PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

PART 177
PHARMACY PRACTICE AND DRUG CONTROL

333.17701 Meanings of words and phrases; general definitions and principles of construction.

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

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

History: 1978, Act 368, Eff. Sept. 30, 1978.

Compiler's note: For transfer of powers and duties of certain health-related functions, boards, and commissions from the Department of Licensing and Regulation to the Department of Commerce, see E.R.O. No. 1991-9, compiled at MCL 338.3501 of the Michigan Compiled Laws.

Popular name: Act 368

333.17702 Definitions; 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.

(2) "Automated device" means a mechanical system that performs an operation or activity, other than compounding or administration, relating to the storage, packaging, dispensing, or delivery of a drug and that collects, controls, and maintains transaction information.

(3) "Biological drug product" means a biological product as that term is defined in 42 USC 262.

(4) "Brand name" means the registered trademark name given to a drug product by its manufacturer.

(5) Except as otherwise provided in subsection (6), "compounding" means the preparation, mixing, assembling, packaging, and labeling of a drug or device by a pharmacist under the following circumstances:

(a) Upon the receipt of a prescription for a specific patient.

(b) Upon the receipt of a medical or dental order from a prescriber or agent for use in the treatment of patients within the course of the prescriber's professional practice.

(c) In anticipation of the receipt of a prescription or medical or dental order based on routine, regularly observed prescription or medical or dental order patterns.

(d) For the purpose of or incidental to research, teaching, or chemical analysis and not for the purpose of sale or dispensing.

(6) "Compounding" does not include any of the following:

(a) Except as provided in section 17748c, the compounding of a drug product that is essentially a copy of a commercially available product.

(b) The reconstitution, mixing, or other similar act that is performed pursuant to the directions contained in approved labeling provided by the manufacturer of a commercially available product.

(c) The compounding of allergenic extracts or biologic products.

(7) "Compounding pharmacy" means a pharmacy that is licensed under this part and is authorized to offer compounding services under sections 17748, 17748a, and 17748b.

(8) "Current selling price" means the retail price for a prescription drug that is available for sale from a pharmacy.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1986, Act 304, Eff. Mar. 31, 1987;—Am. 2006, Act 672, Imd. Eff. Jan. 10, 2007;—Am. 2012, Act 209, Imd. Eff. June 27, 2012;—Am. 2014, Act 280, Eff. Sept. 30, 2014;—Am. 2016, Act 528, Eff. Apr. 9, 2017;—Am. 2018, Act 41, Eff. May 29, 2018.

Popular name: Act 368

333.17703 Definitions; D, E.

Sec. 17703. (1) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from 1 person to another.

(2) "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.

(3) "Dispense" means the preparation, compounding, packaging, or labeling of a drug pursuant to any of the following:

(a) A prescription.

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(b) An authorization issued by a prescriber.

(c) Section 17724a or 17744f.

(4) "Dispensing prescriber" means a prescriber, other than a veterinarian, who dispenses prescription drugs.

(5) Except as otherwise provided in section 17780, "distribute" or "distribution" means to sell, offer for sale, deliver, offer to deliver, broker, give away, or transfer a drug, whether by passage of title or physical movement. The term does not include any of the following:

(a) Dispensing or administering a drug.

(b) The delivery of a drug, or offering to deliver a drug, by a common carrier in the usual course of business as a common carrier.

(c) The delivery of a drug via an automated device under section 17760.

(6) "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.

(7) "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.

(8) "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 email transmission that contains the same information it contained when the prescriber or the prescriber's agent transmitted the prescription. Electronically transmitted prescription does not include a prescription or refill authorization transmitted by telephone or facsimile machine.

(9) "Emergency contraceptive" means a drug approved by the FDA to prevent pregnancy as soon as possible following unprotected sexual intercourse or a known or suspected contraceptive failure.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1980, Act 431, Eff. Mar. 31, 1981;—Am. 1992, Act 281, Imd. Eff. Dec. 18, 1992;—Am. 2006, Act 672, Imd. Eff. Jan. 10, 2007;—Am. 2012, Act 209, Imd. Eff. June 27, 2012;—Am. 2014, Act 285, Eff. Dec. 22, 2014;—Am. 2016, Act 528, Eff. Apr. 9, 2017;—Am. 2021, Act 36, Imd. Eff. July 1, 2021;—Am. 2023, Act 97, Imd. Eff. July 19, 2023;—Am. 2024, Act 242, Eff. Apr. 2, 2025.

Popular name: Act 368

333.17704 Definitions; F to I.

Sec. 17704. (1) "Federal act" means the federal food, drug, and cosmetic act, 21 USC 301 to 399i.

(2) "Food and Drug Administration" or "FDA" means the United States Food and Drug Administration.

(3) "Generic name" means the established or official name of a drug or drug product.

(4) "Harmful drug" means a drug intended for use by human beings that 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 that is designated as harmful by a rule promulgated under this part.

(5) "Hormonal contraceptive patch" means a transdermal patch applied to the skin of an individual that releases a drug composed of a combination of hormones that is approved by the FDA to prevent pregnancy.

(6) "Interchangeable biological drug product" means either of the following, as applicable:

(a) A biological drug product that is licensed by the FDA and that the FDA has determined meets the standards for interchangeability under 42 USC 262(k)(4).

(b) Until March 23, 2021, a biological drug product that the FDA has determined to be therapeutically equivalent as set forth in "Approved Drug Products with Therapeutic Equivalence Evaluations", an FDA publication that is commonly referred to as the "Orange Book".

(7) "Internship" means an educational program of professional and practical experience for an intern.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 2014, Act 280, Eff. Sept. 30, 2014;—Am. 2018, Act 41, Eff. May 29, 2018;—Am. 2024, Act 242, Eff. Apr. 2, 2025.

Popular name: Act 368

333.17705 Definitions; 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

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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 means a pharmacy license, drug control license, or a manufacturer, wholesale distributor, or wholesale distributor-broker of drugs or devices license.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1986, Act 304, Eff. Mar. 31, 1987;—Am. 2020, Act 142, Imd. Eff. July 14, 2020.

Popular name: Act 368

333.17706 Definitions; M, O.

Sec. 17706. (1) "Manufacturer" means a person that 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 that 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. Manufacturer does not include a pharmacy unless the pharmacy meets the requirements described in section 17748f.

(2) "Official compendium" means the United States Pharmacopoeia and the National Formulary, or the Homeopathic Pharmacopoeia of the United States, as applicable. If an official compendium is revised after September 30, 2014, the department shall officially take notice of the revision. Within 30 days after taking notice of the revision, the department, in consultation with the board, shall decide whether the revision continues to protect the public health as it relates to the manner that the official compendium is used in this act. If the department, in consultation with the board, decides that the revision continues to protect the public health, the department may issue an order to incorporate the revision by reference. If the department issues an order under this subsection to incorporate the revision by reference, the department shall not make any changes to the revision.

(3) "Outsourcing facility" means that term as defined in 21 USC 353b.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1986, Act 304, Eff. Mar. 31, 1987;—Am. 2014, Act 280, Eff. Sept. 30, 2014;—Am. 2020, Act 142, Imd. Eff. July 14, 2020.

Popular name: Act 368

333.17707 Definitions; P.

Sec. 17707. (1) "Parent pharmacy" means a pharmacy that operates a remote pharmacy through a telepharmacy system.

(2) "Personal charge" means the immediate physical presence of a pharmacist or dispensing prescriber.

(3) "Pharmacist" means an individual who is licensed under this article to engage in the practice of pharmacy.

(4) "Pharmacist in charge" or "PIC" means the pharmacist who is designated by a pharmacy, manufacturer, wholesale distributor, or wholesale distributor-broker as its pharmacist in charge under section 17748(2).

(5) "Pharmacist intern" or "intern" means an individual who satisfactorily completes the requirements set forth in rules promulgated by the department in consultation with 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.

(6) "Pharmacy" means a facility or part of a facility that is licensed under this part to dispense prescription drugs or prepare prescription drugs for delivery or distribution. Pharmacy does not include the office of a dispensing prescriber or an automated device. For the purpose of a duty placed on a pharmacy under this part, "pharmacy" means the person to which the pharmacy license is issued, unless otherwise specifically provided.

(7) "Pharmacy technician" means an individual who is required to hold a health profession subfield license under this part to serve as a pharmacy technician.

(8) "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. Practice of pharmacy includes the direct or indirect provision of professional functions and services associated with the practice of pharmacy. Professional functions associated with the practice of pharmacy include the following:

(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

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possible adverse reactions or interactions of drugs.

(f) Ordering and administering qualified immunizing agents in accordance with section 17724.

(g) Ordering and administering qualified laboratory tests in accordance with section 17724a.

(h) Issuing prescriptions for hormonal contraceptive patches, self-administered hormonal contraceptives, emergency contraceptives, and vaginal ring hormonal contraceptives in accordance with section 17744g.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1990, Act 333, Eff. Mar. 28, 1991;—Am. 2014, Act 280, Eff. Sept. 30, 2014;—Am. 2014, Act 285, Eff. Dec. 22, 2014;—Am. 2016, Act 528, Eff. Apr. 9, 2017;—Am. 2020, Act 4, Eff. Apr. 26, 2020;—Am. 2020, Act 142, Imd. Eff. July 14, 2020;—Am. 2023, Act 97, Imd. Eff. July 19, 2023;—Am. 2024, Act 242, Eff. Apr. 2, 2025.

Popular name: Act 368

333.17708 Definitions; P to R; limitation on prescription of pharmacological agents.

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 physician's assistant; subject to part 174, a licensed optometrist; subject to section 17211a, an advanced practice registered nurse; a licensed veterinarian; subject to subsection (7), a registered professional nurse who holds a specialty certification as a nurse anesthetist under section 17210 when engaging in the practice of nursing and providing the anesthesia and analgesia services described in section 17210(3); or any other 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. As used in this subsection:

(a) "Advanced practice registered nurse" means that term as defined in section 17201 and includes a licensed advanced practice registered nurse.

(b) "License" means that term as defined in section 16106 and includes an authorization issued under the laws of another state or province of Canada to practice a profession described in this subsection in that state or province of Canada where practice would otherwise be unlawful.

(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 must be electronically recorded, printed, or written and immediately dated by the pharmacist, and that record is considered the original prescription. In a health facility or agency licensed under article 17 or other medical institution, an order for a drug or device in the patient's chart is considered for the purposes of this definition the original prescription. For purposes of this part, prescription also includes a standing order issued under section 17744e and an order to dispense a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive, or a vaginal ring hormonal contraceptive issued by a pharmacist under section 17744g. Subject to section 17751(2) and (5), prescription includes, but is not limited to, an order for a drug, not including a controlled substance except under circumstances described in section 17763(e), 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 prescriber in another state or province of Canada.

(4) Subject to subsection (5), "prescription drug" means a drug to which 1 or more of the following apply:

(a) The drug is dispensed pursuant to a prescription.

(b) The drug bears the federal legend "CAUTION: federal law prohibits dispensing without prescription" or "Rx only".

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

(5) For purposes of this part, prescription drug also includes a drug dispensed pursuant to section 17724a or 17744f.

(6) "Remote pharmacy" means a pharmacy described in sections 17742a and 17742b.

(7) The authority of a registered professional nurse who holds a specialty certification as a nurse anesthetist under section 17210 to prescribe pharmacological agents is limited to pharmacological agents for administration to patients as described in section 17210(3)(b), (c), or (d). Subsection (2) does not require new or additional third party reimbursement or mandated worker's compensation benefits for anesthesia and analgesia services provided under section 17210(3) by a registered professional nurse who holds a specialty certification as a nurse anesthetist under section 17210.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1994, Act 384, Eff. Mar 30, 1995;—Am. 1997, Act 153, Eff. Mar. 31, 1998;—Am. 2005, Act 85, Imd. Eff. July 19, 2005;—Am. 2006, Act 672, Imd. Eff. Jan. 10, 2007;—Am. 2009, Act 150, Imd. Eff. Nov. 19, 2009;—Am. 2011, Act 155, Imd. Eff. Sept. 27, 2011;—Am. 2012, Act 209, Imd. Eff. June 27, 2012;—Am. 2016, Act 49, Eff. June 13, 2016;

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—Am. 2016, Act 379, Eff. Mar. 22, 2017;—Am. 2016, Act 383, Eff. Mar. 28, 2017;—Am. 2016, Act 499, Eff. Apr. 9, 2017;—Am. 2020, Act 4, Eff. Apr. 26, 2020;—Am. 2021, Act 36, Imd. Eff. July 1, 2021;—Am. 2021, Act 53, Eff. Oct. 11, 2021;—Am. 2022, Act 80, Eff. Mar. 29, 2023;—Am. 2023, Act 97, Imd. Eff. July 19, 2023;—Am. 2024, Act 242, Eff. Apr. 2, 2025.

Compiler's note: Enacting section 1 of Act 49 of 2016 provides:

"Enacting section 1. Section 16349 of the public health code, 1978 PA 368, MCL 333.16349, as amended by this amendatory act, applies to licensing fees required to be paid after December 31, 2018."

Popular name: Act 368

333.17709 Definitions; S to W.

Sec. 17709. (1) "Self-administered hormonal contraceptive" means a drug composed of a single hormone or combination of hormones that is approved by the FDA to prevent pregnancy and that the individual to whom the drug is prescribed may take orally, inject, or otherwise self-administer.

(2) "Sign" means to affix one's signature manually to a document or to use an electronic signature when transmitting a prescription electronically.

(3) "Sterile pharmaceutical" means a dosage form of a drug that is essentially free from living microbes and chemical or physical contamination to the point at which it poses no present risk to the patient, in accordance with USP standards. As used in this subsection, "dosage form" includes, but is not limited to, parenteral, injectable, and ophthalmic dosage forms.

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

(5) "Surveillance system" means a real-time, continuous audio and visual camera system that connects a pharmacist at a parent pharmacy with a remote pharmacy for the purposes of providing oversight and security surveillance.

(6) "Telepharmacy system" means an interoperable computer system that meets all of the following requirements:

(a) Shares real-time data and uses a real-time audio and video link to connect a pharmacist at a parent pharmacy with a remote pharmacy operated by the parent pharmacy.

(b) Uses a camera that is of sufficient quality and resolution to allow a pharmacist at a parent pharmacy who is reviewing a prescription to visually identify the markings on tablets and capsules at the remote pharmacy.

(7) "USP standards" means the pharmacopeial standards for drug substances, dosage forms, and compounded preparations based on designated levels of risk as published in the official compendium.

(8) "Wholesale distributor" means a person, other than a manufacturer or wholesale distributor-broker, that 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 of the drug or device. A wholesale distributor does not include a pharmacy unless the pharmacy meets the requirements of section 17748f.

(9) "Wholesale distributor-broker" means a person that meets both of the following:

(a) The person facilitates the delivery or trade of a drug or device salable on prescription only, other than a controlled substance, between pharmacies, or between a pharmacy and a qualified pharmacy as that term is defined in section 17748e, for the purpose of filling a prescription for an identified patient.

(b) The person does not take possession or ownership of a drug or device salable on prescription only or coordinate warehousing of the drug or device.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 2006, Act 672, Imd. Eff. Jan. 10, 2007;—Am. 2014, Act 280, Eff. Sept. 30, 2014;—Am. 2020, Act 4, Eff. Apr. 26, 2020;—Am. 2020, Act 142, Imd. Eff. July 14, 2020;—Am. 2024, Act 242, Eff. Apr. 2, 2025.

Popular name: Act 368

333.17711 Practice of pharmacy or pharmacy technician; license or authorization required; use of words, titles, or letters.

Sec. 17711. (1) An individual shall not engage in the practice of pharmacy unless licensed or otherwise authorized by this article. Beginning October 1, 2015, an individual shall not serve as a pharmacy technician unless licensed or otherwise authorized by this article.

(2) The following words, titles, or letters or a combination of words, titles, or letters, 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", "Pharm.D", "doctor of pharmacy", "pharmacy intern", "pharmacy technician", "licensed pharmacy technician", "certified pharmacy technician", "CPhT", "apothecary", "dispensary", "drugstore", "druggist", "medicine store", "prescriptions", and "r.ph.".

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History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 2006, Act 390, Imd. Eff. Sept. 27, 2006;—Am. 2014, Act 285, Eff. Dec. 22, 2014 ;—Am. 2014, Act 413, Eff. Mar. 30, 2015;—Am. 2015, Act 91, Imd. Eff. June 25, 2015.

Popular name: Act 368

333.17713 Temporary regulations of pharmacists and prescriptions during qualified order or declaration; definitions.

Sec. 17713. (1) Notwithstanding any provision of this article or rule promulgated under this article to the contrary, beginning on December 29, 2020, all of the following apply while a qualified order or declaration is in effect:

(a) A pharmacist may temporarily operate a pharmacy in a location that is not designated on a pharmacy license. However, the pharmacy described in this subdivision may not prepare a sterile drug product beyond a low-risk preparation, as defined by USP standards, for immediate inpatient administration.

(b) A pharmacist may substitute a therapeutically equivalent drug for a drug that is the subject of a critical shortage. A pharmacist substituting a drug under this subdivision shall inform the patient of the substitution and notify the prescriber of the substitution within a reasonable period of time. A prescriber is not subject to criminal prosecution, civil liability, or administrative sanction as a result of a pharmacist's substitution under this subdivision.

(c) A preceptor may supervise a student pharmacist remotely to fulfill eligibility requirements for licensure and to avoid a delay in graduation.

(d) A pharmacist may oversee a pharmacy technician and other pharmacy staff remotely through the use of a real-time, continuous audiovisual camera system that is capable of allowing the pharmacist to visually identify the markings on tablets and capsules. The pharmacist must have access to all relevant patient information to accomplish remote oversight and must be available at all times during the oversight to provide real-time patient consultation. A pharmacy technician shall not perform sterile or nonsterile compounding without a pharmacist on the premises.

(e) An out-of-state pharmacy that is in good standing is considered licensed to do business in this state. An out-of-state pharmacy shall not deliver a controlled substance into this state, except that, notwithstanding article 7 or any rule promulgated under that article, an out-of-state pharmacy may deliver a controlled substance that is compounded for a drug shortage, as determined by the FDA. An out-of-state pharmacy shall comply with this part and the rules promulgated by this part, except that an out-of-state pharmacy is not required to designate a pharmacist in charge for the out-of-state pharmacy. To provide sterile compounding services to a patient in this state, an out-of-state pharmacy shall hold a current accreditation from a national organization approved by the board.

(f) A manufacturer or wholesale distributor that is licensed in another state is considered to be licensed to do business in this state. Notwithstanding article 7 or any rule promogulated under that article, a manufacturer or wholesale distributor that holds a license in good standing in another state may temporarily distribute a controlled substance in this state to a hospital or to a manufacturer or wholesale distributor that is licensed under this part. An out-of-state license described in this subdivision is not considered to be in good standing for purposes of this subdivision if it has been suspended or revoked or is the subject of pending disciplinary action in another state. If an out-of-state license described in this subdivision contains restrictions or conditions, those restrictions or conditions apply in this state for purposes of this subdivision.

(g) A pharmacy may confirm the delivery of a prescription drug, excluding a controlled substance, to a patient by any reasonable means, including, but not limited to, a telephone call, a text message, or email.

(2) As used in this section:

(a) "Out-of-state pharmacy" means a facility or part of a facility that is located outside of this state and that is licensed in another state to dispense prescription drugs or prepare prescription drugs for delivery or distribution.

(b) "Qualified epidemic" means an epidemic involving a respiratory disease that can easily spread between individuals and may result in serious illness or death.

(c) "Qualified order or declaration" means 1 of the following issued in response to a qualified epidemic:

(*i*) An emergency order under section 2253.

(*ii*) A state of disaster or state of emergency declared under the emergency management act, 1976 PA 390, MCL 30.401 to 30.421.

History: Add. 2020, Act 324, Imd. Eff. Dec. 29, 2020;—Am. 2023, Act 97, Imd. Eff. July 19, 2023.

Popular name: Act 368

333.17721 Michigan board of pharmacy; creation; membership; terms.

Sec. 17721. (1) The Michigan board of pharmacy is created in the department and consists of the following

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11 voting members who meet the requirements of part 161:

(a) Six pharmacists.

(b) One pharmacy technician.

(c) Four 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.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1993, Act 79, Eff. Apr. 1, 1994;—Am. 2006, Act 390, Imd. Eff. Sept. 27, 2006;—Am. 2014, Act 285, Eff. Dec. 22, 2014.

Popular name: Act 368

333.17722 Michigan board of pharmacy; duties generally.

Sec. 17722. In addition to the functions set forth in part 161, except as otherwise provided in this part, the board shall do the following:

(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, wholesale distributor, or wholesale distributor-broker that meets the requirements for the license.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 2020, Act 4, Eff. Apr. 26, 2020;—Am. 2020, Act 142, Imd. Eff. July 14, 2020.

Popular name: Act 368

Administrative rules: R 338.3971 et seq. of the Michigan Administrative Code.

333.17723 Pilot project to maintain or improve patient care in delivery of pharmacy services and improving patient outcomes.

Sec. 17723. (1) Subject to this section, the board may approve a pilot project that is designed to utilize new or expanded technology or processes and to provide patients with better pharmacy products or provide pharmacy services in a more efficient manner. The board shall ensure that a pilot project it approves under this section is focused on maintaining or improving patient care in the delivery of pharmacy services and improving patient outcomes. The department may charge petitioners a filing fee sufficient to cover the department's costs incurred while administering and monitoring the pilot project under this section.

(2) The department shall do all of the following:

(a) Establish and administer a process to receive, review, and accept or deny petitions for proposed pilot projects.

(b) Establish time frames for the receipt, review, and approval or denial of petitions for proposed pilot projects.

(c) Designate the individuals who will review and evaluate petitions for proposed pilot projects.

(3) The board shall not approve more than 10 pilot projects under this section. If it determines necessary, the board or department may further limit the number of approved pilot projects based on the scope and type of petitions for proposed pilot projects received.

(4) The board shall not approve a pilot project that does any of the following:

(a) Expands the definition of the practice of pharmacy.

(b) Provides for the therapeutic substitution or substitution of medical devices used in patient care.

(c) Allows a pharmacy or pharmacist to be involved with a pilot project if the pharmacy's or pharmacist's license is not current or is under investigation for or subject to a sanction for a violation of this act.

(5) The department, in consultation with the board, may grant to a petitioner conducting an approved pilot project under this section an exception to a rule promulgated under this part. The department shall not grant an exception under this subsection from any law relating to the practice of pharmacy. The department shall grant an exception under this subsection for a specified period of time, which period must not exceed 18 months unless extended under subsection (12).

(6) A petitioner who wishes the board to consider a pilot project for approval under this section shall

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submit to the department a petition that contains all of the following information:

(a) The name, address, telephone number, electronic mail address, and Michigan license number of the pharmacist responsible for overseeing the proposed pilot project.

(b) The specific location where the proposed pilot project will be conducted. The petitioner shall include the Michigan license number of the pharmacy and a statement that the Michigan license of the pharmacy and any pharmacist involved with the pilot project is current, is not under investigation for or subject to a sanction for a violation of this act, and will remain in good standing for the duration of the pilot project.

(c) A detailed summary of the proposed pilot project that includes all of the following:

(*i*) The goals, hypothesis, and objectives, as applicable, of the proposed pilot project.

(*ii*) A full explanation of the proposed pilot project and how the project will be conducted.

(*iii*) The initial time frame for the pilot project, including the proposed start date and length of the project, which initial time frame must not exceed 18 months.

(*iv*) All background information and literature review, as applicable, to support the proposed pilot project.

(*v*) If applicable, identification of the rules promulgated under this part from which the petitioner is requesting an exception as provided in subsection (5) in order to complete the proposed pilot project and a request for that exception.

(*vi*) If applicable, procedures the petitioner will use during the proposed pilot project to ensure that the public's health and safety are not compromised as a result of an exception to a rule being granted under subsection (5).

(*vii*) The procedures the petitioner will use to protect the identity and privacy of patients in accordance with existing federal and state law and consistent with regulations promulgated under the health insurance portability and accountability act of 1996, Public Law 104-191.

(7) Upon approval of a petition for a pilot project, the department shall specify a time period for the operation of that pilot project, which period must not exceed 18 months unless extended under subsection (11). The department, in consultation with the board, may include appropriate conditions or qualifications on the approval of a pilot project. The department or board may suspend the operation of a pilot project if it determines that the petitioner or any person involved with the pilot project has deviated the operation of the pilot project from the plan of operation that was approved.

(8) If determined appropriate for the pilot project approved under this section, the board or department may require the petitioner to notify patients that pharmacy services are being provided as part of a pilot project. If required under this subsection, the petitioner shall notify patients in the manner required by the board or department.

(9) The petitioner shall allow the department to inspect and review pilot project documentation and the pilot project site at any time during the review process and after the pilot project is approved. The pharmacist responsible for overseeing an approved pilot project shall forward all of the following to the department:

(a) Progress reports at intervals specified by the department.

(b) A summary of the results of the project and conclusions drawn from the results of the project within 3 months after completion of the pilot project.

(10) The individuals designated to review and evaluate petitions under subsection (2)(c) shall review the progress reports and the summary of the results of the pilot project submitted under subsection (9). Within 90 days after receipt of the summary of the results of the pilot project under subsection (9), the individuals designated to review and evaluate petitions under subsection (2)(c) shall submit a written report to the department regarding the results of the pilot project. The department shall provide a copy of the written report submitted under this subsection to the board. The individuals designated to review and evaluate petitions under subsection (2)(c) shall submit a copy of the written report to the petitioner at least 2 weeks before the board meeting at which the report will be considered by the board. Upon the request of the petitioner, the board shall allow the petitioner to make a presentation to the board.

(11) If determined appropriate by the board at the meeting at which the written report is considered under subsection (10), and if approved by the department, the specified period of time for conducting a pilot project under subsection (7) may be extended for an additional period of up to 18 months. The board or department shall not grant an extension that would result in a specified period of time for conducting a pilot project under this section to exceed 36 months.

(12) If the department, in consultation with the board, determines that a pilot project for which an exception to a rule has been granted under subsection (5) should be extended so that rules may be promulgated in order to allow the pilot project to be conducted on a permanent basis, the department may extend the exception to the rule for an additional period of up to 18 months.

History: Add. 2013, Act 267, Eff. Mar. 30, 2014.

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Popular name: Act 368

333.17724 Ordering and administration of qualified immunizing agent by pharmacist; requirements and duties; promulgation of rules; exception emergency order; definitions.

Sec. 17724. (1) Subject to this section, a pharmacist may, without acting under the direction of a physician, order and administer a qualified immunizing agent to an individual who is 3 years of age or older.

(2) Before ordering or administering a qualified immunizing agent under this section, a pharmacist shall comply with all of the following:

(a) Successfully complete a training program approved under subsection (4).

(b) If the pharmacist is ordering a qualified immunizing agent for or administering a qualified immunizing agent to an individual who is less than 19 years of age and the pharmacy does not participate in the Vaccines for Children Program administered by the Centers for Disease Control and Prevention, inform the individual that the individual may qualify for the Vaccines for Children Program and notify the individual of local providers that participate in the program. This subdivision does not apply if a public or private third-party payer provides coverage for the cost of ordering or administering the qualified immunizing agent to the individual.

(3) A pharmacist who administers a qualified immunizing agent under this section shall do all of the following:

(a) Comply with rules promulgated under this section in addition to any other requirement established by law.

(b) If the qualified immunizing agent is administered to an individual who is 20 years of age or older, report the administration of the qualified immunizing agent to the Michigan care improvement registry within 72 hours after administering the qualified immunizing agent in the same manner as required under section 9206 for a health care provider who is administering an immunizing agent to a child.

(4) The department, in consultation with the board, shall promulgate rules to implement this section. The rules must require the training program required under this section to include a course on the administration of vaccines that is provided by an entity accredited by the Accreditation Council for Pharmacy Education.

(5) This section does not prohibit a pharmacist from ordering or administering an immunizing agent pursuant to federal law or an emergency order.

(6) As used in this section:

(a) "Immunizing agent" means that term as defined in section 9201.

(b) "Michigan care improvement registry" means the Michigan care improvement registry established under section 9207.

(c) "Qualified immunizing agent" means an immunizing agent that meets all of the following requirements:

(*i*) Is a vaccine that is recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention.

(*ii*) Is a vaccine that is approved or authorized for use by the Food and Drug Administration or has been authorized for emergency use by the Food and Drug Administration.

History: Add. 2023, Act 97, Imd. Eff. July 19, 2023.

Popular name: Act 368

333.17724a Ordering and administration of qualified laboratory tests by pharmacist; requirements and duties; promulgation of rules; exceptions; "qualified laboratory test" defined.

Sec. 17724a. (1) Subject to this section, a pharmacist may order a qualified laboratory test for and administer the qualified laboratory test to an individual if the qualified laboratory test meets all of the following requirements:

(a) The qualified laboratory test is classified as waived by the Food and Drug Administration.

(b) The qualified laboratory test requires only the use of a specimen collected by a nasal or throat swab or a finger prick.

(c) The qualified laboratory test is used to detect or screen for any of the following:

(*i*) COVID-19.

(*ii*) Influenza.

(*iii*) A respiratory infection.

(2) Before ordering or administering a qualified laboratory test under this section, a pharmacist shall successfully complete the training program approved under subsection (5).

(3) A pharmacist who orders a qualified laboratory test for or administers a qualified laboratory test to an individual under this section shall advise the individual of the test result and refer the individual to a

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physician, or another health professional, designated by the individual.

(4) A pharmacist who orders a qualified laboratory test for and administers that qualified laboratory test to an individual under this section for purposes of detecting or screening for COVID-19 or influenza may, without a prescription, dispense a drug to the individual if all of the following are met:

(a) The pharmacist determines that the drug is needed to treat the individual for COVID-19 or influenza based on the individual's test result.

(b) The drug is an antiviral drug and is available at the pharmacy.

(c) The drug is provided pursuant to protocols established by the Centers for Disease Control and Prevention or public health guidelines established by the department of health and human services.

(d) The pharmacist complies with subsection (3) and any other requirement established by rule under this section.

(5) The department, in consultation with the board, shall promulgate rules to implement this section. The rules must require the training program required under this section to require a pharmacist to demonstrate sufficient knowledge of how to administer and interpret each laboratory test that the pharmacist may order or administer under this section and to demonstrate sufficient knowledge of each illness, condition, or disease described in subsection (1) for which the pharmacist provides treatment based on the results of a qualified laboratory test.

(6) This section does not prohibit a pharmacist from doing any of the following:

(a) Ordering or administering a laboratory test as a delegated act of a physician or another health professional under section 16215.

(b) Ordering or administering a laboratory test pursuant to federal law or an emergency order.

(c) Dispensing a drug to a patient without a prescription pursuant to federal law or an emergency order.

(7) As used in this section, "qualified laboratory test" means a laboratory test meeting the requirements described in subsection (1).

History: Add. 2023, Act 97, Imd. Eff. July 19, 2023.

Popular name: Act 368

333.17726 Certificate of licensure; issuance.

Sec. 17726. The department shall issue a certificate of licensure to an applicant who is granted a license under this part.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 2020, Act 4, Eff. Apr. 26, 2020.

Popular name: Act 368

333.17731 Renewal of pharmacist or pharmacy technician license; continuing education; rules.

Sec. 17731. (1) Notwithstanding the requirements of part 161, the board may require either of the following:

(a) That a licensee seeking renewal of a pharmacist's license furnish the department with satisfactory evidence that during the 2 years immediately preceding application for renewal, he or she attended continuing education courses or programs, approved by the board, totaling not less than 30 hours or satisfactorily completed a proficiency examination according to rules promulgated by the department in consultation with the board.

(b) That a licensee seeking renewal of a pharmacy technician's license furnish the department with satisfactory evidence that during the 2 years immediately preceding application for renewal, he or she has attended at least 20 hours of continuing education courses or programs, approved by the board, or satisfactorily completed a proficiency examination according to rules promulgated by the department in consultation with the board.

(2) The department in consultation with 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.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1986, Act 290, Imd. Eff. Dec. 22, 1986;—Am. 1994, Act 234, Imd. Eff. June 30, 1994;—Am. 2014, Act 285, Eff. Dec. 22, 2014.

Popular name: Act 368

Administrative rules: R 338.3041 et seq. of the Michigan Administrative Code.

333.17733 Relicensure of pharmacist; requirements.

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

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pharmacy experience of at least 200 hours, as determined by the board.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1981, Act 215, Imd. Eff. Jan. 5, 1982;—Am. 1988, Act 462, Eff. Sept. 1, 1989.

Popular name: Act 368

333.17737 Rules establishing standards for internship program; limited license required.

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.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.17739 Pharmacy technician; functions; licensure.

Sec. 17739. (1) An individual who performs any of the following functions is considered to be serving as a pharmacy technician and, except as otherwise provided in this part, is required to be licensed under this part as a pharmacy technician:

(a) Assisting in the dispensing process.

(b) Handling transfer of prescriptions, except controlled substances prescriptions.

(c) Compounding drugs.

(d) Preparing or mixing intravenous drugs for injection into a human patient.

(e) Contacting prescribers concerning prescription drug order clarification, which does not include drug regimen review or clinical or therapeutic interpretation.

(f) Receiving verbal orders for prescription drugs, except orders for controlled substances.

(g) Subject to section 16215, performing any other functions authorized under rules promulgated by the department in consultation with the board.

(2) A pharmacy or dispensing prescriber that utilizes the services of a pharmacy technician shall ensure that all of the following requirements, as applicable, are met:

(a) The pharmacy technician is licensed or otherwise authorized to serve as a pharmacy technician under this part.

(b) The pharmacy technician only performs the activities or functions that he or she is licensed or otherwise authorized to perform under this part or rules promulgated under this part.

(c) Except for a remote pharmacy or as otherwise provided by rule promulgated by the department in consultation with the board, the pharmacy technician only performs the activities or functions described in subdivision (b) under the supervision and personal charge of the pharmacist or dispensing prescriber.

History: Add. 2014, Act 285, Eff. Dec. 22, 2014;—Am. 2020, Act 4, Eff. Apr. 26, 2020.

Popular name: Act 368

333.17739a Pharmacy technician; licensure; requirements; exemption from certain requirements.

Sec. 17739a. (1) Subject to subsection (2), the department may license an individual who meets all of the following requirements as a pharmacy technician under this part:

(a) Submits a completed application to the department on a form prescribed by the department.

(b) Except as otherwise provided in subsection (4), graduated from an accredited high school or comparable school or educational institution or passed the general educational development test or other graduate equivalency examination.

(c) Satisfies the requirements of section 16174.

(d) Except as otherwise provided in subsection (4), passes and submits proof to the department of passage of any of the following:

(*i*) The certified pharmacy technician examination given by the Pharmacy Technician Certification Board.

(*ii*) The certified pharmacy technician examination given by the National Healthcareer Association.

(*iii*) Any other nationally recognized and administered certification examination approved by the board.

(*iv*) An employer-based training program examination that is approved by the board and covers job descriptions, pharmacy security, commonly used medical abbreviations, routes of administration, product selection, final check by pharmacists, guidelines for the use of pharmacy technicians, pharmacy terminology, basic drug information, basic calculations, quality control procedures, state and federal laws and regulations regarding pharmacy technician duties, pharmacist duties, pharmacy intern duties, prescription or drug order processing procedures, drug record-keeping requirements, patient confidentiality, and pharmacy security and drug storage.

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(2) An individual who is not a pharmacist, pharmacist intern, or pharmacy technician shall not perform any of the functions described in section 17739(1) for a pharmacy.

(3) A pharmacist shall not allow any individual employed or otherwise under the personal charge of the pharmacist to violate subsection (2). A person that owns, manages, operates, or conducts a pharmacy shall not allow any individual employed or otherwise under the control of that person to violate subsection (2).

(4) An individual who meets any of the following is not required to meet the requirements of subsection (1)(b) and (d) to be eligible for a license under subsection (1):

(a) As provided in section 16171(a), is a student in a pharmacy technician program approved by the board.

(b) Is applying for a temporary license under section 17739b.

(c) Is applying for a limited license under section 17739c.

History: Add. 2014, Act 285, Eff. Dec. 22, 2014;—Am. 2015, Act 133, Imd. Eff. Sept. 30, 2015.

Popular name: Act 368

333.17739b Pharmacy technician; temporary license.

Sec. 17739b. (1) Subject to section 17739a(4), the department may issue a temporary license as a pharmacy technician to an individual who is preparing for the examination under section 17739a(1)(d). Notwithstanding section 16181, the term of a temporary license issued under this section expires 1 year after the date the temporary license is issued.

(2) An individual requesting a temporary license under this section shall submit a completed application, on a form prescribed by the department, to the department and pay the applicable fee under section 16333.

(3) An individual who holds a temporary license as a pharmacy technician issued under subsection (1) is subject to all of the requirements of this part, and rules promulgated by the department in consultation with the board, applicable to pharmacy technicians except the examination requirement under section 17739a(1)(d).

History: Add. 2014, Act 285, Eff. Dec. 22, 2014;—Am. 2015, Act 133, Imd. Eff. Sept. 30, 2015.

Popular name: Act 368

333.17739c Pharmacy technician; limited license.

Sec. 17739c. (1) In addition to the requirement of section 16182 and subject to section 17739a(4), the department may issue a limited license as a pharmacy technician to an individual if all of the following are met:

(a) The individual was employed as a pharmacy technician by a pharmacy on December 22, 2014 and has been continuously employed by that pharmacy since that date.

(b) The individual submits a completed application to the department on a form prescribed by the department and meets the requirements of section 16174.

(c) The individual provides documentation of satisfactory employment as a pharmacy technician for a minimum of 1,000 hours during the 2-year period immediately preceding the date of his or her application under subdivision (b).

(d) The applicable fee under section 16333 is paid.

(2) Except as otherwise provided in subsection (5), an individual who holds a limited license under this section may only act as a pharmacy technician for the pharmacy described in subsection (1)(a) and only until 1 of the following occurs:

(a) He or she is no longer employed by that pharmacy to perform those functions.

(b) He or she performs any of those functions for another pharmacy.

(3) The term of a limited pharmacy technician license issued by the department under this section is the same as a pharmacy technician license issued by the department under section 17739a.

(4) An individual who holds a limited pharmacy technician license issued under this section is subject to all of the requirements of this part, and the rules promulgated by the department in consultation with the board, except the examination requirement under section 17739a(1)(d).

(5) An individual who is employed as a pharmacy technician by an employer that operates multiple licensed pharmacy locations may work as a limited license pharmacy technician at any of the employer's licensed pharmacy locations in this state.

History: Add. 2014, Act 285, Eff. Dec. 22, 2014;—Am. 2015, Act 133, Imd. Eff. Sept. 30, 2015.

Popular name: Act 368

333.17741 Pharmacy license required; personal charge of pharmacy by pharmacist; responsibility for compliance with laws; control and personal charge of pharmacy

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services; remote pharmacy exception; effect of violation on pharmacy license.

Sec. 17741. (1) A pharmacy must not be operated unless licensed under this part.

(2) Except for a remote pharmacy, a pharmacy open for business must be under the personal charge of a pharmacist. A pharmacist shall not simultaneously have personal charge of more than 1 pharmacy.

(3) 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. Except for a remote pharmacy, pharmacy services must be conducted under the control and personal charge of a pharmacist.

(4) A sanction for a violation of this part only affects the pharmacy license of the place of business where the violation occurred.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 2020, Act 4, Eff. Apr. 26, 2020.

Popular name: Act 368

333.17742 Disclosure; "applicant" defined.

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

(2) As used in this section and sections 17742a, 17748, 17748a, 17748e, and 17768, "applicant" means a person applying for a pharmacy, manufacturer's, wholesale distributor's, or wholesale distributor-broker'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.

History: Add. 1987, Act 250, Imd. Eff. Dec. 28, 1987;—Am. 2014, Act 280, Eff. Sept. 30, 2014;—Am. 2020, Act 4, Eff. Apr. 26, 2020;—Am. 2020, Act 142, Imd. Eff. July 14, 2020.

Popular name: Act 368

333.17742a Remote pharmacy; operation; licensure requirements; location waiver; exception.

Sec. 17742a. (1) A parent pharmacy shall not operate a remote pharmacy in this state unless the parent pharmacy and the remote pharmacy are each located in this state and licensed as a pharmacy under this part.

(2) The department shall grant a pharmacy license to an applicant seeking to operate a remote pharmacy if the applicant meets all of the following:

(a) Submits a completed application and pays the applicable fee under section 16333.

(b) Demonstrates to the satisfaction of the department that the parent pharmacy and the proposed remote pharmacy share common ownership.

(c) Subject to subsection (3), demonstrates to the satisfaction of the department that, at the time of the application, the location of the proposed remote pharmacy is not within 10 miles of another pharmacy. This subdivision does not apply if the remote pharmacy is located at a hospital or mental health facility.

(d) Meets any other requirement for licensure as a pharmacy as established by the department, in consultation with the board, by rule.

(3) An applicant seeking a pharmacy license under subsection (2) may apply to the board for a waiver of the mileage requirement described in subsection (2)(c). The board shall only grant a request for a waiver if the applicant demonstrates to the satisfaction of the board that the location of the proposed remote pharmacy is in an area where there is limited access to pharmacy services and that there are compelling circumstances that justify waiving the requirement.

(4) If a pharmacy license is granted to a pharmacy that is located within 10 miles of a remote pharmacy after the remote pharmacy's license is granted or renewed, the remote pharmacy may continue to operate.

History: Add. 2020, Act 4, Eff. Apr. 26, 2020.

Popular name: Act 368

333.17742b Staffing of remote pharmacy; requirements; written policy and procedure manual; public notice display; operation requirements and limitations; "qualified pharmacy technician" defined.

Sec. 17742b. (1) If a remote pharmacy open for business is not under the personal charge of a pharmacist,

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the pharmacist in charge of the parent pharmacy shall ensure that the remote pharmacy is staffed by a qualified pharmacy technician who, while assisting in the dispensing process, is overseen through the use of a surveillance system and a telepharmacy system by a pharmacist who meets the requirements described in subsection (2).

(2) Subject to subsection (10), a pharmacist who is located at a parent pharmacy may only oversee the activities at a remote pharmacy if the pharmacist has access to all relevant patient information that is maintained by the parent pharmacy and he or she is employed by or under contract with the parent pharmacy or a pharmacy that has contracted with the parent pharmacy.

(3) For purposes of this code, a prescription dispensed under this section, including a prescription for a controlled substance, is considered dispensed at the remote pharmacy by the pharmacist described in subsection (2).

(4) The pharmacist in charge of the parent pharmacy shall establish and maintain a written policy and procedure manual that must be made available to the department for inspection upon request and that contains each of the following, subject to this section:

(a) A description of how the remote pharmacy will comply with federal and state laws, rules, and regulations.

(b) The procedure by which a pharmacist described in subsection (2) oversees a qualified pharmacy technician at the remote pharmacy who is assisting in the dispensing process and the procedure by which the pharmacist provides counseling to patients at the remote pharmacy.

(c) The procedure for reviewing each of the following:

(*i*) Subject to section 7321, prescription drug inventory at the remote pharmacy.

(*ii*) Prescriptions or equivalent records approved by the board that are on file at the remote pharmacy.

(d) The policy and procedure for providing adequate security to protect the confidentiality and integrity of a patient's protected health information.

(e) The procedure for recovering from an event that interrupts or prevents a pharmacist described in subsection (2) from overseeing the operations of the remote pharmacy through the surveillance system or telepharmacy system. The procedure must require that the remote pharmacy be closed to the public during a time period in which any component of the surveillance system or telepharmacy system is malfunctioning, unless a pharmacist is present at the remote pharmacy during that time period.

(f) The procedure for ensuring that a pharmacist described in subsection (2) complies with the electronic system for monitoring schedule 2, 3, 4, and 5 controlled substances established under section 7333a before a controlled substance is dispensed under this section.

(g) The specific acts, tasks, and functions that a qualified pharmacy technician may perform at the remote pharmacy. However, a qualified pharmacy technician shall not do any of the following at the remote pharmacy:

(*i*) Provide consultation regarding a prescription or regarding medical information contained in a patient medication record or patient chart.

(*ii*) Perform compounding of sterile or nonsterile drugs, except for the reconstitution of prepackaged prescription drugs.

(h) A requirement that a pharmacist described in subsection (2) complete a monthly, in-person inspection of the remote pharmacy that includes, at a minimum, conducting inventory reconciliation for controlled substances and reviewing any video recording from the surveillance system that the pharmacist considers necessary.

(i) A policy that requires the pharmacist described in subsection (2) to retain audio and video recordings from the surveillance system for at least 45 calendar days.

(5) The pharmacist in charge of the parent pharmacy shall display at the remote pharmacy in a conspicuous location, visible to the public, a notice that provides all of the following information:

(a) That the pharmacy services are being provided at a remote pharmacy.

(b) That if patient counseling is provided, it may be provided by a pharmacist using audio and video communication.

(c) The address of the parent pharmacy.

(6) A pharmacist described in subsection (2) shall review a prescription as required by state and federal law, rules, and regulations before the drug or device that is the subject of the prescription is dispensed under this section. The pharmacist shall ensure that the pharmacist's and the qualified pharmacy technician's initials or other means of identifying the pharmacist and the qualified pharmacy technician involved in the dispensing process are recorded on the prescription and that the specific acts, tasks, or functions performed by the pharmacist or qualified pharmacy technician during the dispensing process are recorded in the pharmacy management system. When submitting a claim or otherwise seeking reimbursement for a public or private

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third party payer for a drug or device that is dispensed under this section, the pharmacist shall identify the remote pharmacy as the pharmacy from which the drug or device was dispensed.

(7) If a remote pharmacy open for business is not under the personal charge of a pharmacist, any patient counseling that is required by rule must be provided before the drug or device is dispensed at the remote pharmacy and must be provided by a pharmacist described in subsection (2) through the telepharmacy system in a manner that complies with the health insurance portability and accountability act of 1996, Public Law 101-191, or regulations promulgated under that act, 45 CFR parts 160 and 164.

(8) If a pharmacist described in subsection (2) is not present at the parent pharmacy, the remote pharmacy must be closed for business unless a pharmacist is present at the remote pharmacy.

(9) A remote pharmacy shall not dispense more than an average of 150 prescriptions per day during a 90-day period.

(10) A pharmacist described in subsection (2) shall not simultaneously oversee the activities of 3 or more remote pharmacies.

(11) As used in this section, "qualified pharmacy technician" means a pharmacy technician who meets all of the following requirements:

(a) He or she holds a pharmacy technician license other than a temporary license under section 17739b or limited license under section 17739c.

(b) He or she has accumulated at least 1,000 hours of experience working in a pharmacy after he or she was granted a temporary pharmacy technician license under section 17739b, a limited pharmacy technician license under section 17739c, or a pharmacy technician license under section 17739a.

(c) He or she holds a national certification as a pharmacy technician from an organization approved by the board.

History: Add. 2020, Act 4, Eff. Apr. 26, 2020.

Popular name: Act 368

333.17743 Pharmacy license; contents; duration.

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.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.17744 Designation of agent by prescriber; issuance of prescription; limitation; transmission of prescription to pharmacy.

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) Except as otherwise provided in this part, only a prescriber who is acting within the scope of the prescriber's 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 or 17754a. The prescriber issuing a prescription and the pharmacist issuing a prescription in accordance with this part or 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 the prescriber's 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 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 to 5 controlled substances and noncontrolled substances on the same form.

History: Add. 2012, Act 209, Imd. Eff. June 27, 2012;—Am. 2020, Act 136, Imd. Eff. July 8, 2020;—Am. 2024, Act 242, Eff. Apr. 2, 2025.

Popular name: Act 368

333.17744a Auto-injectable epinephrine; prescribing or issuing to authorizing entity.

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Sec. 17744a. (1) Notwithstanding any provision of this act to the contrary, a prescriber may issue a prescription for and a dispensing prescriber or pharmacist may dispense auto-injectable epinephrine to an authorized entity. When issuing a prescription for or dispensing auto-injectable epinephrine to an authorized entity as authorized under this section, the prescriber, dispensing prescriber, or pharmacist, as appropriate, shall insert the name of the authorized entity as the name of the patient.

(2) A school employee who is a licensed registered professional nurse or who is trained in the administration of an epinephrine auto-injector under section 1179a of the revised school code, 1976 PA 451, MCL 380.1179a, may possess and administer an epinephrine auto-injector dispensed to a school board under this section.

(3) An authorized entity as defined in subsection (6)(b) may acquire and stock a supply of auto-injectable epinephrine under a prescription as authorized in this section. An authorized entity as defined in subsection (6)(b) that acquires and stocks a supply of auto-injectable epinephrine is subject to section 17744d.

(4) A law enforcement officer or firefighter of an authorized entity as defined in subsection (6)(c) may, subject to section 2 of the law enforcement and firefighter access to epinephrine act, possess and administer auto-injectable epinephrine dispensed to the entity under this section.

(5) A prescriber who issues a prescription for or a dispensing prescriber or pharmacist who dispenses auto-injectable epinephrine to an authorized entity as authorized under this section is not liable in a civil action for a properly stored and dispensed epinephrine auto-injector that was a proximate cause of injury or death to an individual due to the administration of or failure to administer the epinephrine auto-injector.

(6) As used in this section, "authorized entity" means any of the following:

(a) A school board for the purpose of meeting the requirements of section 1179a of the revised school code, 1976 PA 451, MCL 380.1179a.

(b) A person or governmental entity that operates or conducts a business or activity at which allergens capable of causing anaphylaxis may be present, including, but not limited to, a recreation camp, youth sports league, amusement park, nonpublic school, religious institution, or sports arena.

(c) An eligible entity authorized to purchase, possess, and distribute auto-injectable epinephrine under the law enforcement and firefighter access to epinephrine act.

History: Add. 2013, Act 186, Eff. Mar. 14, 2014;—Am. 2015, Act 221, Eff. Mar. 16, 2016;—Am. 2020, Act 311, Imd. Eff. Dec. 29, 2020.

Popular name: Act 368

333.17744b Prescribing, possessing, or dispensing opioid antagonist; liability.

Sec. 17744b. (1) Notwithstanding any provision of this act to the contrary, a prescriber may issue a prescription for and a dispensing prescriber or pharmacist may dispense an opioid antagonist to any of the following:

(a) An individual patient at risk of experiencing an opioid-related overdose.

(b) A family member, friend, or other individual in a position to assist an individual at risk of experiencing an opioid-related overdose.

(c) A person other than an individual that meets all of the following requirements:

(*i*) Acts at the direction of the prescriber or dispensing prescriber.

(*ii*) Upon receipt of an opioid antagonist, stores the opioid antagonist in compliance with this part.

(*iii*) Dispenses or administers an opioid antagonist under a valid prescription issued to an individual or a patient.

(*iv*) Performs the requirements under this subsection without charge or compensation.

(d) An agency authorized to purchase or otherwise obtain, possess, and distribute an opioid antagonist under the administration of opioid antagonists act, 2019 PA 39, MCL 15.671 to 15.677.

(2) When issuing a prescription for or dispensing an opioid antagonist as authorized under this section to an agency described in subsection (1)(d) or a person other than a patient, the prescriber, dispensing prescriber, or pharmacist, as appropriate, shall insert the name of the agency or the person as the name of the patient.

(3) Notwithstanding any provision of this act to the contrary, a person that is acting in good faith and with reasonable care may possess and dispense an opioid antagonist.

(4) Notwithstanding any provision of this act to the contrary, an agency described in subsection (1)(d) or an employee or agent of an agency described in subsection (1)(d) may, subject to the administration of opioid antagonists act, 2019 PA 39, MCL 15.671 to 15.677, possess, administer, and distribute an opioid antagonist dispensed to the agency under this section.

(5) A prescriber who issues a prescription for or a dispensing prescriber or pharmacist who dispenses an opioid antagonist as authorized under this section is not liable in a civil action for a properly stored and dispensed opioid antagonist that was a proximate cause of injury or death to an individual due to the

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administration of or failure to administer the opioid antagonist.

History: Add. 2014, Act 311, Imd. Eff. Oct. 14, 2014;—Am. 2016, Act 384, Eff. Mar. 29, 2017;—Am. 2019, Act 36, Eff. Sept. 24, 2019;—Am. 2024, Act 232, Eff. Apr. 2, 2025.

Popular name: Act 368

333.17744c Person administering opioid antagonist under certain conditions; immunity from criminal prosecution or sanction.

Sec. 17744c. A person that administers an opioid antagonist to an individual who he or she believes is suffering an opioid-related overdose and that acts in good faith and with reasonable care is immune from criminal prosecution or sanction under any professional licensing act for that act.

History: Add. 2014, Act 313, Imd. Eff. Oct. 14, 2014.

Popular name: Act 368

333.17744d Auto-injectable epinephrine; storage, maintenance, general oversight, and use by designated employee or agent; training program; certificate; liability; report; administration by person other than employee, agent, or individual described in subsection (2); "authorized health care provider" defined.

Sec. 17744d. (1) This section only applies to an authorized entity as defined in section 17744a(6)(b) that acquires and stocks a supply of auto-injectable epinephrine as authorized in section 17744a. An authorized entity shall store auto-injectable epinephrine in a location readily accessible in an emergency and in accordance with the auto-injectable epinephrine's instructions for use and any additional requirements that are established by the department. An authorized entity shall designate an employee or agent who has completed the training required under this section to be responsible for the storage, maintenance, and general oversight of the auto-injectable epinephrine acquired by the authorized entity.

(2) An employee or agent of an authorized entity or other individual, which employee, agent, or individual has completed the training required under this section, may, on the premises of or in connection with the conduct of the business or activity of the authorized entity, use auto-injectable epinephrine prescribed under section 17744a to do any of the following:

(a) Provide auto-injectable epinephrine to an individual who the employee, agent, or other individual believes in good faith is experiencing anaphylaxis for immediate self-administration, regardless of whether the individual has a prescription for auto-injectable epinephrine or has previously been diagnosed with an allergy.

(b) Administer auto-injectable epinephrine to an individual who the employee, agent, or other individual believes in good faith is experiencing anaphylaxis, regardless of whether the individual has a prescription for auto-injectable epinephrine or has previously been diagnosed with an allergy.

(3) Before providing or administering auto-injectable epinephrine made available by an authorized entity, an employee, agent, or other individual described in subsection (2) must complete an initial anaphylaxis training program and a subsequent anaphylaxis training program at least every 2 years following completion of the most recently completed anaphylaxis training program that meets all of the following requirements:

(a) Is conducted by a nationally recognized organization experienced in training laypersons in emergency health treatment or by a person, entity, or class of individuals approved by the department.

(b) Is conducted online or in person.

(c) At a minimum, covers all of the following:

(*i*) Techniques on how to recognize symptoms of severe allergic reactions, including anaphylaxis.

(*ii*) Standards and procedures for the storage and administration of auto-injectable epinephrine.

(*iii*) Emergency follow-up procedures.

(4) An organization, person, entity, or class of individuals that conducts an anaphylaxis training program described in subsection (3) shall issue a certificate, on a form developed or approved by the department, to each individual who successfully completes the anaphylaxis training program.

(5) Except as otherwise provided in this section, an authorized entity and its employees, agents, and other trained individuals that have acted in accordance with the requirements of subsections (1) to (4); an individual who uses auto-injectable epinephrine obtained in accordance with the requirements of subsections (1) to (4) and made available under subsection (10); or an organization, person, entity, or class of individuals that conducts an anaphylaxis training program described in and conducted in accordance with subsection (3), is not subject to any of the following:

(a) For an authorized entity or person other than an individual described in this subsection, civil liability for injury, death, or damages that result from the administration or self-administration of auto-injectable

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epinephrine, the failure to administer auto-injectable epinephrine, or any other act or omission taken pursuant to this section, if the conduct does not constitute gross negligence as that term is defined in section 7 of 1964 PA 170, MCL 691.1407, that is the proximate cause of the injury, death, or damages.

(b) For an individual described in this subsection, civil liability for injury, death, or damages that result from the administration or self-administration of auto-injectable epinephrine, the failure to administer auto-injectable epinephrine, or any other act or omission taken pursuant to this section, if the conduct does not constitute willful or wanton misconduct that is the proximate cause of the injury, death, or damages.

(c) For an authorized entity or person including an individual described in this subsection, criminal prosecution for purchasing, possessing, or distributing auto-injectable epinephrine, the administration or self-administration of auto-injectable epinephrine, the failure to administer auto-injectable epinephrine, or any other act or omission taken pursuant to this section.

(6) The administration of auto-injectable epinephrine as authorized in this section is not the practice of medicine.

(7) This section does not eliminate, limit, or reduce any other immunity or defense that may be available under the laws of this state.

(8) An authorized entity located in this state is not civilly liable for any injuries or related damages that result from providing or administering auto-injectable epinephrine by its employees or agents outside of this state if either of the following requirements is met:

(a) The authorized entity or its employee or agent would not have been civilly liable for the injuries or related damages had the provision or administration occurred in this state.

(b) The authorized entity or its employee or agent is not civilly liable for the injuries or related damages under the law of the state in which the provision or administration occurred.

(9) An authorized entity shall submit to the department, on a form prescribed by the department, a report of each incident on the premises of or in connection with the conduct of the business or activity of the authorized entity that involves the administration of auto-injectable epinephrine. The department shall annually publish a report that summarizes and analyzes all reports submitted to it under this subsection.

(10) An authorized entity may make auto-injectable epinephrine available to an individual other than an employee, agent, or individual described in subsection (2), and the other individual may administer auto-injectable epinephrine to any individual he or she believes in good faith to be experiencing anaphylaxis, if the auto-injectable epinephrine is stored in a locked, secure container and is made available only upon remote authorization by an authorized health care provider after consultation with the authorized health care provider by audio, televideo, or other similar means of electronic communication. Consultation with an authorized health care provider for the purpose of this subsection is not the practice of telemedicine and does not violate any law or rule regulating the authorized health care provider's scope of practice. As used in this subsection, "authorized health care provider" means a prescriber as that term is defined in section 17708 other than a licensed dentist, licensed optometrist, or licensed veterinarian.

History: Add. 2015, Act 221, Eff. Mar. 16, 2016;—Am. 2020, Act 311, Imd. Eff. Dec. 29, 2020.

Popular name: Act 368

333.17744e Dispensing opioid antagonist to individual pursuant to standing order issued by chief medical executive; "community-based organization" defined.

Sec. 17744e. (1) Notwithstanding any provision of this act to the contrary, the chief medical executive in the office of chief medical executive created within the department of health and human services may issue a standing order that does not identify particular patients at the time it is issued for any of the following purposes:

(a) A pharmacist dispensing opioid antagonists to individuals under this section.

(b) A community-based organization or a staff member of the community-based organization distributing opioid antagonists to individuals under this section.

(2) Notwithstanding any provision of this act to the contrary, a pharmacist may dispense or a community-based organization or a staff member of the community-based organization may distribute an opioid antagonist to any individual pursuant to a standing order issued by the chief medical executive under subsection (1) and the rules promulgated under this section.

(3) The following are not liable in a civil action for damages resulting from the dispensing of an opioid antagonist or the administration of or failure to administer the opioid antagonist:

(a) The chief medical executive who issues a standing order for the opioid antagonist under this section.

(b) A pharmacist who dispenses the opioid antagonist as authorized under this section.

(c) A community-based organization that, or a staff member of the community-based organization who, distributes the opioid antagonist as authorized under this section.

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(4) The department, in consultation with the department of health and human services and local health departments, may promulgate rules regarding dispensing, training, distribution, and referral to implement this section.

(5) As used in this section, "community-based organization" means a public or private organization that provides health or human services to meet the needs of a community, including, but not limited to, a nonprofit organization, a social service provider, or an organization providing substance use disorder prevention, treatment, recovery, or harm reduction services. A community-based organization does not include an agency as that term is defined in section 101 of the administration of opioid antagonists act, 2019 PA 39, MCL 15.671.

History: Add. 2016, Act 383, Eff. Mar. 28, 2017;—Am. 2022, Act 176, Imd. Eff. July 21, 2022.

Compiler's note: For transfer of powers and duties of chief medical executive to the new chief medical executive in the office of chief medical executive created within the department of health and human services, and abolishment of the position of chief medical executive, see E.R.O. No. 2016-4, compiled at MCL 333.26369.

Popular name: Act 368

333.17744f Dispensing emergency supply of insulin; requirements; limitation; liability; rules; definitions.

Sec. 17744f. (1) Subject to subsection (2), a pharmacist may dispense an emergency supply of insulin to an individual if the individual has a qualified prescription for insulin in the individual's name with no remaining authorized refills, the individual has previously had a prescription for insulin dispensed at the pharmacy, and, in the pharmacist's professional judgment, a failure to dispense the emergency supply of insulin might interrupt the individual's ongoing care and have a significant adverse effect on the individual's well-being. A pharmacist who dispenses an emergency supply of insulin under this section shall comply with all of the following:

(a) Before dispensing the emergency supply of insulin, make a reasonable effort to communicate with the prescriber who issued the qualified prescription for insulin regarding dispensing the emergency supply of insulin and document the efforts made.

(b) Document all of the following:

(*i*) The name of the individual receiving the emergency supply of insulin and the date of the dispensing.

(*ii*) The reason for dispensing the emergency supply of insulin.

(*iii*) Evidence of the individual's qualified prescription for insulin.

(*iv*) Information on the individual's diabetes management.

(*v*) Any other information required by the board by rule.

(c) Within 5 business days after dispensing the emergency supply of insulin, inform the prescriber who issued the qualified prescription for insulin, in writing, that an emergency supply of insulin was dispensed under this section.

(d) Inform the individual receiving the emergency supply of insulin that the insulin was dispensed under this section.

(2) An individual shall not receive more than 3 emergency supplies of insulin under this section in 1 calendar year. After an emergency supply of insulin is dispensed to an individual under this section, a pharmacist shall not dispense a subsequent emergency supply of insulin under this section within the same calendar year to that individual unless the individual has since obtained a new qualified prescription for insulin with no remaining authorized refills.

(3) A prescriber or pharmacist is not subject to criminal prosecution, civil liability, or administrative sanction as a result of the pharmacist dispensing an emergency supply of insulin under this section.

(4) The board shall promulgate rules to implement this section.

(5) As used in this section:

(a) "Emergency supply" means up to a 30-day supply.

(b) "Qualified prescription for insulin" means a prescription for insulin that was issued within the 12-month period immediately preceding the date the individual requests an emergency supply of insulin under this section.

History: Add. 2021, Act 36, Imd. Eff. July 1, 2021.

Popular name: Act 368

333.17744g Prescribing and dispensing certain hormonal contraceptives; promulgation of rules; self-screening risk assessment tool.

Sec. 17744g. (1) Subject to the rules promulgated under this section, a pharmacist may issue a prescription for a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive,

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or a vaginal ring hormonal contraceptive to an individual, regardless of the individual's age and regardless of whether the individual has evidence of a previous prescription from a prescriber for a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive, or a vaginal ring hormonal contraceptive.

(2) By 18 months after the effective date of the amendatory act that added this section, the department, in consultation with the board, shall promulgate rules to implement this section. The rules must establish a standard procedure for issuing a prescription for a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive, and a vaginal ring hormonal contraceptive under this section. The rules must also prohibit a pharmacist from issuing a prescription for a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive, or a vaginal ring hormonal contraceptive to an individual described in subsection (1) if the individual has not completed the self-screening risk assessment tool developed under subsection (3) and must require that a pharmacist comply with all of the following:

(a) Complete a training program that is approved by the board for issuing a prescription for a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive, or a vaginal ring hormonal contraceptive.

(b) Provide the self-screening risk assessment tool that is developed under subsection (3) to an individual described in subsection (1) before issuing a prescription for a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive, or a vaginal ring hormonal contraceptive to the individual.

(c) Upon issuing a prescription for the hormonal contraceptive patch, self-administered hormonal contraceptive, emergency contraceptive, or vaginal ring hormonal contraceptive to an individual described in subsection (1), refer the individual to the individual's primary care physician, or if the individual does not have a primary care physician, to another licensed health professional that the pharmacist considers appropriate.

(d) Provide an individual described in subsection (1) with a written record of the hormonal contraceptive patch, self-administered hormonal contraceptive, emergency contraceptive, or vaginal ring hormonal contraceptive for which the individual is issued the prescription and advise the individual to consult with a physician or other licensed health professional.

(e) If an individual described in subsection (1) has not had a physical examination in the previous 12 months, refer the individual to the individual's primary care provider for a physical examination after issuing a prescription for the hormonal contraceptive patch, self-administered hormonal contraceptive, emergency contraceptive, or vaginal ring hormonal contraceptive to the individual.

(f) Dispense the hormonal contraceptive patch, self-administered hormonal contraceptive, emergency contraceptive, or vaginal ring hormonal contraceptive to an individual described in subsection (1) as soon as practicable after issuing the prescription for the hormonal contraceptive patch, self-administered hormonal contraceptive, emergency contraceptive, or vaginal ring hormonal contraceptive to the individual, or transmit the prescription to another pharmacy of the individual's choice if authorized pursuant to rules promulgated by the department.

(3) The department, in consultation with the board, shall by rule develop a self-screening risk assessment tool to be used by an individual who is seeking a prescription for a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive, or a vaginal ring hormonal contraceptive under this section.

History: Add. 2024, Act 242, Eff. Apr. 2, 2025.

Popular name: Act 368

333.17745 Drug control license; patient's chart or clinical record to include record of drugs dispensed; delegating authority to dispense drugs; storage of drugs; container; label; complimentary starter dose drug; information; compliance with MCL 333.7303a; inspection of locations; limitation on delegation; receipt of complimentary starter dose drugs by pharmacist; "complimentary starter dose" defined.

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 or if the dispensing involves only the issuance of complimentary starter dose drugs.

(2) Except as otherwise authorized for expedited partner therapy in section 5110 or as provided in section

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17744a or 17744b, 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, prescription drugs prescribed for the patient, prescription drugs dispensed or prescribed for expedited partner therapy as authorized in section 5110, and prescription drugs dispensed or prescribed as authorized under section 17744a or 17744b. 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 ensure 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 must be limited to individuals authorized to dispense prescription drugs in compliance with this part and article 7.

(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) Except as otherwise authorized under section 5110, 17744a, or 17744b, 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, 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.

(8) A dispensing prescriber who dispenses a complimentary starter dose drug to a patient, or an advanced practice registered nurse as that term is defined in section 17201 who dispenses a complimentary starter dose drug to a patient under section 17212, shall give the patient the information required in this subsection, by dispensing the complimentary starter dose drug to the patient in a container that bears a label containing the required information or by giving the patient a written document that may include, but is not limited to, a preprinted insert that comes with the complimentary starter dose drug and that contains the required information. The information required to be given to the patient under this subsection includes all of the following:

(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.

(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, 17211a, 17212, and 17548.

(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 in 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.

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(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.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1980, Act 431, Eff. Mar. 31, 1981;—Am. 1986, Act 304, Eff. Mar. 31, 1987;—Am. 1990, Act 333, Eff. Mar. 28, 1991;—Am. 1992, Act 281, Imd. Eff. Dec. 18, 1992;—Am. 1993, Act 305, Imd. Eff. Dec. 28, 1993;—Am. 1996, Act 355, Imd. Eff. July 1, 1996;—Am. 1997, Act 186, Eff. Mar. 31, 1998;—Am. 2006, Act 672, Imd. Eff. Jan. 10, 2007;—Am. 2011, Act 210, Imd. Eff. Nov. 8, 2011;—Am. 2013, Act 186, Eff. Mar. 14, 2014;—Am. 2014, Act 311, Imd. Eff. Oct. 14, 2014;—Am. 2014, Act 525, Imd. Eff. Jan. 14, 2015;—Am. 2016, Act 379, Eff. Mar. 22, 2017;—Am. 2016, Act 499, Eff. Apr. 9, 2017.

Popular name: Act 368

333.17745a Definitions; public health program without on-site pharmacy; individuals delegated authority to dispense prescriptions; delegating delivery of certain oral contraceptives; circumstances; delegating delivery of methadone.

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, 42 USC 1396 to 1396w-5.

(b) "Medicare" means the federal Medicare program established under title XVIII of the social security act, 42 USC 1395 to 1395*lll*.

(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 42 USC 254b and 254c.

(*iii*) A family planning program designated by the department of health and human services 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 health and human services.

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

(*v*) A rural health clinic.

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

(d) "Rural health clinic" means a rural health clinic as defined in section 42 USC 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 a registered professional nurse licensed under part 172.

(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 a registered professional nurse or a licensed practical nurse licensed under part 172.

(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.

History: Add. 1993, Act 305, Imd. Eff. Dec. 28, 1993;—Am. 1999, Act 190, Imd. Eff. Nov. 24, 1999;—Am. 2016, Act 379, Eff. Mar. 22, 2017.

Popular name: Act 368

333.17745b Industrial clinic or prescriber practice without on-site pharmacy; dispensing prescription drug.

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 a registered professional nurse licensed under part 172.

(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:

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(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.

History: Add. 1993, Act 306, Imd. Eff. Dec. 28, 1993;—Am. 2016, Act 379, Eff. Mar. 22, 2017.

Popular name: Act 368

333.17746 Hospice emergency care services in patients' homes; medication box exchange program.

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.

History: Add. 1993, Act 305, Imd. Eff. Dec. 28, 1993.

Popular name: Act 368

Administrative rules: R 338.471 et seq. of the Michigan Administrative Code.

333.17747 Drug control license; contents; duration; renewal; conditions; license as automatically 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 and the other requirements of this article and article 7.

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

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1980, Act 431, Eff. Mar. 31, 1981;—Am. 1990, Act 333, Eff. Mar. 28, 1991;—Am. 1993, Act 79, Eff. Apr. 1, 1994.

Popular name: Act 368

333.17748 Pharmacy, manufacturer, wholesale distributor; or wholesale distributor-broker, license required; compounding services; renewal; designation of pharmacist in charge; joint responsibility; exemption; report of change in ownership, management, location, or PIC or facility manager; duties of pharmacist in charge; submission of fingerprints; criminal history check; exception; investigation or inspection of out-of-state applicant or compounding pharmacy; reimbursement for expenses.

Sec. 17748. (1) Except for a qualified pharmacy as that term is defined in section 17748e, to do business in this state, a pharmacy, manufacturer, wholesale distributor, or wholesale distributor-broker, whether or not located in this state, must be licensed under this part. To do business in this state, a person that provides compounding services must be licensed as a pharmacy or manufacturer under this part and, if a pharmacy,

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authorized to provide compounding services under this section and sections 17748a and 17748b. To do business in this state, an outsourcing facility must be licensed as a pharmacy under this part. Licenses are renewable biennially.

(2) Except for a remote pharmacy, a pharmacy shall designate a pharmacist licensed in this state as the pharmacist in charge for the pharmacy. For a remote pharmacy, the pharmacist designated as the pharmacist in charge of the parent pharmacy shall also serve as the pharmacist in charge of the remote pharmacy. Except as otherwise provided in this subsection, a manufacturer shall designate a pharmacist licensed in or outside of this state as the pharmacist in charge for the manufacturer or, if the manufacturer does not hold a license as a pharmacy, shall designate an employee with the appropriate education or experience, or both, to assume responsibility for compliance with licensing requirements as facility manager for the manufacturer. Except as otherwise provided in this subsection, a wholesale distributor or wholesale distributor-broker shall designate a pharmacist licensed in or outside of this state as the pharmacist in charge for the wholesale distributor or wholesale distributor-broker or shall designate an employee with the appropriate education or experience, or both, to assume responsibility for compliance with licensing requirements as facility manager for the wholesale distributor or wholesale distributor-broker. The pharmacy, manufacturer, wholesale distributor, or wholesale distributor-broker and the individual designated as the PIC or facility manager under this subsection are jointly responsible for the pharmacy's, manufacturer's, wholesale distributor's, or wholesale distributor-broker's compliance with this part and rules promulgated under this part. A person that is a manufacturer, wholesale distributor, or wholesale distributor-broker with respect to a device salable on prescription only but not with respect to any drug salable on prescription only is exempt from this subsection.

(3) Subject to this subsection, a pharmacist may be designated as the PIC for not more than 3 pharmacies, including remote pharmacies. A PIC described in this subsection shall work an average of at least 8 hours per week at each pharmacy for which he or she is the PIC unless he or she is serving as the PIC of a remote pharmacy. The PIC of a remote pharmacy is not required to be physically present at the remote pharmacy to satisfy the hour requirement described in this subsection, but may satisfy the requirement through the use of a telepharmacy system. The pharmacy and the PIC shall maintain appropriate records and demonstrate compliance with this subsection on the request of the board or its designee.

(4) A pharmacy, manufacturer, wholesale distributor, or wholesale distributor-broker shall report to the department a change in ownership, management, location, or its PIC or facility manager designated under subsection (2) not later than 30 days after the change occurs.

(5) A pharmacist designated as the PIC for a pharmacy shall supervise the practice of pharmacy for the pharmacy. The duties of the PIC include, but are not limited to, the following:

(a) Supervision of all activities of pharmacy employees as they relate to the practice of pharmacy including the purchasing, storage, compounding, repackaging, dispensing, and distribution of drugs and devices to ensure that those activities are performed in compliance with this part and the rules promulgated under this part.

(b) Enforcement and oversight of policies and procedures applicable to the employees of the pharmacy for the procurement, storage, compounding, and dispensing of drugs and the communication of information to the patient in relation to drug therapy.

(c) Establishment and supervision of the method and manner for storage and safekeeping of pharmaceuticals, including maintenance of security provisions to be used when the pharmacy is closed.

(d) Establishment and supervision of the record-keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs and devices.

(e) Establishment of policies and procedures for individuals who are delegated responsibilities for any of the tasks described in this subsection by the PIC.

(6) Except as otherwise provided in subsection (8), fingerprints for the following individuals must be submitted with an application for a new pharmacy, manufacturer, wholesale distributor, or wholesale distributor-broker license in the same manner as required in section 16174 for the purpose of a criminal history check:

(a) If the application is from an individual, who is not a health professional licensed or otherwise authorized to engage in a health profession under this article or who is a health professional but was licensed or otherwise authorized to engage in his or her health profession under this article before October 1, 2008, fingerprints for that individual.

(b) If the application is from a partnership, fingerprints for all partners and any individual who will manage the day-to-day operations of the new pharmacy, manufacturer, wholesale distributor, or wholesale distributor-broker.

(c) If the application is from a privately held corporation, fingerprints for any individual who will manage the day-to-day operations of the new pharmacy, manufacturer, or wholesale distributor. This subdivision only

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applies to a privately held corporation that in the aggregate owns fewer than 75 pharmacies, manufacturers, wholesale distributors, or wholesale distributor-brokers on the date the corporation submits its license application.

(7) The board, department, and department of state police shall conduct the criminal history check on the individuals described in subsection (6) in the same manner as described in section 16174.

(8) Subsection (6) does not apply if a criminal history check that meets the requirements of section 16174 has been obtained for the individuals described in subsection (6) within the 2 years preceding the date of the application for a new pharmacy, manufacturer, wholesale distributor, or wholesale distributor-broker license under this part. To qualify for the exception under this subsection, an applicant shall submit proof of the previous criminal history check for each individual described in subsection (6), as applicable, with the application for a new pharmacy, manufacturer, wholesale distributor, or wholesale distributor-broker license under this part. If the department or board determines that a criminal history check for an individual described in subsection (6) does not meet the requirements of section 16174 or was not obtained within the time period prescribed, fingerprints must be submitted for the individual as required under subsection (6).

(9) If, as authorized or required under this article, the department inspects or investigates an applicant for a new pharmacy license for a pharmacy that will provide compounding services or a compounding pharmacy, and the applicant or compounding pharmacy is located outside of this state, the applicant or compounding pharmacy shall reimburse the department for its expenses incurred in carrying out its authority or duty to inspect or investigate the applicant or licensee under this article.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1978, Act 625, Imd. Eff. Jan. 6, 1979;—Am. 1988, Act 462, Eff. Sept. 1, 1989;—Am. 2014, Act 280, Eff. Sept. 30, 2014;—Am. 2014, Act 413, Eff. Mar. 30, 2015;—Am. 2015, Act 169, Eff. Dec. 3, 2015;—Am. 2020, Act 4, Eff. Apr. 26, 2020;—Am. 2020, Act 142, Imd. Eff. July 14, 2020.

Popular name: Act 368

333.17748a Compounding services for sterile pharmaceuticals; accreditation; notification of complaint; maintenance and retention of records; resale of excess compounded pharmaceuticals prohibited; distribution of samples or complimentary starter doses; advertisement or promotion of compounding services; compounding pharmaceutical that is unavailable in marketplace; compounding and manufacturing at same location; rules.

Sec. 17748a. (1) Beginning September 30, 2014, an applicant for a new pharmacy license for a pharmacy that will provide compounding services for sterile pharmaceuticals shall submit verification of current accreditation through a national accrediting organization approved by the board or verify the pharmacy is in the accreditation process. The department shall not issue a license to a pharmacy described in this subsection that is not accredited unless the applicant demonstrates compliance with USP standards in a manner determined by the board.

(2) By September 30, 2016, a pharmacy that is licensed on September 30, 2014 and that provides compounding services for sterile pharmaceuticals must be accredited by a national accrediting organization approved by the board, be verified by the board as being in the accreditation process, or be in compliance with USP standards in a manner determined by the board.

(3) Notwithstanding any provision of part 161 to the contrary, a pharmacy that provides compounding services for sterile pharmaceuticals shall submit with a license renewal application verification of current accreditation or compliance with USP standards, as applicable.

(4) A person that provides services consistent with an outsourcing facility shall comply with requirements of the FDA applicable to compounding services for sterile pharmaceuticals.

(5) A pharmacy shall notify the department of a complaint filed by another state in which the pharmacy is licensed for violations of that state's pharmacy laws, an investigation by federal authorities regarding violations of federal law, or an investigation by any agency into violations of accreditation standards regarding compounding activities within 30 days of knowledge of the complaint or investigation.

(6) Except for distribution within a hospital or another health care entity under common control when regulated by federal law, a pharmacist shall maintain a record of a compounded sterile pharmaceutical in the same manner and for the same retention period as prescribed in rules for other prescription records. The pharmacist shall include, but is not limited to including, all of the following information in the record required under this subsection:

(a) The name, strength, quantity, and dosage form of the compounded pharmaceutical.

(b) The formula to compound that includes mixing instructions, all ingredients and their quantities, and any additional information needed to prepare the compounded pharmaceutical.

(c) The prescription number or assigned internal identification number.

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(d) The date of preparation.

(e) The manufacturer and lot number of each ingredient.

(f) The expiration or beyond-use date.

(g) The name of the person who prepared the compounded pharmaceutical.

(h) The name of the pharmacist who approved the compounded pharmaceutical.

(7) A pharmacist shall not offer excess compounded pharmaceuticals to other pharmacies for resale. A compounding pharmacy shall not distribute samples or complimentary starter doses of a compounded pharmaceutical to a health professional.

(8) A compounding pharmacy may advertise or otherwise promote the fact that they provide compounding services.

(9) Based on the existence of a health professional/patient relationship and the presentation of a valid prescription, or in anticipation of the receipt of a prescription based on routine, regularly observed prescription patterns, a pharmacist may compound for a patient a nonsterile or sterile pharmaceutical that is not commercially available in the marketplace.

(10) Notwithstanding any provision of this act to the contrary, a person shall not compound and manufacture drug products or allow the compounding and manufacturing of drug products at the same location.

(11) The department, in consultation with the board, may promulgate rules regarding conditions and facilities for the compounding of nonsterile and sterile pharmaceuticals.

History: Add. 2014, Act 280, Eff. Sept. 30, 2014;—Am. 2015, Act 133, Imd. Eff. Sept. 30, 2015.

Popular name: Act 368

333.17748b Compounding nonsterile or sterile pharmaceuticals for prescriber or health facility or agency to administer to patients without prescription; authorization; report of adverse event; list of authorized pharmacies and pharmacists; selling or redispensing to prescriber or health facility or agency.

Sec. 17748b. (1) Except as otherwise provided in this subsection, a pharmacist or pharmacy shall not compound nonsterile or sterile pharmaceuticals for a prescriber or health facility or agency licensed under article 17 to administer to the prescriber's, facility's, or agency's patients without a prescription, unless the pharmaceutical compounded by the pharmacist or pharmacy complies with the most recent guidance on pharmacy compounding of human drug products under 21 USC 353a. Upon application by a pharmacist or compounding pharmacy, the department may authorize the pharmacist or compounding pharmacy to compound nonsterile or sterile pharmaceuticals for a prescriber or health facility or agency licensed under article 17 to administer to the prescriber's, facility's, or agency's patients in limited quantities without a prescription. This subsection does not apply to the compounding of topical nonsterile pharmaceuticals. The department shall prescribe the form of the application for use under this subsection, which application must include at least all of the following information:

(a) The name and license number of the pharmacist or pharmacy requesting authorization to compound under this subsection.

(b) The name of the specific prescriber or health facility or agency that is requesting compounded pharmaceuticals and an affidavit from the prescriber or designated agent of the health facility or agency attesting to the need and that the compounded pharmaceuticals are only for patients located in this state or in states immediately adjacent to this state.

(c) The pharmaceuticals to be compounded and the reason for the need to compound the pharmaceuticals.

(d) The anticipated quantities of pharmaceuticals to be compounded each month and the frequency of the need to compound before receipt of a prescription or documentation supporting the anticipated quantities.

(e) The conditions of operation including practices consistent with USP standards and requirements for sterility testing.

(2) A pharmacist or compounding pharmacy that is authorized to compound nonsterile or sterile pharmaceuticals for a prescriber or health facility or agency under subsection (1) shall do all of the following:

(a) Maintain complete and accurate records on a monthly basis of requests from and pharmaceuticals compounded for each prescriber or health facility or agency.

(b) Provide the information described in subdivision (a) to the department as specified in rules or upon request.

(3) The authorization granted under subsection (1) is for a 2-year period consistent with the 2-year license cycle of the pharmacy. The department may, without prior notice to the pharmacist or pharmacy, physically inspect the facility where the compounding of nonsterile or sterile pharmaceuticals occurs.

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(4) The department shall not authorize a pharmacist or compounding pharmacy to compound nonsterile or sterile pharmaceuticals without a prescription if the pharmacist or pharmacy is under investigation, is in the process of being disciplined, or is in a disciplinary status.

(5) Except as otherwise provided in this subsection, the department may immediately revoke the authorization granted under subsection (1) if there is a confirmed deviation or violation of the compounding process or if an adverse event directly related to sterility or integrity of the product and associated with a compounded nonsterile or sterile pharmaceutical is detected. If the health, safety, and welfare of the public are not in immediate jeopardy, the department shall provide at least 30 days' notice of the revocation of authorization under this subsection.

(6) A pharmacy or pharmacist authorized to compound pharmaceuticals under this section that becomes aware of an adverse event attributed to the integrity of the product of a compounded pharmaceutical shall report the adverse event to the department not later than 10 calendar days after becoming aware of the adverse event. For purposes of this subsection, an adverse event does not include an isolated allergic reaction to a substance included in the compound if the allergic reaction is treated and relieved with standard protocol.

(7) The department shall post and maintain a list of pharmacies and pharmacists who are authorized to compound pharmaceuticals under this section on its internet website. The department shall update the list required under this subsection at least quarterly.

(8) A prescriber or health facility or agency that obtains compounded pharmaceuticals under this section shall not redispense or sell the compounded pharmaceutical to a patient, a prescriber, or health facility or agency.

History: Add. 2014, Act 280, Eff. Sept. 30, 2014.

Popular name: Act 368

333.17748c Compounding pharmaceutical; commercial availability.

Sec. 17748c. Except for pharmaceuticals on the Michigan pharmaceutical product list maintained by the department of community health, a pharmacist shall not compound a pharmaceutical that is commercially available unless 1 of the following requirements is met:

(a) The commercially available pharmaceutical is modified to produce a significant difference, in the professional judgment of the prescriber, between the compounded pharmaceutical for the patient and the comparable commercially available pharmaceutical.

(b) The commercially available pharmaceutical is not available from normal distribution channels in a timely manner to meet the patient's needs and the dispensing of the compounded pharmaceutical has been approved by the prescriber and the patient. A pharmacist who compounds a commercially available pharmaceutical as provided in this subdivision shall maintain documentation of the reason for the compounding.

History: Add. 2014, Act 280, Eff. Sept. 30, 2014.

Popular name: Act 368

333.17748d Violation of MCL 333.17748a or 17748b; penality.

Sec. 17748d. (1) Except as otherwise provided in this section, a person that violates section 17748a or 17748b is guilty of a misdemeanor.

(2) Except as otherwise provided in this section, a person that knowingly or willfully violates section 17748a or 17748b or a person that falsifies prescriptions in order to compound a pharmaceutical in bulk 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.

(3) Except as otherwise provided in this section, a person that knowingly or willfully violates section 17748a or 17748b or a person that falsifies prescriptions in order to compound a pharmaceutical in bulk, which activity 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.

(4) A person that knowingly or willfully violates section 17748a or 17748b or a person that falsifies prescriptions in order to compound a pharmaceutical in bulk, which activity 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.

(5) A person that knowingly or willfully violates section 17748a or 17748b or a person that falsifies prescriptions in order to compound a pharmaceutical in bulk, which activity 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.

(6) The state attorney general or county prosecutor may bring and prosecute criminal charges described in

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this section.

History: Add. 2014, Act 280, Eff. Sept. 30, 2014.

Popular name: Act 368

333.17748e Out-of-state pharmacy; facilitation of delivery or trade; use of wholesale distributor-broker; requirements; liability; license requirements; transaction records; notification; investigation; definitions.

Sec. 17748e. (1) An out-of-state pharmacy that is not licensed under this part as a pharmacy may deliver or trade a drug or device salable on prescription only to a person located in this state only if the out-of-state pharmacy meets both of the following requirements:

(a) The out-of-state pharmacy holds a license in good standing as a pharmacy from the state in which it is located.

(b) The out-of-state pharmacy uses a wholesale distributor-broker that is licensed in this state to facilitate the transaction.

(2) Except as otherwise provided in this part, a pharmacy that is using a wholesale distributor-broker shall only deliver or trade a drug or device salable on prescription only that it receives from 1 or more of the following:

(a) A manufacturer.

(b) A wholesale distributor.

(c) Subject to subsection (3), a pharmacy.

(d) Subject to subsection (3), a qualified pharmacy.

(3) A drug salable on prescription only must not be delivered or traded between pharmacies, or between a pharmacy and a qualified pharmacy that is using a wholesale distributor-broker, unless all of the following are met:

(a) The pharmacy or qualified pharmacy from which the drug is being obtained receives a request for the drug that identifies the drug's brand name or generic name, lot number, expiration date, quality, quantity, and size.

(b) The drug is approved by the United States Food and Drug Administration.

(c) The drug is not expired at the time of the delivery or trade.

(d) The drug is not a controlled substance.

(e) Before delivering or trading the drug, the pharmacy or qualified pharmacy from which the drug is being obtained confirms with the pharmacy or qualified pharmacy receiving the drug that the drug is available for delivery or trade.

(f) The pharmacy or qualified pharmacy from which the drug is being obtained includes with the drug a packaging checklist, confirming that the drug being delivered or traded matches the information identified on the request described in subdivision (a).

(g) The drug is delivered or traded in the original manufacturer's packaging, whether sealed or unsealed, with the drug's national drug code, lot number, and expiration date conspicuously identified on the packaging. If the original manufacturer's packaging is unsealed at the time of the delivery or trade, the delivery or trade may include a quantity of the drug that is less than the quantity contained in the original manufacturer's packaging. However, the pharmacies, or the pharmacy and qualified pharmacy, shall not trade or deliver more than 1 unsealed or partial quantity of the drug during any consecutive 90-day period.

(h) If 1 of the pharmacies involved in the delivery or trade is a qualified pharmacy, the delivery or trade is intended to fill a prescription for an identified patient.

(4) A wholesale distributor-broker is not liable in a civil action for personal injury or death resulting from a drug or device salable on prescription only that was delivered or traded by a pharmacy or qualified pharmacy under this section, regardless of whether the wholesale distributor-broker is subject to disciplinary action under this part, if the wholesale distributor-broker's conduct does not amount to gross negligence as that term is defined in section 7 of 1964 PA 170, MCL 691.1407.

(5) To receive a license as a wholesale distributor-broker under this part, an applicant shall meet the requirements for licensure established by the department in consultation with the board by rule. The rules must require the applicant to demonstrate to the satisfaction of the board that, at the time of the application for initial licensure, the applicant facilitates deliveries or trades for at least 50 qualified pharmacies that are each licensed in good standing in their state of licensure. If the number of qualified pharmacies described in this subsection with which a wholesale distributor-broker facilitates deliveries and trades falls below 50, the wholesale distributor-broker may continue to do business in this state. However, a wholesale distributor-broker seeking renewal of its license shall, in addition to meeting any requirements for renewal under section 16201, demonstrate to the satisfaction of the board that the wholesale distributor-broker

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facilitates deliveries and trades for at least 50 qualified pharmacies at the time of license renewal.

(6) A wholesale distributor-broker shall provide a transaction history, transaction statement, or transaction information to a pharmacy purchasing a drug or device from a pharmacy or qualified pharmacy through the wholesale distributor-broker under this section if any of the following are met:

(a) A transaction history, transaction statement, or transaction information is required under the drug supply chain security act, Public Law 113-54.

(b) The qualified pharmacy provided the transaction history, transaction statement, or transaction information to the wholesale distributor-broker, and the wholesale distributer-broker receives a request for the document from the purchasing pharmacy. A wholesale distributor-broker that receives a document described in this subdivision shall retain the document for at least 7 years.

(7) A wholesale distributor-broker that receives notification from a pharmacy or qualified pharmacy that a delivery or trade facilitated by the wholesale distributor-broker involved a drug or device salable on prescription only that is a suspect product or illegitimate product shall immediately notify each of the following:

(a) The department.

(b) The United States Food and Drug Administration.

(c) Each pharmacy that received the product from the pharmacy or qualified pharmacy.

(8) Before facilitating the delivery or trade of a drug or device salable on prescription only to a pharmacy, the wholesale distributor-broker shall notify the pharmacy, in writing, that the wholesale distributor-broker will not examine the drug or device for quality or accuracy before the pharmacy receives the drug or device.

(9) A wholesale distributor-broker shall not facilitate a delivery or trade of a drug or device salable on prescription only between a pharmacy and a qualified pharmacy unless both of the following are met:

(a) The pharmacy's or qualified pharmacy's license is in good standing in its state of licensure at the time of the delivery or trade and the wholesale distributor-broker has no knowledge of pending disciplinary action against the pharmacy or qualified pharmacy in its state of licensure.

(b) The wholesale distributor-broker has, for the quarter in which the delivery or trade will occur, received from the pharmacy and qualified pharmacy a signed attestation that the pharmacy or qualified pharmacy holds a license in good standing in its state of licensure and that the pharmacy or qualified pharmacy is in compliance with all applicable federal and state laws. The wholesale distributor-broker shall make an attestation received under this subdivision available to the department on the department's request.

(10) A wholesale distributor-broker shall cooperate with the department if the department is investigating a transaction involving the wholesale distributor-broker or a qualified pharmacy with which the wholesale distributor-broker facilitates transactions.

(11) As used in this section:

(a) "Illegitimate product" means that term as defined in 21 USC 360eee.

(b) "Out-of-state pharmacy" means a facility or part of a facility that is located outside of this state and that dispenses prescription drugs or prepares prescription drugs for delivery or distribution under the laws of the state in which it is located.

(c) "Qualified pharmacy" means an out-of-state pharmacy that meets the requirements described in subsection (1).

(d) "Suspect product" means that term as defined in 21 USC 360eee.

(e) "Transaction history" means that term as defined in 21 USC 360eee.

(f) "Transaction information" means that term as defined in 21 USC 360eee.

(g) "Transaction statement" means that term as defined in 21 USC 360eee.

History: Add. 2020, Act 142, Imd. Eff. July 14, 2020.

Popular name: Act 368

333.17748f Licensure of a pharmacy as a wholesale distributor or manufacturer; requirements.

Sec. 17748f. (1) A pharmacy shall obtain a license as a wholesale distributor under this part if the total number of dosage units of all prescription drugs distributed by the pharmacy to a person during any consecutive 12-month period is more than 5% of the total number of dosage units of prescription drugs distributed and dispensed by the pharmacy during the same 12-month period. The calculation of the 5% threshold described in this subsection must not include a distribution of a prescription drug that is exempt from the definition of wholesale distribution under 21 USC 353(e)(4).

(2) A pharmacy shall obtain a license as a manufacturer under this part if, during any consecutive 12-month period, the total number of dosage units of all prescription drugs that are prepared or compounded by the pharmacy for the resale, compounding, or dispensing by another person is more than 5% of the total

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number of dosage units of prescription drugs prepared by the pharmacy during the same 12-month period.

History: Add. 2020, Act 142, Imd. Eff. July 14, 2020;—Am. 2021, Act 130, Imd. Eff. Dec. 17, 2021.

Popular name: Act 368

333.17749 Dispensing of diagnostic or therapeutic pharmaceutical agents by wholesale distributor or pharmacist to optometrist; condition; “therapeutic pharmaceutical agent” and “diagnostic pharmaceutical agent” defined.

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.

History: Add. 1984, Act 42, Eff. Apr. 12, 1984;—Am. 1994, Act 384, Eff. Mar. 30, 1995.

Popular name: Act 368

333.17750 Person who distributes complimentary starter doses to prescribers; records; access by board; “complimentary starter dose” defined.

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).

History: Add. 1990, Act 333, Eff. Mar. 28, 1991.

Popular name: Act 368

333.17750a Dispensing of prescription for therapeutic pharmaceutical agent by pharmacist.

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 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.

History: Add. 1994, Act 384, Eff. Mar. 30, 1995.

Popular name: Act 368

333.17751 Dispensing prescription drug or device requiring prescription; requirements; exceptions.

Sec. 17751. (1) Except as otherwise provided in sections 17724a and 17744f, 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. A pharmacist described in section 17742b(2) may dispense a drug pursuant to an original prescription received at a remote pharmacy if the pharmacist receives, reviews, and verifies an exact digital image of the prescription received at the remote pharmacy before the drug is dispensed at the remote pharmacy.

(2) Subject to this subsection and subsections (1) and (5), a pharmacist may dispense a drug or device pursuant to 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 prescriber in another state or province of Canada, but not including a prescription for a controlled substance except under circumstances described in section 17763(e). Before dispensing a drug or device pursuant to a prescription under this subsection, the pharmacist, in the exercise of the pharmacist's professional judgment, must determine all of the following:

(a) Except as otherwise authorized under section 5110, 17744a, or 17744b, if the prescriber is not a veterinarian, that the prescription was issued pursuant to an existing prescriber-patient relationship.

(b) That the prescription is authentic.

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(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 drug or device pursuant to a prescription only if the prescription falls within the scope of practice of the prescriber or if the prescription was issued by a pharmacist in accordance with this part.

(4) A pharmacist shall not knowingly dispense a drug or device pursuant to a prescription after the death of the patient.

(5) A pharmacist shall not dispense a drug or device pursuant to 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 any of the following:

(a) A prescription that is transmitted by a computer to a facsimile machine if that prescription complies with section 17754 or 17754a.

(b) A prescription that is received by a remote pharmacy and made available to a pharmacist described in section 17742b(2) for review and verification in the manner required under subsection (1).

(6) After consultation with and agreement from the prescriber, a pharmacist may add or change a patient's address, a dosage form, a drug strength, a drug quantity, a direction for use, or an 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 or, if the drug is dispensed at a remote pharmacy, on the digital image of the prescription described in subsection (1), and shall maintain that documentation with the prescription as required in section 17752. 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, 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 or other medical institution and that is transmitted to a pharmacy under section 17744 is the original prescription. If all other requirements of this part are met, a pharmacist shall dispense a drug or device pursuant to a prescription described in this subsection. A pharmacist may dispense a drug or device pursuant to 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.

(8) If, after consulting with a patient, a pharmacist determines in the exercise of the pharmacist's professional judgment that dispensing additional quantities of a prescription drug is appropriate for the patient, the pharmacist may dispense, at one time, additional quantities of the prescription drug up to the total number of dosage units authorized by the prescriber on the original prescription for the patient and any refills of the prescription. Except for a controlled substance included in schedule 5 that does not contain an opioid, this subsection does not apply to a prescription for a controlled substance.

(9) Notwithstanding any provision of this section, a pharmacist who receives a prescription under subsection (2) from an advanced practice registered nurse prescriber or physician's assistant prescriber in another state or province of Canada may dispense the drug or device without determining whether the advanced practice registered nurse prescriber or physician's assistant prescriber is authorized under the laws of the other state or province of Canada to issue the prescription.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1997, Act 153, Eff. Mar. 31, 1998;—Am. 2005, Act 85, Imd. Eff. July 19, 2005;—Am. 2006, Act 672, Imd. Eff. Jan. 10, 2007;—Am. 2011, Act 155, Imd. Eff. Sept. 27, 2011;—Am. 2012, Act 209, Imd. Eff. June 27, 2012;—Am. 2013, Act 186, Eff. Mar. 14, 2014;—Am. 2014, Act 311, Imd. Eff. Oct. 14, 2014;—Am. 2014, Act 525, Imd. Eff. Jan. 14, 2015;—Am. 2016, Act 49, Eff. June 13, 2016;—Am. 2017, Act 165, Eff. Feb. 11, 2018;—Am. 2020, Act 4, Eff. Apr. 26, 2020;—Am. 2020, Act 136, Imd. Eff. July 8, 2020;—Am. 2021, Act 36, Imd. Eff. July 1, 2021;—Am. 2022, Act 80, Eff. Mar. 29, 2023;—Am. 2023, Act 97, Imd. Eff. July 19, 2023;—Am. 2024, Act 242, Eff. Apr. 2, 2025.

Compiler's note: Enacting section 1 of Act 49 of 2016 provides:

"Enacting section 1. Section 16349 of the public health code, 1978 PA 368, MCL 333.16349, as amended by this amendatory act, applies to licensing fees required to be paid after December 31, 2018."

Popular name: Act 368

333.17752 Prescription or equivalent record; preservation; disclosure; providing copies; refilling copy; applicability of subsection (3) to pharmacies sharing real-time, on-line database and remote pharmacies; "equivalent record" defined.

Sec. 17752. (1) A licensee or dispensing prescriber shall preserve a prescription, or an equivalent record of the prescription approved by the board, 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

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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 must 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 must be a duplicate of the original prescription except that it must 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 must be used for information purposes only and clearly marked "for informational or reference purposes only".

(4) Subsection (3) does not apply to any of the following:

(a) Pharmacies that share a real-time, on-line database or other equivalent means of communication.

(b) Pharmacies that transfer prescriptions pursuant to a written contract for centralized prescription processing services as provided under section 17753.

(c) A parent pharmacy if the parent pharmacy receives a copy of a prescription from a remote pharmacy that it operates.

(d) A remote pharmacy if the remote pharmacy receives a copy of a prescription from a parent pharmacy.

(5) For purposes of this section, "equivalent record of the prescription approved by the board" or "equivalent record" includes a digital image described in section 17751(1).

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 2005, Act 73, Imd. Eff. July 19, 2005;—Am. 2020, Act 4, Eff. Apr. 26, 2020.

Popular name: Act 368

333.17753 Centralized prescription processing; conditions for performing or contracting; maintenance of policy and procedures manual; 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.

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(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.

History: Add. 2005, Act 72, Imd. Eff. July 19, 2005.

Popular name: Act 368

333.17754 Electronic transmission of prescription; conditions; information; confidentiality; professional judgment as to accuracy, validity, and authenticity; original prescription; inapplicable after October 1, 2021.

Sec. 17754. (1) Except as otherwise provided under article 7, article 8, 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, or regulations promulgated under that act, 45 CFR parts 160 and 164, by a prescriber or his or her agent and the data are not altered or modified in the transmission process. The electronically transmitted prescription must include all of the following information:

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

(b) Except as otherwise authorized under section 5110, 17744a, or 17744b, 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 must 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 must be communicated in a retrievable, recognizable form acceptable to the intended recipient. The electronic form utilized in the transmission of a prescription must 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.

(5) This section does not apply beginning on the date on which section 17754a applies.

History: Add. 2006, Act 672, Imd. Eff. Jan. 10, 2007;—Am. 2012, Act 209, Imd. Eff. June 27, 2012;—Am. 2013, Act 186, Eff. Mar. 14, 2014;—Am. 2013, Act 268, Imd. Eff. Dec. 30, 2013;—Am. 2014, Act 311, Imd. Eff. Oct. 14, 2014;—Am. 2014, Act 525, Imd. Eff. Jan. 14, 2015;—Am. 2020, Act 134, Imd. Eff. July 8, 2020.

Popular name: Act 368

333.17754a Electronic transmission of prescription; conditions; information; confidentiality; professional judgment as to accuracy, validity, and authenticity; exceptions; waiver; rules; delayed implementation.

Sec. 17754a. (1) Except as otherwise provided under article 8, the federal act, or subsection (5), and subject to subsection (10), beginning October 1, 2021, a prescriber or his or her agent shall electronically transmit a prescription, including a prescription for a controlled substance, directly to a pharmacy of the patient's choice. A prescription that is transmitted electronically under this section must be in compliance with the health insurance portability and accountability act of 1996, Public Law 104-191, or regulations promulgated under that act, 45 CFR parts 160 and 164, and the data must not be altered or modified in the transmission process. The electronically transmitted prescription must include all of the following information:

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

(b) Except as otherwise authorized under section 5110, 17744a, or 17744b, 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.

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(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 under this section must 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 under this section must be communicated in a retrievable, recognizable form acceptable to the intended recipient. The electronic form utilized in the transmission of a prescription must not include "dispense as written" or "d.a.w." as the default setting.

(3) Before dispensing a prescription that is electronically transmitted under this section, 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.

(5) The requirement to transmit a prescription electronically under subsection (1) does not apply under any of the following circumstances:

(a) If the prescription is issued by a prescriber who is a veterinarian licensed under this article.

(b) If the prescription is issued under a circumstance in which electronic transmission is not available due to a temporary technological or electrical failure.

(c) If the prescription is issued by a prescriber who has received a waiver from the department under subsection (7).

(d) If the prescription is issued by a prescriber who reasonably believes that electronically transmitting the prescription would make it impractical for the patient who is the subject of the prescription to obtain the prescription drug in a timely manner and that the delay would adversely affect the patient's medical condition. A prescriber who does not electronically transmit a prescription under this subdivision shall document the specific reason for his or her belief that the delay would adversely affect the patient's medical condition.

(e) If the prescription is orally prescribed under section 7333(3) or (4).

(f) If the prescription is issued by a prescriber to be dispensed outside of this state.

(g) If the prescription is issued by a prescriber who is located outside of this state to be dispensed by a pharmacy located inside of this state.

(h) If the prescription is issued and dispensed in the same health care facility and the individual for whom the prescription is issued uses the drug exclusively in the health care facility. As used in this subdivision, "health care facility" includes, but is not limited to, any of the following:

(*i*) A hospital.

(*ii*) A hospice.

(*iii*) A dialysis treatment clinic.

(*iv*) A freestanding surgical outpatient facility.

(*v*) A skilled nursing facility.

(*vi*) A long-term care facility that provides rehabilitative, restorative, or ongoing skilled nursing care to an individual who is in need of assistance with activities of daily living.

(i) If the prescription contains content that is not supported by the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard.

(j) If the prescription is for a drug for which the FDA requires the prescription to contain content that cannot be transmitted electronically.

(k) If the prescription is issued under circumstances in which the prescriber is not required to include on the prescription a name of a patient for whom the prescription is issued including, but not limited to, a prescription issued under section 5110.

(*l*) If the prescription is issued by a prescriber who is prescribing the drug under a research protocol.

(m) If the prescription is dispensed by a dispensing prescriber.

(n) If the prescription is for a dialysis-related drug that is administered as part of or incident to a home-based dialysis treatment.

(6) If a prescriber has not been granted a waiver from the department under subsection (7) and the prescriber does not electronically transmit a prescription under an exception described in subsection (5), the prescriber shall document the applicable exception and provide that documentation to the department on request.

(7) If a prescriber cannot meet the requirements of subsection (1) or (2), the prescriber may apply to the department for a waiver in a form and manner required by the department. The department shall establish by rule the requirements for obtaining a waiver under this subsection. The rules must not establish requirements that are more stringent than any requirements used by the federal Centers for Medicare and Medicaid Services for waiving the Medicare requirement for the electronic transmission of controlled substance prescriptions. If

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a prescriber provides evidence satisfactory to the department that the prescriber has received a waiver of the Medicare requirement for the electronic transmission of controlled substances prescriptions from the federal Centers for Medicare and Medicaid Services, the department shall grant a waiver to the prescriber under this subsection. A waiver that is granted by the department under this subsection is valid for a period not to exceed 2 years and is renewable.

(8) A pharmacist who receives a prescription that was not transmitted electronically to the pharmacy may dispense the prescription without determining whether an exception under subsection (5) applies.

(9) The department, in consultation with the board, shall promulgate rules to implement this section.

(10) If the federal Centers for Medicare and Medicaid Services delays the Medicare requirement for the electronic transmission of prescriptions for controlled substances beyond October 1, 2021, then the department shall delay the implementation date of subsection (1) to the date established by the federal Centers for Medicare and Medicaid Services for the Medicare requirement.

History: Add. 2020, Act 134, Imd. Eff. July 8, 2020;—Am. 2021, Act 94, Imd. Eff. Oct. 29, 2021.

Popular name: Act 368

333.17755 Dispensing lower cost generically equivalent drug product or interchangeable biological drug product; notice; contents of prescription label; limitation; restrictions; limitation on total charge; communication to be provided prescriber; exception; link on website to Purple Book; report; definitions.

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

(2) If a pharmacist substitutes a lower cost generically equivalent drug product or interchangeable biological drug product to a purchaser who is not submitting a claim to a third-party payment source, the pharmacist shall charge the purchaser not more than the current selling price for the lower cost drug product.

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

(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 that 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.

(5) Except as otherwise provided in subsection (6), within 5 days after dispensing an interchangeable biological drug product, the dispensing pharmacist or his or her designee shall communicate to the prescriber the specific interchangeable biological drug product provided to the patient, including the name of the interchangeable biological drug product and its manufacturer. The communication required under this subsection must be made as follows:

(a) By making an entry that is electronically accessible to the prescriber through an interoperable electronic medical records system, an electronic prescribing technology, a pharmacy benefit management system, a health information exchange, or a pharmacy record. An entry made as described in this subdivision is presumed to provide notice to the prescriber.

(b) If the methods described in subdivision (a) are not available, then by facsimile, telephone, electronic transmission, or other prevailing means.

(6) Subsection (5) does not apply if either of the following occurs:

(a) There is no FDA-licensed interchangeable biological drug product for the product prescribed.

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(b) A refill authorization does not change the product that was dispensed on the prior filling of the prescription.

(7) The board shall maintain a link on its website to the current Purple Book.

(8) Beginning June 1, 2018 and annually thereafter, the department shall submit a report on all of the following to the house and senate standing committees on health policy, the speaker of the house of representatives, and the senate majority leader:

(a) A list of each biological drug product that the FDA had previously determined to be therapeutically equivalent as set forth in the Orange Book that is now included in the Purple Book.

(b) The anticipated date that every biological drug product that the FDA has determined to be therapeutically equivalent as set forth in the Orange Book will be included in the Purple Book.

(9) As used in this section:

(a) "Orange Book" means "Approved Drug Products with Therapeutic Equivalence Evaluations", an FDA publication that is commonly referred to as the "Orange Book".

(b) "Purple Book" means "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations", an FDA publication that is commonly referred to as the "Purple Book".

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 2018, Act 41, Eff. May 29, 2018;—Am. 2018, Act 246, Eff. Sept. 26, 2018.

Popular name: Act 368

333.17756 Label on prescription; contents.

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.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1993, Act 73, Eff. Jan. 1, 1994.

Popular name: Act 368

333.17757 Price information; prohibited conduct; notice; receipt evidencing transactions; omission; retention of copy of receipt; rules.

Sec. 17757. (1) When a pharmacist engaged in the business of selling drugs receives a prescription, the pharmacist may, or, when the pharmacist receives a request made in person or by telephone, the pharmacist shall provide the current selling price of a drug dispensed by that pharmacy or comparative current selling prices of generic and brand name drugs or biosimilar drug products dispensed by that pharmacy. If information is provided under this subsection, it must be provided before a drug is dispensed. A person that makes a request for or receives price information under this subsection is not obligated to purchase the drug for which the price or comparative prices are requested or received. A pharmacy or a pharmacist described in this subsection shall not enter into a contract that prohibits the disclosure of the information described in this subsection.

(2) A pharmacist engaged in the business of selling drugs 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) must 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.

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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 that 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) must also contain the address and phone number of the board and the department. The text of the notice must be in at least 32-point bold type and be printed on paper at least 11 inches by 17 inches in size. The notice may be printed on multiple pages.

(5) The department shall provide a copy of the notice required under subsection (2) to each licensee. The department shall provide additional copies if needed. 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.

(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 that contains all of 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, a reference to the standing order issued under section 17744e, or, if the prescription drug is dispensed pursuant to section 17724a or 17744f, a reference to the applicable section.

(g) The date the prescription was originally dispensed, if applicable.

(h) The name of the prescriber or, if prescribed under the prescriber's delegatory authority, the name of the delegatee. If the prescription drug is dispensed pursuant to section 17744f, the name of the original prescriber and the pharmacist dispensing the prescription drug. If the prescription drug is dispensed pursuant to section 17724a, the name of the pharmacist dispensing the prescription drug. If the prescription was issued under section 17744g, the name of the pharmacist issuing the prescription.

(i) Except as otherwise authorized under section 5110, 17744a, 17744b, or 17744e, the name of the patient for whom the drug was prescribed or dispensed.

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

(7) The items required under subsection (6)(a), (b), and (c) may be omitted from a receipt by a pharmacist only if the omission is expressly required by the prescriber. The pharmacist shall retain a copy of each receipt furnished under subsection (6) for 90 days. Including the items required under subsection (6) on the prescription container label is a valid receipt to the purchaser. Including the items required under subsection (6) on the written prescription form and retaining the form constitutes retention of a copy of the receipt.

(8) The department, in consultation with the board, may promulgate rules to implement this section.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1986, Act 304, Eff. Mar. 31, 1987;—Am. 2011, Act 210, Imd. Eff. Nov. 8, 2011;—Am. 2013, Act 186, Eff. Mar. 14, 2014;—Am. 2014, Act 311, Imd. Eff. Oct. 14, 2014;—Am. 2014, Act 525, Imd. Eff. Jan. 14, 2015;—Am. 2016, Act 383, Eff. Mar. 28, 2017;—Am. 2021, Act 36, Imd. Eff. July 1, 2021;—Am. 2022, Act 13, Imd. Eff. Feb. 23, 2022;—Am. 2023, Act 97, Imd. Eff. July 19, 2023;—Am. 2024, Act 242, Eff. Apr. 2, 2025.

Popular name: Act 368

333.17757a Providing selling price of drugs dispensed upon request; notice to consumers about prescription drugs; contents; form; display; copies.

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:

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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.

History: Add. 1990, Act 333, Eff. Mar. 28, 1991;—Am. 1993, Act 305, Imd. Eff. Dec. 28, 1993.

Popular name: Act 368

333.17757b Contracts with pharmacy benefit managers; prohibited terms.

Sec. 17757b. (1) A pharmacy or pharmacist engaged in the business of selling drugs shall not enter into a contract with a pharmacy benefit manager that violates section 26 of the third party administrator act, 1984 PA 218, MCL 550.926, or that prevents or interferes with in any manner a patient's choice to receive an eligible prescription drug from a 340b entity or a pharmacy when dispensing a 340b drug.

(2) As used in this section:

(a) "340b drug" means a covered drug as that term is defined in 42 USC 256b.

(b) "340b entity" means a covered entity as that term is defined in 42 USC 256b.

(c) "Pharmacy benefit manager" means that term as defined in section 2 of the third party administrator act, 1984 PA 218, MCL 550.902.

History: Add. 2022, Act 13, Imd. Eff. Feb. 23, 2022.

Popular name: Act 368

333.17758 Repealed. 1986, Act 304, Eff. Mar. 31, 1987.

Compiler's note: The repealed section pertained to changing current selling price of drug and adjusting posted price.

Popular name: Act 368

333.17759 Dispensing harmful drug; requirements.

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.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.17760 Operation of automated device not located at same address as pharmacy; control and supervision by pharmacist; delegation of tasks.

Sec. 17760. (1) A pharmacy that is owned and operated by a hospital licensed under article 17 may operate an automated device at a location that is affiliated with the hospital but that is not located at the same physical address as the pharmacy. A pharmacy that operates an automated device under this section shall notify the department of the automated device's location.

(2) An automated device that is operated under this section must be under the control and supervision of the pharmacist in charge for the pharmacy described in subsection (1). The pharmacist in charge for the pharmacy described in subsection (1) may, in accordance with the requirements for delegation and supervision in this article, delegate the stocking of the automated device, the removal of medication from the automated device, the maintenance of the automated device, and other tasks related to the operation of the

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automated device, but he or she is not required to be immediately physically present to supervise a delegated task. The operation of the automated device is limited to licensed health professionals.

History: Add. 2016, Act 528, Eff. Apr. 9, 2017.

Popular name: Act 368

333.17761 Display of notice; dispensing prescription in safety closure container.

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 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.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1980, Act 431, Eff. Mar. 31, 1981;—Am. 1986, Act 304, Eff. Mar. 31, 1987.

Popular name: Act 368

333.17762 Misbranded prescription.

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.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

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

Sec. 17763. In addition to the grounds set forth in part 161, 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), dispensing a prescription for a controlled substance as defined in section 7104 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, dentist prescriber, or veterinarian prescriber in another state, unless the prescription is issued by a physician prescriber, dentist prescriber, or veterinarian prescriber who is authorized under the laws of that state to practice dentistry, medicine, osteopathic medicine and surgery, or veterinary medicine and to prescribe controlled substances.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1993, Act 79, Eff. Apr. 1, 1994;—Am. 1997, Act 153, Eff. Mar. 31, 1998;—Am. 2004, Act 214, Eff. Oct. 12, 2004;—Am. 2004, Act 536, Imd. Eff. Jan. 3, 2005;—Am. 2005, Act 85, Imd. Eff. July 19, 2005;—Am. 2006, Act 672, Imd. Eff. Jan. 10, 2007;—Am. 2009, Act 150, Imd. Eff. Nov. 19, 2009;—Am. 2011, Act 155, Imd. Eff. Sept. 27, 2011;—Am. 2012, Act 209, Imd. Eff. June 27, 2012;—Am. 2016, Act 49, Eff. June 13, 2016.

Compiler's note: Enacting section 1 of Act 49 of 2016 provides:

"Enacting section 1. Section 16349 of the public health code, 1978 PA 368, MCL 333.16349, as amended by this amendatory act, applies to licensing fees required to be paid after December 31, 2018."

Popular name: Act 368

333.17764 Conduct constituting misdemeanor; violation; penalty; other violations.

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

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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.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 2004, Act 214, Eff. Oct. 12, 2004.

Popular name: Act 368

333.17765 Adulteration or misbranding; guaranty or undertaking as protection against penalties for violation; exception; notice to seller, manufacturer, or wholesale distributor.

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.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.17766 Additional conduct constituting misdemeanor.

Sec. 17766. Except as provided in sections 17766d, 17780, and 21418, a person that 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,

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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.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1990, Act 30, Eff. Mar. 28, 1991;—Am. 2004, Act 329, Imd. Eff. Sept. 23, 2004;—Am. 2006, Act 416, Imd. Eff. Sept. 29, 2006;—Am. 2018, Act 396, Eff. Mar. 19, 2019.

Popular name: Act 368

333.17766a Repealed. 2001, Act 236, Imd. Eff. Jan. 3, 2002.

Compiler's note: The repealed section pertained to use, possession, or delivery of androgenic anabolic steroid.

Popular name: Act 368

333.17766b Repealed. 2001, Act 231, Eff. Jan. 6, 2003.

Compiler's note: The repealed section pertained to recording prescription for androgenic anabolic steriod, methyltestosterone, testosterone, or fluoxymensterone.

Popular name: Act 368

333.17766c Purchase or possession of ephedrine or pseudoephedrine or mixture prohibited; violation; penalty; exceptions.

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.

(d) Purchase or possess any amount of ephedrine or pseudoephedrine knowing or having reason to know that it is to be used to manufacture methamphetamine.

(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.

(c) A person who violates subsection (1)(d) 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. This subdivision does not prohibit the person from being charged with, convicted of, and sentenced for any other violation of law arising out of the violation of subsection (1)(d).

(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.

History: Add. 1994, Act 38, Eff. June 1, 1994;—Am. 2003, Act 308, Eff. Apr. 1, 2004;—Am. 2011, Act 86, Imd. Eff. July 15, 2011;—Am. 2014, Act 216, Eff. Jan. 1, 2015.

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333.17766d Pharmacy operated by department of corrections or under contract with county jail; resale or redistribution of prescription drug; definitions.

Sec. 17766d. (1) Notwithstanding section 17766(f), 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

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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.

History: Add. 2004, Act 329, Imd. Eff. Sept. 23, 2004.

Popular name: Act 368

333.17766e Sale of ephedrine or pseudoephedrine; requirements of retail distributor; exceptions; violation; fine; 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, including, but not limited to, the number of clandestine methamphetamine lab incidents before and after this legislation.

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History: Add. 2005, Act 87, Eff. Dec. 15, 2005;—Am. 2011, Act 85, Imd. Eff. July 15, 2011;—Am. 2011, Act 86, Imd. Eff. July 15, 2011.

Popular name: Act 368

333.17766f Possession of products containing ephedrine or pseudoephedrine; prohibited conduct; exceptions; violation; penalty; affirmative defense; rebuttal; conflict of local requirements with section.

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 under 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.

(e) Sell any product described under this subsection to an individual during the period in which a stop sale alert is generated for that individual based upon criminal history record information provided under the methamphetamine abuse reporting act. The NPLEx system shall contain an override function that may be used by a dispenser of ephedrine or pseudoephedrine who has a reasonable fear of imminent bodily harm if the dispenser does not complete a sale. Each instance in which the override function is utilized shall be logged by the system.

(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 under 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, 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.

History: Add. 2005, Act 86, Imd. Eff. July 20, 2005;—Am. 2011, Act 86, Imd. Eff. July 15, 2011;—Am. 2014, Act 275, Eff. Jan. 1, 2015.

Popular name: Act 368

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333.17766g Sale, trade, or purchase of dextromethorphan to minor; prohibition; exception for valid prescription; preemption; violation; civil infraction and fine.

Sec. 17766g. (1) Except as otherwise provided in subsection (4), a person shall not knowingly or willfully sell or trade a finished drug product containing any quantity of dextromethorphan to a minor.

(2) A person making a retail sale of a finished drug product containing any quantity of dextromethorphan must require and obtain proof of age from the purchaser before completing the sale, unless from the purchaser's outward appearance the person making the sale would reasonably presume the purchaser to be at least 25 years of age.

(3) Except as otherwise provided in subsection (4), a minor shall not purchase a finished drug product containing any quantity of dextromethorphan.

(4) This section does not apply to a medication containing dextromethorphan that is sold pursuant to a valid prescription.

(5) This section preempts any county, city, village, or township ordinance or resolution regulating the sale, distribution, receipt, or possession of dextromethorphan. A county, city, village, or township shall not enact, adopt, maintain, or enforce an ordinance or resolution that imposes conflicting, different, or additional standards or requirements than those provided in this section on the sale, distribution, receipt, or possession of dextromethorphan.

(6) A person that violates subsection (1) 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 $100.00 for each violation.

(7) An individual who violates subsection (3) 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 $50.00 for each violation.

(8) As used in this section:

(a) "Dextromethorphan" means the dextrorotatory isomer of 3-methoxy-N-methyl-morphinan and its salts.

(b) "Finished drug product" means that term as defined in 21 CFR 207.1.

(c) "Proof of age" means a valid government-issued photo identification that includes the purchaser's name and date of birth, including, but not limited to, a military identification card, passport, or driver license.

History: Add. 2019, Act 123, Eff. July 1, 2020.

Popular name: Act 368

333.17767 Rules and determinations as to licensing.

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

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1993, Act 79, Eff. Apr. 1, 1994;—Am. 2020, Act 142, Imd. Eff. July 14, 2020.

Popular name: Act 368

Administrative rules: R 338.471 et seq. and R 338.3971 et seq. of the Michigan Administrative Code.

333.17768 Grounds for fine, reprimand, or probation, or for denying, limiting, suspending, or revoking license or ordering restitution or community service; applicability of subsection (2)(b).

Sec. 17768. (1) In a manner consistent with part 161, the disciplinary subcommittee may fine, reprimand, or place on probation a person licensed under this part, may deny, limit, suspend, or revoke a person's license, or may 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, may deny, limit, suspend, or revoke a license issued under this part, or may order restitution or community service if the board finds that any of the following apply to an applicant; a partner, officer, or member of the board of directors of a pharmacy, manufacturer, wholesale distributor, or wholesale distributor-broker licensed under this part; a stockholder of a pharmacy, manufacturer, wholesale distributor, or wholesale distributor-broker that is a privately held corporation licensed under this part; or a facility manager for a manufacturer, wholesale distributor, or wholesale distributor-broker designated under section 17748(2):

(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.

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(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 maintained a financial interest in a pharmacy, manufacturer, wholesale distributor, or wholesale distributor-broker that has been denied a license or federal registration, has had its license or federal registration limited, suspended, or revoked, or has 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 or article 8 or the rules promulgated under article 7 or article 8.

(f) The applicant or other person described in this subsection has violated section 17748.

(3) Except for a conviction for a misdemeanor under section 7404(2)(d) 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 on an unintentional error or omission involving a clerical or record-keeping function.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1987, Act 250, Imd. Eff. Dec. 28, 1987;—Am. 1993, Act 79, Eff. Apr. 1, 1994;—Am. 2013, Act 268, Imd. Eff. Dec. 30, 2013;—Am. 2014, Act 413, Eff. Mar. 30, 2015;—Am. 2020, Act 4, Eff. Apr. 26, 2020;—Am. 2020, Act 142, Imd. Eff. July 14, 2020.

Popular name: Act 368

333.17770 Exceptions.

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.

History: 1978, Act 368, Eff. Sept. 30, 1978.

Popular name: Act 368

333.17775 "Program for utilization of unused prescription drugs"; definitions; unused prescription drug repository and distribution program; rules; standards and procedures.

Sec. 17775. (1) This section and section 17776 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.

(b) "Cancer drug" means that term as defined in section 17780.

(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 under section 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.

(*v*) Provides on an outpatient basis for a period of less than 24 consecutive hours to persons not residing or

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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.

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

(*iii*) A dentist licensed under part 166.

(*iv*) An optometrist licensed under part 174.

(*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 or article 8 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

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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 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.

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(*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.

History: Add. 2012, Act 383, Eff. Mar. 28, 2013;—Am. 2013, Act 268, Imd. Eff. Dec. 30, 2013.

333.17776 Destruction and disposal of certain drugs and medications.

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.

History: Add. 2012, Act 384, Eff. Mar. 28, 2013.

333.17780 Cancer drug repository program.

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

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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.

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(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 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.

History: Add. 2006, Act 416, Imd. Eff. Sept. 29, 2006.

Popular name: Act 368

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