07

Wisconsin Administrative Code Currentness
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Chapter Phar 13. Distributor Requirements (Refs & Annos)
Phar 13.07 Application review.

The board shall act upon an application for a license within 60 business days after receiving the completed application, as provided in s. SPS 4.03. If the license is denied, the applicant may request a hearing pursuant to ch. SPS 1.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; am., Register, December, 1998, No. 516, eff. 1-1-99; **correction made under s. 13.92 (4) (b) 7., Stats., Register November 2011 No. 671.**

Wis. Adm. Code s Phar 13.07, WI ADC s Phar 13.07

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Wis. Admin. Code s Phar 13.08

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 13. Distributor Requirements (Refs & Annos)
Phar 13.08 Personnel.

A distributor shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; EmR0815: emerg. am. eff. 6-1-08; CR 08-051: am. Register November 2008 No. 635, eff. 12-1-08.

Wis. Adm. Code s Phar 13.08, WI ADC s Phar 13.08

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Wis. Admin. Code s Phar 13.09

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 13. Distributor Requirements (Refs & Annos)
➡➡ Phar 13.09 Facility requirements.

All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened;

(4) Be maintained in a clean and orderly condition; and

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; EmR0815: emerg. am. (intro.) and (3), eff. 6-1-08; CR 08-051: am. (intro.) and (3) Register November 2008 No. 635, eff. 12-1-08.

Wis. Adm. Code s Phar 13.09, WI ADC s Phar 13.09

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Wis. Admin. Code s Phar 13.10

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 13. Distributor Requirements (Refs & Annos)
➡➡ Phar 13.10 Security requirements.

All facilities shall require that:

(1) Access from outside the premises is kept to a minimum and be well controlled;

(2) The outside perimeter of the premises is well lighted;

(3) Entry into areas where prescription drugs are held is limited to authorized personnel;

(4) An alarm system is maintained to detect entry after hours; and

(5) A security system is maintained that will provide suitable protection against theft and diversion, including, when appropriate, a system that provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; EmR0815: emerg. am. (3), eff. 6-1-08; CR 08-051: am. (3) Register November 2008 No. 635, eff. 12-1-08.

Wis. Adm. Code s Phar 13.10, WI ADC s Phar 13.10

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Wis. Admin. Code s Phar 13.11

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 13. Distributor Requirements (Refs & Annos)
Phar 13.11 Storage requirements.

(1) All prescription drugs stored in a facility shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such products, or with requirements in the current edition of an official compendium.

(2) If no storage requirements are established for a prescription drug, the product may be held at a controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(3) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, or logs shall be utilized to document proper storage of prescription drugs.

(4) The recordkeeping requirements in s. Phar 13.14 shall be followed for all stored drugs.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; EmR0815: emerg. am. eff. 6-1-08; CR 08-051: am. Register November 2008 No. 635, eff. 12-1-08.

Wis. Adm. Code s Phar 13.11, WI ADC s Phar 13.11

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Wis. Admin. Code s Phar 13.12

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 13. Distributor Requirements (Refs & Annos)
Phar 13.12 Examination of materials requirements.

(1) Upon receipt by a facility, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs, or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment from a facility shall be carefully inspected for identity of the prescription drug and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in s. Phar 13.14 shall be followed for all incoming and outgoing prescription drugs at a facility.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; EmR0815: emerg. am. eff. 6-1-08; CR 08-051: am. Register November 2008 No. 635, eff. 12-1-08.

Wis. Adm. Code s Phar 13.12, WI ADC s Phar 13.12

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Wis. Admin. Code s Phar 13.13

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 13. Distributor Requirements (Refs & Annos)
Phar 13.13 Returned, damaged and outdated prescription drug requirements.

(1) Prescription drugs in a facility that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

(2) Any prescription drugs in a facility whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned to a facility cast doubt on the product's safety, identity, strength, quality, or purity, then the product shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the product meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a product has been returned cast doubt on its safety, identity, strength, quality, or purity, the distributor shall consider, among other things, the conditions under which the product has been held, stored, or shipped before or during its return and the condition of the product and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in s. Phar 13.14 shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; EmR0815: emerg. am. eff. 6-1-08; CR 08-051: am. Register November 2008 No. 635, eff. 12-1-08.

Wis. Adm. Code s Phar 13.13, WI ADC s Phar 13.13

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Wis. Admin. Code s Phar 13.14

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 13. Distributor Requirements (Refs & Annos)
Phar 13.14 Recordkeeping requirements.

(1) A distributor shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

(a) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped:

(b) The identity and quantity of the drugs received and distributed or disposed of; and

(c) The dates of receipt and distribution or other disposition of the drugs.

(2) Inventories and records shall be made available for inspection and copying by the board, its authorized representatives, and authorized representatives of federal, state and local law enforcement agencies for a period of 3 years following distribution or other disposition of the drugs.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by the board or its authorized representative.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; EmR0815: emerg. am. (1) and (2), eff. 6-1-08; CR 08-051: am. (1) and (2) Register November 2008 No. 635, eff. 12-1-08.

Wis. Adm. Code s Phar 13.14, WI ADC s Phar 13.14

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Wis. Admin. Code s Phar 13.15

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 13. Distributor Requirements (Refs & Annos)
Phar 13.15 Written policies and procedures.

A distributor shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. A distributor shall include in their written policies and procedures the following:

(1) A procedure to ensure that the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of prescription drugs. The procedure shall be adequate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other governmental agency, including the board;

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(c) Any action undertaken to promote public health and safety by the replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that a distributor prepares for, protects against, and handles any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(4) A procedure to ensure that any outdated prescription drugs are segregated from other products and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for 3 years after disposition of the outdated drugs.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; EmR0815: emerg. am. (intro.), (1), (2) (intro.), (b) and (4), eff. 6-1-08; CR 08-051: am. (intro.), (1), (2) (intro.), (b) and (4) Register November 2008 No. 635, eff.

Wis. Admin. Code s Phar 13.15

12-1-08.

Wis. Adm. Code s Phar 13.15, WI ADC s Phar 13.15

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Wis. Admin. Code s Phar 13.16

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 13. Distributor Requirements (Refs & Annos)
Phar 13.16 Responsible persons.

A distributor shall establish and maintain lists of officers, directors, managers, and the designated representative in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; EmR0815: emerg. am. eff. 6-1-08; CR 08-051: am. Register November 2008 No. 635, eff. 12-1-08.

Wis. Adm. Code s Phar 13.16, WI ADC s Phar 13.16

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Wis. Admin. Code s Phar 13.17

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 13. Distributor Requirements (Refs & Annos)
Phar 13.17 Compliance with federal, state and local laws.

(1) A distributor shall operate in compliance with applicable federal, state, and local laws and regulations. A distributor shall operate in compliance with any applicable federal electronic track and trace pedigree system implemented after July 1, 2011, unless an earlier implementation date is mandated by federal law which explicitly preempts state law. A distributor that deals in controlled substances shall register with the drug enforcement administration.

(2) Failure to comply with applicable federal, state, and local laws and regulations constitutes unprofessional conduct for purposes of s. 450.10, Stats.

(3) A distributor shall permit the board or its authorized representatives and authorized federal, state and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to a distributor's premises and delivery vehicles.

History: Cr. Register, July, 1992, No. 439, eff. 8-1-92; EmR0815: emerg. am. (1), eff. 6-1-08; CR 08-051: am. (1) Register November 2008 No. 635, eff. 12-1-08.

Wis. Adm. Code s Phar 13.17, WI ADC s Phar 13.17

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Wis. Admin. Code s Phar 15.01

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 15. Sterile Pharmaceuticals
Phar 15.01 Authority.

The rules in this chapter are adopted pursuant to the authority in ss. 15.08 (5) (b), 227.11 (2) and 450.02 (3), Stats.

History: Cr. Register, March, 2000, No. 531, eff. 4-1-00.

Wis. Adm. Code s Phar 15.01, WI ADC s Phar 15.01

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Wis. Admin. Code s Phar 15.02

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 15. Sterile Pharmaceuticals
Phar 15.02 Definitions.

In this chapter:

(1) “Aseptic preparation” means preparation using procedures designed to preclude contamination of drugs, packaging equipment or supplies by microorganisms during processing.

(2) “Biological safety cabinet” means a containment unit suitable for preparation of low- to moderate- risk agents where there is a need for protection of the product, personnel and environment, according to national sanitation foundations standard 49.

(3) “Class 100 environment” means an atmospheric environment that contains less than 100 particles 0.5 microns in diameter per cubic foot of air, as described in federal standard 209.

Note: “Federal Standard 209” refers to Federal standard 209E: airborne particulate cleanliness classes in cleanrooms and clean zones by the Institute of Environmental Sciences published by the Institute of Environmental Sciences in 1992 and used by the United States General Services Administration as the standard required for use by federal agencies utilizing clean room controlled environments.

(4) “Critical activities” means activities that are different from other activities due to the increased potential opportunity for contamination to occur.

(5) “Critical objects” means objects that are different from other objects due to the increased potential opportunity for contamination to occur.

(6) “Cytotoxic drug” means a pharmaceutical used therapeutically as a toxin to alter biochemical activities of phases of cellular division which uniquely contribute to normal cell growth.

(7) “OSHA” means the federal occupational safety and health administration.

(8) “Parenteral” means a preparation of drugs for injection through one or more layers of skin.

Wis. Admin. Code s Phar 15.02

(9) “Practice of pharmacy” has the meaning given in s. 450.01 (16), Stats.

(10) “Sterile pharmaceutical” means any dosage form devoid of viable microorganisms, including but not limited to parenterals, injectables and ophthalmics.

History: Cr. Register, March, 2000, No. 531, eff. 4-1-00.

Wis. Adm. Code s Phar 15.02, WI ADC s Phar 15.02

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Wis. Admin. Code s Phar 15.03

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 15. Sterile Pharmaceuticals
Phar 15.03 Policy and procedure manual.

(1) A pharmacy shall prepare and maintain a policy and procedure manual for compounding, dispensing, delivery, administration, storage and use of sterile pharmaceuticals.

(2) The policy and procedure manual shall include a quality assurance program for the purpose of monitoring personnel qualifications, training and performance, product integrity, equipment, and facilities and include guidelines regarding patient education and the provision of pharmaceutical services. In addition, the manual shall include up-to-date information on the preparation of sterile pharmaceuticals.

(3) The policy and procedure manual shall be available to all personnel and updated annually or as needed to reflect current practice.

(4) The policy and procedure manual shall be current and available for inspection by the board or its designee.

History: Cr. Register, March, 2000, No. 531, eff. 4-1-00.

Wis. Adm. Code s Phar 15.03, WI ADC s Phar 15.03

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Wis. Admin. Code s Phar 15.04

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 15. Sterile Pharmaceuticals
Phar 15.04 Physical requirements.

(1) A pharmacy shall have a designated area for preparing sterile pharmaceuticals. This area shall be a room structurally isolated from other areas, with entry and access restricted to designated personnel and shall be designed to avoid unnecessary traffic and airflow disturbances. The designated area shall only be used for preparation and documentation of sterile pharmaceuticals. The designated area shall be of sufficient size to accommodate a laminar airflow hood and to provide for proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation and security. Additional drug inventory and bulk supplies shall be stored in an area separate from the designated area for preparing sterile pharmaceuticals.

(2) A pharmacy shall maintain an environment in the designated area suitable for aseptic preparation of sterile pharmaceuticals and shall have all of the following:

(a) Appropriate environment control devices that are capable of maintaining at least a class 100 environment during normal activity in the workplace where critical objects are exposed and critical activities are performed.

(b) Appropriate disposal containers as required by OSHA in 29 CFR PART 1910 for used needles and syringes, and for disposal of other items in compounding and, if applicable, for cytotoxic waste from the preparation of chemotherapy agents and infectious wastes. This should be disposed of in a timely manner.

(c) Appropriate environmental controls including class II biological safety cabinetry in pharmacies where cytotoxic drug products are prepared.

(d) Temperature-controlled delivery containers as necessary.

(e) For hand washing, a sink with hot and cold running water in close proximity.

(f) Administration devices as necessary.

(3) A pharmacy shall have sufficient reference materials related to sterile pharmaceuticals to meet the needs of the pharmacy staff.

Wis. Admin. Code s Phar 15.04

(4) The designated area shall be closed and disinfected at regular intervals with appropriate agents.

History: Cr. Register, March, 2000, No. 531, eff. 4-1-00.

Wis. Adm. Code s Phar 15.04, WI ADC s Phar 15.04

Current through Wisconsin Register 696, published December, 2013

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Wis. Admin. Code s Phar 15.05

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 15. Sterile Pharmaceuticals
Phar 15.05 Records and reports.

(1) Specific records and reports shall be maintained describing the preparation of sterile pharmaceuticals in the pharmacy. These records and reports shall include:

(a) Training and competency evaluations of personnel.

(b) Documentation of refrigerator and freezer temperatures.

(c) Certification of laminar airflow hoods.

(2) The following minimum labeling requirements shall be met for sterile pharmaceuticals prepared for a single patient if the pharmaceuticals are to be completely administered within 28 hours:

(a) The identity of all solutions and ingredients and their corresponding amounts, concentration or volumes on the final preparation container in such a manner as to allow the locating of problematic final products.

(b) The identity of personnel involved in preparation.

(c) The date and time of pharmacy preparation where applicable.

(d) The final sterile pharmaceuticals expiration date and storage requirements, where applicable.

History: Cr. Register, March, 2000, No. 531, eff. 4-1-00.

Wis. Adm. Code s Phar 15.05, WI ADC s Phar 15.05

Current through Wisconsin Register 696, published December, 2013

END OF DOCUMENT

Wis. Admin. Code s Phar 15.06

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 15. Sterile Pharmaceuticals
Phar 15.06 Delivery service.

The pharmacist shall assure the appropriate environmental control of all products shipped.

History: Cr. Register, March, 2000, No. 531, eff. 4-1-00.

Wis. Adm. Code s Phar 15.06, WI ADC s Phar 15.06

Current through Wisconsin Register 696, published December, 2013

END OF DOCUMENT

Wis. Admin. Code s Phar 15.07

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 15. Sterile Pharmaceuticals
Phar 15.07 Emergency kits.

(1) When sterile pharmaceuticals are provided to home care patients, the dispensing pharmacy shall supply the patient or the patient's agent with emergency drugs, when authorized by the physician under protocol, if an emergency situation has been anticipated by either the physician, nurse or pharmacist.

(2) The dispensing pharmacy shall be responsible for providing written instructions on the storage and recordkeeping requirements for the emergency kit.

History: Cr. Register, March, 2000, No. 531, eff. 4-1-00.

Wis. Adm. Code s Phar 15.07, WI ADC s Phar 15.07

Current through Wisconsin Register 696, published December, 2013

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Wis. Admin. Code s Phar 15.08

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 15. Sterile Pharmaceuticals
Phar 15.08 Cytotoxic drugs.

In addition to the minimum requirements for a pharmacy established by rule of the board, the following requirements are necessary for those pharmacies that prepare cytotoxic drugs:

(1) All cytotoxic drugs shall be compounded in a vertical flow, class II, biological safety cabinet. If non-exposed surfaces become contaminated with cytotoxic agents, no products other than cytotoxic drugs may be compounded in this cabinet until such time as the cabinet is decontaminated utilizing appropriate techniques to eradicate the contaminant.

(2) Personnel shall be protected by a protective barrier or apparel which shall include gloves, gowns and other applicable protective apparel as described in 29 CFR PART 1910 of OSHA regulations.

(3) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile pharmaceuticals.

(4) Pharmacy disposal and patient and caregiver education regarding disposal of cytotoxic waste shall comply with all applicable local, state and federal requirements.

(5) Written procedures for the handling of both major and minor spills of cytotoxic agents shall be developed and shall be included in the pharmacy policy and procedure manual.

(6) Prepared doses of cytotoxic drugs shall be dispensed, labeled with proper precautions on the primary and shipping container and should be shipped in a manner to minimize the risk of accidental rupture of the primary container.

History: Cr. Register, March, 2000, No. 531, eff. 4-1-00.

Wis. Adm. Code s Phar 15.08, WI ADC s Phar 15.08

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Wis. Admin. Code s Phar 15.08

END OF DOCUMENT

Wis. Admin. Code s Phar 15.09

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 15. Sterile Pharmaceuticals
Phar 15.09 Labeling.

In addition to the labeling requirements of s. 450.11 (4), Stats., the following shall also be included on the labels of sterile pharmaceuticals:

(1) Control or lot number.

(2) Expiration date and time, when applicable.

(3) Appropriate auxiliary labeling, including precautions.

(4) Storage requirements.

(5) Identification of the responsible pharmacist.

History: Cr. Register, March, 2000, No. 531, eff. 4-1-00.

Wis. Adm. Code s Phar 15.09, WI ADC s Phar 15.09

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Wis. Admin. Code s Phar 15.10

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 15. Sterile Pharmaceuticals
Phar 15.10 Patient training.

A pharmacist is responsible for documenting the patient's training and competency in managing the type of therapy provided by the pharmacist to the patient if administered by the patient or a caregiver. A pharmacist is responsible for the provision of or supervision of the patient training process in any area that relates to drug compounding, administration, labeling, storage, stability or incompatibility. A pharmacist shall be responsible for seeing that the patient's competency in the above areas is reassessed on an ongoing basis.

History: Cr. Register, March, 2000, No. 531, eff. 4-1-00.

Wis. Adm. Code s Phar 15.10, WI ADC s Phar 15.10

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Wis. Admin. Code s Phar 15.11

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 15. Sterile Pharmaceuticals
Phar 15.11 Quality assurance.

(1) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment and facilities. Appropriate samples of finished products shall be examined to assure that the pharmacy is capable of consistently preparing sterile pharmaceuticals meeting specifications.

(2) The area designated for preparing sterile pharmaceuticals and all horizontal and vertical laminar flow hoods shall be certified to be operationally efficient and meet the standards of a class 100 environment by an independent contractor. All biological safety cabinets shall be certified according to national sanitation foundations standard 49 or manufacturer's specifications. Certification shall take place before initial use or after relocation and at least annually. Certification records shall be maintained.

Note: “National Sanitation Foundations Standard 49” refers to National Sanitation Foundation standard no 49 for class II (laminar flow) biohazard cabinetry / as prepared by the NSF Advisory Committee on Biohazard Cabinetry; and recommended for adoption by the NSF Council of Public Health Consultants by the National Sanitation Foundation (U.S.) published in 1983 by the National Sanitation Foundation of Ann Arbor, Michigan.

(3) A pharmacy shall have written procedures requiring sampling for microbial contamination through a validation procedure, simulation of actual aseptic preparation, and by using bacterial growth medium to culture environmental samples.

(4) If compounding of parenteral solutions is performed using non-sterile chemicals, extensive end-product sterility testing shall be documented. If any parenteral solution fails the testing, procedures shall be in place to quarantine future products for sterility testing to assure end-product sterility prior to release of the products from quarantine. The compounding process shall utilize components and techniques that assure a sterile and particulate-free product.

(5) A pharmacy shall have written justification of the assigned expiration date for pharmacy prepared sterile pharmaceuticals.

(6) A pharmacy shall have documentation of quality assurance audits, including infection control and sterile technique audits at least annually.

Wis. Admin. Code s Phar 15.11

(7) A pharmacy shall have procedures to assure consistent preparation of sterile pharmaceuticals.

History: Cr. Register, March, 2000, No. 531, eff. 4-1-00.

Wis. Adm. Code s Phar 15.11, WI ADC s Phar 15.11

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Wis. Admin. Code s Phar 16.01

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 16 Continuing Education for Pharmacists
Phar 16.01 Authority and purpose.

The rules in this chapter are adopted by the pharmacy examining board pursuant to the authority delegated by ss. 15.08 (5) (b), 227.11 (2) and 450.02 (2g) (a), Stats.

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

Wis. Adm. Code s Phar 16.01, WI ADC s Phar 16.01

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Wis. Admin. Code s Phar 16.02

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 16 Continuing Education for Pharmacists
Phar 16.02 Continuing education required; waiver.

(1) Each pharmacist required to complete the continuing education requirement provided under s. 450.085, Stats ., shall, at the time of making application for renewal of a license under s.450.08 (2) (a), Stats., sign a statement on the application for renewal certifying that the pharmacist has completed at least 30 hours of acceptable continuing education programs within the 2-year period immediately preceding the date of his or her application for renewal. The 30 hours of continuing education for pharmacists first applies to applications that are submitted to the department to renew a license to practice pharmacy that expires on June 1, 2000. This subsection does not apply to an application for renewal of a license that expires on the first renewal date after the date on which the board initially granted the license.

(2) A pharmacist may apply to the board for waiver of the requirements of this chapter on grounds of exceptional circumstances such as prolonged illness, disability or other similar circumstances that the pharmacist indicates have prevented him or her from meeting the requirements. The board will consider each application for waiver individually on its merits.

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

Wis. Adm. Code s Phar 16.02, WI ADC s Phar 16.02

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Wis. Admin. Code s Phar 16.03

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 16 Continuing Education for Pharmacists
Phar 16.03 Acceptable continuing educational programs.

The board recognizes only those educational programs offered by a provider approved by the American council on pharmaceutical education at the time of the pharmacist's attendance, or other board approved programs.

Note: A list of board approved programs is available from the Department of Safety and Professional Services, Bureau of Health Professions, 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708. As of August 9, 1999, the board has not approved any programs other than programs offered by a provider approved by the American Council on Pharmaceutical Education.

History: Cr. Register, November, 1999, No. 527, eff. 12-1-99; reprinted to correct printing error, Register, February, 2000, No. 530.

Wis. Adm. Code s Phar 16.03, WI ADC s Phar 16.03

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Wis. Admin. Code s Phar 16.04

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 16 Continuing Education for Pharmacists
Phar 16.04 Evidence of compliance.

The board accepts as evidence of compliance with this chapter certification by a providing institution or organization that a pharmacist has attended and completed continuing education programs approved under the provisions of s. Phar 16.03. Certification may be the original, or verified copies of, documents certifying attendance and completion.

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

Wis. Adm. Code s Phar 16.04, WI ADC s Phar 16.04

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Wis. Admin. Code s Phar 16.05

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 16 Continuing Education for Pharmacists
Phar 16.05 Retention requirement.

The pharmacist shall retain evidence of compliance for 3 years following the renewal date for the biennium for which 30 hours of credit are required for renewal of a license.

Note: For example, a pharmacist who renews his or her license on June 1, 2000, must retain proof of having obtained 30 hours of continuing education in the 2 years preceding renewal until June 1, 2003.

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

Wis. Adm. Code s Phar 16.05, WI ADC s Phar 16.05

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Wis. Admin. Code s Phar 16.06

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 16 Continuing Education for Pharmacists
Phar 16.06 Audit.

The board may require any pharmacist to submit his or her evidence of compliance with the continuing education requirements to audit compliance.

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

Wis. Adm. Code s Phar 16.06, WI ADC s Phar 16.06

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Wis. Admin. Code s Phar 17.01

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 17. **Pharmacy** Internship
Phar 17.01 Authority.

The rules in this chapter are adopted pursuant to the authority in ss. 15.08 (5) (b), 227.11 (2), 450.03 (1) (g) and 450.04 (3) (b), Stats.

History: CR 01-134: cr. Register July 2002 No. 559, eff. 8-1-02.

Wis. Adm. Code s Phar 17.01, WI ADC s Phar 17.01

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Wis. Admin. Code s Phar 17.02

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 17. **Pharmacy** Internship
Phar 17.02 Definitions.

In this chapter:

(1) "Academic internship" means a practical experience program consisting of the practice of pharmacy sponsored by a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.

(2) "Direct supervision" means immediate on premises availability to continually coordinate, direct and inspect at first hand the practice of another.

(3) "Foreign graduate internship" means the practice of pharmacy by a person who has first filed an application with the board for original licensure under s. Phar 2.02 and has not graduated from a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.

(4) "Intern" means a person engaged in the practice of pharmacy pursuant to subs. (1), (3), (6) and (8) or s. 450.03 (1) (g), Stats.

(5) "Internship in the practice of pharmacy" means the completion of a minimum of 1500 hours in aggregate in the practice of pharmacy under subs. (1), (3), (6), (7) or (8).

(6) "Postgraduate internship" means the practice of pharmacy by a person who has first filed an application with the board for original licensure under s. Phar 2.02 and has graduated from a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.

(7) "Practical experience internship" means practical experience acquired in another state which is comparable to an internship as described in subs. (1), (3), (6) and (8).

(8) "Student non-academic internship" means the practice of pharmacy by a person which is not acquired in an academic internship.

(9) "Supervising pharmacist" means a pharmacist who supervises and is responsible for the actions of an intern in the practice of pharmacy.

Wis. Admin. Code s Phar 17.02

History: CR 01-134: cr. Register July 2002 No. 559, eff. 8-1-02.

Wis. Adm. Code s Phar 17.02, WI ADC s Phar 17.02

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Wis. Admin. Code s Phar 17.03

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 17. **Pharmacy** Internship
Phar 17.03 Academic internship.

A person participating in an academic internship is not required to register as an intern with the board. There is no restriction in the number of hours earned in an academic internship.

History: CR 01-134: cr. Register July 2002 No. 559, eff. 8-1-02.

Wis. Adm. Code s Phar 17.03, WI ADC s Phar 17.03

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Wis. Admin. Code s Phar 17.04

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 17. **Pharmacy** Internship
Phar 17.04 Foreign graduate internship.

(1) Prior to performing duties as an intern or to receiving credit for hours participating in a foreign graduate internship the person must file an application with the board for original licensure under s. Phar 2.02, and submit evidence satisfactory to the board of having obtained certification by the foreign pharmacy graduate examination committee.

(2) A foreign graduate internship is limited to performing duties constituting the practice of pharmacy under the supervision of a supervising pharmacist. The supervising pharmacist shall keep a written record of the hours and location worked by an intern under his or her supervision, signed by the intern and the supervising pharmacist. The written record shall be produced to the board upon request. Prior to performing duties as an intern or to receiving credit for hours in an internship in the practice of pharmacy under this section the supervising pharmacist shall be disclosed in the initial application and any change of a supervising pharmacist shall be disclosed to the board prior to further performing duties constituting the practice of pharmacy as an intern.

(4) Upon completing a maximum of 2000 hours of the practice of pharmacy in a foreign graduate internship, the internship is terminated and the person shall not further engage in the practice of pharmacy until obtaining licensure from the board.

History: CR 01-134: cr. Register July 2002 No. 559, eff. 8-1-02; **CR 06-050: am. (1), (2) and (4), r. (3) and (5) Register October 2006 No. 610, eff. 11-1-06** .

Wis. Adm. Code s Phar 17.04, WI ADC s Phar 17.04

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Wis. Admin. Code s Phar 17.05

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 17. **Pharmacy** Internship
Phar 17.05 Postgraduate internship.

(1) Prior to performing duties as an intern or to receiving credit for hours participating in a postgraduate internship, the person must file an application with the board for original licensure under s. Phar 2.02 and submit to the board evidence of having been graduated from a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.

(2) A postgraduate internship is limited to performing duties constituting the practice of pharmacy under the supervision of a supervising pharmacist. The supervising pharmacist shall keep a written record of the hours and location worked by an intern under his or her supervision, signed by the intern and the supervising pharmacist. The written record shall be produced to the board upon request.

(3) Upon completing a maximum of 2000 hours of the practice of pharmacy in a postgraduate internship, the internship is terminated and the person shall not further engage in the practice of pharmacy until obtaining licensure from the board.

History: CR 01-134: cr. Register July 2002 No. 559, eff. 8-1-02; **CR 06-050: am. (2) Register October 2006 No. 610, eff. 11-1-06** .

Wis. Adm. Code s Phar 17.05, WI ADC s Phar 17.05

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Wis. Admin. Code s Phar 17.06

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 17. **Pharmacy** Internship
Phar 17.06 Practical experience internship.

There is no restriction in the number of hours earned in a practical experience internship. In determining comparable practical experience the board shall consider the duties performed constituting the practice of pharmacy as described in s. 450.01 (16), Stats.

History: CR 01-134: cr. Register July 2002 No. 559, eff. 8-1-02.

Wis. Adm. Code s Phar 17.06, WI ADC s Phar 17.06

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Wis. Admin. Code s Phar 17.07

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 17. **Pharmacy** Internship
Phar 17.07 Student non-academic internship.

(1) Prior to performing duties as an intern or to receiving credit for hours participating in a student non-academic internship the person must successfully complete his or her second year in and be enrolled at a professional bachelor's of science degree in pharmacy or doctor of pharmacy degree granting institution located in this or another state.

(2) A student non-academic internship is limited to performing duties constituting the practice of pharmacy under the direct supervision of a supervising pharmacist. The supervising pharmacist shall keep a written record of the hours and location worked by an intern under his or her direct supervision, signed by the intern and the supervising pharmacist. The written record shall be produced to the board upon request.

History: CR 01-134: cr. Register July 2002 No. 559, eff. 8-1-02.

Wis. Adm. Code s Phar 17.07, WI ADC s Phar 17.07

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Wis. Admin. Code s Phar 18.01

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 18. Prescription Drug Monitoring Program
Phar 18.01 Authority and scope.

The rules in this chapter are adopted under authority in ss. 15.08 (5) (b), 227.11 (2) (a), 961.31, 450.02 (3) (a), and 450.19, Stats., for the purpose of creating a prescription drug monitoring program to collect and maintain information relating to the prescribing and dispensing of prescription drugs.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13.

Wis. Adm. Code s Phar 18.01, WI ADC s Phar 18.01

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END OF DOCUMENT

Wis. Admin. Code s Phar 18.02

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 18. Prescription Drug Monitoring Program
Phar 18.02 Definitions.

As used in this chapter:

(1) "Access" means to have the ability to view PDMP information through an account established with the board.

(2) "Administer" has the meaning given in s. 450.01 (1), Stats.

(3) "Animal" has the meaning given in s. 453.02 (1m), Stats.

(4) "Board" has the meaning given in s. 450.01 (2), Stats.

(5) "Controlled substance" means a drug, substance, analog, or precursor described in any of the following:

(a) Schedule I, II, III, IV, or V in the federal controlled substances act, 21 USC 812 (b)(1) to (b)(5) and (c), as changed and updated by 21 CFR 1308.

(b) Schedule I, II, III, IV, or V in subch. II. of ch. 961, Stats., as amended by ch. CSB 2.

(6) "Department" means the department of safety and professional services.

(7) "Dispense" has the meaning given in s. 450.01 (7), Stats.

(8) "Dispenser" means all of the following:

(a) A pharmacy from where a pharmacist dispenses a monitored prescription drug.

Note: A site of remote dispensing authorized under s. 450.062, Stats., and s. Phar 7.095 is under the supervision of a pharmacy.

(b) A practitioner who dispenses a monitored prescription drug.

(9) “Dispenser delegate” means an agent or employee of a dispenser to whom the task of inputting or accessing PDMP information has been delegated.

(10) “Dispensing data” means data compiled pursuant to s. Phar 18.04.

(11) “Drug” has the meaning given in s. 450.01 (10), Stats.

(12) (a) “Monitored prescription drug” means all of the following:

1. A controlled substance included in s. 450.19 (1), Stats.

2. A drug identified by the board as having a substantial potential for abuse in s. Phar 18.03.

(b) “Monitored prescription drug” does not mean a controlled substance that by law may be dispensed without a prescription order.

(13) “Patient” has the meaning given in s. 450.01 (14), Stats.

(14) “Person authorized by the patient” means person authorized by the patient in s. 146.81 (5), Stats., and includes persons with delegated authority under s. 48.979, Stats.

(15) “PDMP information” means all of the following:

(a) The data compiled and stored by the board from dispensing data submitted to it by dispensers.

(b) The information created by the board to satisfy the requirements in s. Phar 18.12.

(16) “Pharmacy” means any place of practice licensed by the board under ss. 450.06 or 450.065, Stats.

(17) “Practitioner” has the meaning given in s. 450.01 (17), Stats.

(18) “Practitioner delegate” means an agent or employee of a practitioner to whom the practitioner has delegated the task of accessing PDMP information.

(19) “Prescription” has the meaning given in s. 450.01 (19), Stats.

(20) “Prescription order” has the meaning given in s. 450.01 (21), Stats.

(21) “Program” means the prescription drug monitoring program established under this chapter.

(22) “Veterinary dispenser” means a dispenser licensed in this state or licensed in another state and recognized by this state as a dispenser authorized to dispense monitored prescription drugs solely to animal patients.

(23) “Zero report” means a report that indicates that a dispenser has not dispensed a monitored prescription drug since the previous submission of dispensing data or a zero report.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; correction in (5) (b) made under s. 13.92 (4) (b) 7., Stats., Register October 2012 No. 682.

Wis. Adm. Code s Phar 18.02, WI ADC s Phar 18.02

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Wis. Admin. Code s Phar 18.03

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 18. Prescription Drug Monitoring Program
Phar 18.03 Drugs that have a substantial potential for abuse.

Pursuant to s. 450.19 (1), Stats., the board has identified all of the following drugs as having a substantial potential for abuse:

(1) A controlled substance identified in schedule II, III, IV or V in the federal controlled substances act, 21 USC 812 (b)(2) to (b)(5) and (c), as changed and updated by 21 CFR 1308.

(2) A controlled substance identified in schedule IV or V in subch. II. of ch. 961, Stats., as amended by ch. CSB 2.

(3) Tramadol.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13; correction in (2) made under s. 13.92 (4) (b) 7., Stats., Register October 2012 No. 682.

Wis. Adm. Code s Phar 18.03, WI ADC s Phar 18.03

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Wis. Admin. Code s Phar 18.04

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 18. Prescription Drug Monitoring Program
Phar 18.04 Dispensing data.

(1) As used in this section:

(a) “DEA registration number” means the registration number issued to a dispenser or practitioner by the federal department of justice, drug enforcement administration.

(b) “Dispenser identifier” means the DEA registration number, NPI number or unique state—issued credential, permit or license number issued to a dispenser.

(c) “NDC number” means national drug code number, the universal product identifier used in the U.S. to identify a specific drug product.

(d) “NPI number” means national provider identifier number, the registration number issued to a dispenser or practitioner by the national provider identifier registry.

(e) “Practitioner identifier” means the DEA registration number, NPI number or unique state—issued credential, permit or license number issued to a practitioner.

(2) Subject to s. Phar 18.08, a dispenser shall compile dispensing data that contains information about each time he or she dispenses a monitored prescription drug to a patient.

(3) The dispensing data shall contain all of the following information:

(a) The dispenser's full name.

(b) The dispenser identifier.

(c) The date dispensed.

(d) The prescription number, if applicable.

(e) The NDC number or the name and strength of the monitored prescription drug.

(f) The quantity dispensed.

(g) The estimated number of days of drug therapy.

(h) The practitioner's full name.

(i) The practitioner identifier.

(j) The date prescribed.

(k) The quantity prescribed.

(l) The patient's full name.

(m) The patient's address, or if the patient is an animal, the owner of the patient's address, including street address, city, state and ZIP code.

(n) The patient's date of birth, or if the patient is an animal, the owner of the patient's date of birth.

(o) The patient's gender.

(4) A dispenser who fails to compile dispensing data as required by subs. (2) and (3) may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13.

Wis. Adm. Code s Phar 18.04, WI ADC s Phar 18.04

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Wis. Admin. Code s Phar 18.05

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 18. Prescription Drug Monitoring Program
Phar 18.05 Electronic submission of dispensing data.

(1) A dispenser shall create an account with the board through which the dispenser shall submit dispensing data to the board.

Note: The application to create an account may be completed online at www.dsps.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

(2) The dispensing data shall be submitted to the board in compliance with the data standards in the version and release of the American Society for Automation in Pharmacy (ASAP) implementation guide for prescription monitoring programs identified by the board or other electronic format identified by the board.

Note: The guide for dispensers which specifies the data standards in the version and release of the ASAP implementation guide for prescription monitoring programs identified by the board and other electronic formats identified by the board may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

(3) If a dispenser is not able to create an account or submit dispensing data as required by subs. (1) and (2), the board may grant a waiver to a dispenser who satisfies all of the following conditions:

(a) The dispenser agrees to begin filing dispensing data on a paper form identified by the board for each monitored prescription drug dispensed.

(b) The dispenser files with the board a written application for a waiver on a form provided by the board.

Note: The application for a waiver may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

Wis. Admin. Code s Phar 18.05

(4) A dispenser who fails to create an account with the board and submit dispensing data as required by subs. (1) and (2) or be granted a waiver under sub. (3) may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13.

Wis. Adm. Code s Phar 18.05, WI ADC s Phar 18.05

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Wis. Admin. Code s Phar 18.06

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 18. Prescription Drug Monitoring Program
Phar 18.06 Frequency of submissions.

(1) A dispenser, other than a veterinary dispenser, shall submit dispensing data to the board within 7 days of dispensing a monitored prescription drug.

(2) If a dispenser, other than a veterinary dispenser, does not dispense a monitored prescription drug for 7 days, the dispenser shall submit a zero report to the board.

(3) If a dispenser, other than a veterinary dispenser, is not able to submit dispensing data within 7 days of dispensing a monitored prescription drug as required by sub. (1), the board may grant an emergency waiver to a dispenser who satisfies all of the following conditions:

(a) The dispenser is not able to submit dispensing data because of circumstances beyond its control.

(b) The dispenser files with the board a written application for an emergency waiver on a form provided by the board prior to the required submission of dispensing data.

Note: The application for an emergency waiver may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

(4) A veterinary dispenser shall submit dispensing data to the board within 90 days of dispensing a monitored prescription drug.

(5) If a veterinary dispenser does not dispense a monitored prescription drug for 90 days, the veterinary dispenser shall submit a zero report to the board.

(6) If a veterinary dispenser is not able to submit dispensing data within 90 days of dispensing a monitored prescription drug as required by sub. (4), the board may grant an emergency waiver to a veterinary dispenser who satisfies all of the following conditions:

Wis. Admin. Code s Phar 18.06

(a) The veterinary dispenser is not able to submit dispensing data because of circumstances beyond its control.

(b) The veterinary dispenser files with the board a written application for an emergency waiver on a form provided by the board prior to the required submission of dispensing data.

Note: The application for an emergency waiver may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

(7) Unless otherwise specified by the board, an emergency waiver granted under subs. (3) or (6) shall only be effective for 7 days.

(8) A dispenser who fails to submit dispensing data or a zero report as required by subs. (1) and (2), be granted an emergency waiver under sub. (3), or submits false information to the board may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

(9) A veterinary dispenser who fails to submit dispensing data or a zero report as required by subs. (4) and (5), be granted an emergency waiver under sub. (6), or submits false information to the board may be subject to disciplinary action by the licensing board that issued the license under which the dispenser is authorized to dispense monitored prescription drugs.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13.

Wis. Adm. Code s Phar 18.06, WI ADC s Phar 18.06

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Wis. Admin. Code s Phar 18.07

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 18. Prescription Drug Monitoring Program
Phar 18.07 Correction of dispensing data.

If a dispenser discovers omissions or inaccuracies in previously submitted dispensing data or other PDMP information, the dispenser shall notify the board in writing within 7 days and submit documentation that identifies the erroneous information and includes the correct information.

Note: The written notice to the board may be submitted through an account with the board, sent by electronic mail or sent by U.S. mail to the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13.

Wis. Adm. Code s Phar 18.07, WI ADC s Phar 18.07

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Wis. Admin. Code s Phar 18.08

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 18. Prescription Drug Monitoring Program
Phar 18.08 Exemptions from compiling and submitting dispensing data.

(1) The board shall exempt a dispenser from compiling and submitting dispensing data and from submitting a zero report as required under this chapter until the dispenser is required to renew his or her license, or until the dispenser dispenses a monitored prescription drug, if the dispenser satisfies all of the following conditions:

(a) The dispenser provides evidence sufficient to the board that he or she does not dispense monitored prescription drugs.

(b) The dispenser files with the board a written request for exemption on a form provided by the board.

Note: The application for an exemption may be obtained online at www.dsps.wi.gov or at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708. A dispenser who is already exempt can renew his or her exemption as part of the licensure renewal process.

(2) A dispenser is not required to compile or submit dispensing data when the monitored prescription drug is administered directly to a patient.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13.

Wis. Adm. Code s Phar 18.08, WI ADC s Phar 18.08

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Wis. Admin. Code s Phar 18.09

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 18. Prescription Drug Monitoring Program
Phar 18.09 Direct access to PDMP information.

(1) Dispensers, dispenser delegates, practitioners, and practitioner delegates may access PDMP information in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter and other state or federal laws and regulations relating to the privacy of patient health care records.

(2) To obtain access to PDMP information, dispensers, dispenser delegates, practitioners, and practitioner delegates shall create an account with the board on a form provided by the board.

Note: The application to create an account may be completed online at www.dsps.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

(3) The board may deny, suspend, revoke or otherwise restrict or limit a dispenser's, dispenser delegate's, practitioner's, or practitioner delegate's direct access to PDMP information for any of the following reasons:

(a) The dispenser, dispenser delegate, practitioner, or practitioner delegate uses PDMP information in violation of s. 146.82 or 450.19, Stats., this chapter, or other state or federal laws or regulations relating to the privacy of patient health care records.

(b) The dispenser, dispenser delegate, practitioner, or practitioner delegate is no longer licensed in this state or another state and recognized by this state as a person authorized to prescribe or dispense monitored prescription drugs.

(c) The board, other licensing board, or regulatory agency takes adverse action against the dispenser, dispenser delegate, practitioner, or practitioner delegate.

(d) A licensing board or equivalent regulatory agency in another jurisdiction takes adverse action against the dispenser, dispenser delegate, practitioner, or practitioner delegate.

Wis. Admin. Code s Phar 18.09

(e) The federal department of justice, drug enforcement administration takes adverse action against the dispenser, dispenser delegate, practitioner, or practitioner delegate.

(f) The dispenser, dispenser delegate, practitioner, or practitioner delegate is convicted of a crime substantially related to the prescribing or dispensing of a monitored prescription drug.

(g) The dispenser delegate or practitioner delegate is no longer delegated the task of inputting or accessing PDMP information.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13.

Wis. Adm. Code s Phar 18.09, WI ADC s Phar 18.09

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Wis. Admin. Code s Phar 18.10

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 18. Prescription Drug Monitoring Program
Phar 18.10 Requests for review.

(1) A dispenser, dispenser delegate, practitioner, or practitioner delegate may request that the board review any of the following:

(a) The denial of a waiver requested pursuant to s. Phar 18.05 (3).

(b) The denial of an emergency waiver requested pursuant to ss. Phar 18.06 (3) or (6).

(c) The denial, suspension, revocation or other restriction or limitation imposed on the dispenser's, dispenser delegate's, practitioner's, or practitioner delegate's account pursuant to s. Phar 18.09 (3).

(2) To request a review, the dispenser, dispenser delegate, practitioner, or practitioner delegate shall file a written request with the board within 20 days after the mailing of the notice of the action in sub. (1). The request shall be in writing and include all of the following:

(a) The dispenser's, dispenser delegate's, practitioner's, or practitioner delegate's name and address, including street address, city, state and ZIP code.

(b) The reason for requesting a review.

(3) The board shall conduct the review at its next regularly scheduled meeting and notify the dispenser, dispenser delegate, practitioner, or practitioner delegate of the time and place of the review.

(4) No discovery is permitted.

(5) The board shall preside over the review. The review shall be recorded by audio tape unless otherwise specified by the board.

(6) The board shall provide the dispenser, dispenser delegate, practitioner, or practitioner delegate with an opportunity to submit written documentation, make a personal appearance before the board and present a statement. The board may establish a time limit for making a presentation. Unless otherwise determined by the

board, the time for making a personal appearance shall be 20 minutes.

(7) If the dispenser, dispenser delegate, practitioner, or practitioner delegate fails to appear for a review, or withdraws the request for a review, the board may note the failure to appear in the minutes and affirm its original decision without further action.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13.

Wis. Adm. Code s Phar 18.10, WI ADC s Phar 18.10

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Wis. Admin. Code s Phar 18.11

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 18. Prescription Drug Monitoring Program
Phar 18.11 Methods of obtaining PDMP information.

(1) The board shall disclose PDMP information about a patient to the patient if he or she does all of the following:

(a) Appears in person at the department with two forms of valid proof of identity, one of which is valid government—issued photographic identification.

(b) Makes a request for the PDMP information on a form provided by the board.

(2) The board shall disclose PDMP information about a patient to a person authorized by the patient if the person authorized by the patient does all of the following:

(a) Appears in person at the department with two forms of valid proof of identity, one of which is valid government—issued photographic identification.

(b) Provides proof sufficient to the board of the authorization or delegation from the patient.

(c) Makes a request for the PDMP information on a form provided by the board.

(3) The board shall disclose the minimum amount of PDMP information necessary to designated staff of a relevant agency in another state in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides proof sufficient to the board that the relevant agency in another state is entitled to the information under ss. 146.82 and 450.19 (2) (c), Stats.

(c) Makes a request for the PDMP information through its account with the board.

(4) The board shall disclose the minimum amount of PDMP information necessary to a health care facility staff committee, or accreditation or health care services review organization in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides proof sufficient to the board that the health care facility staff committee, or accreditation or health care services review organization is entitled to the information under s. 146.82 (2) (a) 1., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(5) The board shall disclose the minimum amount of PDMP information necessary to designated staff of a federal or state governmental agency in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides proof sufficient to the board that the federal or state governmental agency is entitled to the information under s. 146.82 (2) (a) 5., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(6) The board shall disclose the minimum amount of PDMP information necessary to designated staff of the department who is charged with investigating dispensers, dispenser delegates, practitioners, and practitioner delegates in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides proof sufficient to the board that the department is entitled to the information under s. 146.82 (2) (a) 5., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(7) The board shall disclose the minimum amount of PDMP information necessary to a prisoner's health care provider, the medical staff of a prison or jail in which a prisoner is confined, the receiving institution intake staff at a prison or jail to which a prisoner is being transferred or a person designated by a jailer to maintain prisoner medical records or designated staff of the department of corrections in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides proof sufficient to the board that the person is entitled to the information under s. 146.82 (2) (a) 21., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(8) The board shall disclose the minimum amount of PDMP information necessary to a coroner, deputy coroner, medical examiner, or medical examiner's assistant following the death of a patient in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides proof sufficient to the board that the person is entitled to the information under s. 146.82 (2) (a) 18., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(9) The board shall disclose the minimum amount of PDMP information necessary to a researcher in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the person does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides proof sufficient to the board that the person is entitled to the information under s. 146.82 (2) (a) 6. or 20., Stats.

(c) Makes a request for the PDMP information through its account with the board.

(10) The board shall disclose the minimum amount of PDMP information to designated staff of a law enforcement authority in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar confidential patient health care records under ss. 146.82 and 450.19, Stats., this chapter, and other state or federal laws and regulations relating to the privacy of patient health care records if the designated staff does all of the following:

(a) Creates an account with the board on a form provided by the board.

(b) Provides a lawful order of a court of record under s. 146.82 (2) (a) 4., Stats., or provides evidence satisfactory to the board that the law enforcement agency is entitled to the information under s. 146.82 (2) (a) 11., Stats.

(c) Makes a request for PDMP information through its account with the board.

Note: The application to create an account and form to request PDMP information may be completed online at www.dsps.wi.gov or obtained at no charge from the Department of Safety and Professional Services, 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13.

Wis. Adm. Code s Phar 18.11, WI ADC s Phar 18.11

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Wis. Admin. Code s Phar 18.12

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 18. Prescription Drug Monitoring Program
Phar 18.12 Use of PDMP information by the board and department.

(1) The board shall develop and maintain a PDMP database to store PDMP information.

(2) The PDMP database shall store PDMP information in an encrypted format.

(3) The board shall maintain a log of persons to whom the board grants access to PDMP information.

(4) The board shall maintain a log of information submitted and accessed by each dispenser, dispenser delegate, practitioner, and practitioner delegate.

(5) The board shall maintain a log of requests for PDMP information.

(6) Board and department staff assigned administrative duties over the PDMP, vendors, and other agents of the board shall only have access to the minimum amount of PDMP information necessary for all of the following purposes:

(a) The design, implementation, operation, and maintenance of the program, including the PDMP database, as part of the assigned duties and responsibilities of their employment.

(b) The collection of dispensing data as part of the assigned duties and responsibilities under s. 450.19, Stats ., and this chapter.

(c) Evaluating and responding to legitimate requests for PDMP information.

(d) Other legally authorized purposes.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13.

Wis. Adm. Code s Phar 18.12, WI ADC s Phar 18.12

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Wis. Admin. Code s Phar 18.12

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Wis. Admin. Code s Phar 18.13

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 18. Prescription Drug Monitoring Program
Phar 18.13 Confidentiality of PDMP information.

(1) The PDMP information maintained by the board, department or a vendor contracting with the department which is submitted to, maintained, or stored as a part of the program is not subject to inspection or copying under s. 19.35, Stats.

(2) A person who discloses PDMP information in violation of s. 146.82 or 450.19, Stats., this chapter, or other state or federal laws or regulations relating to the privacy of patient health care records, may be subject to disciplinary action by the licensing board that issued the license under which the person is authorized to prescribe or dispense monitored prescription drugs and all appropriate civil and criminal penalties.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13.

Wis. Adm. Code s Phar 18.13, WI ADC s Phar 18.13

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Wis. Admin. Code s Phar 18.14

Wisconsin Administrative Code Currentness
Pharmacy Examining Board
Chapter Phar 18. Prescription Drug Monitoring Program
Phar 18.14 Exchange of PDMP information.

(1) The board may exchange PDMP information with a prescription monitoring program operated by a relevant agency in another jurisdiction if the prescription monitoring program satisfies all of the following conditions:

(a) The prescription monitoring program is compatible with the program.

(b) The relevant agency operating the prescription monitoring program agrees to exchange similar information with the program.

(2) In determining the compatibility of a prescription monitoring program to the program, the board may consider any of the following:

(a) The safeguards for privacy of patient records and the prescription monitoring program's success in protecting patient privacy.

(b) The persons authorized to access the information stored by the prescription monitoring program.

(c) The schedules of controlled substances monitored by the prescription monitoring program.

(d) The information required by the agency to be submitted regarding the dispensing of a prescription drug.

(e) The costs and benefits to the board of sharing information.

(3) The board may assess a prescription monitoring program's continued compatibility with the program at any time.

History: CR 12-009: cr. Register October 2012 No. 682, eff. 1-1-13.

Wis. Adm. Code s Phar 18.14, WI ADC s Phar 18.14

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Wis. Admin. Code s Phar 18.14

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