CHAPTER 450

PHARMACY EXAMINING BOARD

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) A practitioner or his or her authorized agent.

(b) A patient or research subject at the direction of a practitioner.

(c) A pharmacist.

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

(1p) "Affiliated group" has the meaning given in section 1504 of the Internal Revenue Code.

(1t) "Authenticate" means to affirmatively verify, before wholesale distribution of a prescription drug occurs, that each transaction listed on a pedigree has occurred.

(1x) "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. For purposes of this subsection, an ongoing relationship exists between a wholesale distributor and a manufacturer if all of the following apply:

(a) The wholesale distributor, including any affiliated group of the wholesale distributor, has in effect a written agreement with the manufacturer evidencing the ongoing relationship.

(b) The wholesale distributor, including any affiliated group of the wholesale distributor, is included in the manufacturer's current list of authorized distributors of record.

(2) "Board" means the pharmacy examining board.

(2m) "Colicensed" means, with respect to a partner or product, that 2 or more parties have the right to engage in marketing or manufacturing of a product consistent with the federal food and drug administration's implementation of the federal prescription drug marketing act.

(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).

NOTE: Section 450.07 (2) was repealed by 2007 Wis. Act 20.

(9m) "Drop shipment" means a sale of a prescription drug to a wholesale distributor by the manufacturer of the drug, by the manufacturer's colicensed product partner, by the manufacturer's 3rd party logistics provider, or by the manufacturer's exclusive distributor, to which all of the following apply:

(a) The wholesale distributor or chain pharmacy warehouse takes title to, but not physical possession of, the drug.

(b) The wholesale distributor invoices a pharmacy, a chain pharmacy warehouse, or a person authorized to dispense or administer the drug to a patient.

(c) The pharmacy, chain pharmacy warehouse, or person authorized to dispense or administer the drug receives delivery of the drug directly from the manufacturer, the manufacturer's 3rd party logistics provider, or the manufacturer's exclusive distributor.

(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.

(11m) "Facility" means a location where a wholesale distributor stores, handles, repackages, or offers for sale prescription drugs.

(11r) "Intracompany sales" means any transaction or transfer between any division, subsidiary, parent, or affiliated or related company under common ownership and control of a corporate entity or any transaction or transfer between colicensees of a colicensed product.

(12) "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 guidances implementing the federal prescription drug marketing act.

(12m) "Manufacturer's exclusive distributor" means a person that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer and who takes title to the manufacturer's prescription drug but who does not have general responsibility to direct the sale or disposition of the drug.

(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.

(13r) (a) "Normal distribution channel" means a chain of custody for a prescription drug that runs, directly or by drop shipment, from the manufacturer of a drug, from the manufacturer to the manufacturer's colicensed partner, from the manufacturer to the manufacturer's 3rd−party logistics provider, or from the manufacturer to the manufacturer's exclusive distributor, and continues as described in any of the following:

1. To a pharmacy or to a person authorized to dispense or administer a drug to a patient.

2. To an authorized distributor of record, and then to a pharmacy or to a person authorized to dispense or administer a drug to a patient.

3. To an authorized distributor of record, then to one other authorized distributor of record, then to an office−based practitioner.

4. To a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy, then to a patient or to a person authorized to dispense or administer a drug to a patient.

5. To an authorized distributor of record, then to a pharmacy warehouse, then to the pharmacy warehouse's intracompany pharmacy, then to a patient or to a person authorized to dispense or administer a drug to a patient.

(b) For purposes of this subsection, a distribution of a prescription drug to a warehouse or to another entity that redistributes the drug by intracompany sale to a pharmacy or to another person authorized to dispense or administer the drug constitutes a distribution to the pharmacy or to the person authorized to dispense or administer the drug.

(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.

(14m) "Pedigree" means a document or electronic file containing information that records each distribution of a prescription drug.

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

(15m) "Pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales.

(15r) "Physician assistant" has the meaning given in s. 448.01 (6).

(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.

(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.

3. The patient's physician assistant.

(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 all of the following, but does not include blood, blood components intended for transfusion, or biological products that are also medical devices:

(a) A drug, drug product, or drug−containing preparation that is subject to 21 USC 353 (b) or 21 CFR 201.105.

(b) A controlled substance included in schedules II to V of ch. 961, whether by statute or rule, except a substance that by law may be dispensed without the prescription order of a practitioner. Con-

trolled 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.

(21e) "Repackage" means to repack or otherwise change the container, wrapper, or label of a prescription drug, except that "repackage" does not include any of the following:

(a) An action by a pharmacist with respect to a prescription drug that the pharmacist is dispensing.

(b) An action by a pharmacist who receives a prescription drug or device that the pharmacist dispensed to a patient, if, after altering the packaging or labeling of the prescription drug or device, the pharmacist returns the prescription drug or device to the patient.

(21m) "Repackager" means a person that repackages.

(21s) "Third party logistics provider" means a person that contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer but that does not take title to the manufacturer's prescription drug or have general responsibility to direct the prescription drug's sale or disposition.

(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.

(23) "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.

(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 USC 353 (d).

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

(e) The sale of minimal quantities, as defined by the board in an administrative rule, of prescription drugs by retail pharmacies to licensed practitioners for office use.

(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 or under 21 CFR 203.39.

(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.

(24) "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: 1985 a. 146; 1987 a. 65; 1991 a. 114; 1995 a. 448; 1997 a. 27, 68; 1997 a. 237 s. 727m; 2005 a. 187; 2007 a. 20; 2009 a. 142; 2011 a. 161, 260.

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 paragraph 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. 257.03.

(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; 2009 a. 42.

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 pharmacist may not administer a vaccine under this subsection to a person who is under the age of 6.

(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; 2011 a. 32.

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 ss. Phar 2.02, 2.03, and 17.04, 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 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) Except as provided in s. 450.062, 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 initial credential fee determined by the department under s. 440.03 (9) (a) 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; 2007 a. 20, 202.

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

450.062 Remote dispensing. Pursuant to rules promulgated by the board, a pharmacist may dispense at the following locations:

(1) A health care facility under s. 150.84 (2) or a facility identified under s. 980.065.

(2) The office or clinic of a practitioner.

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

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

History: 2007 a. 202.

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 initial credential fee determined by the department under s. 440.03 (9) (a).

(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; 2007 a. 20.

450.07 Manufacturers; 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 initial credential fee determined by the department under s. 440.03 (9) (a).

(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.

(c) The rules adopted by the board under par. (b) shall require a manufacturer to maintain and to update at least once per month a list of the manufacturer's authorized distributors of record.

History: 1985 a. 146; 1991 a. 39; 2005 a. 14; 2007 a. 20.

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

450.071 Wholesale distributors; licensure. (1) No person may engage in the wholesale distribution of a prescription drug in this state without obtaining a license from the board for each facility from which the person distributes prescription drugs. The board shall exempt a manufacturer that distributes prescription drugs or devices manufactured by the manufacturer from licensing and other requirements under this section to the extent the license or requirement is not required under federal law or regulation, unless the board determines that it is necessary to apply a requirement to a manufacturer.

(2) An applicant shall submit a form provided by the board showing all of the following and swear or affirm the truthfulness of each item in the application:

(a) The name, business address, and telephone number of the applicant.

(b) All trade or business names used by the applicant.

(c) Names, addresses, and telephone numbers of contact persons for all facilities used by the applicant for the storage, handling, and distribution of prescription drugs.

(d) The type of ownership or operation for the applicant's business.

(e) If the applicant's wholesale distribution business is a partnership, the name of each partner and the name of the partnership.

(f) If the applicant's wholesale distribution business is a corporation, the name of each corporate officer and director, the name of the corporation, and the state of incorporation.

(g) If the applicant's wholesale distribution business is a sole proprietorship, the name of the sole proprietor and the name of the business entity.

(h) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs.

(i) The name, address, and telephone number of a designated representative.

(j) For the person listed in par. (i), a personal information statement that contains all of the following:

1. The person's date and place of birth.

2. The person's places of residence for the 7−year period immediately preceding the date of the application.

3. The person's occupations, positions of employment, and offices held during the 7−year period immediately preceding the date of the application.

4. The name and addresses for each business, corporation, or other entity listed in subd. 3.

5. A statement indicating whether the person has been, during the 7−year period immediately preceding the date of the application, the subject of any proceeding for the revocation of any business or professional license and the disposition of the proceeding.

6. A statement indicating whether the person has been, during the 7−year period immediately preceding the date of the application, enjoined by a court, either temporarily or permanently, from possessing, controlling, or distributing any prescription drug, and a description of the circumstances surrounding the injunction.

7. A description of any involvement by the person during the past 7 years with any business, including investments other than the ownership of stock in a publicly traded company or mutual fund, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products or drugs, and a list of any lawsuits in which such a business was named as a party.

8. A description of any misdemeanor or felony criminal offense of which the person was, as an adult, found guilty, whether adjudication of guilt was withheld or the person pleaded guilty or no contest. If the person is appealing a criminal conviction, the application shall include a copy of the notice of appeal, and the applicant shall submit a copy of the final disposition of the appeal not more than 15 days after a final disposition is reached.

9. A photograph of the person taken within the 12−month period immediately preceding the date of the application.

(k) A statement that each facility used by the applicant for the wholesale distribution of prescription drugs has been inspected 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 such inspection.

(3) The board shall grant a license to the applicant to engage in the wholesale distribution of prescription drugs if all of the following apply:

(a) The applicant pays the fee under s. 440.05 (1) (a).

(b) The inspections conducted pursuant to sub. (2) (k) satisfy requirements adopted by the board for wholesale distribution facilities.

(c) All of the following apply to each person identified by the applicant as a designated representative:

1. The person is at least 21 years old.

2. The person has been employed full time for at least 3 years in a pharmacy or with a wholesale prescription drug distributor in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs.

3. The person is employed by the applicant full time in a managerial level position.

4. The person is physically present at the wholesale prescription drug distributor's facility during regular business hours and is involved in and aware of the daily operation of the wholesale prescription drug distributor. This subdivision does not preclude the designated representative from taking authorized sick leave and vacation time or from being absent from the facility for other authorized business or personal purposes.

5. The person is actively involved in and aware of the daily operations of the wholesale distributor.

6. The person is a designated representative for only one applicant at any given time. This subdivision does not apply if more than one wholesale distributor is located at the facility and

the wholesale distributors located at the facility are members of an affiliated group.

7. The person has not been convicted of violating any federal, state, or local law relating to wholesale or retail prescription drug distribution or distribution of a controlled substance.

8. The person has not been convicted of a felony.

9. The person submits to the department 2 fingerprint cards, each bearing a complete set of the applicant's fingerprints. The department of justice shall provide for the submission of the fingerprint cards to the federal bureau of investigation for the purposes of verifying the identity of the applicant and obtaining the applicant's criminal arrest and conviction record. This subdivision does not apply to a person accredited by the national association of boards of pharmacy's verified−accredited wholesale distributor program.

(3m) Notwithstanding subs. (2) and (3), the board may grant a license to engage in the wholesale distribution of prescription drugs to a person who is domiciled in another state and is licensed to engage in the wholesale distribution of prescription drugs in another state, if the board determines that the standards for licensure in the state in which the person is licensed are at least as stringent as the standards for licensure under this section.

(4) The board may set, by rule, continuing education requirements for designated representatives under this section.

(5) (a) The board shall require every wholesale distributor to submit a surety bond acceptable to the board in an amount not to exceed $100,000 or other equivalent means of security acceptable to the board, except that the board shall not require submission of a bond or other security under this subsection by a chain pharmacy warehouse that is engaged only in intracompany transfers. A wholesale distributor that operates more than one facility is not required to submit a bond or other security under this paragraph for each facility.

(b) The bond or other security under this subsection shall be used to secure payment of fees or costs that relate to the issuance of a license under this section and that have not been paid within 30 days after the fees or costs have become final. No claim may be made against a wholesale distributor's bond or other security under this subsection more than one year after the date on which the wholesale distributor's license expires.

(**6)** Applications for licensure under this section are not subject to inspection or copying under s. 19.35, and may not be disclosed to any person except as necessary for compliance with and enforcement of the provisions of this chapter.

History: 2007 a. 20; 2009 a. 180.

450.072 Wholesale distributors; restrictions on transactions. (1) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy, a person authorized to administer or dispense drugs, or a pharmacy's intracompany warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. A wholesale distributor that receives returns of expired, damaged, recalled, or otherwise nonsaleable prescription drugs may distribute the prescription drugs only to the original manufacturer of the products or to a 3rd party returns processor. Notwithstanding s. 450.073, returns or exchanges of saleable or nonsaleable prescription drugs, including any redistribution by a receiving wholesaler, are not subject to pedigree requirements under s. 450.073 if the returns or exchanges are exempt from the pedigree requirement under the federal food and drug administration's current guidance on the federal prescription drug marketing act. A person licensed under s. 450.071 or a pharmacy or other person authorized to administer or dispense drugs shall ensure that the person or pharmacy's return process is secure and does not permit the entry of adulterated and counterfeit products.

(2) (a) A manufacturer or wholesale distributor may not deliver prescription drugs to a person unless the person is licensed under s. 450.071 or 450.06 or by the appropriate licensing authority of another state or unless the person is a faculty member of an institution of higher education, as defined in s. 36.32 (1), and is obtaining the prescription drugs for the purpose of lawful research, teaching, or testing and not for resale. A manufacturer or wholesale distributor may not deliver prescription drugs to a person that is not known to the manufacturer or wholesale distributor unless the manufacturer or wholesale distributor has verified with the board or with the licensing authority of the state in which the person is located that the person is licensed to receive prescription drugs or unless the person is a faculty member of an institution of higher education, as defined in s. 36.32 (1), and is obtaining the prescription drugs for the purpose of lawful research, teaching, or testing and not for resale.

(b) A manufacturer or wholesale distributor may distribute a prescription drug only to the premises listed on the person's license or authorization, except that a manufacturer or wholesale distributor may distribute the prescription drugs to an authorized agent of the person at the premises of the manufacturer or wholesale distributor if all of the following are true:

1. The manufacturer or wholesale distributor documents the authorized agent's name and address.

2. Distribution to an authorized agent is necessary to promote or protect the immediate health or safety of the authorized agent's patient.

(c) A manufacturer or wholesale distributor may distribute a prescription drug to a hospital pharmacy receiving area if a licensed pharmacist or another authorized recipient signs, at the time of the distribution, a receipt that shows the type and quantity of prescription drugs distributed. If there is a discrepancy between the type and quantity of prescription drugs indicated on the receipt and the type and quantity of prescription drugs received at the hospital pharmacy receiving area, the discrepancy shall be reported to the manufacturer or wholesale distributor that distributed the prescription drugs no later than the day immediately following the date on which the prescription drugs were distributed to the hospital pharmacy receiving area.

(d) No manufacturer or wholesale distributor may accept payment for, or allow the use of, a person's credit to establish an account for the purchase of a prescription drug from any person other than the owner of record, the chief executive officer, or the chief financial officer identified on the license or authorization of a person who may receive prescription drugs. Any account established for the purchase of prescription drugs shall bear the name of the licensed or authorized person.

History: 2007 a. 20; 2011 a. 100.

450.073 Wholesale distributors; pedigree. (1) A wholesale distributor shall establish and maintain a pedigree for each prescription drug that leaves, or has ever left, the normal distribution channel. Before a wholesale distribution of a prescription drug leaves the normal distribution channel, a wholesale distributor shall provide a copy of the pedigree to the person receiving the drug. This section does not apply to a retail pharmacy or pharmacy intracompany warehouse unless the pharmacy or pharmacy intracompany warehouse engages in the wholesale distribution of prescription drugs.

(2) A pedigree shall contain all necessary identifying information concerning each sale in the chain of the distribution of the prescription drug from the manufacturer of the prescription drug or the manufacturers 3rd−party logistics provider, colicensed product partner, or exclusive distributor until final sale or distribution to a pharmacy or a person dispensing or distributing the prescription drug. The pedigree shall include all of the following:

(a) The name, address, telephone number, and, if available, electronic mail address of each recipient or distributor of the prescription drug in the chain of distribution, until the final sale or distribution described in sub. (2) (intro.).

(b) The name and address of each facility from which the prescription drug was distributed, if different from the address provided in par. (a).

(c) The date of each distribution.

(d) A certification that every recipient has authenticated the pedigree before distribution of the prescription drug to the next point in the chain of distribution.

(e) The name, dosage strength, size and number of containers, lot number, and name of the manufacturer for each prescription drug.

(3) The board shall promulgate rules implementing an electronic track and trace pedigree system. Not later than July 1, 2010, the board shall determine the date on which the system will be implemented. The system may not be implemented before July 1, 2011, and the board may delay the implementation date in increments if the board determines that the technology to implement the system is not yet universally available across the prescription drug supply chain or is not capable of adequately protecting patient safety.

(4) A person who is engaged in the wholesale distribution of a prescription drug, including a repackager but not including the original manufacturer of the prescription drug, who possesses a pedigree for the prescription drug, and who intends to further distribute the prescription drug, shall verify that each transaction recorded on the pedigree has occurred before the person may distribute the prescription drug.

(5) (a) A pedigree shall be maintained by a person who purchases prescription drugs identified in the pedigree and by a wholesale distributor who distributes prescription drugs identified in the pedigree for not less than 3 years from the date of sale or distribution.

(b) A person maintaining a pedigree under par. (a) shall make the pedigree available for inspection or use by a law enforcement officer within 7 days after the law enforcement officer's request.

History: 2007 a. 20.

450.074 Wholesale distributors; prohibited actions, enforcement, penalties. (1) If the board finds that there is a reasonable probability that a wholesale distributor, other than a manufacturer, has done any of the following, that continued distribution of a prescription drug involved in the occurrence could cause death or serious adverse health consequences, and that additional procedures would result in an unreasonable delay, the board shall issue an order requiring that distribution of a prescription drug in this state cease immediately:

(a) Violated a provision of ss. 450.071 to 450.073.

(b) Falsified a pedigree or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use.

(2) If the board issues an order under sub. (1), the board shall provide the person who is the subject of the order an opportunity for an informal hearing not more than 10 days after the date on which the order is issued. If, after a hearing, the board determines that the order was issued without sufficient grounds, the board shall vacate the order.

(3) Any person who knowingly does any of the following is guilty of a Class H felony:

(a) Fails to obtain a license required under s. 450.071.

(b) Purchases or otherwise receives a prescription drug from a pharmacy in violation of s. 450.072 (1).

(c) Violates s. 450.072 (2) (a), if the person is required to obtain a license under s. 450.071.

(d) Violates s. 450.072 (2) (b).

(e) Violates s. 450.072 (2) (d).

(f) Violates s. 450.073.

(g) Provides false or fraudulent records to, or makes a false or fraudulent statement to, the board, a representative of the board, or a federal official.

(h) Obtains or attempts to obtain a prescription drug by fraud, deceit, or misrepresentation, or engages in misrepresentation or fraud in the distribution of a prescription drug.

(i) Manufactures, repackages, sells, transfers, delivers, holds, or offers for sale a prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or otherwise unfit for distribution, except for wholesale distribution by a manufacturer of a prescription drug that has been delivered into commerce pursuant to an application approved by the federal food and drug administration.

(j) Adulterates, misbrands, or counterfeits a prescription drug, except for wholesale distribution by a manufacturer of a prescription drug that has been delivered into commerce pursuant to an application approved by the federal food and drug administration.

(k) Receives a prescription drug that has been adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeited, or suspected of being counterfeited, and delivers or proffers such a drug.

(L) Alters, mutilates, destroys, obliterates, or removes any part of the labeling of a prescription drug or commits another act that results in the misbranding of a prescription drug.

(4) Subsection (3) does not apply to a prescription drug manufacturer or an agent of a prescription drug manufacturer, if the manufacturer or agent is obtaining or attempting to obtain a prescription drug for the sole purpose of testing the authenticity of the prescription drug.

History: 2007 a. 20.

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 determined by the department under s. 440.03 (9) (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 determined by the department under s. 440.03 (9) (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; 2007 a. 20.

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.

450.095 Duty to dispense contraceptives. (1) In this section:

(a) "Contraceptive drug or device" means any drug or device approved by the federal food and drug administration that is used to prevent pregnancy, including a contraceptive drug or device restricted to distribution by a pharmacy.

(b) "Without delay" means within the usual and customary time frame reasonably expected at a pharmacy for dispensing or distributing a prescription that is not a contraceptive drug or device.

(2) Unless one or more of the following applies, a pharmacy shall dispense lawfully prescribed contraceptive drugs and devices and shall deliver contraceptive drugs and devices restricted to distribution by a pharmacy to a patient without delay:

(a) The prescription contains an obvious or known error or contains inadequate instructions.

(b) The prescription is contraindicated for the patient, is incompatible with another drug or device prescribed for the patient, or is prohibited by state or federal law.

(c) The prescription is potentially fraudulent.

(3) Any person who violates this section may be required to forfeit not less than $250 nor more than $2,500 for each violation.

(4) Nothing in this section may be construed to abrogate a pharmacist's legal and ethical obligations to comply with the laws of this state.

History: 2009 a. 28, 276.

450.10 Disciplinary proceedings; immunity; orders. (1) (a) In this subsection, "unprofessional conduct" includes any of the following, but does not include the dispensing of an antimicrobial drug for expedited partner therapy as described in s. 450.11 (1g):

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.

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; 2009 a. 280.

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

Administrative rules describing unprofessional conduct are applied. Noesen v. Department of Regulation and Licensing, 2008 WI App 52, 311 Wis. 2d 237, 751 N.W.2d 385, 06−1110.

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 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. Except as provided in s. 448.035 (2), all prescription orders shall also specify the name and address of the patient. Any oral prescription order shall be immediately reduced to writing by the pharmacist and filed according to sub. (2).

(1g) DISPENSING CERTAIN ANTIMICROBIAL DRUGS FOR EXPEDITED PARTNER THERAPY. (a) In this subsection:

1. "Antimicrobial drug" has the meaning given in s. 448.035 (1) (b).

2. "Expedited partner therapy" has the meaning given in s. 448.035 (1) (c).

(b) A pharmacist may, upon the prescription order of a practitioner providing expedited partner therapy, as specified in s. 448.035, that complies with the requirements of sub. (1), dispense an antimicrobial drug as a course of therapy for treatment of chlamydial infections, gonorrhea, or trichomoniasis to the practitioner's patient or a person with whom the patient has had sexual contact for use by the person with whom the patient has had sexual contact. The pharmacist shall provide a consultation in accordance with rules promulgated by the board for the dispensing of a prescription to the person to whom the antimicrobial drug is dispensed. A pharmacist providing a consultation under this paragraph shall ask whether the person for whom the antimicrobial drug has been prescribed is allergic to the antimicrobial drug and advise that the person for whom the antimicrobial drug has been prescribed must discontinue use of the antimicrobial drug if the person is allergic to or develops signs of an allergic reaction to the antimicrobial drug.

(c) 1. Except as provided in subd. 2., a pharmacist is immune from civil liability for injury to or the death of a person who takes an antimicrobial drug dispensed for that person under this subsection in connection with expedited partner therapy if the antimicrobial drug is dispensed as provided under par. (b).

2. The immunity under subd. 1. does not extend to the distribution or dispensing of an antimicrobial drug by a pharmacist whose act or omission involves reckless, wanton, or intentional misconduct.

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

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

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

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

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

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

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

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

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

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

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

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

disclosed on the label, the practitioner shall specify the symptom or purpose in the prescription order.

(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, physician assistant, 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 and physician assistants.

(bm) The podiatry 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. 187, 195, 196, 242; 2007 a. 97; 2009 a. 113, 280; 2011 a. 159, 161.

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.

(c) The patient's physician assistant.

History: 1985 a. 146; 1991 a. 114; 1997 a. 27; 2005 a. 187; 2011 a. 161.

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.

(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 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 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. 323.02 (4).

(1m) Except as provided in 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).

(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; 2007 a. 20 s. 9121 (6) (a); 2007 a. 97 s. 183; 2009 a. 42.

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.

450.19 Prescription drug monitoring program. (1) In this section, "prescription drug" means a substance identified in s. 961.16 or 961.18 or a drug identified by the board by rule as having a substantial potential for abuse.

(2) The board shall establish by rule a program for monitoring the dispensing of prescription drugs. The program shall do all of the following:

(a) Require a pharmacist or practitioner to generate a record documenting each dispensing of a prescription drug and to deliver the record to the board, except that the program may not require the generation of a record when a drug is administered directly to a patient.

(b) Identify specific data elements to be contained in a record documenting the dispensing of a prescription drug. In identifying specific data elements, the board shall consider data elements identified by similar programs in other states and shall ensure, to the extent possible, that records generated by the program are easily shared with other states.

(c) Specify the persons to whom a record may be disclosed and the circumstances under which the disclosure may occur. The rule promulgated under this paragraph shall permit the board to share a record generated by the program with relevant agencies of other states.

(d) Specify a secure electronic format for delivery of a record generated under the program and authorize the board to grant a pharmacist or practitioner a waiver of the specified format.

(e) Specify a deadline for the delivery of a record to the board.

(f) Specify a penalty for failure to comply with rules promulgated under this subsection.

(g) Maximize the potential for funding the operation of the program with available federal funding sources.

(h) Ensure that the program complies with s. 146.82 and 45 CFR part 164, subpart E.

(3) (a) A pharmacist or practitioner is immune from civil or criminal liability or professional discipline arising from the pharmacist's or practitioner's compliance in good faith with this section or with rules promulgated under this section.

(b) Nothing in this section may be construed to require a pharmacist or practitioner to obtain, before prescribing or dispensing a prescription to a patient, information about the patient that has been collected pursuant to the program described under sub. (2).

(4) Records generated under the program under this section are not subject to inspection or copying under s. 19.35.

(5) The department shall submit a timely application for a federal grant under 42 USC 280g−3 and under the Harold Rogers Prescription Drug Monitoring Program to fund the establishment and operation of the program under this section. If the department fails to obtain federal funding before January 1, 2015, this section is void.

History: 2009 a. 362; 2011 a. 260 s. 81.