

CHAPTER 450

PHARMACY EXAMINING BOARD

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Cross-reference: See definitions in s. 440.01.
Cross Reference: See also Phar, Wis. adm. code.

450.01 Definitions. In this chapter:

(1) “Administer” means the direct application of a vaccine or a prescribed drug or device, whether by injection, ingestion or any other means, to the body of a patient or research subject by any of the following:

- A practitioner or his or her authorized agent.
- A patient or research subject at the direction of a practitioner.
- A pharmacist.

(1m) “Advanced practice nurse prescriber” means an advanced practice nurse who is certified under s. 441.16 (2).

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

(3) “Compound” means to mix, combine or put together various ingredients or drugs for the purpose of dispensing.

(4) “Controlled substance” has the meaning designated in s. 961.01 (4).

(5) “Deliver” or “delivery” means the actual, constructive or attempted transfer of a drug or device from one person to another.

(6) “Device” means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory, which does not achieve any of its principal intended purposes through chemical action within or on the body of a person or other animal, is not dependent upon being metabolized for the achievement of any of its principal intended purposes and is:

(a) Recognized by the U.S. pharmacopoeia and national formulary or official homeopathic pharmacopoeia of the United States, or any supplement to either of them;

(b) Intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or other conditions in persons or other animals; or

(c) Intended to affect the structure or any function of the body of persons or other animals.

(7) “Dispense” means to deliver a prescribed drug or device to an ultimate user or research subject by or pursuant to the prescription order of a practitioner, including the compounding, packaging or labeling necessary to prepare the prescribed drug or device for delivery.

(8) “Distribute” means to deliver, other than by administering or dispensing.

(9) “Distributor” means a person licensed by the board under s. 450.07 (2).

(10) “Drug” means:

(a) Any substance recognized as a drug in the official U.S. pharmacopoeia and national formulary or official homeopathic

pharmacopoeia of the United States or any supplement to either of them;

(b) Any substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or other conditions in persons or other animals;

(c) Any substance other than a device or food intended to affect the structure or any function of the body of persons or other animals; or

(d) Any substance intended for use as a component of any article specified in pars. (a) to (c) but does not include gases or devices or articles intended for use or consumption in or for mechanical, industrial, manufacturing or scientific applications or purposes.

(11) “Drug product” means a specific drug or drugs in a specific dosage form and strength from a known source of manufacture.

(12) “Manufacturer” means a person licensed by the board under s. 450.07 (1).

(13) “Manufacturing” means making, assembling, processing or modifying devices, or mixing, producing or preparing drugs in dosage forms by encapsulating, entableting or other process, or packaging, repackaging or otherwise changing the container, wrapper or label of any package containing a drug or device in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.

(13m) “Nonprescription drug product” means any nonnarcotic drug product which may be sold without a prescription order and which is prepackaged for use by consumers and labeled in accordance with the requirements of state and federal law.

(14) “Patient” means the person or other animal for whom drug products or devices are prescribed or to whom drug products or devices are dispensed or administered.

(15) “Pharmacist” means a person licensed by the board under s. 450.03 or 450.05.

(16) “Practice of pharmacy” means any of the following:

(a) Interpreting prescription orders.

(b) Compounding, packaging, labeling, dispensing and the coincident distribution of drugs and devices.

(c) Participating in drug utilization reviews.

(d) Proper and safe storage of drugs and devices and maintaining proper records of the drugs and devices.

(e) Providing information on drugs or devices which may include, but is not limited to, advice relating to therapeutic values, potential hazards and uses.

(f) Drug product substitution under s. 450.13.

(g) Supervision of pharmacist supportive personnel.

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(h) Making therapeutic alternate drug selections, if made in accordance with written guidelines or procedures previously established by a pharmacy and therapeutics committee of a hospital and approved by the hospital's medical staff and use of the therapeutic alternate drug selection has been approved for a patient during the period of the patient's stay within the hospital by any of the following:

1. The patient's physician.
2. The patient's advanced practice nurse prescriber, if the advanced practice nurse prescriber has entered into a written agreement to collaborate with a physician.

(i) 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.

(j) Performing any act necessary to manage a pharmacy.

(k) Administering prescribed drug products and devices under s. 450.035 (1r) and, pursuant to vaccination protocols, vaccines.

(17) "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.

(18) "Prescribed drug or device" means any drug or device prescribed by a practitioner.

(19) "Prescription" means a drug or device prescribed by a practitioner.

(20) "Prescription drug" means:

(a) Any drug, drug product or drug-containing preparation which is subject to 21 USC 353 (b) or 21 CFR 201.105.

(b) Any controlled substance included in schedules II to V of ch. 961, whether by statute or rule, except substances which by law may be dispensed without the prescription order of a practitioner. Controlled substances are included within this definition for purposes of s. 450.11 (3), (4) (a) and (8) only and for violations thereof punishable under s. 450.11 (9).

(21) "Prescription order" means an order transmitted orally, electronically or in writing by a practitioner for a drug or device for a particular patient.

(22) "Vaccination protocol" means a written protocol agreed to by a physician, as defined in s. 448.01 (5), and a pharmacist that establishes procedures and record-keeping and reporting requirements for the administration of a vaccine by a pharmacist for a period specified in the protocol that may not exceed 2 years.

History: 1985 a. 146; 1987 a. 65; 1991 a. 114; 1995 a. 448; 1997 a. 27, 68; 1997 a. 237 s. 727m; 2005 a. 187.

Vitamins not intended for use in the diagnosis, cure, investigation, treatment, or prevention of diseases are not drugs under this section. 66 Atty. Gen. 137.

450.02 Pharmacy examining board. **(1)** The department shall keep a record of the proceedings and a register of the names and places of practice or business of pharmacies, manufacturers, distributors and other persons licensed under this chapter, and the books, registers and records of the department shall be prima facie evidence of the matters recorded.

(2) The board shall adopt rules defining the active practice of pharmacy. The rules shall apply to all applicants for licensure under s. 450.05.

(2g) (a) The pharmacy examining board shall, after consultation with the medical examining board and the board of nursing, promulgate rules that establish criteria for approving courses under ss. 450.035 (1r) and (2) and 450.085 (1).

(b) The board shall promulgate rules that establish requirements and procedures for the administration of a drug product or device, as defined in s. 450.035 (1g), by a pharmacist under s. 450.035 (1r). Notwithstanding s. 15.08 (5) (b), the board may promulgate rules under this paragraph only if the rules are identical to rules recommended by the pharmacist advisory council. The board may amend or repeal rules promulgated under this para-

graph only upon the recommendation of the pharmacist advisory council.

(2m) The board shall periodically prepare and distribute letters, bulletins or other types of notice to pharmacists that identify the courses that are approved for purposes of ss. 450.035 (1r) and (2) and 450.085 (1).

(3) The board may promulgate rules:

(a) Relating to the manufacture of drugs and the distribution and dispensing of prescription drugs.

(b) Establishing security standards for pharmacies.

(c) Relating to the manufacture, distribution and dispensing of hypodermic syringes, needles and other objects used, intended for use or designed for use in injecting a drug.

(d) Necessary for the administration and enforcement of this chapter and ch. 961.

(e) Establishing minimum standards for the practice of pharmacy.

(f) Establishing procedures for identifying pharmacists impaired by alcohol or other drugs or physical or mental disability or disease and for assisting those pharmacists in obtaining treatment.

(3m) (a) The board or its designee may grant a variance to a requirement of this chapter or to a rule promulgated by the board if all of the following are true:

1. The board or its designee determines that a natural or man-made disaster or emergency exists or has occurred.

2. A pharmacist has requested the variance.

3. The board or its designee determines that the variance is necessary to protect the public health, safety, or welfare.

(am) If a member of the board disagrees with a decision made by a designee under par. (a), the board chairperson shall call a meeting of the board as soon as practicable to review the decision. The board may affirm or modify the designee's decision.

(b) A variance granted under par. (a) shall be for a stated term not to exceed 90 days, except that the board or its designee may extend the variance upon request by a pharmacist if it determines that an extension is necessary to protect the public health, safety, or welfare.

(4) The board may not promulgate a rule which does any of the following:

(a) Limits to a pharmacist the authority to sell or in any way interferes with the sale of nonnarcotic nonprescription drugs that are prepackaged for consumer use and labeled in compliance with all applicable state and federal laws.

(b) Interprets s. 448.03 (2) (e) to expand the therapeutic alternate drug selection powers of a pharmacist beyond those specified in s. 450.01 (16) (h).

History: 1985 a. 146; 1987 a. 65; 1995 a. 448; 1997 a. 68; 1997 a. 237 s. 727m; 2005 a. 270.

Cross Reference: See also Phar, Wis. adm. code.

450.025 Pharmacist advisory council. The pharmacist advisory council shall recommend rules for promulgation by the board under s. 450.02 (2g) (b) and may recommend the amendment or repeal of any rules promulgated under s. 450.02 (2g) (b). A unanimous vote of the members of the pharmacist advisory council is required for the council to make a recommendation under this section.

History: 1997 a. 68; 1997 a. 237 s. 727m.

450.03 Pharmacist; licensure. **(1)** No person may engage in the practice of pharmacy or use the title "pharmacist" or sell, give away or barter drugs unless the person is licensed as a pharmacist by the board. This subsection does not apply to:

(a) The offer to sell or sale of contraceptive articles, as defined under s. 450.155 (1) (a), by a registered nurse licensed under s. 441.06.

(b) The sale of any nonprescription drug product, in an original unbroken package, which complies with 21 USC 301 to 392.

(c) The sale of pesticides which comply with ss. 94.67 to 94.71.

(d) The delivery of complimentary samples of drug products or devices to a practitioner by a manufacturer or its agent acting in the usual course of business.

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

(f) A person who has successfully completed his or her second year in, and is enrolled at, an accredited school of pharmacy and whose practice of pharmacy is limited to performing duties under the direct supervision of a person licensed as a pharmacist by the board.

(g) A person who has applied for a license under s. 450.05 whose practice of pharmacy is limited to performing duties under the direct supervision of a person licensed as a pharmacist by the board and during the period before which the board takes final action on the person's application.

(h) The provision of services by a health care provider under s. 250.042 (4) (b).

(2) The board shall issue a license as a pharmacist to any person who files satisfactory proof of qualifications under s. 450.04 (3), passes the examination under s. 450.04 and pays the fee specified in s. 440.05 (1), except as provided under s. 450.10.

History: 1985 a. 146; 1987 a. 264; 1991 a. 39; 2001 a. 16; 2005 a. 96.

Cross Reference: See also chs. Phar 2 and 17, Wis. adm. code.

450.035 Administration of drug products and devices; vaccines. (1g) In this section, “drug product or device” does not include a vaccine.

(1r) A pharmacist may not administer by injection a prescribed drug product or device unless he or she has successfully completed a course of study and training in injection technique conducted by a course provider approved by the American Council on Pharmaceutical Education or the board. A pharmacist may administer a prescribed drug product or device under this subsection only in the course of teaching self–administration techniques to a patient. A pharmacist who administers a prescribed drug product or device under this subsection shall comply with the requirements and procedures established in rules promulgated by the board under s. 450.02 (2g) (b).

(1t) A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g) may not administer a prescribed drug product or device unless he or she has successfully completed a course of study and training in administration technique conducted by a course provider approved by the American Council on Pharmaceutical Education or the board. A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g) may administer a prescribed drug product or device under this subsection only under the direct supervision of a pharmacist who has successfully completed a course of study and training in administration technique conducted by a course provider approved by the American Council on Pharmaceutical Education or the board, and only in the course of teaching self–administration techniques to a patient. A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g) who administers a prescribed drug product or device under this subsection shall comply with the requirements and procedures established in rules promulgated by the board under s. 450.02 (2g) (b).

(2) A pharmacist may not administer a vaccine unless he or she has successfully completed 12 hours in a course of study and training, approved by the American Council on Pharmaceutical Education or the board, in vaccination storage, protocols, administration technique, emergency procedures and record keeping and has satisfied the requirements specified in sub. (2t). A phar-

macist may not administer a vaccine under this subsection to a person who is under the age of 18.

(2g) A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g) may not administer a vaccine unless he or she acts under the direct supervision of a pharmacist and he or she and the supervising pharmacist have successfully completed 12 hours in a course of study and training, approved by the American Council on Pharmaceutical Education or the board, in vaccination storage, protocols, administration technique, emergency procedures and record keeping and the supervising pharmacist has satisfied the requirements specified in sub. (2t). A person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g) may not administer a vaccine under this subsection to a person who is under the age of 18.

(2m) Except as provided in sub. (1t) or (2g), a pharmacist may not delegate to any person any administration of a prescribed drug product or device or vaccine under sub. (1r) or (2).

(2t) A pharmacist may not administer a vaccine under sub. (2) or supervise a person administering a vaccine under sub. (2g) unless the pharmacist satisfies each of the following:

(a) The pharmacist has in effect liability insurance that covers the pharmacist and a person who administers a vaccine under sub. (2g) against loss, expense and liability resulting from errors, omissions or neglect in the administration of vaccines 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.

(b) The pharmacist maintains proof that he or she satisfies the requirement specified in par. (a) and, upon request, provides copies of such proof to the department or the board.

(3) A pharmacist or a person engaged in the practice of pharmacy under s. 450.03 (1) (f) or (g) who successfully completes a course of study and training specified in sub. (1r), (1t), (2), or (2g) shall maintain proof of completion and, upon request, provide copies of such proof to the department or the board.

History: 1997 a. 68; 1997 a. 237 s. 727m; 2003 a. 181.

450.04 Examinations. (1) Examinations for licensure as a pharmacist shall be designed to determine whether an applicant is competent to engage in the practice of pharmacy.

(2) Examinations shall be conducted at least semiannually.

(3) Every candidate for examination for licensure as a pharmacist shall submit an application on a form provided by the department and pay the fee specified in s. 440.05 (1) at least 30 days before the date of examination. Every candidate shall also submit proof to the board that he or she:

(a) Has received a professional degree from a pharmacy program approved by the board; and

(b) Has completed an internship in the practice of pharmacy or has practical experience acquired in another state which is comparable to that included in an internship and 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.

History: 1985 a. 146; 1991 a. 39; 1997 a. 27; 1997 a. 237 s. 722u; 2001 a. 16.

Cross Reference: See also ch. Phar 4 and s. Phar 2.03, Wis. adm. code.

Post–examination review with applicants discussed. 68 Atty. Gen. 48.

450.05 Pharmacist licensed in other state; licensure. The board may, upon application and payment of the fee specified in s. 440.05 (2), license as a pharmacist any person who is licensed in another state if the person produces satisfactory evidence of having met requirements comparable to those that existed in this state at the time the person became licensed in the other state. The board shall not license as a pharmacist under this section any person whose license to practice pharmacy in another state has been voluntarily surrendered, limited, suspended or revoked. The board may require an applicant under this section to pass an equivalency examination administered by the board. If the board requires an equivalency examination, any person licensed as a

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pharmacist in another state who is engaged in the active practice of pharmacy may only be required to pass an examination on state and federal laws, rules and regulations.

History: 1985 a. 146.

Cross Reference: See also chs. Phar 2 and 5, Wis. adm. code.

This chapter applies to out-of-state pharmacies that regularly and continually solicit mail orders for retail sale of prescription drugs to Wisconsin residents. 72 Atty. Gen. 121.

450.06 Pharmacies located in this state; licensure.

(1) No pharmacist may dispense at any location in this state that is not licensed as a pharmacy by the board. No person in this state may use or display the title “pharmacy,” “drugstore,” “apothecary,” or any other title, symbol, or insignia having the same or similar meanings, except for a place of practice which is licensed under this section as a pharmacy by the board.

(2) The board shall issue a license to operate a pharmacy at a specific location in this state if:

(a) An application is made on forms provided by the board showing all of the following:

1. The location of the pharmacy.
2. A floor plan of the pharmacy.
3. The name and address of the person holding title and ownership control of the location.
4. The name of the managing pharmacist of the pharmacy under s. 450.09 (1).

(b) The location of the pharmacy is inspected and found to meet all the requirements of this chapter.

(c) The fee under s. 440.05 (1) is paid.

(2m) The board may request, but may not require, that practice-related information be submitted on the application under sub. (2) (a).

(3) No pharmacy located in this state may be opened or kept open for practice following a change of ownership or change of location unless the pharmacy is licensed for the new owner or at the new location, notwithstanding any remaining period of validity under the pharmacy’s license under the previous owner or at the previous location.

(4) Any person who fails to license his or her place of practice as required under this section may be assessed a forfeiture of not less than \$25 nor more than \$50 for each separate offense. Each day of violation constitutes a separate offense.

History: 1985 a. 146; 1991 a. 39; 2005 a. 242.

Cross Reference: See also ch. Phar 6, Wis. adm. code.

450.065 Out-of-state pharmacies; licensure. (1) No pharmacy that is in another state may ship, mail, or otherwise deliver a prescribed drug or device to persons in this state unless the pharmacy is licensed under sub. (2).

(2) The board shall issue a license to a pharmacy that is located outside this state if the pharmacy does all of the following:

(a) Applies on a form provided by the board that shows all of the following:

1. The location of the pharmacy.
2. The name and address of the person holding title and ownership control of the location.
3. The name of the managing pharmacist of the pharmacy.

(b) Submits a statement in a form prescribed by the board from the owner of the pharmacy or, if the pharmacy is not a sole proprietorship, from the managing pharmacist of the pharmacy that indicates that the owner or managing pharmacist, whichever is applicable, knows the laws relating to the practice of pharmacy in this state.

(c) Submits evidence satisfactory to the board that it is licensed in the state in which it is located.

(d) Pays the fee under s. 440.05 (1).

(3) A pharmacy that applies for a license under sub. (2) may not be required to comply with any provision in this chapter or any rule promulgated under this chapter relating to the professional

service area of a pharmacy or the minimum equipment requirements for a pharmacy.

(4) (a) Notwithstanding s. 450.03, a pharmacist employed in a pharmacy licensed under this section is not required to be licensed under this chapter.

(b) Notwithstanding s. 450.09, a pharmacy licensed under this section is not required to be under the control of a managing pharmacist licensed under this chapter.

(5) A pharmacy licensed under this section shall provide a telephone number that allows a person in this state to contact the pharmacy during the pharmacy’s regular hours of business and that is available for use by a person in this state for not less than 40 hours per week.

History: 2005 a. 242.

450.07 Manufacturers and distributors; licensure.

(1) No person may engage in manufacturing in this state unless the person obtains a manufacturer’s license from the board. For the issuance of a license under this subsection, the applicant shall pay the fee specified in s. 440.05 (1).

(2) No person may engage in the sale or distribution at wholesale of a prescription drug or device in this state without first obtaining a distributor’s license from the board. For the issuance of a license under this subsection, the applicant shall pay the fee specified in s. 440.05 (1).

(3) No manufacturer or distributor may sell or distribute a prescription drug or device at wholesale to any person other than:

- (a) Pharmacists.
- (b) Practitioners.
- (c) Persons who procure prescription drugs or devices for the purpose of lawful research, teaching or testing and not for resale.
- (d) Hospitals and other institutions which procure prescription drugs or devices for administration to patients.
- (e) Officers or employees of the federal government who are authorized to receive prescription drugs or devices in the performance of their official duties.
- (f) Distributors.

(4) (a) The issuance of licenses under this section is subject to rules the board adopts for the protection of the public health and safety.

(b) The board shall adopt rules prescribing minimum standards for manufacturing and distributing drugs. Rules adopted under this paragraph may not impose requirements regarding the storage of a controlled substance in a safe, a steel cabinet, a vault, or any other secure storage compartment, area, room, or building unless one of the following applies:

1. The controlled substance is included in schedule I, II, III, or IV under ch. 961.
2. The controlled substance is also a controlled substance under federal law.

History: 1985 a. 146; 1991 a. 39; 2005 a. 14.

Cross Reference: See also chs. Phar 12 and 13, Wis. adm. code.

450.08 License renewal. (1) The renewal date for all licenses granted by the board is specified under s. 440.08 (2) (a). Only a holder of an unexpired license may engage in his or her licensed activity.

(2) (a) A pharmacist’s license may be renewed by complying with continuing education requirements under s. 450.085 and paying the applicable fee specified under s. 440.08 (2) (a) on or before the applicable renewal date specified under s. 440.08 (2) (a). Failure to obtain renewal within the time period specified under this paragraph terminates the right of the person to be licensed as a pharmacist, and such right can only be acquired by passing an examination to the satisfaction of the board.

(b) A pharmacy, manufacturer’s or distributor’s license may be renewed by paying the applicable fee specified under s. 440.08

(2) (a) on or before the applicable renewal date specified under s. 440.08 (2) (a).

History: 1985 a. 146; 1991 a. 39; 1997 a. 68; 1997 a. 237 s. 727m.

450.085 Continuing education. (1) An applicant for renewal of a license under s. 450.08 (2) (a) shall submit proof that he or she has completed, within the 2-year period immediately preceding the date of his or her application, 30 hours of continuing education in courses conducted by a provider that is approved by the American Council on Pharmaceutical Education or in courses approved by the board. Courses specified in s. 450.035 (1r) and (2) are courses in continuing education for purposes of this subsection. This subsection does not apply to an applicant for renewal of a license that expires on the first renewal date after the date on which the board initially granted the license.

(2) The board may waive all or part of any requirement in sub. (1) if it finds that exceptional circumstances such as prolonged illness, disability or other similar circumstances have prevented a pharmacist from meeting the requirement.

History: 1997 a. 68; 1997 a. 237 s. 727m.

Cross Reference: See also ch. Phar 16, Wis. adm. code.

450.09 Pharmacy practice. (1) **MANAGING PHARMACIST.**

(a) Every pharmacy shall be under the control of the managing pharmacist who signed the pharmacy license application, the most recent license renewal application or the most recent amended schedule of operations. The managing pharmacist shall be responsible for the professional operations of the pharmacy. A pharmacist may be the managing pharmacist of not more than one community and one institutional pharmacy at any time and shall be engaged in the practice of pharmacy at each location he or she supervises. The board shall by rule define community pharmacy and institutional pharmacy for the purposes of this section.

(b) If the managing pharmacist anticipates being continuously absent for a period of more than 30 days from a pharmacy he or she supervises, the managing pharmacist shall delegate the supervisory responsibility to another pharmacist for the duration of the absence by written power of attorney which shall be kept on file in the pharmacy to which the power of attorney applies. The pharmacist designated to assume the supervisory responsibility for the pharmacy during the managing pharmacist's absence shall be engaged in the practice of pharmacy at the pharmacy to which the power of attorney applies.

(2) **PRESENCE OF PHARMACIST.** No pharmaceutical service may be provided to any person unless a pharmacist is present in the pharmacy to provide or supervise the service.

(3) **PHARMACEUTICAL EQUIPMENT.** Every pharmacy shall be equipped with proper pharmaceutical utensils for compounding and dispensing prescriptions. The board shall prescribe, by rule, minimum standards of professional and technical equipment.

(4) **CONDITION OF PHARMACY.** The pharmacy shall be maintained in a clean and orderly manner and the professional service area shall be equipped with proper fixtures and equipment for sanitation.

(5) **DISPLAY OF LICENSE.** Every original license issued by the board and the renewal license currently in force, if any, shall be displayed in the place of practice.

(6) **MEDICATION PROFILE RECORD SYSTEM.** Every pharmacy shall maintain a medication profile record system of all drug products dispensed for a particular patient according to the minimum standards for such systems established by the board by rule. Every practitioner shall maintain a record of all drug products dispensed to each patient according to standards established by the appropriate examining board by rule. The standards established by each examining board shall require the recording of all renewal dispensing information required by federal and state law and related rules and regulations.

(7) **SELECTION OF DRUGS.** Drug products purchased for subsequent sale and dispensing at a pharmacy shall be selected for purchase by a pharmacist.

(7m) **STATE PRISONS.** A prescription drug that is returned to a pharmacy that primarily serves patients confined in a state prison may be dispensed to any patient in any state prison, but only if all of the following are satisfied:

(a) The prescription drug was never in the possession of the patient to whom it was originally prescribed.

(b) The prescription drug is returned in its original container.

(c) A pharmacist determines that the prescription drug has not been adulterated or misbranded.

(8) **PENALTIES.** (a) Except as provided under par. (b), any person who violates this section may be assessed a forfeiture of not less than \$25 nor more than \$50 for each separate offense. Each day of violation constitutes a separate offense.

(b) Any person who violates sub. (5) shall forfeit \$10 for each separate offense. Each day of violation constitutes a separate offense.

History: 1985 a. 146; 2003 a. 54.

Cross Reference: See also ch. Phar 7, Wis. adm. code.

450.10 Disciplinary proceedings; immunity; orders.

(1) (a) In this subsection, "unprofessional conduct" includes, but is not limited to:

1. Making any materially false statement or giving any materially false information in connection with an application for a license or for renewal or reinstatement of a license.

2. Violating this chapter or, subject to s. 961.38 (4r), ch. 961 or any federal or state statute or rule which substantially relates to the practice of the licensee.

3. Practicing pharmacy while the person's ability to practice is impaired by alcohol or other drugs or physical or mental disability or disease.

4. Engaging in false, misleading or deceptive advertising.

5. Making a substantial misrepresentation in the course of practice which is relied upon by another person.

6. Engaging in conduct in the practice of the licensee which evidences a lack of knowledge or ability to apply professional principles or skills.

7. Obtaining or attempting to obtain compensation by fraud or deceit.

8. Violating any order of the board.

(b) Subject to subch. II of ch. 111 and the rules adopted under s. 440.03 (1), the board may reprimand the licensee or deny, revoke, suspend or limit the license or any combination thereof of any person licensed under this chapter who has:

1. Engaged in unprofessional conduct.

2. Been adjudicated mentally incompetent by a court.

3. Been found guilty of an offense the circumstances of which substantially relate to the practice of the licensee.

(2) In addition to or in lieu of a reprimand or denial, limitation, suspension or revocation of a license under sub. (1), the board may, for the violations enumerated under sub. (1), assess a forfeiture of not more than \$1,000 for each separate offense. Each day of violation constitutes a separate offense.

(3) (a) In this subsection, "health care professional" means any of the following:

1. A pharmacist licensed under this chapter.

2. A nurse licensed under ch. 441.

3. A chiropractor licensed under ch. 446.

4. A dentist licensed under ch. 447.

5. A physician, physician assistant, podiatrist, physical therapist, physical therapist assistant, occupational therapist, or occupational therapy assistant licensed under ch. 448.

5m. A dietitian certified under subch. V of ch. 448.

5q. An athletic trainer licensed under subch. VI of ch. 448.

6. An optometrist licensed under ch. 449.

7. An acupuncturist certified under ch. 451.

8. A veterinarian licensed under ch. 453.

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9. A psychologist licensed under ch. 455.

10. A social worker, marriage and family therapist, or professional counselor certified or licensed under ch. 457.

11. A speech–language pathologist or audiologist licensed under subch. II of ch. 459 or a speech and language pathologist licensed by the department of public instruction.

(b) Any health care professional who in good faith provides another health care professional with information concerning a violation of this chapter or ch. 961 by any person shall be immune from any civil or criminal liability that results from any act or omission in providing such information. In any administrative or court proceeding, the good faith of the health care professional providing such information shall be presumed.

(4) (a) The secretary may, in case of the need for emergency action, issue general and special orders necessary to prevent or correct actions by any pharmacist under this section that would be cause for suspension or revocation of a license.

(b) Special orders may direct a pharmacist to cease and desist from engaging in particular activities.

History: 1985 a. 146; 1987 a. 264, 399; 1989 a. 31, 316; 1991 a. 39, 160; 1993 a. 222, 443; 1995 a. 27 s. 9145 (1); 1995 a. 448; 1997 a. 27, 67, 75, 175; 1999 a. 9, 32, 180; 2001 a. 70, 80.

Cross Reference: See also ch. Phar 10, Wis. adm. code.

450.11 Prescription drugs and prescription devices.

(1) DISPENSING. No person may dispense any prescribed drug or device except upon the prescription order of a practitioner. All prescription orders shall specify the date of issue, the name and address of the patient, the name and address of the practitioner, the name and quantity of the drug product or device prescribed, directions for the use of the drug product or device, the symptom or purpose for which the drug is being prescribed if required under sub. (4) (a) 8., and, if the order is written by the practitioner, the signature of the practitioner. Any oral prescription order shall be immediately reduced to writing by the pharmacist and filed according to sub. (2).

NOTE: Sub. (1) is shown as amended eff. 10–1–06 by 2005 Wis. Act 196. Prior to 10–1–06 it reads:

(1) DISPENSING. No person may dispense any prescribed drug or device except upon the prescription order of a practitioner. All prescription orders shall specify the date of issue, the name and address of the patient, the name and address of the practitioner, the name and quantity of the drug product or device prescribed, directions for the use of the drug product or device and, if the order is written by the practitioner, the signature of the practitioner. Any oral prescription order shall be immediately reduced to writing by the pharmacist and filed according to sub. (2).

(1m) ELECTRONIC TRANSMISSION. Except as provided in s. 453.068 (1) (c) 4., a practitioner may transmit a prescription order electronically only if the patient approves the transmission and the prescription order is transmitted to a pharmacy designated by the patient.

(2) PRESCRIPTION ORDER FILE. Every prescription order shall be filed in a suitable book or file and preserved for at least 5 years. Subject to s. 961.38 (2), prescription orders transmitted electronically may be filed and preserved in electronic format.

(3) PREPARATION OF PRESCRIPTION DRUGS. No person other than a pharmacist or practitioner or their agents and employees as directed, supervised and inspected by the pharmacist or practitioner may prepare, compound, dispense or prepare for delivery for a patient any prescription drug.

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

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

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

2. The date on which the prescription was dispensed.

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

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

5. The full name of the patient.

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

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

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

NOTE: Subd. 8. is created eff. 10–1–06 by 2005 Wis. Act 196.

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

(4g) BRAND NAME PERMITTED ON LABEL. (a) In this subsection:

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

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

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

(b) If a pharmacist, pursuant to a prescription order that specifies a drug product by its brand name, dispenses the drug product equivalent of the drug product specified in the prescription order, the label required under sub. (4) (a) may include both the generic name of the drug product equivalent and the brand name specified in the prescription order, unless the prescribing practitioner requests that the brand name be omitted from the label.

NOTE: Sub. (4g) was created as sub. (4m) by 2005 Wis. Act 195 and renumbered by the revisor under s. 13.93 (1) (b).

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

NOTE: Sub. (4m) is created eff. 10–1–06 by 2005 Wis. Act 196.

(5) RENEWALS. No prescription may be renewed except as designated on the prescription order. An accurate record of renewal dispensing shall be maintained showing the date and amount. No prescription may be renewed unless the requirements of sub. (1) and, if applicable, sub. (1m) have been met and written, oral or electronic authorization has been given by the prescribing practitioner.

(6) SALES OF PRESCRIPTION DRUGS. In the event of any sale of prescription drugs in bankruptcy, at public auction or any other sale of prescription drugs other than in the normal course of business or practice, the seller shall give written notice of the sale to the board at least one week prior to the date of sale and shall make a complete and accurate written report of the sale to the board within 10 days after the sale, showing the name and address of all of the purchasers of prescription drugs together with an itemized inventory of the prescription drugs sold to each purchaser. This subsection does not apply to the sale of a manufacturer, distributor or pharmacy as an ongoing business or practice if the parties first notify the board of the impending sale.

(7) PROHIBITED ACTS. (a) No person may obtain or attempt to obtain a prescription drug, or procure or attempt to procure the administration of a prescription drug, by fraud, deceit or willful misrepresentation or by forgery or alteration of a prescription order; or by willful concealment of a material fact; or by use of a false name or address.

(b) Information communicated to a physician or advanced practice nurse prescriber in an effort to procure unlawfully a prescription drug or the administration of a prescription drug is not a privileged communication.

(c) No person may willfully make a false statement in any prescription order, report or record required by this section.

(d) No person may, for the purpose of obtaining a prescription drug, falsely assume the title of, or represent himself or herself to be, a manufacturer, distributor, pharmacist or practitioner.

(e) No person may make or utter any false or forged prescription order.

(f) No person may willfully affix any false or forged label to a package or receptacle containing prescription drugs.

(g) Except as authorized by this chapter, no person may possess, with intent to manufacture or deliver, a prescription drug. Intent under this paragraph may be demonstrated by, without limitation because of enumeration, evidence of the quantity and monetary value of the substance possessed, the possession of manufacturing implements or paraphernalia, and the activities or statements of the person in possession of the prescription drug prior to, during and after the alleged violation.

(h) No person may possess a prescription drug unless the prescription drug is obtained in compliance with this section.

(i) No pharmacist, manufacturer, distributor, owner or operator of a pharmacy or agent of a pharmacist, manufacturer, distributor or such an owner or operator may give any compensation or anything of value to a practitioner for the purpose of providing, or inducing the practitioner to obtain, any equipment, computer software or access to a service that may be used for the electronic transmission of a prescription order.

(8) RULE-MAKING AUTHORITY. The department of justice may promulgate rules necessary for the enforcement of this section. In addition to all law enforcement officers and agencies, the enforcement of this section is the responsibility of the department and:

(a) The board, insofar as this section applies to pharmacists.

(b) The medical examining board, insofar as this section applies to physicians.

(bm) The podiatrists affiliated credentialing board, insofar as this section applies to podiatrists.

(c) The veterinary examining board, insofar as this section applies to veterinarians.

(d) The dentistry examining board, insofar as this section applies to dentists.

(e) The board of nursing, insofar as this section applies to advanced practice nurse prescribers.

(9) PENALTIES AND ENFORCEMENT PROCEEDINGS. (a) Except as provided in par. (b), any person who violates this section may be fined not more than \$500 or imprisoned not more than 6 months or both.

(b) Any person who delivers, or who possesses with intent to manufacture or deliver, a prescription drug in violation of this section is guilty of a Class H felony.

(c) In any action or proceeding brought for the enforcement of this section, it shall not be necessary to negate any exception or exemption contained in this section, and the burden of proof of any such exception or exemption shall be upon the defendant.

History: 1985 a. 146; 1997 a. 27, 175, 283; 2001 a. 109; 2005 a. 195, 196; s. 13.93 (1) (b); 2005 a. 187, 242.

450.12 Labeling of prescription drugs and prescription drug products. (1) In this section:

(a) “Brand name” means the name, other than the generic name, that the labeler of a drug or drug product places on its commercial container at the time of packaging.

(b) “Generic name” means the official or established name given a drug by the U.S. department of health and human services or the U.S. adopted names council.

(2) The manufacturer’s or distributor’s commercial container of every prescription drug or prescription drug product delivered to any pharmacist, practitioner, hospital or nursing home shall bear a label containing the generic name of the drug, if any, the brand name of the drug or drug product, if any, the name and

address of the manufacturer of the drug or drug product and, if different from the manufacturer, the name and address of the distributor of the drug or drug product.

(3) Every prescription order or medication profile record shall include the brand name, if any, or the name of the manufacturer or distributor of the drug product dispensed.

History: 1985 a. 146.

450.125 Drugs for animal use. In addition to complying with the other requirements in this chapter for distributing and dispensing, a pharmacist who distributes or dispenses a drug for animal use shall comply with s. 453.068.

History: 1991 a. 306.

450.13 Using drug product equivalent in dispensing prescriptions. (1) DRUG PRODUCT OR EQUIVALENT TO BE USED.

Except as provided in sub. (2), a pharmacist shall dispense every prescription using either the drug product prescribed or its drug product equivalent, if its drug product equivalent is lower in price to the consumer than the drug product prescribed, and shall inform the consumer of the options available in dispensing the prescription. In this section, “drug product equivalent” means a drug product that is designated the therapeutic equivalent of another drug product by the federal food and drug administration.

(2) EXCEPTION. A prescriber may indicate, by writing on the face of the prescription order or, with respect to a prescription order transmitted electronically, by designating in electronic format the phrase “No substitutions” or words of similar meaning or the initials “N.S.”, that no substitution of the drug product prescribed may be made under sub. (1). If such indication is made, the pharmacist shall dispense the prescription with the specific drug product prescribed. No preprinted statement regarding drug product substitution may appear on the face of the prescription order.

(3) RENEWED PRESCRIPTIONS. Prescriptions dispensed with a drug product equivalent may be renewed with a different drug product equivalent only if the pharmacist informs the consumer of the change.

(4) LIMITATION ON LIABILITY. A pharmacist who dispenses a prescription with a drug product equivalent under this section assumes no greater liability than would be incurred had the pharmacist dispensed the prescription with the drug product prescribed.

(5) USE OF DRUG PRODUCT EQUIVALENT IN HOSPITALS. Subsections (1) to (4) do not apply to a pharmacist who dispenses a drug product equivalent that is prescribed for a patient in a hospital if the pharmacist dispenses the drug product equivalent in accordance with written guidelines or procedures previously established by a pharmacy and therapeutics committee of the hospital and approved by the hospital’s medical staff and use of the drug product equivalent has been approved for a patient during the period of the patient’s stay within the hospital by any of the following:

(a) The patient’s individual physician.

(b) The patient’s advanced practice nurse prescriber, if the advanced practice nurse prescriber has entered into a written agreement to collaborate with a physician.

History: 1985 a. 146; 1991 a. 114; 1997 a. 27; 2005 a. 187.

450.14 Poisons. (1) In this section, “highly toxic” has the meaning specified under 15 USC 1261 (h).

(2) No person may deliver any highly toxic substance unless the delivery is made on the prescription order of a practitioner or complies with pars. (a) to (d):

(a) The container shall be plainly labeled with the name of the substance, the name and address of the person delivering the substance and, except as provided in sub. (3), the word “Poison”.

(b) The person delivering the substance shall ascertain that the recipient is aware of the poisonous character of the substance and desires it for a lawful purpose.

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(c) Before delivery, the person delivering the substance shall record in a book kept for that purpose the name of the article or substance, the quantity, the purpose, the date, the name and address of the person for whom procured and the signature of the individual personally delivering the article or substance. The record shall be signed by the person to whom the substance is delivered. Each book containing records required under this paragraph shall be preserved by the owner of the book for at least 3 years after the date of the last entry and shall be open to inspection by authorized officers.

(d) If the recipient is under 18 years of age, he or she must have the written order of an adult.

(3) A “Poison” label under sub. (2) (a) is not required for liniments, ointments or other external preparations which are plainly labeled “for external use only”.

(4) This section does not apply to manufacturers or distributors selling at wholesale nor to pesticides which comply with ss. 94.67 to 94.71.

(5) Any person who violates this section is guilty of a Class H felony.

History: 1985 a. 146; 1997 a. 283; 2001 a. 109.

450.145 Reporting potential causes of public health emergency. (1) Within 24 hours after an occurrence of any of the following, a pharmacist or pharmacy shall report the occurrence electronically, by fax machine, by telephone, or in writing to a local health department, as defined in s. 250.01 (4), or the department of health and family services:

(a) An unusual increase in the number of prescriptions dispensed or nonprescription drug products sold by the pharmacist or pharmacy for the treatment of medical conditions specified by the department of health and family services by rule under s. 252.02 (7).

(b) An unusual increase in the number of prescriptions dispensed by the pharmacist or pharmacy that are antibiotic drugs.

(c) The dispensing of a prescription by the pharmacist or pharmacy for treatment of a disease that is relatively uncommon or may be associated with bioterrorism, as defined in s. 166.02 (1r).

(1m) Except as provided in s. 450.145 (2) [sub. (2)], a pharmacist or pharmacy may not report personally identifying information concerning an individual who is dispensed a prescription or who purchases a nonprescription drug product as specified in sub. (1) (a), (b), or (c).

NOTE: Sub. (1m) is shown as renumbered by the revisor under s. 13.93 (1) (b), from s. 440.142 (2) as affected by 2005 Wis. Act 198 s. 20. The correct cross-reference is shown in brackets. Corrective legislation is pending.

(2) In submitting a report under sub. (1), a pharmacist or pharmacy shall include personally identifying information other than a social security number concerning an individual who is dispensed a prescription or who purchases a nonprescription drug product as specified in sub. (1) (a), (b), or (c).

History: 2005 a. 198 ss. 18 to 21; s. 13.93 (1) (b).

450.15 Placing prescription drugs prohibited.

(1) Except as otherwise provided by law, no person may put, or cause to be put, any prescription drug in any public place, or upon any private premises without the consent of the owner or occupant.

(2) Any person who violates this section is guilty of a Class H felony.

History: 1985 a. 146; 1997 a. 283; 2001 a. 109.

As applied to the defendant, s. 450.09 [now 450.15] was not unconstitutionally overbroad or vague. *Butala v. State*, 71 Wis. 2d 569, 239 N.W.2d 32 (1976).

450.155 Exhibition, display or advertisement of certain vending machines by use of certain material prohibited. (1) **DEFINITIONS.** In this section:

(a) “Contraceptive article” means any drug, medicine, mixture, preparation, instrument, article or device of any nature used or intended or represented to be used to prevent a pregnancy.

(b) “Material” means any visual representation, image, printed matter however reproduced or sound recording.

(c) “Harmful to minors” means that quality of any description or representation, in whatever form, of nudity, sexual conduct, sexual excitement, or sadomasochistic abuse, when it does all of the following:

1. Predominantly appeals to the prurient, shameful or morbid interest of minors.

2. Is patently offensive to prevailing standards in the adult community as a whole with respect to what is suitable material for minors.

3. Lacks serious literary, artistic, political or scientific value, if taken as a whole, for minors.

(d) “Knowledge of the minor’s age” means knowledge or information that the person is a minor.

(e) “Knowledge of the nature of the material” means any of the following:

1. Knowledge of the character and content of any material described herein.

2. Knowledge or information that the material described herein has been adjudged to be harmful to minors in a proceeding instituted under sub. (2), or is the subject of a pending proceeding instituted under sub. (2).

(f) “Minor” means any person under the age of 18 years.

(g) “Nudity” means the showing of the human male or female genitals, pubic area or buttocks with less than a full opaque covering, or the showing of the female breast with less than a fully opaque covering of any portion thereof below the top of the nipple, or the depiction of covered male genitals in a discernibly turgid state.

(h) “Person” means any individual, partnership, firm, association, corporation or other legal entity.

(i) “Sadomasochistic abuse” means the infliction of force, pain or violence upon a person for the purpose of sexual arousal or gratification.

(j) “Sexual conduct” means acts of masturbation, homosexuality, sexual intercourse or physical contact with a person’s clothed or unclothed genitals, pubic area, buttocks or, if such person is a female, breast.

(k) “Sexual excitement” means the condition of human male or female genitals when in a state of sexual stimulation or arousal.

(L) “Vending machine” means any mechanical device which automatically dispenses contraceptive articles upon the deposit in it of specified coins in payment for the contraceptive articles.

(2) **EXHIBITION, DISPLAY OR ADVERTISEMENT OF CERTAIN VENDING MACHINES BY USE OF MATERIAL HARMFUL TO MINORS.** (a) No person with knowledge of the nature of the material and with knowledge of a minor’s age, may, for commercial purposes, exhibit, display or advertise by use of any material which is harmful to minors a vending machine that dispenses contraceptive articles.

(b) Whoever violates par. (a) may be fined not more than \$10,000 or imprisoned for not more than 9 months or both.

History: 1985 a. 146.

450.16 Sale of contraceptives prohibited in certain areas. (1) As used in this section:

(a) “Contraceptive article” has the meaning under s. 450.155 (1) (a).

(b) “Vending machine” has the meaning under s. 450.155 (1) (L).

(2) No person may have in the person’s possession or under the person’s control, any vending machine that is located in a public school, as specified under s. 115.01 (1).

(3) Any person violating this section may be fined not more than \$10,000 or imprisoned for not more than 9 months or both.

History: 1985 a. 146.

450.17 Violations. Each member of the board shall investigate and institute actions for violations of this chapter by any person and for violation of ch. 961 by pharmacists. The district attorney of the proper county shall promptly prosecute any such violation upon notice from any source.

History: 1985 a. 146; 1995 a. 448.

450.18 Penalties. Except as otherwise provided in this chapter, any person who violates this chapter or any rule promulgated under the authority of this chapter may be fined not less than \$50 nor more than \$100 or imprisoned not less than 30 days nor more than 90 days or both.

History: 1985 a. 146.