Michigan Compiled Laws Annotated Currentness

Chapter 338. Professions and Occupations (Refs & Annos)

Pharmacies, Drug Stores, and Apothecary Shops (Refs & Annos)

338.481. Ownership of pharmacies and drug stores; requirements, exceptions

Sec. 1. (1) A pharmacy, drugstore, or apothecary shop shall be owned by a pharmacist and a partnership or corporation shall not own a drugstore, pharmacy, or apothecary shop unless at least 25% of the interest in the partnership or the stock of the corporation is held by pharmacists. A corporation, organized and existing under the laws of this state, or another state, authorized to do business in this state and empowered by its charter to own and conduct a pharmacy, drugstore, or apothecary shop and which, at the time of the passage of this act, owns and conducts a drugstore, pharmacy, or apothecary shop in this state may continue to own and conduct the drugstore, pharmacy, or apothecary shop and may establish and own additional pharmacies, drugstores, or apothecary shops pursuant to this act.

(2) A corporation which does not continue to own at least 1 pharmacy, drugstore, or apothecary shop theretofore owned by it, or ceases to be actively engaged in the practice of pharmacy in this state, shall not be permitted thereafter to own a drugstore, pharmacy, or apothecary shop.

(3) A person who is not a pharmacist and who at the time of the passage of this act owns a pharmacy, drugstore, or apothecary shop in this state, may continue to own and conduct the pharmacy, drugstore, or apothecary shop pursuant to existing laws and rules.

(4) The administrator, executor, or trustee of the estate of a deceased owner of a pharmacy, drugstore, or apothecary shop, or the widow, heirs, or next of kin of the deceased owner, may continue to own and conduct the pharmacy, drugstore, or apothecary shop pursuant to existing laws and rules.

(5) This act shall not apply to hospitals licensed by the department of public health pursuant to Act No. 368 of the Public Acts of 1978, as amended, being sections 333.1101 to 333.25211 of the Michigan Compiled Laws.

(6) This act shall not apply to a health maintenance organization licensed by the department of public health pursuant to Act No. 368 of the Public Acts of 1978, as amended.

(7) This act shall not apply to a pharmacy in an institution of higher education established by law having authority to grant a baccalaureate degree if the pharmacy is under the personal charge of a pharmacist.

338.482. Violations; penalties

Sec. 2. Any individual, firm or corporation violating the provisions of this act shall be deemed guilty of a

misdemeanor and upon conviction shall be subject to a fine of not less than 500 dollars and cost of prosecution.

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Michigan Compiled Laws Annotated Currentness
Chapter 333. Health
Public Health Code (Refs & Annos)
Article 15. Occupations
Part 177. Pharmacy Practice and Drug Control (Refs & Annos)

333.17701. Meaning of words and phrases generally; general definitions and principles of construction

Sec. 17701. (1) For purposes of this part the words and phrases defined in sections 17702 to 17709 [FN1] have the meanings ascribed to them in those sections.

(2) In addition, article 1 [FN2] contains general definitions and principles of construction applicable to all articles in this code and part 161 [FN3] contains definitions applicable to this part.

[FN1] M.C.L.A. §§ 333.17702 to 333.17709.

[FN2] M.C.L.A. § 333.1101 et seq.

[FN3] M.C.L.A. § 333.16101 et seq.

333.17702. Definitions; terms commencing “a” to “c”

Sec. 17702. (1) “Agent” means an individual designated by a prescriber to act on behalf of or at the discretion of that prescriber as provided in section 17744. [FN1]

(2) “Brand name” means the registered trademark name given to a drug product by its manufacturer.

(3) “Current selling price” means the retail price for a prescription drug that is available for sale from a pharmacy.

[FN1] M.C.L.A. § 333.17744.

333.17703. Definitions; terms commencing “d” and “e”

Sec. 17703. (1) “Device” means an instrument, apparatus, or contrivance, including its components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals, or to affect the structure or function of the body of human beings or other animals.

(2) “Dispense” means to issue 1 or more doses of a drug for subsequent administration to, or use by, a patient.

(3) “Dispensing prescriber” means a prescriber, other than a veterinarian, who dispenses prescription drugs.

(4) “Drug” means any of the following:

(a) A substance recognized or for which the standards or specifications are prescribed in the official compendium.

(b) A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals.

(c) A substance, other than food, intended to affect the structure or a function of the body of human beings or other animals.

(d) A substance intended for use as a component of a substance specified in subdivision (a), (b), or (c), but not including a device or its components, parts, or accessories.

(5) “Electronic signature” means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

(6) “Electronically transmitted prescription” means the communication of an original prescription or refill authorization by electronic means including computer to computer, computer to facsimile machine, or electronic mail transmission that contains the same information it contained when the prescriber or his or her agent transmitted the prescription. Electronically transmitted prescription does not include a prescription or refill authorization transmitted by telephone or facsimile machine.

➡333.17704. Definitions; terms commencing “f” to “i”

Sec. 17704. (1) “Federal act” means the federal food, drug, and cosmetic act of 1938, 21 U.S.C. 301 to 392.

(2) “Generic name” means the established or official name of a drug or drug product.

(3) “Harmful drug” means a drug intended for use by human beings which is harmful because of its toxicity, habit-forming nature, or other potential adverse effect, the method of its use, or the collateral measures necessary to its safe and effective use, and which is designated as harmful by the board according to rule.

(4) “Internship” means an educational program of professional and practical experience for an intern.

➡333.17705. Definitions; terms commencing *“l”*

Sec. 17705. (1) “Label” means a display of written, printed, or graphic matter on the immediate container of a drug or device, but does not include package liners. A requirement made by or under authority of this part that a word, statement, or other information appear on the label is not complied with unless the word, statement, or other information appears on the outside container or wrapper of the retail package of the drug or device as displayed for sale or is easily legible through an outside container or wrapper.

(2) “Labeling” means the labels and other written, printed, or graphic matter on a drug or device or its container or wrapper, or accompanying the drug or device.

(3) “License” in addition to the definition in section 16106 [FN1] means a pharmacy license, drug control license, or a manufacturer or wholesale distributor of drugs or devices license.

[FN1] M.C.L.A. § 333.16106.

333.17706. Definitions; terms commencing “m” and “o”

Sec. 17706. (1) “Manufacturer” means a person who prepares, produces, derives, propagates, compounds, processes, packages, or repackages a drug or device salable on prescription only, or otherwise changes the container or the labeling of a drug or device salable on prescription only, and who supplies, distributes, sells, offers for sale, barters, or otherwise disposes of that drug or device and any other drug or device salable on prescription only, to another person for resale, compounding, or dispensing.

(2) “Official compendium” means the United States pharmacopoeia and national formulary, homeopathic pharmacopoeia of the United States, or a supplement thereof existing on July 1, 1983.

333.17707. Definitions; terms commencing “p”

Sec. 17707. (1) “Personal charge” means the immediate physical presence of a pharmacist or dispensing prescriber.

(2) “Pharmacist” means an individual licensed under this article to engage in the practice of pharmacy.

(3) “Pharmacist intern” or “intern” means an individual who satisfactorily completes the requirements set forth in rules promulgated by the board and is licensed by the board for the purpose of obtaining instruction in the practice of pharmacy from a preceptor approved by the board.

(4) “Pharmacy” means a building or part of a building in which the practice of pharmacy is conducted.

(5) “Practice of pharmacy” means a health service, the clinical application of which includes the encouragement of safety and efficacy in the prescribing, dispensing, administering, and use of drugs and

related articles for the prevention of illness, and the maintenance and management of health. Professional functions associated with the practice of pharmacy include:

(a) The interpretation and evaluation of the prescription.

(b) Drug product selection.

(c) The compounding, dispensing, safe storage, and distribution of drugs and devices.

(d) The maintenance of legally required records.

(e) Advising the prescriber and the patient as required as to contents, therapeutic action, utilization, and possible adverse reactions or interactions of drugs.

333.17708. Definitions; terms commencing “p”

Sec. 17708. (1) “Preceptor” means a pharmacist approved by the board to direct the training of an intern in an approved pharmacy.

(2) “Prescriber” means a licensed dentist, a licensed doctor of medicine, a licensed doctor of osteopathic medicine and surgery, a licensed doctor of podiatric medicine and surgery, a licensed optometrist certified under part 174 [FN1] to administer and prescribe therapeutic pharmaceutical agents, a licensed veterinarian, or another licensed health professional acting under the delegation and using, recording, or otherwise indicating the name of the delegating licensed doctor of medicine or licensed doctor of osteopathic medicine and surgery.

(3) “Prescription” means an order by a prescriber to fill, compound, or dispense a drug or device written and signed; written or created in an electronic format, signed, and transmitted by facsimile; or transmitted electronically or by other means of communication. An order transmitted in other than written or hard-copy form shall be electronically recorded, printed, or written and immediately dated by the pharmacist, and that record constitutes the original prescription. In a health facility or agency licensed under article 17 [FN2] or other medical institution, an order for a drug or device in the patient's chart constitutes for the purposes of this definition the original prescription. Subject to section 17751(2) and (5), [FN3] prescription includes, but is not limited to, an order for a drug, not including a controlled substance as defined in section 7104 [FN4] except under circumstances described in section 17763(e), [FN5] written and signed; written or created in an electronic format, signed, and transmitted by facsimile; or transmitted electronically or by other means of communication by a physician prescriber or dentist prescriber licensed to practice dentistry, medicine, or osteopathic medicine and surgery in a state other than Michigan.

(4) “Prescription drug” means 1 or more of the following:

(a) A drug dispensed pursuant to a prescription.

(b) A drug bearing the federal legend “CAUTION: federal law prohibits dispensing without prescription” or “Rx only”.

(c) A drug designated by the board as a drug that may only be dispensed pursuant to a prescription.

[FN1] M.C.L.A. § 333.17401 et seq.

[FN2] M.C.L.A. § 333.20101 et seq.

[FN3] M.C.L.A. § 333.17751.

[FN4] M.C.L.A. § 333.7104.

[FN5] M.C.L.A. § 333.17763.

333.17709. Definitions; terms commencing “s” to “w”

Sec. 17709. (1) “Sign” means to affix one's signature manually to a document or to use an electronic signature when transmitting a prescription electronically.

(2) “Substitute” means to dispense, without the prescriber's authorization, a different drug in place of the drug prescribed.

(3) “Wholesale distributor” means a person, other than a manufacturer, who supplies, distributes, sells, offers for sale, barters, or otherwise disposes of, to other persons for resale, compounding, or dispensing, a drug or device salable on prescription only that the distributor has not prepared, produced, derived, propagated, compounded, processed, packaged, or repackaged, or otherwise changed the container or the labeling thereof.

333.17711. Necessity of license or other authorization; use of certain words, titles, or letters

Sec. 17711. (1) A person shall not engage in the practice of pharmacy unless licensed or otherwise authorized by this article.

(2) The following words, titles, or letters or a combination thereof, with or without qualifying words or phrases, are restricted in use only to those persons authorized under this part to use the terms and in a way prescribed in this part: “pharmacy”, “pharmacist”, “apothecary”, “drugstore”, “druggist”, “medicine store”, “prescriptions”, and “r.ph.”.

333.17721. Board of pharmacy; creation; members, qualifications, terms of office

Sec. 17721. (1) The Michigan board of pharmacy is created in the department and shall consist of the following 11 voting members who shall meet the requirements of part 161: [FN1] 6 pharmacists and 5 public members.

(2) The terms of office of the individual members of the board created under this section, except those appointed to fill vacancies, expire 4 years after appointment on June 30 of the year in which the term expires.

[FN1] M.C.L.A. § 333.16101 et seq.

333.17722. Board of pharmacy; powers and duties

Sec. 17722. In addition to the functions set forth in part 161, [FN1] the board shall:

(a) Regulate, control, and inspect the character and standard of pharmacy practice and of drugs and devices manufactured, distributed, prescribed, dispensed, administered, or issued in this state and procure samples and limit or prevent the sale of drugs and devices that do not comply with this part.

(b) Prescribe minimum criteria for the use of professional and technical equipment and references in the compounding and dispensing of drugs and devices.

(c) Grant a pharmacy license for each separate place of practice in which the compounding or dispensing of prescription drugs or devices, or both, or the receiving of prescription orders in this state is to be conducted.

(d) Grant a drug control license for the place of practice of a dispensing prescriber who meets the requirements for the license.

(e) Grant a license to a manufacturer or a wholesale distributor of prescription drugs who meets the requirements for the license.

[FN1] M.C.L.A. § 333.16101 et seq.

333.17726. Licenses; issuance

Sec. 17726. The department shall issue a license to an applicant who is granted a license by the board.

333.17731. Renewal of license; evidence required; promulgation of rules

Sec. 17731. (1) Notwithstanding the requirements of part 161, [FN1] the board may require a licensee seeking

renewal of a pharmacist's license to furnish the board with satisfactory evidence that during the 2 years immediately preceding application for renewal the applicant has attended continuing education courses or programs, approved by the board, totaling not less than 30 hours or the satisfactory completion of a proficiency examination according to rules promulgated by the board.

(2) As required under section 16204,[FN2] the board shall promulgate rules requiring each applicant for license renewal to complete as part of the continuing education or proficiency examination requirement of subsection (1) an appropriate number of hours or courses in pain and symptom management.

[FN1] M.C.L.A. § 333.16101 et seq.

[FN2] M.C.L.A. § 333.16204.

➡333.17733. Pharmacist not actively engaged in practice of pharmacy; relicensure; program of practical pharmacy experience

Sec. 17733. A pharmacist who has not actively engaged in the practice of pharmacy for more than 3 consecutive years may be granted relicensure upon application and completion of a program of practical pharmacy experience of at least 200 hours, as determined by the board.

➡333.17737. Internship programs

Sec. 17737. (1) The board shall promulgate rules to establish standards for an internship program and participation therein by interns and preceptors.

(2) An individual shall not engage in an internship program which includes the practice of pharmacy without a limited license under this part.

➡333.17741. Operation of pharmacy; license; control; violations

Sec. 17741. (1) A pharmacy shall not be operated unless licensed by this part.

(2) A pharmacy open for business shall be under the personal charge of a pharmacist. A pharmacist shall not simultaneously have personal charge of more than 1 pharmacy. The person to whom a pharmacy license is issued and the pharmacists on duty are responsible for compliance with federal and state laws regulating the distribution of drugs and the practice of pharmacy. Pharmacy services shall be conducted under the control and personal charge of a pharmacist.

(3) A penalty for violation of this part does not affect the pharmacy license of other than the place of business where the violation occurred.

333.17742. Disclosure of identity of partners, stockholders, officers, etc.; applicant, definition

Sec. 17742. (1) The board may require an applicant or the holder of a pharmacy, manufacturer's, or wholesale distributor's license to fully disclose the identity of each partner, stockholder, officer, or member of the board of directors of the pharmacy, manufacturer, or wholesale distributor, as applicable.

(2) As used in this section and section 17768, [FN1] "applicant" means a person applying for a pharmacy, manufacturer's, or wholesale distributor's license under this article. Applicant includes only 1 or more of the following:

(a) An individual, if the person applying is an individual.

(b) All partners, including limited partners, if the person applying is a partnership.

(c) All stockholders, officers, and members of the board of directors, if the person applying is a privately held corporation.

[FN1] M.C.L.A. § 333.17768.

333.17743. License; contents; operative period

Sec. 17743. (1) A pharmacy license shall contain the name of the licensee, the address of the place of practice, a description of the pharmacy and the premises thereof, and other information the board requires.

(2) A pharmacy license is valid for 2 years, commencing on the date of issue and terminating on the date prescribed for pharmacists in section 16194. [FN1]

[FN1] M.C.L.A. § 333.16194.

333.17744. Agents of prescribers; designation; issuance and transmission of prescriptions

Sec. 17744. (1) A prescriber may designate an agent to act on behalf of or at the discretion of that prescriber. A designation of an agent by a prescriber under this section is not required to be in writing to be a valid designation. If a designation of an agent by a prescriber under this section is contained in a written document, the prescriber or the agent may transmit that document to a pharmacy that will dispense a prescription issued by that prescriber.

(2) Only a prescriber acting within the scope of his or her practice may issue a prescription. An agent may prepare and transmit a prescription that has been signed by the prescriber, including a signature that meets the requirements of section 17754. [FN1] The prescriber issuing a prescription and the pharmacist dispensing a drug or device under a prescription is responsible for all of the requirements of state and federal law, rules,

and regulations regarding the issuance of prescriptions and dispensing of drugs or devices under prescriptions.

(3) A prescriber or his or her agent may transmit to a pharmacy a prescription that is contained within a patient's chart in a health facility or agency licensed under article 17 [FN2] or other medical institution. A prescription that is contained within a patient's chart in a health facility or agency licensed under article 17 or other medical institution and that is created in an electronic format may contain more than 6 prescriptions and may contain prescriptions for schedule 3 through 5 controlled substances and noncontrolled substances on the same form.

[FN1] M.C.L.A. § 333.17754.

[FN2] M.C.L.A. § 333.20101 et seq.

➡333.17745. Drug control license; records of drugs dispensed; delegating authority to dispense drugs; storage of drugs; containers; limitations

<Section effective until March 14, 2014. See, also, section effective March 14, 2014.>

Sec. 17745. (1) Except as otherwise provided in this subsection, a prescriber who wishes to dispense prescription drugs shall obtain from the board a drug control license for each location in which the storage and dispensing of prescription drugs occur. A drug control license is not necessary if the dispensing occurs in the emergency department, emergency room, or trauma center of a hospital licensed under article 17 [FN1] or if the dispensing involves only the issuance of complimentary starter dose drugs.

(2) A dispensing prescriber shall dispense prescription drugs only to his or her own patients.

(3) A dispensing prescriber shall include in a patient's chart or clinical record a complete record, including prescription drug names, dosages, and quantities, of all prescription drugs dispensed directly by the dispensing prescriber or indirectly under his or her delegatory authority. If prescription drugs are dispensed under the prescriber's delegatory authority, the delegatee who dispenses the prescription drugs shall initial the patient's chart, clinical record, or log of prescription drugs dispensed. In a patient's chart or clinical record, a dispensing prescriber shall distinguish between prescription drugs dispensed to the patient and prescription drugs prescribed for the patient. A dispensing prescriber shall retain information required under this subsection for not less than 5 years after the information is entered in the patient's chart or clinical record.

(4) A dispensing prescriber shall store prescription drugs under conditions that will maintain their stability, integrity, and effectiveness and will assure that the prescription drugs are free of contamination, deterioration, and adulteration.

(5) A dispensing prescriber shall store prescription drugs in a substantially constructed, securely lockable cabinet. Access to the cabinet shall be limited to individuals authorized to dispense prescription drugs in

compliance with this part and article 7. [FN2]

(6) Unless otherwise requested by a patient, a dispensing prescriber shall dispense a prescription drug in a safety closure container that complies with the poison prevention packaging act of 1970, 15 USC 1471 to 1477.

(7) A dispensing prescriber shall dispense a drug in a container that bears a label containing all of the following information:

(a) The name and address of the location from which the prescription drug is dispensed.

(b) The patient's name and record number.

(c) The date the prescription drug was dispensed.

(d) The prescriber's name or, if dispensed under the prescriber's delegatory authority, shall list the name of the delegatee.

(e) The directions for use.

(f) The name and strength of the prescription drug.

(g) The quantity dispensed.

(h) The expiration date of the prescription drug or the statement required under section 17756. [FN3]

(8) A dispensing prescriber who dispenses a complimentary starter dose drug to a patient shall give the patient at least all of the following information, either by dispensing the complimentary starter dose drug to the patient in a container that bears a label containing the information or by giving the patient a written document which may include, but is not limited to, a preprinted insert that comes with the complimentary starter dose drug, that contains the information:

(a) The name and strength of the complimentary starter dose drug.

(b) Directions for the patient's use of the complimentary starter dose drug.

(c) The expiration date of the complimentary starter dose drug or the statement required under section 17756.

(9) The information required under subsection (8) is in addition to, and does not supersede or modify, other state or federal law regulating the labeling of prescription drugs.

(10) In addition to meeting the requirements of this part, a dispensing prescriber who dispenses controlled substances shall comply with section 7303a. [FN4]

(11) The board may periodically inspect locations from which prescription drugs are dispensed.

(12) The act, task, or function of dispensing prescription drugs shall be delegated only as provided in this part and sections 16215, 17048, 17076, 17212, and 17548. [FN5]

(13) A supervising physician may delegate in writing to a pharmacist practicing in a hospital pharmacy within a hospital licensed under article 17 the receipt of complimentary starter dose drugs other than controlled substances as defined by article 7 or federal law. When the delegated receipt of complimentary starter dose drugs occurs, both the pharmacist's name and the supervising physician's name shall be used, recorded, or otherwise indicated in connection with each receipt. A pharmacist described in this subsection may dispense a prescription for complimentary starter dose drugs written or transmitted by facsimile, electronic transmission, or other means of communication by a prescriber.

(14) As used in this section, “complimentary starter dose” means a prescription drug packaged, dispensed, and distributed in accordance with state and federal law that is provided to a dispensing prescriber free of charge by a manufacturer or distributor and dispensed free of charge by the dispensing prescriber to his or her patients.

[FN1] M.C.L.A. § 333.20101 et seq.

[FN2] M.C.L.A. § 333.7101 et seq.

[FN3] M.C.L.A. § 333.17756.

[FN4] M.C.L.A. § 333.7303a.

[FN5] M.C.L.A. §§ 333.16215, 333.17048, 333.17076, 333.17212, and 333.17548.

333.17745a. Public health programs; delegation; delivery

Sec. 17745a. (1) As used in this section:

(a) “Medicaid” means the program of medical assistance established under title XIX of the social security act, chapter 531, 49 Stat . 620, 42 U.S.C. 1396 to 1396f, 1396g-1 to 1396r-6, and 1396r-8 to 1396v.

(b) “Medicare” means the federal medicare program established under title XVIII of the social security act,

chapter 531, 49 Stat. 620, 42 U.S.C. 1395 to 1395b, 1395b-2, 1395b-6 to 1395b-7,1395c to 1395i, 1395i-2 to 1395i-5, 1395j to 1395t, 1395u to 1395w, 1395w-2to1395w-4, 1395w-21 to 1395w-28, 1395x to 1395yy, and 1395bbb to 1395ggg.

(c) “Public health program” means 1 of the following:

(*i*) A local health department.

(*ii*) A migrant health center or a community health center as defined under sections 329 and 330 of subpart I of part C of title III of the public health service act, 42 U.S.C. 254b and 254c.

(*iii*) A family planning program designated by the family independence agency as a provider type 23 under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b, and verified by the department of community health.

(*iv*) A methadone treatment program licensed under article 6. [FN1]

(*v*) A rural health clinic.

(*vi*) A hospice rendering emergency care services in a patient's home as described in section 17746. [FN2]

(d) “Rural health clinic” means a rural health clinic as defined in section 1861 of part C of title XVIII of the social security act, 42 U.S.C. 1395x, that is certified to participate in medicaid and medicare.

(2) Except as otherwise provided in subsections (3) and (4), in a public health program without an on-site pharmacy, a dispensing prescriber may delegate the dispensing of prescription drugs only to the following individuals:

(a) A registered professional nurse licensed under part 172. [FN3]

(b) A physician's assistant licensed under part 170 or part 175, [FN4] if the delegating dispensing prescriber is responsible for the clinical supervision of the physician's assistant.

(3) In a public health program without an on-site pharmacy, a dispensing prescriber may delegate the delivery of prescription drugs consisting only of prelabeled, prepackaged oral contraceptives under the following circumstances:

(a) The delivery is delegated to an appropriately trained individual.

(b) The delivery is performed pursuant to specific, written protocols.

(4) In a methadone treatment program licensed under article 6 without an on-site pharmacy, a dispensing prescriber may delegate the delivery of a prescription drug consisting only of 1 or more single doses of methadone, up to the maximum number of single doses allowed by law, to a registered client of the methadone treatment program, if all of the following requirements are met:

(a) The delivery is delegated to 1 of the following individuals:

(*i*) A registered professional nurse or a licensed practical nurse licensed under part 172.

(*ii*) A physician's assistant licensed under part 170 or part 175, but only if the delegating dispensing prescriber is responsible for the clinical supervision of the physician's assistant.

(b) The delivery is performed pursuant to specific, written protocols.

(c) The prescription drug described in this subsection is labeled in accordance with section 17745. [FN5]

[FN1] M.C.L.A. § 333.6101 et seq.

[FN2] M.C.L.A. § 333.17746.

[FN3] M.C.L.A. § 333.17200 et seq.

[FN4] M.C.L.A. §§ 333.17001 et seq. or 333.17501 et seq.

[FN5] M.C.L.A. § 333.17745.

333.17745b. Dispensing prescribers; delegation to individuals; duties; charging for dispensing drugs

Sec. 17745b. (1) Subject to subsection (3), in an industrial clinic or other prescriber practice location without an on-site pharmacy, a dispensing prescriber may delegate the dispensing of prescription drugs only to the following individuals:

(a) A registered professional nurse licensed under part 172. [FN1]

(b) A physician's assistant licensed under part 170 [FN2] or part 175, [FN3] if the dispensing prescriber is responsible for the clinical supervision of the physician's assistant.

(2) In an industrial clinic or other prescriber practice location without an on-site pharmacy, if a dispensing prescriber does not delegate the dispensing of a prescription drug, the dispensing prescriber shall do both of

the following:

(a) Be physically present at the time the prescription drug is dispensed.

(b) Immediately before the prescription drug is dispensed, perform a final inspection of the type of prescription drug, labeling, dosage, and amount of the prescription drug dispensed.

(3) A dispensing prescriber who delegates the dispensing of a prescription drug to a patient in an industrial clinic or other prescriber practice location without an on-site pharmacy shall not delegate the dispensing of more than a 72-hour supply of the prescription drug.

(4) Before dispensing a prescription drug to a patient in an industrial clinic or other prescriber practice location without an on-site pharmacy, a dispensing prescriber who intends to charge for dispensing the drug shall give a written prescription to the patient and shall instruct the patient that he or she may elect to have the prescription filled by the dispensing prescriber or the patient's pharmacy of choice.

(5) If a dispensing prescriber intends to charge for dispensing a prescription drug to a patient in an industrial clinic or other prescriber practice location without an on-site pharmacy, the dispensing prescriber shall inform the patient of that fact before dispensing the prescription drug to the patient. The dispensing prescriber also shall list the charge for dispensing the prescription drug as a separate item on the patient's bill.

(6) This section does not apply to public health programs as defined in section 17745a. [FN4]

[FN1] M.C.L.A. § 333.17201 et seq.

[FN2] M.C.L.A. § 333.17001 et seq.

[FN3] M.C.L.A. § 333.17501 et seq.

[FN4] M.C.L.A. § 333.17745a.

➡ 333.17746. Medication box exchange program; hospice emergency care services

Sec. 17746. A pharmacy may establish a medication box exchange program for hospice emergency care services rendered in patients' homes, pursuant to this section and rules promulgated under this section. The pharmacist in charge of the pharmacy shall be responsible for developing, implementing, and coordinating the program in conjunction with the medical director of the hospice program. The pharmacist in charge of the pharmacy shall be responsible for obtaining prescriptions from the hospice medical director for the drugs dispensed from a medication box. The board may promulgate rules to implement this section.

➡ 333.17747. Drug control license; contents; operative period; renewal; void

Sec. 17747. (1) A drug control license shall contain the name and address of the dispensing prescriber and each location in which the storage and dispensing of drugs occur and other information the board requires.

(2) A drug control license is valid until the date on which the dispensing prescriber's professional license must be renewed, at which time the drug control license shall be renewed. The drug control license shall be renewed automatically, if both of the following conditions are met:

(a) The dispensing prescriber indicates that he or she dispenses drugs and desires to continue to do so.

(b) The dispensing prescriber renews his or her professional license.

(3) A dispensing prescriber whose drug control license is renewed pursuant to subsection (2) is subject to section 16226 [FN1] and the other requirements of this article and article 7. [FN2]

(4) A drug control license is automatically void if a board suspends or revokes the licensee's health professional license.

[FN1] M.C.L.A. § 333.16226.

[FN2] M.C.L.A. § 333.7101 et seq.

➡333.17748. Distributors of prescription drugs; licensing

Sec. 17748. A pharmacy, manufacturer, or wholesale distributor of prescription drugs, whether or not located in this state but doing business in this state, shall be licensed by the board in accordance with this part. Licenses shall be renewed biennially. A pharmacy, manufacturer, or wholesale distributor may designate an individual to be the licensee for the pharmacy, manufacturer, or wholesale distributor and the licensee is responsible for compliance with this part.

➡333.17749. Diagnostic or therapeutic pharmaceutical agents; dispensing by wholesale distributor or pharmacist to licensed optometrist

Sec. 17749. (1) Notwithstanding any provision of this act or any rule promulgated under this act, a wholesale distributor or pharmacist may dispense a diagnostic pharmaceutical agent or a therapeutic pharmaceutical agent to a licensed optometrist for subsequent administration to optometric patients, if the optometrist provides the wholesale distributor or pharmacist with the number of the optometrist's certification of qualification to administer diagnostic pharmaceutical agents and the number of the optometrist's certification of qualification to administer and prescribe therapeutic pharmaceutical agents.

(2) As used in this section, “therapeutic pharmaceutical agent” and “diagnostic pharmaceutical agent” mean

those terms as defined in section 17401. [FN1]

[FN1] M.C.L.A. § 333.17401.

➡333.17750. Distribution of complimentary starter doses; records; contents, board access to records, definition

Sec. 17750. (1) A person who distributes complimentary starter doses to prescribers shall maintain records that include at least all of the following information:

(a) The name and address of the manufacturer distributing the complimentary starter doses.

(b) The name and address of each prescriber to whom complimentary starter doses were distributed.

(c) The type and amount of complimentary starter doses distributed to each prescriber.

(2) Upon request of the board, a person who distributes complimentary starter doses to prescribers shall provide the board access to the records required under subsection (1).

(3) As used in this section, “complimentary starter dose” means that term as defined in section 17745(1). [FN1]

[FN1] M.C.L.A. § 333.17745.

➡333.17750a. Dispensing prescriptions for therapeutic pharmaceutical agents prescribed by a certified optometrist

Sec. 17750a. (1) A pharmacist may dispense a prescription for a therapeutic pharmaceutical agent issued by an optometrist certified by the Michigan board of optometry under part 174 [FN1] as qualified to administer and prescribe therapeutic pharmaceutical agents.

(2) As used in this section, “therapeutic pharmaceutical agent” means that term as defined in section 17401. [FN2]

[FN1] M.C.L.A. § 333.17401 et seq.

[FN2] M.C.L.A. § 333.17401.

➡333.17751. Dispensing prescription drug; requirements; additions or changes to prescriptions; documentation

<Section effective until March 14, 2014. See, also, section effective March 14, 2014.>

Sec. 17751. (1) A pharmacist shall not dispense a drug requiring a prescription under the federal act or a law of this state except under authority of an original prescription or an equivalent record of an original prescription approved by the board.

(2) Subject to subsection (5), a pharmacist may dispense a prescription written and signed; written or created in an electronic format, signed, and transmitted by facsimile; or transmitted electronically or by other means of communication by a physician prescriber or dentist prescriber in a state other than Michigan, but not including a prescription for a controlled substance as defined in section 7104 [FN1] except under circumstances described in section 17763(e), [FN2] only if the pharmacist in the exercise of his or her professional judgment determines all of the following:

(a) That the prescription was issued pursuant to an existing physician-patient or dentist-patient relationship.

(b) That the prescription is authentic.

(c) That the prescribed drug is appropriate and necessary for the treatment of an acute, chronic, or recurrent condition.

(3) A pharmacist or a prescriber shall dispense a prescription only if the prescription falls within the scope of practice of the prescriber.

(4) A pharmacist shall not knowingly dispense a prescription after the death of the prescriber or patient.

(5) A pharmacist shall not dispense a drug or device under a prescription transmitted by facsimile or created in electronic format and printed out for use by the patient unless the document is manually signed by the prescriber. This subsection does not apply to a prescription that is transmitted by a computer to a facsimile machine if that prescription complies with section 17754. [FN3]

(6) After consultation with and agreement from the prescriber, a pharmacist may add or change a patient's address, dosage form, drug strength, drug quantity, directions for use, or issue date with regard to a prescription. A pharmacist shall note the details of the consultation and agreement required under this subsection on the prescription and shall maintain that documentation with the prescription as required in section 17752. [FN4] A pharmacist shall not change the patient's name, controlled substance prescribed unless authorized to dispense a lower cost generically equivalent drug product under section 17755, [FN5] or the prescriber's signature with regard to a prescription.

(7) A prescription that is contained within a patient's chart in a health facility or agency licensed under article 17 [FN6] or other medical institution and that is transmitted to a pharmacy under section 17744 [FN7] is the

original prescription. If all other requirements of this part are met, a pharmacist shall dispense a drug or device under a prescription described in this subsection. A pharmacist may dispense a drug or device under a prescription described in this subsection even if the prescription does not contain the quantity ordered. If a prescription described in this subsection does not contain the quantity ordered, the pharmacist shall consult with the prescriber to determine an agreed-upon quantity. The pharmacist shall record the quantity dispensed on the prescription and shall maintain that documentation with the prescription as required in section 17752.

[FN1] M.C.L.A. § 333.7104.

[FN2] M.C.L.A. § 333.17763.

[FN3] M.C.L.A. § 333.17754.

[FN4] M.C.L.A. § 333.17752.

[FN5] M.C.L.A. § 333.17755.

[FN6] M.C.L.A. § 333.20101 et seq.

[FN7] M.C.L.A. § 333.17744.

333.17752. Records; confidentiality; disclosure; refilling copy of prescription

Sec. 17752. (1) A prescription, or an equivalent record of the prescription approved by the board, shall be preserved by a licensee or dispensing prescriber for not less than 5 years.

(2) A prescription or equivalent record on file in a pharmacy is not a public record. A person having custody of or access to prescriptions shall not disclose their contents or provide copies without the patient's authorization, to any person except to any of the following:

(a) The patient for whom the prescription was issued, or another pharmacist acting on behalf of the patient.

(b) The authorized prescriber who issued the prescription, or a licensed health professional who is currently treating the patient.

(c) An agency or agent of government responsible for the enforcement of laws relating to drugs and devices.

(d) A person authorized by a court order.

(e) A person engaged in research projects or studies with protocols approved by the board.

(3) A pharmacist may refill a copy of a prescription from another pharmacy if the original prescription has

remaining authorized refills, and the copy is issued according to the following procedure:

(a) The pharmacist issuing a written or oral copy of a prescription shall cancel the original prescription and record the cancellation. The record of cancellation shall include the date the copy was issued, to whom issued, and the identification of the pharmacist who issued the copy.

(b) The written or oral copy issued shall be a duplicate of the original prescription except that it shall also include the prescription number, the name of the pharmacy issuing the copy, the date the copy was issued, and the number of authorized refills remaining available to the patient.

(c) The pharmacist receiving a written or oral copy of the prescription shall exercise reasonable diligence to determine whether it is a valid copy, and having done so may treat the copy as an original prescription.

(d) Except as described in this part, all other copies furnished shall be used for information purposes only and clearly marked “for informational or reference purposes only”.

(4) Subsection (3) does not apply to pharmacies that share a real-time, on-line database or other equivalent means of communication or to pharmacies that transfer prescriptions pursuant to a written contract for centralized prescription processing services as provided under section 17753. [FN1]

[FN1] M.C.L.A. § 333.17753.

➡333.17753. Centralized prescription processing services; conditions, policy and procedures manual, documentation, definition

Sec. 17753. (1) A pharmacy may perform centralized prescription processing services or outsource those services to another pharmacy if each of the following conditions is satisfied:

(a) The pharmacies have the same owner or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state laws and regulations.

(b) The pharmacies share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to prepare a prescription drug order.

(c) The pharmacies comply with federal and state laws and regulations.

(2) A pharmacy that performs, or contracts for, centralized prescription processing services shall maintain a policy and procedures manual, along with documentation that implementation is occurring, and each shall be made available to the board for inspection and review upon request and the manual shall include, but is not

limited to, a detailed description of how the pharmacies will do all of the following:

(a) Maintain appropriate records to identify the responsible pharmacist, or pharmacists, in the various stages of the drug product preparation, dispensing, and counseling process.

(b) Track the prescription drug order during each step in the drug product preparation, dispensing, and counseling process.

(c) Identify on the prescription label each pharmacy involved in the preparation and dispensing of the prescription drug order.

(d) Provide adequate security to protect the confidentiality and integrity of a patient's protected health information.

(e) Implement and maintain a quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

(3) As used in this section, “centralized prescription processing” means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, performing drug utilization review, completing claims adjudication, obtaining refill authorizations, initiating therapeutic interventions, and other functions related to the practice of pharmacy.

➡333.17754. Electronic transmission of prescription; conditions; information; confidentiality; professional judgment as to accuracy, validity, and authenticity; original prescription

Sec. 17754. (1) Except as otherwise provided under article 7, [FN1] article 8, [FN2] and the federal act, a prescription may be transmitted electronically if the prescription is transmitted in compliance with the health insurance portability and accountability act of 1996, Public Law 104-191, [FN3] or regulations promulgated under that act, 45 CFR parts 160 and 164, [FN4] by a prescriber or his or her agent and the data are not altered or modified in the transmission process. The electronically transmitted prescription shall include all of the following information:

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

(b) Except as otherwise authorized under section 17744a, [FN5] the full name of the patient for whom the prescription is issued.

(c) An electronic signature or other identifier that specifically identifies and authenticates the prescriber or his

or her agent.

(d) The time and date of the transmission.

(e) The identity of the pharmacy intended to receive the transmission.

(f) Any other information required by the federal act or state law.

(2) The electronic equipment or system utilized in the transmission and communication of prescriptions shall provide adequate confidentiality safeguards and be maintained to protect patient confidentiality as required under any applicable federal and state law and to ensure against unauthorized access. The electronic transmission of a prescription shall be communicated in a retrievable, recognizable form acceptable to the intended recipient. The electronic form utilized in the transmission of a prescription shall not include "dispense as written" or "d.a.w." as the default setting.

(3) Before dispensing a prescription that is electronically transmitted, the pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the transmitted prescription.

(4) An electronically transmitted prescription that meets the requirements of this section is the original prescription.

[FN1] M.C.L.A. § 333.7101 et seq.

[FN2] M.C.L.A. § 333.8101 et seq.

[FN3] Classified principally to 29 U.S.C.A. § 1181 et seq.; for full classifications, see U.S.C.A. tables.

[FN4] 45 C.F.R. §§ 160.101 et seq. and 164.102 et seq.

[FN5] M.C.L.A. § 333.17744a.

333.17755. Generically equivalent drugs; dispensing

Sec. 17755. (1) When a pharmacist receives a prescription for a brand name drug product, the pharmacist may, or when a purchaser requests a lower cost generically equivalent drug product, the pharmacist shall dispense a lower cost but not higher cost generically equivalent drug product if available in the pharmacy, except as provided in subsection (3). If a drug is dispensed which is not the prescribed brand, the purchaser shall be notified and the prescription label shall indicate both the name of the brand prescribed and the name of the brand dispensed and designate each respectively. If the dispensed drug does not have a brand name, the prescription label shall indicate the generic name of the drug dispensed, except as otherwise provided in section 17756. [FN1]

(2) If a pharmacist dispenses a generically equivalent drug product, the pharmacist shall pass on the savings in cost to the purchaser or to the third party payment source if the prescription purchase is covered by a third party pay contract. The savings in cost is the difference between the wholesale cost to the pharmacist of the 2 drug products.

(3) The pharmacist shall not dispense a generically equivalent drug product under subsection (1) if any of the following applies:

(a) The prescriber, in the case of a prescription in writing signed by the prescriber, writes in his or her own handwriting “dispense as written” or “d.a.w.” on the prescription.

(b) The prescriber, having preprinted on his or her prescription blanks the statement “another brand of a generically equivalent product, identical in dosage, form, and content of active ingredients, may be dispensed unless initialed d.a.w.”, writes in his or her own handwriting, the initials “d.a.w.” in a space, box, or square adjacent to the statement.

(c) The prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates the prescription is to be dispensed as communicated.

(4) A pharmacist may not dispense a drug product with a total charge that exceeds the total charge of the drug product originally prescribed, unless agreed to by the purchaser.

[FN1] M.C.L.A. § 333.17756.

333.17756. Label to contain name of medication dispensed

Sec. 17756. (1) A prescription dispensed by a pharmacist shall bear upon the label the name of the medication in the container, unless the prescriber writes “do not label” on the prescription. The prescription shall also bear upon the label the following statement: “Discard this medication 1 year after the date it is dispensed.”, unless the medication expires on another date under applicable state or federal law or rules or regulations or other state or federal standards. If the medication expires on another date, the pharmacist dispensing the prescription shall strike or omit the statement required under this subsection and shall specify on the label the actual expiration date of the medication.

(2) A label on a prescription dispensed by a dispensing prescriber shall include the name of the medication in the container. The label shall also include the statement required under subsection (1) or the actual expiration date of the medication in the container in the same manner required under subsection (1) for a prescription dispensed by a pharmacist.

333.17757. Current drug selling price lists; consumer notice about prescription drugs, form; transaction

receipts

<Section effective until March 14, 2014. See, also, section effective March 14, 2014.>

Sec. 17757. (1) Upon a request made in person or by telephone, a pharmacist engaged in the business of selling drugs at retail shall provide the current selling price of a drug dispensed by that pharmacy or comparative current selling prices of generic and brand name drugs dispensed by that pharmacy. The information shall be provided to the person making the request before a drug is dispensed to the person. A person who makes a request for price information under this subsection shall not be obligated to purchase the drug for which the price or comparative prices are requested.

(2) A pharmacist engaged in the business of selling drugs at retail shall conspicuously display the notice described in subsection (3) at each counter over which prescription drugs are dispensed.

(3) The notice required under subsection (2) shall be in substantially the following form:

NOTICE TO CONSUMERS

ABOUT PRESCRIPTION DRUGS

Under Michigan law, you have the right to find out the price of a prescription drug before the pharmacist fills the prescription. You are under no obligation to have the prescription filled here and may use this price information to shop around at other pharmacies. You may request price information in person or by telephone.

Every pharmacy has the current selling prices of both generic and brand name drugs dispensed by the pharmacy.

Ask your pharmacist if a lower-cost generic drug is available to fill your prescription. A generic drug contains the same medicine as a brand name drug and is a suitable substitute in most instances.

A generic drug may not be dispensed by your pharmacist if your doctor has written “dispense as written” or the initials “d.a.w.” on the prescription.

If you have questions about the drugs which have been prescribed for you, ask your doctor or pharmacist for more information.

To avoid dangerous drug interactions, let your doctor and pharmacist know about any other medications you are taking. This is especially important if you have more than 1 doctor or have prescriptions filled at more

than 1 pharmacy.

(4) The notice required under subsection (2) shall also contain the address and phone number of the board and the department. The text of the notice shall be in at least 32-point bold type and shall be printed on paper at least 11 inches by 17 inches in size. The notice may be printed on multiple pages.

(5) A copy of the notice required under subsection (2) shall be provided to each licensee by the department. Additional copies shall be available if needed from the department. A person may duplicate or reproduce the notice if the duplication or reproduction is a true copy of the notice as produced by the department, without any additions or deletions whatsoever.

(6) The pharmacist shall furnish to the purchaser of a prescription drug at the time the drug is delivered to the purchaser a receipt evidencing the transactions, which contains the following:

(a) The brand name of the drug, if applicable.

(b) The name of the manufacturer or the supplier of the drug, if the drug does not have a brand name.

(c) The strength of the drug, if significant.

(d) The quantity dispensed, if applicable.

(e) The name and address of the pharmacy.

(f) The serial number of the prescription.

(g) The date the prescription was originally dispensed.

(h) The name of the prescriber or, if prescribed under the prescriber's delegatory authority, shall list the name of the delegatee.

(i) The name of patient for whom the drug was prescribed.

(j) The price for which the drug was sold to the purchaser.

(7) Subsection (6)(a), (b), and (c) may be omitted by a pharmacist only if the omission is expressly required by the prescriber. The pharmacist shall retain a copy of each receipt for 90 days. The inclusion of subsection (6) on the prescription container label is a valid receipt to the purchaser. Including subsection (6) on the

written prescription form and retaining the form constitutes retention of a copy of the receipt.

(8) The board may promulgate rules to implement this section.

➡ 333.17757a. Dispensing prescribers; notice to consumers

Sec. 17757a. (1) Upon a request made in person or by telephone, a dispensing prescriber engaged in the business of selling prescription drugs shall provide the current selling price of a drug dispensed by that dispensing prescriber or comparative current selling prices of generic and brand name drugs dispensed by that dispensing prescriber. The information shall be provided to the person making the request before a prescription drug is dispensed to the person. A person who makes a request for price information under this subsection is not obligated to purchase the prescription drug for which the price or comparative prices are requested.

(2) A dispensing prescriber engaged in the business of selling prescription drugs shall conspicuously display the notice described in subsection (3) in the location within the dispensing prescriber's practice where the dispensing occurs.

(3) The notice required under subsection (2) shall be in substantially the following form:

NOTICE TO CONSUMERS ABOUT PRESCRIPTION DRUGS

Under Michigan law, you have the right to find out the price of a prescription drug before the doctor provides a prescription drug directly to you. You are under no obligation to have the prescription filled here and may use this price information to shop around.

You may choose to have the prescription filled by your doctor or the pharmacy of your choice. Your doctor may not force you to have the prescription filled by the doctor. Your doctor cannot charge you for medications marked “sample.”

Ask your doctor or pharmacist if a lower-cost generic drug is available to fill your prescription. A generic drug contains the same medicine as a brand name drug and is a suitable substitute in most cases.

If you have questions about the drugs which have been prescribed for you, ask your doctor or pharmacist for more information.

To avoid dangerous drug interactions, let your doctor and pharmacist know about any other medications you are taking. This is especially important if you have more than 1 doctor or have prescriptions filled at more than 1 location.

(4) The notice required under subsection (2) shall also contain the address and phone number of the board and the department. The text of the notice shall be in at least 32-point bold type and shall be printed on paper at least 11 inches by 17 inches in size. The notice may be printed on multiple pages.

(5) A copy of the notice required under subsection (2) shall be provided to each dispensing prescriber by the department. Additional copies shall be available if needed from the department. A person may duplicate or reproduce the notice if the duplication or reproduction is a true copy of the notice as produced by the department, without any additions or deletions.

➡333.17758. Repealed by P.A.1986, No. 304, § 2, Eff. March 31, 1987

➡333.17759. Harmful drugs; dispensing

Sec. 17759. A harmful drug shall be dispensed only:

(a) As a prescription drug.

(b) Under the control of a licensed pharmacist or prescriber, who maintains records for the dispensing of these drugs which are the same as records required for the dispensing of prescriptions.

➡333.17761. Display of consumer notice about prescription drugs; safety closure containers

Sec. 17761. (1) A pharmacy, except for a pharmacy which only dispenses drugs for inpatient use at a health care facility, shall display the notice required under section 17757 [FN1] in accordance with this part and the rules promulgated under this part.

(2) Unless otherwise requested by a patient, a prescription shall be dispensed in a safety closure container which complies with the definitions and the requirements of the poison prevention packaging act of 1970, 15 U.S.C. sections 1471 to 1476.

[FN1] M.C.L.A. § 333.17757.

➡333.17762. Misbranded drugs

Sec. 17762. (1) A prescription drug is considered misbranded unless the manufacturer's label states the name and place of business of the manufacturer of the finished dosage form of a drug and, if different, the name and place of business of the packer or distributor.

(2) As used in this section, “finished dosage form of a drug” means that form of the drug which is or is

intended to be dispensed or administered to the patient and does not require further manufacturing or processing other than packaging or labeling, or both.

➡333.17763. Grounds for fine, reprimand, or probation, or for denying, limiting, suspending, or revoking license

Sec. 17763. In addition to the grounds set forth in part 161, [FN1] the disciplinary subcommittee may fine, reprimand, or place a pharmacist licensee on probation, or deny, limit, suspend, or revoke the license of a pharmacist or order restitution or community service for a violation or abetting in a violation of this part or rules promulgated under this part, or for 1 or more of the following grounds:

(a) Permitting the dispensing of prescriptions by an individual who is not a pharmacist, pharmacist intern, or dispensing prescriber.

(b) Permitting the dispensing of prescriptions by a pharmacist intern, except in the presence and under the personal charge of a pharmacist.

(c) Selling at auction drugs in bulk or in open packages unless the sale has been approved in accordance with rules of the board.

(d) Promoting a prescription drug to the public in any manner.

(e) In addition to the prohibition contained in section 7405(1)(e), [FN2] dispensing a prescription for a controlled substance as defined in section 7104 [FN3] that is written and signed; written or created in an electronic format, signed, and transmitted by facsimile; or transmitted electronically or by other means of communication by a physician prescriber or dentist prescriber in a state other than Michigan, unless the prescription is issued by a physician prescriber or dentist prescriber who is authorized under the laws of that state to practice dentistry, medicine, or osteopathic medicine and surgery and to prescribe controlled substances.

[FN1] M.C.L.A. § 333.16101 et seq.

[FN2] M.C.L.A. § 333.7405.

[FN3] M.C.L.A. § 333.7104.

➡333.17764. Sale, offer for sale, manufacture for sale, etc., of drug or device bearing or accompanied by misleading label; adulteration, misbranding, etc., of drug or device; sale, offer for sale, manufacture for sale, etc., of adulterated or misbranded drug; penalties

Sec. 17764. (1) A person shall not sell, offer for sale, possess for sale, or manufacture for sale a drug or device

bearing or accompanied by a label that is misleading as to the contents, uses, or purposes of the drug or device. A person who violates this subsection is guilty of a misdemeanor. In determining whether a label is misleading, consideration shall be given to the representations made or suggested by the statement, word, design, device, sound, or any combination thereof, and the extent to which the label fails to reveal facts material in view of the representations made or material as to consequences that may result from use of the drug or device to which the label relates under conditions of use prescribed in the label or under customary or usual conditions of use.

(2) A person shall not knowingly or recklessly do either of the following:

(a) Adulterate, misbrand, remove, or substitute a drug or device knowing or intending that the drug or device shall be used.

(b) Sell, offer for sale, possess for sale, cause to be sold, or manufacture for sale an adulterated or misbranded drug.

(3) Except as otherwise provided in this section, a person who violates subsection (2) is guilty of a felony punishable by imprisonment for not more than 2 years or a fine of not more than $1,000.00, or both.

(4) A person who violates subsection (2), which violation results in personal injury, is guilty of a felony punishable by imprisonment for not more than 4 years or a fine of not more than $4,000.00, or both.

(5) A person who violates subsection (2), which violation results in serious impairment of a body function, is guilty of a felony punishable by imprisonment for not more than 5 years or a fine of not more than $5,000.00, or both. As used in this subsection, “serious impairment of a body function” means that term as defined in section 58c of the Michigan vehicle code, 1949 PA 300, MCL 257.58c.

(6) A person who violates subsection (2), which violation results in death, is guilty of a felony punishable by imprisonment for not more than 15 years or a fine of not more than $20,000.00, or both.

(7) A person who violates subsection (2) with the intent to kill or to cause serious impairment of a body function of 2 or more individuals, which violation results in death, is guilty of a felony punishable by imprisonment for life without the possibility of parole or life without the possibility of parole and a fine of not more than $40,000.00. It is not a defense to a charge under this subsection that the person did not intend to kill a specific individual, or did not intend to cause serious impairment of a body function of 2 or more specific individuals.

(8) This section does not prohibit an individual from being charged with, convicted of, or punished for any other violation of law that is committed by that individual while violating this section.

➡333.17765. Adulterated or misbranded drugs; exemption from penalties

Sec. 17765. A person is not subject to penalties for a violation of this part dealing with adulteration or misbranding, if the person establishes that a guaranty or undertaking was made in accordance with the federal act, or that a guaranty was signed by and contains the name and address of the person residing in this state from whom the former person received in good faith the drug or device, to the effect that the drug or device is not adulterated or misbranded within the meaning of this part. The guaranty does not protect the seller if the product is adulterated or misbranded under this part and the board has previously given written notice to the seller of that fact. The board shall not serve notice on the seller until the board has notified the manufacturer or wholesale distributor of the findings of the state analyst with reference to the product. The notice to the manufacturer or wholesale distributor shall be written and shall be mailed at least 10 days before a notice is given to a seller under this section.

➡333.17766. Prohibited acts generally; penalties

Sec. 17766. Except as provided in sections 17766d and 17780, [FN1] a person who does any of the following is guilty of a misdemeanor:

(a) Obtains or attempts to obtain a prescription drug by giving a false name to a pharmacist or other authorized seller, prescriber, or dispenser.

(b) Obtains or attempts to obtain a prescription drug by falsely representing that he or she is a lawful prescriber, dispenser, or licensee, or acting on behalf of a lawful prescriber, dispenser, or licensee.

(c) Falsely makes, utters, publishes, passes, alters, or forges a prescription.

(d) Knowingly possesses a false, forged, or altered prescription.

(e) Knowingly attempts to obtain, obtains, or possesses a drug by means of a prescription for other than a legitimate therapeutic purpose, or as a result of a false, forged, or altered prescription.

(f) Possesses or controls for the purpose of resale, or sells, offers to sell, dispenses, or gives away, a drug, pharmaceutical preparation, or chemical that has been dispensed on prescription and has left the control of a pharmacist.

(g) Possesses or controls for the purpose of resale, or sells, offers to sell, dispenses, or gives away, a drug, pharmaceutical preparation, or chemical that has been damaged by heat, smoke, fire, water, or other cause and is unfit for human or animal use.

(h) Prepares or permits the preparation of a prescription drug, except as delegated by a pharmacist.

(i) Sells a drug in bulk or in an open package at auction, unless the sale has been approved in accordance with rules of the board.

[FN1] M.C.L.A. §§ 333.17766d and 333.17780.

333.17766a. Repealed by P.A.2001, No. 236, § 1, Imd. Eff. Jan. 3, 2002

333.17766b. Repealed by P.A.2001, No. 231, § 1, Eff. Jan. 6, 2003

333.17766c. Purchase or possession of ephedrine or pseudoephedrine; penalties

Sec. 17766c. (1) A person shall not do any of the following:

(a) Purchase more than 3.6 grams of ephedrine or pseudoephedrine alone or in a mixture within a single calendar day.

(b) Purchase more than 9 grams of ephedrine or pseudoephedrine alone or in a mixture within a 30-day period.

(c) Possess more than 12 grams of ephedrine or pseudoephedrine alone or in a mixture.

(2) A person who violates this section is guilty of a crime as follows:

(a) A person who violates subsection (1)(a) or (b) is guilty of a misdemeanor punishable by imprisonment for not more than 93 days or a fine of not more than $500.00, or both.

(b) A person who violates subsection (1)(c) is guilty of a felony punishable by imprisonment for not more than 2 years or a fine of not more than $2,000.00, or both.

(3) This section does not apply to any of the following:

(a) A person who possesses ephedrine or pseudoephedrine pursuant to a license issued by this state or the United States to manufacture, deliver, dispense, possess with intent to manufacture or deliver, or possess a controlled substance, prescription drug, or other drug.

(b) An individual who possesses ephedrine or pseudoephedrine pursuant to a prescription.

(c) A person who possesses ephedrine or pseudoephedrine for retail sale pursuant to a license issued under the general sales tax act, 1933 PA 167, MCL 205.51 to 205.78.

(d) A person who possesses ephedrine or pseudoephedrine in the course of his or her business of selling or transporting ephedrine or pseudoephedrine to a person described in subdivision (a) or (c).

(e) A person who, in the course of his or her business, stores ephedrine or pseudoephedrine for sale or distribution to a person described in subdivision (a), (c), or (d).

(f) Any product that the state board of pharmacy, upon application of a manufacturer, exempts from this section because the product has been formulated in such a way as to effectively prevent the conversion of the active ingredient into methamphetamine.

(g) Possession of any pediatric product primarily intended for administration to children under 12 years of age according to label instructions.

➡333.17766d. Accepting, returning to stock, repackaging, labeling, and redispensing of prescription drugs by pharmacies operated by or under control of department of corrections

Sec. 17766d. (1) Notwithstanding section 17766(f), [FN1] a pharmacy operated by the department of corrections or under contract with the department of corrections or a county jail may accept for the purpose of resale or redispensing a prescription drug that has been dispensed and has left the control of the pharmacist if the prescription drug is being returned by a state correctional facility or a county jail that has a licensed physician's assistant, a registered professional nurse, or a licensed practical nurse, who is responsible for the security, handling, and administration of prescription drugs within that state correctional facility or county jail and if all of the following are met:

(a) The pharmacist is satisfied that the conditions under which the prescription drug has been delivered, stored, and handled before and during its return were such as to prevent damage, deterioration, or contamination that would adversely affect the identity, strength, quality, purity, stability, integrity, or effectiveness of the prescription drug.

(b) The pharmacist is satisfied that the prescription drug did not leave the control of the registered professional nurse or licensed practical nurse responsible for the security, handling, and administration of that prescription drug and that the prescription drug did not come into the physical possession of the individual for whom it was prescribed.

(c) The pharmacist is satisfied that the labeling and packaging of the prescription drug are accurate, have not been altered, defaced, or tampered with, and include the identity, strength, expiration date, and lot number of the prescription drug.

(d) The prescription drug was dispensed in a unit dose package or unit of issue package.

(2) A pharmacy operated by the department of corrections or under contract with the department of corrections or a county jail shall not accept for return prescription drugs as provided under this section until the pharmacist in charge develops a written set of protocols for accepting, returning to stock, repackaging, labeling, and redispensing prescription drugs. The written protocols shall be maintained on the premises and shall be readily accessible to each pharmacist on duty. The written protocols shall include, at a minimum, each of the following:

(a) Methods to ensure that damage, deterioration, or contamination has not occurred during the delivery, handling, storage, and return of the prescription drugs which would adversely affect the identity, strength, quality, purity, stability, integrity, or effectiveness of those prescription drugs or otherwise render those drugs unfit for distribution.

(b) Methods for accepting, returning to stock, repackaging, labeling, and redispensing the prescription drugs returned under this section.

(c) A uniform system of recording and tracking prescription drugs that are returned to stock, repackaged, labeled, and redistributed under this section.

(3) If the integrity of a prescription drug and its package is maintained, a prescription drug returned under this section shall be returned to stock and redistributed as follows:

(a) A prescription drug that was originally dispensed in the manufacturer's unit dose package or unit of issue package and is returned in that same package may be returned to stock, repackaged, and redispensed as needed.

(b) A prescription drug that is repackaged into a unit dose package or a unit of issue package by the pharmacy, dispensed, and returned to that pharmacy in that unit dose package or unit of issue package may be returned to stock, but it shall not be repackaged. A unit dose package or unit of issue package prepared by the pharmacist and returned to stock shall only be redispensed in that same unit dose package or unit of issue package and shall only be redispensed once. A pharmacist shall not add unit dose package drugs to a partially used unit of issue package.

(4) This section does not apply to any of the following:

(a) A controlled substance.

(b) A prescription drug that is dispensed as part of a customized patient medication package.

(c) A prescription drug that is not dispensed as a unit dose package or a unit of issue package.

(d) A prescription drug that is not properly labeled with the identity, strength, lot number, and expiration date.

(e) A prescription drug that is dispensed in a medical institution and returned to stock for redistribution in accordance with R 338.486 of the Michigan administrative code.

(5) As used in this section:

(a) "County jail" means a facility operated by a county for the physical detention and correction of persons charged with, or convicted of, criminal offenses or ordinance violations or persons found guilty of civil or criminal contempt.

(b) "Customized patient medication package" means a package that is prepared by a pharmacist for a specific patient that contains 2 or more prescribed solid oral dosage forms.

(c) "Repackage" means a process by which the pharmacy prepares a unit dose package, unit of issue package, or customized patient medication package for immediate dispensing pursuant to a current prescription.

(d) "State correctional facility" means a facility or institution that houses a prisoner population under the jurisdiction of the department of corrections.

(e) "Unit dose package" means a package that contains a single dose drug with the name, strength, control number, and expiration date of that drug on the label.

(f) "Unit of issue package" means a package that provides multiple doses of the same drug, but each drug is individually separated and includes the name, lot number, and expiration date.

[FN1] M.C.L.A. § 333.17766.

➡333.17766e. Retail sale of products containing ephedrine or pseudoephedrine; security measures; identification and recordkeeping; penalties; report

Sec. 17766e. (1) Except as otherwise provided under this section, a person who possesses ephedrine or pseudoephedrine for retail sale pursuant to a license issued under the general sales tax act, 1933 PA 167, MCL 205.51 to 205.78, shall maintain all products that contain any compound, mixture, or preparation containing any detectable quantity of ephedrine or pseudoephedrine, a salt or optical isomer of ephedrine or pseudoephedrine, or a salt of an optical isomer of ephedrine or pseudoephedrine in accordance with 1 of the following:

(a) Behind a counter where the public is not permitted.

(b) Within a locked case so that a customer wanting access to the product must ask a store employee for assistance.

(2) A person who sells a product described in subsection (1) shall do each of the following:

(a) Require the purchaser of a product described under subsection (1) to produce a valid government-issued photo identification that includes the individual's name and date of birth.

(b) Maintain a log or some type of record detailing the sale of a product described under subsection (1), including the date of the sale and the time of purchase, the name, address, and date of birth of the buyer, the amount and description of the product sold, and a description of the identification used to make the purchase, such as the state in which a driver license used for identification was issued and number of that license. The seller shall also require the purchaser to sign the log at the time of sale. Information entered into the national precursor log exchange (NPLEX) satisfies the requirement to maintain a log or some type of record detailing the sale under this subdivision. The log or other means of recording the sale as required under this subdivision shall be maintained for a minimum of 6 months and made available to only a law enforcement agency upon request. The log or other means of recording the sale is not a public record and is not subject to the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246. A person shall not sell or provide a copy of the log or other means of recording the sale to another for the purpose of surveys, marketing, or solicitations.

(3) This section does not apply to the following:

(a) A pediatric product primarily intended for administration to children under 12 years of age according to label instructions.

(b) A product containing pseudoephedrine that is in a liquid form if pseudoephedrine is not the only active ingredient.

(c) A product that the state board of pharmacy, upon application of a manufacturer or certification by the United States drug enforcement administration as inconvertible, exempts from this section because the product has been formulated in such a way as to effectively prevent the conversion of the active ingredient into methamphetamine.

(d) A product that is dispensed pursuant to a prescription.

(4) A person who violates this section is responsible for a state civil infraction as provided under chapter 88 of the revised judicature act of 1961, 1961 PA 236, MCL 600.8801 to 600.8835, and may be ordered to pay a civil fine of not more than $500.00 for each violation.

(5) By December 15, 2006, the department of state police shall submit a written report to the legislature

regarding the impact and effectiveness of the amendatory act that added this section and section 17766f, [FN1] including, but not limited to, the number of clandestine methamphetamine lab incidents before and after this legislation.

[FN1] M.C.L.A. § 333.17766f.

➡333.17766f. Retail sale of product containing ephedrine or pseudoephedrine; penalties; affirmative defense; rebuttal testimony; enactment of conflicting laws by cities, villages, counties, etc.

Sec. 17766f. (1) A person who possesses products that contain any compound, mixture, or preparation containing any detectable quantity of ephedrine or pseudoephedrine, a salt or optical isomer of ephedrine or pseudoephedrine, or a salt of an optical isomer of ephedrine or pseudoephedrine for retail sale pursuant to a license issued under the general sales tax act, 1933 PA 167, MCL 205.51 to 205.78, shall not knowingly do any of the following:

(a) Sell any product described under this subsection to an individual under 18 years of age.

(b) Sell more than 3.6 grams of ephedrine or pseudoephedrine alone or in a mixture to any individual on any single calendar day.

(c) Sell more than 9 grams of ephedrine or pseudoephedrine alone or in a mixture to any individual within a 30-day period.

(d) Sell in a single over-the-counter sale more than 2 personal convenience packages containing 2 tablets or capsules each of any product described under this subsection to any individual.

(2) This section does not apply to the following:

(a) A pediatric product primarily intended for administration to children under 12 years of age according to label instructions.

(b) A product containing pseudoephedrine that is in a liquid form if pseudoephedrine is not the only active ingredient.

(c) A product that the state board of pharmacy, upon application of a manufacturer or certification by the United States drug enforcement administration as inconvertible, exempts from this section because the product has been formulated in such a way as to effectively prevent the conversion of the active ingredient into methamphetamine.

(d) A product that is dispensed pursuant to a prescription.

(3) A person who violates this section is responsible for a state civil infraction as provided under chapter 88 of the revised judicature act of 1961, 1961 PA 236, MCL 600.8801 to 600.8835, and may be ordered to pay a civil fine of not more than $500.00 for each violation.

(4) It is an affirmative defense to a citation issued pursuant to subsection (1)(a) that the defendant had in force at the time of the citation and continues to have in force a written policy for employees to prevent the sale of products that contain any compound, mixture, or preparation containing any detectable quantity of ephedrine or pseudoephedrine, a salt or optical isomer of ephedrine or pseudoephedrine, or a salt of an optical isomer of ephedrine or pseudoephedrine to persons under 18 years of age and that the defendant enforced and continues to enforce the policy. A defendant who proposes to offer evidence of the affirmative defense described in this subsection shall file and serve notice of the defense, in writing, upon the court and the prosecuting attorney. The notice shall be served not less than 14 days before the hearing date.

(5) A prosecuting attorney who proposes to offer testimony to rebut the affirmative defense described in subsection (4) shall file and serve a notice of rebuttal, in writing, upon the court and the defendant. The notice shall be served not less than 7 days before the hearing date and shall contain the name and address of each rebuttal witness.

(6) Notwithstanding any other provision of law, beginning December 15, 2005, a city, township, village, county, other local unit of government, or political subdivision of this state shall not impose any new requirement or prohibition pertaining to the sale of a product described under subsection (1) that is contrary to, or in any way conflicting with, this section. This subsection does not invalidate or otherwise restrict a requirement or prohibition described in this subsection existing on December 15, 2005.

➡ 333.17767. Rules and determinations necessary or appropriate to licensing

Sec. 17767. The board may promulgate rules and make determinations necessary or appropriate to the licensing of pharmacists, drugs, dispensers, manufacturers, and wholesalers under this part.

➡ 333.17768. Violation; fine, reprimand, or probation; deny, limit, suspend, or revoke license; restitution or community service; additional grounds

Sec. 17768. (1) In a manner consistent with part 161, [FN1] the disciplinary subcommittee may fine, reprimand, or place on probation, a person licensed under this part, or deny, limit, suspend, or revoke a person's license or order restitution or community service for a violation of this part or rules promulgated under this part.

(2) In addition to the grounds set forth in subsection (1), and in a manner consistent with part 161, the board may fine, reprimand, or place on probation a person licensed under this part, or deny, limit, suspend, or revoke a license issued under this part or order restitution or community service if the board finds that any of the following categories apply to an applicant or a partner, officer, or member of the board of directors of a

pharmacy, manufacturer, or wholesale distributor licensed under this part or a stockholder of a pharmacy, manufacturer, or wholesale distributor which is a privately held corporation licensed under this part:

(a) The applicant or other person described in this subsection lacks good moral character.

(b) Subject to subsection (3), the applicant or other person described in this subsection has been convicted of a misdemeanor or a felony under a state or federal law relating to a controlled substance or the practice of pharmacy.

(c) The applicant or other person described in this subsection has furnished false or fraudulent material information or has knowingly omitted material information in an application filed under this part.

(d) The applicant or other person described in this subsection has previously maintained a financial interest in a pharmacy, manufacturer, or wholesale distributor which has been denied a license or federal registration, has had its license or federal registration limited, suspended, or revoked, or been subject to any other criminal, civil, or administrative penalty.

(e) The applicant or other person described in this subsection is not in compliance with article 7 [FN2]or article 8 [FN3] or the rules promulgated under article 7 or article 8.

(3) Except for a conviction for a misdemeanor under section 7404(2)(d) [FN4] or a local ordinance that is substantially similar to section 7404(2)(d), the reference to a misdemeanor in subsection (2)(b) applies only to a conviction for a misdemeanor that is directly related to the manufacture, delivery, possession, possession with intent to manufacture or deliver, use, distribution, prescription, or dispensing of a controlled substance. Subsection (2)(b) does not apply to a conviction for a misdemeanor based upon an unintentional error or omission involving a clerical or record-keeping function.

[FN1] M.C.L.A. § 333.16101 et seq.

[FN2] M.C.L.A. § 333.7101 et seq.

[FN3] M.C.L.A. § 333.8101 et seq.

[FN4] M.C.L.A. § 333.7404.

➡ 333.17770. Exemptions from act

Sec. 17770. Except as to the labeling of poisonous or deleterious drugs and to adulterating, misbranding, and substituting, this part shall not apply:

(a) To the sale of paris green, white hellebore, and other insecticides.

(b) To the sale of any substance for use in the arts.

(c) To the retailing of non-narcotic, or nonprescription medicine or drug which is prepackaged, fully prepared by the manufacturer or producer for use by the consumer, and labeled in accordance with the requirements of the state and federal act.

(d) To the sale by merchants of ammonia, sulphur, any nonpoisonous flavoring essences or extracts, salt, bicarbonate of soda, or other prepackaged common household remedies or any food or food product which may also be found in any of the official compendiums and is not also considered as a poisonous, deleterious, or habit forming drug.

(e) To surgical or dental instruments and accessories, hearing aids, gases, oxygen tents, gas pressure reducing regulators, x-ray apparatus, therapeutic lamps, splints, and stethoscopes, and their component parts and accessories, or to equipment, instruments, apparatus, and contrivances used to render the articles effective in medical, surgical, or dental treatment; or to articles intended for external use.

(f) To articles or substances intended for generally recognized mechanical, agricultural, horticultural, or industrial consumption or use or photographic chemicals for home use.

➡333.17775. Program for utilization of unused prescription drugs; definitions; purpose; participation; criteria for accepting unused or donated prescription drugs; powers and duties of participating pharmacy or charitable clinic; resale; criminal or civil liability; promulgation of rules and standards; donation; conflicts of law

Sec. 17775. (1) This section and section 17776 [FN1] shall be known and may be referred to as the “program for utilization of unused prescription drugs”.

(2) As used in this section and section 17776:

(a) “Board” means the Michigan board of pharmacy created under section 17721. [FN2]

(b) “Cancer drug” means that term as defined in section 17780. [FN3]

(c) “Charitable clinic” means a charitable nonprofit corporation or facility that meets all of the following requirements:

(*i*) Is organized as a not-for-profit corporation pursuant to the nonprofit corporation act, 1982 PA 162, MCL 450.2101 to 450.3192.

(*ii*) Holds a valid exemption from federal income taxation issued undersection 501(a) of the internal revenue code of 1986, 26 USC 501.

(*iii*) Is listed as an exempt organization under section 501(c) of the internal revenue code of 1986, 26 USC 501 .

(*iv*) Is organized under or operated as a part of a health facility or agency licensed under article 17. [FN4]

(*v*) Provides on an outpatient basis for a period of less than 24 consecutive hours to persons not residing or confined at the facility advice, counseling, diagnosis, treatment, surgery, care, or services relating to the preservation or maintenance of health.

(*vi*) Has a licensed pharmacy.

(d) “Eligible facility” means a medical institution as that term is defined in R 338.486 of the Michigan administrative code.

(e) “Eligible participant” means an individual who meets all of the following requirements:

(*i*) Is a resident of this state.

(*ii*) Is eligible to receive medicaid or medicare or has no health insurance and otherwise lacks reasonable means to purchase prescription drugs, as prescribed in rules promulgated under this section.

(f) “Health professional” means any of the following individuals licensed and authorized to prescribe and dispense drugs or to provide medical, dental, or other health-related diagnoses, care, or treatment within the scope of his or her professional license:

(*i*) A physician licensed to practice medicine or osteopathic medicine and surgery under part 170 or 175. [FN5]

(*ii*) A physician's assistant licensed under part 170, 175, or 180. [FN6]

(*iii*) A dentist licensed under part 166. [FN7]

(*iv*) An optometrist licensed under part 174. [FN8]

(*v*) A pharmacist licensed under this part.

(*vi*) A podiatrist licensed under part 180.

(g) “Program” means the statewide unused prescription drug repository and distribution program known as the program for utilization of unused prescription drugs that is established under this section.

(3) The board shall establish, implement, and administer a statewide unused prescription drug repository and distribution program consistent with public health and safety through which unused or donated prescription drugs, other than controlled substances, may be transferred from an eligible facility or manufacturer to a pharmacy or a charitable clinic that elects to participate in the program. The program is created to dispense unused or donated prescription drugs, other than controlled substances, to eligible participants and to provide for the destruction and disposal of prescription drugs or other medications that are ineligible for dispensing under the program.

(4) Participation in the program by an eligible facility, manufacturer, pharmacy, or charitable clinic is voluntary. Nothing in this section or section 17776 requires any eligible facility, manufacturer, pharmacy, or charitable clinic to participate in the program.

(5) Pharmacies, health professionals, and charitable clinics that participate in the program shall use the following criteria in accepting unused or donated prescription drugs from eligible facilities or manufacturers for use in the program:

(a) Only prescription drugs in their original sealed, tamper-evident, and unopened unit dose packaging may be accepted for dispensing. However, prescription drugs packaged in single-unit dose packaging may be accepted for dispensing even if the outside packaging is open as long as the single-unit dose packaging is unopened.

(b) The following shall not be accepted for dispensing:

(*i*) Expired prescription drugs.

(*ii*) Controlled substances as defined in article 7 [FN9]or article 8 [FN10] or by federal law.

(*iii*) Drugs that have been held outside of a health professional's control where sanitation and security cannot be assured.

(*iv*) Drugs that can only be dispensed to a patient registered with the drug's manufacturer under federal food and drug administration requirements.

(c) A prescription drug shall not be accepted for dispensing if the person accepting the drug has reason to believe that the drug is adulterated.

(d) Subject to the limitations prescribed in this subsection, unused or donated prescription drugs dispensed for purposes of a medical assistance program or drug product donation program may be accepted for dispensing under the program.

(e) Any additional criteria established in rules promulgated under this section.

(6) A pharmacy or charitable clinic that meets the eligibility requirements for participation in the program and any rules promulgated under this section may do any of the following:

(a) Dispense prescription drugs accepted under the program to eligible participants.

(b) If established by rule under this section, charge eligible participants who receive prescription drugs under the program a handling fee for the service.

(7) A pharmacy or charitable clinic that participates in the program and accepts prescription drugs for the program shall do all of the following:

(a) Comply with all applicable federal laws and regulations and state laws and rules related to the storage and distribution of harmful drugs.

(b) Inspect all accepted prescription drugs before dispensing the prescription drugs to determine that the drugs are not adulterated.

(c) Dispense prescription drugs only pursuant to a prescription issued by a health professional.

(8) A pharmacy, health professional, or charitable clinic that accepts prescription drugs under the program shall not resell the prescription drugs. Receipt of a fee from an eligible participant, if established in rules promulgated under this section, or reimbursement from a governmental agency to a charitable clinic does not constitute resale of prescription drugs under this subsection.

(9) For purposes of the lawful donation, acceptance, or dispensing of prescription drugs under the program, the following persons that are in compliance with the program, this section and section 17776, and any rules promulgated under this section and in the absence of bad faith or gross negligence are not subject to criminal or civil liability for injury other than death, or loss to person or property, or professional disciplinary action:

(a) The board.

(b) The department.

(c) An eligible facility or manufacturer that donates prescription drugs to the program.

(d) A manufacturer or its representative that directly donates prescription drugs in professional samples to a charitable clinic under the program.

(e) A pharmacy, charitable clinic, or health professional that accepts or dispenses prescription drugs for the program.

(f) A pharmacy or charitable clinic that employs a health professional who accepts prescription drugs for the program and who may legally dispense prescription drugs under this part.

(10) A manufacturer is not, in the absence of bad faith, subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by the manufacturer that is donated by any person under the program, including, but not limited to, liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.

(11) Subject to subsection (12), the department, in consultation with the board, shall promulgate rules under the administrative procedures act of 1969 [FN11] and establish procedures necessary to establish, implement, and administer the program. The board shall provide technical assistance to eligible facilities, manufacturers, pharmacies, and charitable clinics that participate in the program.

(12) The department, in consultation with the board, shall promulgate emergency rules under the administrative procedures act of 1969 on or before September 28, 2013 to establish, implement, and administer the program. The department, in consultation with the board, shall promulgate permanent rules under the administrative procedures act of 1969 as soon as practical after emergency rules have been promulgated under this subsection. The department and the board shall include all of the following in rules promulgated under this section:

(a) Eligibility criteria for pharmacies and charitable clinics authorized to accept and dispense prescription drugs for the program.

(b) Eligibility criteria for eligible participants.

(c) A list of prescription drugs that are not eligible for acceptance and dispensing under the program.

(d) Standards and procedures for transfer, transportation, acceptance, safe storage, security, and dispensing of prescription drugs.

(e) A process for seeking input from the department of human services and the department of community health in establishing provisions that affect eligible facilities.

(f) A process for seeking input from the department of human services and the department of community health in establishing provisions that affect mental health and substance abuse clients.

(g) Standards and procedures for inspecting accepted prescription drugs to ensure that the prescription drugs meet the requirements of the program and to ensure that, in the professional judgment of the pharmacist, the prescription drugs meet all federal and state standards for product integrity.

(h) Procedures for the destruction and environmentally sound disposal of prescription drugs or other medications that are accepted and that are ineligible for dispensing under the program.

(i) Procedures for verifying whether the charitable clinic, pharmacy, pharmacist, or other health professionals participating in the program are licensed and in good standing with the applicable licensing board.

(j) Standards for acceptance of unused or donated prescription drugs from eligible facilities.

(k) Standards for the acceptance by a pharmacy, health professional, or charitable clinic that participates in the program from any person of a prescription drug or any other medication that is ineligible for dispensing under the program for destruction and disposal.

(*l*) Any other standards and procedures the department, in consultation with the board, considers appropriate or necessary to establish, implement, and administer the program.

(13) Pursuant to the rules promulgated and standards and procedures established for the program under this section, a resident of an eligible facility or the representative or guardian of a resident of an eligible facility may donate unused prescription drugs for dispensing to eligible participants under the program.

(14) Pursuant to rules promulgated and standards and procedures established for the program under this section, a person may deliver to a pharmacy, health professional, or charitable clinic that participates in the program a prescription drug or any other medication that is ineligible for dispensing under the program for destruction and disposal.

(15) This section and section 17776 do not impair or supersede the provisions regarding the cancer drug repository program established in section 17780. If any provision of this section or section 17776 conflicts with a provision of section 17780 with regard to a cancer drug, section 17780 controls.

[FN1] M.C.L.A. § 333.17776.

[FN2] M.C.L.A. § 333.17721.

[FN3] M.C.L.A. § 333.17780.

[FN4] M.C.L.A. § 333.20101 et seq.

[FN5] M.C.L.A. § 333.17001 et seq. or 333.17501 et seq.

[FN6] M.C.L.A. § 333.17001 et seq., 333.17501 et seq., or 333.18001 et seq.

[FN7] M.C.L.A. § 33.16601 et seq.

[FN8] M.C.L.A. § 333.17401 et seq.

[FN9] M.C.L.A. § 333.7101 et seq.

[FN10] M.C.L.A. § 333.8101 et seq.

[FN11] M.C.L.A. § 24.201 et seq.

➡333.17776. Program for utilization of unused prescription drugs; accepting medication ineligible for dispensing; destruction and disposal

Sec. 17776. (1) Subject to all applicable federal laws and regulations and state laws and rules, a pharmacy, health professional, or charitable clinic that participates in the program shall accept from any person a prescription drug or any other medication that is ineligible for distribution under the program for destruction and disposal.

(2) A pharmacy, health professional, or charitable clinic that accepts prescription drugs and other medications under subsection (1) that are ineligible for distribution under the program shall destroy and dispose of those drugs and medications subject to rules promulgated under section 17775. [FN1]

[FN1] M.C.L.A. § 333.17775.

➡333.17780. Cancer drug repository program; establishment; participation; donations; dispensing donated drugs and supplies; eligibility to receive drugs and supplies; handling fee; records; liability; definitions

Sec. 17780. (1) The board shall establish and maintain a cancer drug repository program that would allow a person to donate a cancer drug or supply for use by an individual who meets the eligibility criteria specified under subsection (7). The board shall establish program guidelines, policies, and procedures addressing the cancer drug repository program. Under the cancer drug repository program, donations may be made on the premises of a health facility or pharmacy that elects to participate in the program and meets the requirements specified under subsection (2).

(2) Any health facility or pharmacy that is licensed and in compliance with all federal and state laws, rules, and regulations is eligible to participate in the cancer drug repository program. Participation in the cancer drug repository program is voluntary and a pharmacy or health facility may withdraw from participation in the cancer drug repository program at any time upon notification to the board. A notice to withdraw from participation may be given by telephone or regular mail. A pharmacy or health facility may choose to fully participate in the cancer drug repository program by accepting, storing, and dispensing or administering donated drugs and supplies or the pharmacy or health facility may limit its participation to only accepting and storing donated drugs and supplies. If a pharmacy or health facility chooses to limit its participation, the pharmacy or health facility shall distribute any donated drugs to a fully participating cancer drug repository in accordance with subsection (8). A pharmacy or health facility that elects to participate in the cancer drug repository program shall submit the following information to the board in a form provided by the board that includes, at a minimum, each of the following:

(a) The name, street address, and telephone number of the pharmacy or health facility.

(b) The name and telephone number of a pharmacist who is employed by or under contract with the pharmacy or health facility, or other contact person who is familiar with the pharmacy's or health facility's participation in the cancer drug repository program.

(c) A statement indicating that the pharmacy or health facility is licensed in this state and in compliance with all federal and state laws, rules, and regulations and the chosen level of participation in the cancer drug repository program.

(3) An individual who is at least 18 years of age may donate legally obtained cancer drugs or supplies to a cancer drug repository. If the donated drugs have not been previously dispensed, a pharmacy, health facility, manufacturer, or wholesale distributor may also donate cancer drugs or supplies to a cancer drug repository. Donated drugs or supplies are acceptable for donation if they are determined to be eligible by a pharmacist who is employed by or under contract with a cancer drug repository as follows:

(a) A cancer drug is eligible for donation under the cancer drug repository program only if all of the following requirements are met:

(*i*) The donation is accompanied by a cancer drug repository donor form that is provided by the board and states that to the best of the donor's knowledge the donated drug has been properly stored and that the drug has never been opened, used, tampered with, adulterated, or misbranded. The board shall make the cancer drug repository donor form available on the board's website. The form shall be signed by the person making the donation or that person's authorized representative.

(*ii*) The drug's expiration date is at least 6 months later than the date the drug was donated.

(*iii*) The drug is in its original, unopened, tamper-evident unit dose packaging that includes the drug's lot

number and expiration date. Single unit dose drugs may be accepted if the single unit dose packaging is unopened.

(*iv*) The drug is not adulterated or misbranded.

(b) Cancer supplies are eligible for donation under the cancer drug repository program only if all of the following requirements are met:

(*i*) The supplies are not adulterated or misbranded.

(*ii*) The supplies are in their original, unopened, sealed package.

(*iii*) The donation is accompanied by a cancer drug repository donor form that is provided by the board and states that to the best of the donor's knowledge the donated supply has been properly stored and that the supply has never been opened, used, tampered with, adulterated, or misbranded. The board shall make the cancer drug repository donor form available on the board's website. The form shall be signed by the person making the donation or that person's authorized representative.

(4) Controlled substances are not eligible for donation or acceptance under the cancer drug repository program. Cancer drugs and supplies that do not meet the criteria described under subsection (3) are not eligible for donation or acceptance under the cancer drug repository program. Cancer drugs and supplies may be donated on the premises of a cancer drug repository to a pharmacist designated by the repository. A drop box shall not be used to deliver or accept donations. Cancer drugs and supplies donated under the cancer drug repository program shall be stored in a secure storage area under environmental conditions appropriate for the drugs or supplies being stored. Donated drugs and supplies may not be stored with nondonated inventory.

(5) Cancer drugs and supplies that are donated under the cancer drug repository program shall be dispensed by a pharmacist pursuant to a prescription by a prescriber or may be dispensed or administered by a dispensing prescriber. The cancer drugs and supplies shall be visually inspected by the pharmacist or dispensing prescriber before being dispensed or administered for adulteration, misbranding, and date of expiration. Cancer drugs or supplies that have expired or appear upon visual inspection to be adulterated, misbranded, or tampered with in any way may not be dispensed or administered.

(6) Before a cancer drug or supply may be dispensed or administered to an individual, the individual must provide verification that he or she has a current diagnosis of cancer, provide proof of his or her insurance, if any, and sign a cancer drug repository recipient form provided by the board acknowledging that the individual understands the information stated on the form. The form shall be made available to the public on the board's website. The form shall include, at a minimum, the following information:

(a) That the drug or supply being dispensed or administered has been donated and may have been previously

dispensed.

(b) That a visual inspection has been conducted by the pharmacist or dispensing prescriber to ensure that the drug has not expired, has not been adulterated or misbranded, and is in its original, unopened packaging.

(c) That the pharmacist, the dispensing or administering prescriber, the cancer drug repository, the board, and any other participant of the cancer drug repository program cannot guarantee the safety of the drug or supply being dispensed or administered and that the pharmacist or prescriber has determined that the drug or supply is safe to dispense or administer based on the accuracy of the donor's form submitted with the donated drug or supply and the visual inspection required to be performed by the pharmacist or prescriber before dispensing or administering.

(7) Any resident of this state who is diagnosed with cancer is eligible to receive drugs or supplies under the cancer drug repository program. Cancer drugs and supplies donated under the cancer drug repository program shall not be resold and shall only be dispensed or administered to residents of this state who are diagnosed with cancer. A pharmacist who dispenses those drugs and supplies donated under the cancer drug repository program shall not submit a claim or otherwise seek reimbursement from any public or private third party payer for drugs or supplies dispensed to any eligible individual in accordance with the program, nor shall a public or private third party payer be required to provide reimbursement for donated drugs or supplies dispensed by a pharmacist to an eligible individual in accordance with the program. Cancer drugs and supplies dispensed under the cancer drug repository program shall be dispensed in the following order of priority:

(a) Individuals who are uninsured or do not have insurance coverage for those cancer drugs or supplies.

(b) Individuals who are enrolled in medicaid, medicare, or any other public assistance health care program.

(c) All other individuals who are residents of this state and diagnosed with cancer.

(8) A cancer drug repository may charge the individual receiving a drug or supply a handling fee of not more than 250% of the medicaid dispensing fee or $5.00, whichever is less, for each cancer drug or supply dispensed or administered. Cancer drug repositories may distribute drugs and supplies donated under the cancer drug repository program to other repositories if requested by a participating repository. A cancer drug repository that has elected not to dispense donated drugs or supplies shall distribute any donated drugs and supplies to a participating repository upon request of the repository. If a cancer drug repository distributes drugs or supplies to another participating repository, the repository shall complete a cancer drug repository donor form provided by the board. The completed form and copy of the donor form that was completed by the original donor under subsection (3) shall be provided to the fully participating cancer drug repository at the time of distribution.

(9) Cancer drug repository donor and recipient forms shall be maintained for at least 5 years. A record of destruction of donated drugs and supplies that are not dispensed under subsection (7) shall be maintained by

the dispensing repository for at least 5 years. For each drug or supply destroyed, the record shall include the following information:

(a) The date of destruction.

(b) The name, strength, and quantity of the cancer drug destroyed.

(c) The name of the person or firm that destroyed the drug.

(d) The source of the drugs or supplies destroyed.

(10) A manufacturer is not subject to criminal liability or liability in tort or other civil action for injury, death, or loss to a person or to property for any of the following causes of action:

(a) The intentional or unintentional adulteration or misbranding of the drug or supply by a party not under the control of the manufacturer.

(b) The failure of a party not under the control of the manufacturer to transfer or communicate product or consumer information or the expiration date of the donated drug or supply.

(c) Claims for payment to government or private payers.

(11) A health facility or pharmacy participating in the cancer drug repository program, a pharmacist dispensing a drug or supply pursuant to the program, a prescriber dispensing or administering a drug or supply pursuant to the program, or a donor of a cancer drug or supply is immune from civil liability for an act or omission that causes injury to or the death of an individual to whom the cancer drug or supply is dispensed and no disciplinary action shall be taken against a pharmacist or prescriber as long as the drug or supply is donated, accepted, distributed, and dispensed according to the requirements of this section. This immunity does not apply if the act or omission involves reckless, wanton, or intentional misconduct, or malpractice unrelated to the quality of the cancer drug or supply.

(12) As used in this section:

(a) “Cancer drug” means a prescription drug that is used to treat either of the following:

(*i*) Cancer or the side effects of cancer.

(*ii*) The side effects of any prescription drug that is used to treat cancer or the side effects of cancer.

(b) “Cancer drug repository” means a health facility or pharmacy that has notified the board of its election to participate in the cancer drug repository program.

(c) “Cancer supply” or “supplies” means prescription and nonprescription cancer supplies needed to administer a cancer drug.

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

(e) “Donor” means an individual and not a manufacturer or wholesale distributor who donates a cancer drug or supply according to the requirements of the cancer drug repository program.

(f) “Health facility” means a facility licensed in accordance with article 17 [FN1] as a county medical care facility, freestanding surgical outpatient facility, home for the aged, hospital, hospital long-term care unit, nursing home, and hospice.

(g) “Side effects of cancer” means symptoms of cancer.

(h) “Single unit dose packaging” means a single unit container for articles intended for administration as a single dose, direct from the container.

(i) “Tamper-evident unit dose packaging” means a container within which a drug is sealed so that the contents cannot be opened without obvious destruction of the seal.

[FN1] M.C.L.A. § 333.20101 et seq.

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