PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

PART 73
MANUFACTURE, DISTRIBUTION, AND DISPENSING

333.7301 Rules.

Sec. 7301. The administrator may promulgate rules relating to the licensure and control of the manufacture, distribution, prescribing of controlled substances included in schedule 2, and dispensing of controlled substances in this state.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1986, Act 174, Imd. Eff. July 7, 1986;—Am. 1988, Act 60, Eff. Aug. 1, 1989;—Am. 1993, Act 80, Eff. Apr. 1, 1994.

Compiler's note: Section 3 of Act 174 of 1986 provides: "This amendatory act shall only apply to contested cases filed on or after July 1, 1986."

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

Administrative rules: R 338.471 et seq. and R 338.3101 et seq. of the Michigan Administrative Code.

333.7301a Licensing activities subject to certain provisions.

Sec. 7301a. Licensing activities conducted under this part are subject to sections 16201, 16203, 16299, 16303, 16305, 16307, 16309, and 16313 and article 8.

History: Add. 1988, Act 462, Eff. Sept. 1, 1989;—Am. 2006, Act 392, Imd. Eff. Sept. 27, 2006;—Am. 2013, Act 268, Imd. Eff. Dec. 30, 2013.

Compiler's note: The following sections referenced in MCL 333.7301a have been repealed or do not exist: Secs. 16203, 16309, and 16313.

Popular name: Act 368

333.7302 Labeling controlled substances; contents of label; altering, defacing, or removing label.

Sec. 7302. (1) Controlled substances manufactured or distributed in this state shall have affixed upon each package and container in which the substances are contained, a label showing in legible English the name and address of the principal manufacturer or the distributor, and the name, quantity, kind, and form of controlled substance contained in the package or container.

(2) A person, except a practitioner for the lawful purpose of dispensing controlled substances under this article, shall not alter, deface, or remove a label affixed as required in subsection (1).

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

Popular name: Act 368

333.7302a Identification of certain prescription drugs and manufacturer or distributor; descriptive material; national registry of prescription drugs; exemptions; rules; "prescription drug" defined; violation as misdemeanor; penalty.

Sec. 7302a. (1) A prescription drug that is in finished solid oral dosage form shall not be manufactured or distributed in this state after June 1, 1985 unless the drug is clearly and prominently marked or imprinted with an individual symbol, number, company name, words, letters, marking, national drug code, or a combination of any of the foregoing that identifies the prescription drug and the manufacturer or distributor of the drug.

(2) A person licensed by the administrator under this article to manufacture or distribute prescription drugs shall supply to the department of commerce descriptive material that will identify each current mark or imprint under subsection (1) used by the person who distributes or manufactures the prescription drug.

(3) It is the intent of the legislature that the descriptive material received by the department of commerce pursuant to subsection (2) shall be used in conjunction with similar information from other states by the United States department of health and human services, food and drug administration, or other national agency or organization, to compile a national registry of prescription drugs manufactured or distributed in the United States.

(4) The department of commerce, upon the application of a person who distributes or manufactures a prescription drug, shall exempt a particular prescription drug from the requirements of this section if the department of commerce determines that marking or imprinting the prescription drug is not feasible because of the drug's size, texture, or other unique characteristic.

(5) This section does not apply to a prescription drug that is compounded by a pharmacist licensed under

article 15.

(6) The department of commerce may promulgate rules pursuant to the administrative procedures act of 1969, for purposes of implementing and enforcing this section.

(7) As used in this section, "prescription drug" means a prescription drug as defined in section 17708(4).

(8) A person who knowingly or intentionally violates this section is guilty of a misdemeanor, punishable by imprisonment for not more than 1 year, or a fine of not more than $25,000.00, or both.

History: Add. 1984, Act 254, Eff. Mar. 29, 1985;—Am. 1993, Act 80, Eff. Apr. 1, 1994.

Popular name: Act 368

333.7303 License required; renewal; scope of authority; compliance; additional requirements; persons exempted; waiving or imposing requirement for licensure; separate license for each principal place of business or professional practice; inspection; quarterly report.

Sec. 7303. (1) A person who manufactures, distributes, prescribes, or dispenses a controlled substance in this state or who proposes to engage in the manufacture, distribution, prescribing, or dispensing of a controlled substance in this state shall obtain a license issued by the administrator in accordance with the rules. A person who has been issued a controlled substances license by the administrator under this article and a license under article 15 shall renew the controlled substances license concurrently with the renewal of the license issued under article 15, and for an equal number of years.

(2) A person licensed by the administrator under this article to manufacture, distribute, prescribe, dispense, or conduct research with controlled substances may possess, manufacture, distribute, prescribe, dispense, or conduct research with those substances to the extent authorized by its license and in conformity with the other provisions of this article.

(3) A license issued under this article to manufacture, distribute, prescribe, or dispense pharmaceutical-grade cannabis and the conduct of the licensee is subject to the additional requirements of article 8.

(4) The following persons need not be licensed and may lawfully possess controlled substances or prescription forms under this article:

(a) An agent or employee of a licensed manufacturer, distributor, prescriber, or dispenser of a controlled substance if acting in the usual course of the agent's or employee's business or employment.

(b) A common or contract carrier or warehouseman, or an employee thereof, whose possession of a controlled substance or prescription form is in the usual course of business or employment.

(c) An ultimate user or agent in possession of a controlled substance or prescription form pursuant to a lawful order of a practitioner or in lawful possession of a schedule 5 substance.

(5) The administrator may waive or include by rule the requirement for licensure of certain manufacturers, distributors, prescribers, or dispensers, if it finds the waiver or inclusion is consistent with the public health and safety.

(6) A separate license is required at each principal place of business or professional practice where the applicant manufactures, distributes, prescribes, or dispenses controlled substances.

(7) As a requisite for licensure, the administrator may inspect the establishment of a licensee or applicant for licensure in accordance with the administrator's rule.

(8) A person licensed under this article to distribute controlled substances shall report to the administrator on a quarterly basis all schedule 2 controlled substances and those controlled substances designated by the administrator pursuant to this subsection that are sold to licensed practitioners and retail pharmacies. The report shall be in writing and shall include the name of each licensed practitioner and retail pharmacy to whom the controlled substance was distributed. A report under this subsection may be transmitted electronically, if the transmission is ultimately reduced to writing. The administrator shall designate by rule the controlled substances in schedules 3 to 5 to be reported under this subsection.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1986, Act 174, Imd. Eff. July 7, 1986;—Am. 1988, Act 9, Eff. Aug. 9, 1988;—Am. 1988, Act 60, Eff. Aug. 1, 1989;—Am. 2013, Act 268, Imd. Eff. Dec. 30, 2013.

Compiler's note: Section 3 of Act 174 of 1986 provides: “This amendatory act shall only apply to contested cases filed on or after July 1, 1986.”

Popular name: Act 368

Administrative rules: R 338.471 et seq. and R 338.3101 et seq. of the Michigan Administrative Code.

333.7303a Licensed prescriber; administering or dispensing controlled substance without separate license; prescriber in bona fide prescriber-patient relationship with patient;

follow-up care; use of other controlled substances; recording response; obtaining and reviewing report from electronic system; exceptions; registering with electronic system; records required to be maintained; waiver of requirement under MCL 333.7303.

Sec. 7303a. (1) A prescriber who holds a controlled substances license may administer or dispense a controlled substance listed in schedules 2 to 5 without a separate controlled substances license for those activities.

(2) Except as otherwise provided in rules promulgated under section 16204e and for a patient who is under the care of a hospice, beginning March 31, 2019 or, if rules are promulgated under section 16204e before March 31, 2019, on the date on which rules are promulgated under section 16204e, a licensed prescriber shall not prescribe a controlled substance listed in schedules 2 to 5 unless the prescriber is in a bona fide prescriber-patient relationship with the patient for whom the controlled substance is being prescribed. Except as otherwise provided in this subsection, if a licensed prescriber prescribes a controlled substance under this subsection, the prescriber shall provide follow-up care to the patient to monitor the efficacy of the use of the controlled substance as a treatment of the patient's medical condition. If the licensed prescriber is unable to provide follow-up care, he or she shall refer the patient to the patient's primary care provider for follow-up care or, if the patient does not have a primary care provider, he or she shall refer the patient to another licensed prescriber who is geographically accessible to the patient for follow-up care.

(3) Before prescribing or dispensing a controlled substance to a patient, a licensed prescriber shall ask the patient about other controlled substances the patient may be using. The prescriber shall record the patient's response in the patient's medical or clinical record.

(4) Beginning June 1, 2018, before prescribing or dispensing to a patient a controlled substance in a quantity that exceeds a 3-day supply, a licensed prescriber shall obtain and review a report concerning that patient from the electronic system for monitoring schedule 2, 3, 4, and 5 controlled substances established under section 7333a. This subsection does not apply under any of the following circumstances:

(a) If the dispensing occurs in a hospital or freestanding surgical outpatient facility licensed under article 17 and the controlled substance is administered to the patient in that hospital or facility.

(b) If the patient is an animal as that term is defined in section 18802, the dispensing occurs in a veterinary hospital or clinic and the controlled substance is administered to the patient in that hospital or clinic.

(c) If the controlled substance is prescribed by a licensed prescriber who is a veterinarian and the controlled substance will be dispensed by a pharmacist.

(d) If the patient is under the care of a hospice and the report described in this subsection was obtained and reviewed at the time the patient was admitted to the hospice.

(5) Beginning June 1, 2018, before prescribing or dispensing a controlled substance to a patient, a licensed prescriber shall register with the electronic system for monitoring schedule 2, 3, 4, and 5 controlled substances established under section 7333a.

(6) A licensed prescriber who dispenses controlled substances shall maintain all of the following records separately from other prescription records:

(a) All invoices and other acquisition records for each controlled substance acquired by the prescriber for not less than 5 years after the date the prescriber acquires the controlled substance.

(b) A log of all controlled substances dispensed by the prescriber for not less than 5 years after the date the controlled substance is dispensed.

(c) Records of all other dispositions of controlled substances under the licensee's control for not less than 5 years after the date of the disposition.

(7) The requirement under section 7303 for a license is waived in the following circumstances:

(a) When a controlled substance listed in schedules 2 to 5 is administered on the order of a licensed prescriber by an individual who is licensed under article 15 as a practical nurse or a registered professional nurse.

(b) When methadone or a methadone congener is dispensed on the order of a licensed prescriber in a methadone treatment program licensed under article 6 or when a controlled substance listed in schedules 2 to 5 is dispensed on the order of a licensed prescriber in a hospice rendering emergency care services in a patient's home as described in section 17746 by a registered professional nurse licensed under article 15.

History: Add. 1993, Act 305, Imd. Eff. Dec. 28, 1993;—Am. 2016, Act 379, Eff. Mar. 22, 2017;—Am. 2017, Act 247, Imd. Eff. Dec. 27, 2017;—Am. 2017, Act 248, Imd. Eff. Dec. 27, 2017;—Am. 2017, Act 249, Imd. Eff. Dec. 27, 2017;—Am. 2018, Act 101, Imd. Eff. Apr. 2, 2018;—Am. 2019, Act 43, Imd. Eff. July 8, 2019.

Popular name: Act 368

333.7303b First prescription in single course of treatment for controlled substance

containing opioid; issuance to minor by prescriber; requirements; exceptions; talking consent form authorizing adult to consent to minor's medical treatment; form; definitions.

Sec. 7303b. (1) Except as otherwise provided in this section, beginning June 1, 2018, a prescriber shall comply with all of the following before issuing for a minor the first prescription in a single course of treatment for a controlled substance containing an opioid, regardless of whether the prescriber modifies the dosage during the course of treatment:

(a) Discuss all of the following with the minor, and with the minor's parent or guardian or with another adult authorized to consent to the minor's medical treatment:

(*i*) The risks of addiction and overdose associated with the controlled substance.

(*ii*) The increased risk of addiction to a controlled substance to an individual who is suffering from both mental and substance abuse disorders.

(*iii*) The danger of taking a controlled substance containing an opioid with a benzodiazepine, alcohol, or another central nervous system depressant.

(*iv*) Any other information in the patient counseling information section of the label for the controlled substance that is required under 21 CFR 201.57(c)(18).

(b) Obtain the signature of the minor's parent or guardian, or, subject to subsection (3), the signature of another adult authorized to consent to the minor's medical treatment, on a start talking consent form. The prescriber shall include the signed start talking consent form in the minor's medical record.

(2) Subsection (1) does not apply in any of the following circumstances:

(a) If the minor's treatment is associated with or incident to a medical emergency.

(b) If the minor's treatment is associated with or incident to a surgery, regardless of whether the surgery is performed on an inpatient or outpatient basis.

(c) If, in the prescriber's professional judgment, fulfilling the requirements of subsection (1) would be detrimental to the minor's health or safety.

(d) If the minor's treatment is rendered in a hospice as that term is defined in section 20106 or an oncology department of a hospital that is licensed under article 17.

(e) If the prescriber is issuing the prescription for the minor at the time of discharge from a facility described in subdivision (d).

(f) If the consent of the minor's parent or guardian is not legally required for the minor to obtain treatment.

(3) If the individual signing a start talking consent form is another adult authorized to consent to the minor's medical treatment, the prescriber shall not prescribe more than a single, 72-hour supply of the controlled substance described in subsection (1) to the minor.

(4) A start talking consent form must be on a form that is separate from any other document that a prescriber uses to obtain the informed consent for the treatment of a minor and must contain all of the following:

(a) The name and quantity of the controlled substance being prescribed for the minor and the amount of the initial dose.

(b) A statement indicating that a controlled substance is a drug or other substance that the United States Drug Enforcement Administration has identified as having a potential for abuse.

(c) A statement certifying that the prescriber discussed with the minor, and with the minor's parent or guardian or with another adult authorized to consent to the minor's medical treatment, the topics described in subsection (1).

(d) The number of refills, if any, that are authorized by the prescription.

(e) A space for the signature of the minor's parent or guardian, or the signature of another adult authorized to consent to the minor's medical treatment, and a space to indicate the date that the minor's parent or guardian, or another adult authorized to consent to the minor's medical treatment, signed the form.

(5) As used in this section:

(a) "Another adult authorized to consent to the minor's medical treatment" means an adult to whom a minor's parent or guardian has given written authorization to consent to the minor's medical treatment.

(b) "Medical emergency" means a situation that, in the prescriber's good-faith medical judgment, creates an immediate threat of serious risk to the life or physical health of the minor.

(c) "Minor" means an individual under 18 years of age who is not emancipated under section 4 of 1968 PA 293, MCL 722.4.

(d) "Start talking consent form" means the form described in subsection (4).

History: Add. 2017, Act 246, Imd. Eff. Dec. 27, 2017.

Popular name: Act 368

333.7303c Information to be provided before controlled substance containing opioid is

prescribed; signature; inclusion of signed form in patient's medical or clinical record; controlled substance prescribed for inpatient use; definitions.

Sec. 7303c. (1) Except as otherwise provided in this section, beginning June 1, 2018, before a controlled substance that is an opioid is prescribed to a patient, a licensed prescriber or another health professional shall provide information on all of the following to the patient or the patient's representative:

(a) The danger of opioid addiction.

(b) How to properly dispose of an expired, unused, or unwanted controlled substance.

(c) That the delivery of a controlled substance is a felony under Michigan law.

(d) If the patient is pregnant or is a female of reproductive age, the short- and long-term effects of exposing a fetus to a controlled substance, including, but not limited to, neonatal abstinence syndrome.

(2) After providing the information described in subsection (1), the licensed prescriber or other health professional shall obtain the signature of the patient or the patient's representative on a form prescribed by the department of health and human services, indicating that the patient or the patient's representative has received the information described in subsection (1). The licensed prescriber or other health professional shall include the signed form in the patient's medical or clinical record.

(3) This section does not apply if the controlled substance described in subsection (1) is prescribed for inpatient use.

(4) As used in this section:

(a) "Health professional" means an individual who is licensed, registered, or otherwise authorized to engage in a health profession under article 15.

(b) "Patient" means an individual who receives health care from the licensed prescriber.

(c) "Patient's representative" means a guardian of a patient, if appointed, or a parent, guardian, or person acting in loco parentis, if the patient is a minor, unless the minor lawfully obtained health care without the consent or notification of a parent, guardian, or other person acting in loco parentis.

History: Add. 2017, Act 246, Imd. Eff. Dec. 27, 2017.

Popular name: Act 368

333.7304 Exemptions from licensure.

Sec. 7304. (1) The requirement of licensure is waived for the following persons in the circumstances described in this section:

(a) An officer or employee of the drug enforcement administration while engaged in the course of official duties.

(b) An officer of the United States customs service while engaged in the course of official duties.

(c) An officer or employee of the United States food and drug administration while engaged in the course of official duties.

(d) A federal officer who is lawfully engaged in the enforcement of a federal law relating to controlled substances, drugs, or customs and who is authorized to possess controlled substances in the course of that person's official duties.

(e) An officer or employee of this state, or a political subdivision or agency of this state who is engaged in the enforcement of a state or local law relating to controlled substances and who is authorized to possess controlled substances in the course of that person's official duties.

(2) An official exempted from licensure by this section, when acting in the course of that person's official duties, may possess a controlled substance and may transfer a controlled substance to any other official who is exempted and who is acting in the course of that person's official duties.

(3) An official exempted by this section may procure a controlled substance in the course of an administrative inspection or investigation or in the course of a criminal investigation involving the person from whom the substance was procured.

(4) A law enforcement officer exempted by this section may distribute a controlled substance to another person in the course of that officer's official duties as a means to detect criminal activity or to conduct a criminal investigation.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1994, Act 221, Eff. Mar. 30, 1995.

Popular name: Act 368

333.7305 Permitting certain persons to apply for license; application upon expiration of existing license.

Sec. 7305. The administrator shall initially permit a person who owns, or operates an establishment engaged in the manufacture, distribution, prescription, or dispensing of a controlled substance before

September 30, 1978 and who is licensed by this state to apply for a license pursuant to this article. However, a person who is licensed under existing state law with the administrator or department of commerce is not required to apply for a license pursuant to this article until the expiration of the person's existing license.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1993, Act 80, Eff. Apr. 1, 1994.

Popular name: Act 368

333.7306 License to be granted unless inconsistent with public interest; factors in determining public interest; scope of licensure; license to dispense, prescribe, or conduct research with controlled substances in schedules 2 to 5; registration under federal law to conduct research with schedule 1 substances; effect of compliance with federal law as to registration; limitation on licensure.

Sec. 7306. (1) The administrator shall grant a license to an applicant to manufacture or distribute controlled substances included in sections 7212 to 7220, unless the administrator determines that the issuance of that license would be inconsistent with the public interest. In determining the public interest, the administrator shall consider all of the following factors:

(a) Maintenance of effective controls against diversion of controlled substances to other than legitimate and professionally recognized therapeutic, scientific, or industrial channels.

(b) Compliance with applicable state and local law.

(c) A conviction of the applicant under a federal or state law relating to a controlled substance.

(d) Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion.

(e) Furnishing by the applicant of false or fraudulent material in an application filed under this article.

(f) Suspension or revocation of the applicant's federal registration to manufacture or distribute controlled substances as authorized by federal law.

(g) Any other factor relevant to and consistent with the public health and safety.

(2) Licensure under subsection (1) does not entitle a licensee to manufacture and distribute controlled substances in schedules 1 or 2 other than those specified in the license.

(3) A practitioner shall be licensed to dispense or prescribe any controlled substances or to conduct research with controlled substances in schedules 2 to 5 if the practitioner is authorized to dispense, prescribe, or conduct research under the laws of this state. The administrator need not require separate licensure under this article for a practitioner engaging in research with nonnarcotic controlled substances in schedules 2 to 5 if the licensee is licensed under this article in another capacity. A practitioner registered under federal law to conduct research with schedule 1 substances may conduct research with schedule 1 substances in this state upon furnishing the administrator evidence of that federal registration.

(4) Compliance by a manufacturer or distributor with the provisions of the federal law as to registration, excluding fees, entitles the manufacturer or distributor to be licensed under this article.

(5) Licensure under subsection (1) does not authorize a licensee to dispense, manufacture, distribute, or prescribe a controlled substance if the dispensing, manufacture, distribution, or prescribing is not for legitimate and professionally recognized therapeutic, scientific, or industrial purposes or is not in the scope of practice of a practitioner-licensee.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1986, Act 174, Imd. Eff. July 7, 1986;—Am. 1993, Act 80, Eff. Apr. 1, 1994.

Compiler's note: Section 3 of Act 174 of 1986 provides: “This amendatory act shall only apply to contested cases filed on or after July 1, 1986.”

Popular name: Act 368

333.7311 Actions by disciplinary subcommittee; grounds; limitation; conviction of felony; placing under seal or seizing controlled substances; disposition of controlled substances; judicial order for sale; deposit of proceeds; forfeiture of controlled substances; notice of orders and forfeitures; voiding license under MCL 333.7306; effect of conviction; applicability of subsection (7).

Sec. 7311. (1) A license under section 7306 to manufacture, distribute, prescribe, or dispense a controlled substance may be denied, suspended, or revoked or a licensee may be fined, reprimanded, ordered to perform community service or make restitution, or placed on probation by the disciplinary subcommittee upon a finding that an applicant for licensure or a licensee is subject to any of the following:

(a) The applicant or licensee has furnished false or fraudulent material information in an application filed under this article.

(b) The applicant's or licensee's federal registration to manufacture, distribute, or dispense controlled

substances has been surrendered, suspended, or revoked.

(c) The applicant or licensee has promoted a controlled substance to the general public.

(d) The applicant or licensee is not a practitioner, manufacturer, or distributor.

(e) The applicant or licensee has not maintained effective controls against diversion of controlled substances to other than legitimate and professionally recognized therapeutic, scientific, or industrial uses.

(f) The applicant or licensee is not in compliance with applicable federal, state, and local laws.

(g) The applicant or licensee has manufactured, distributed, or dispensed a controlled substance for other than legitimate or professionally recognized therapeutic, scientific, or industrial purposes or outside the scope of practice of the practitioner-licensee or applicant.

(h) The applicant or licensee has violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate this article or rules of the administrator promulgated under this article.

(2) The disciplinary subcommittee may limit a license under subsection (1) to a particular controlled substance.

(3) A license under section 7306 to manufacture, distribute, prescribe, or dispense a controlled substance shall be denied or revoked by the disciplinary subcommittee if the applicant or licensee has been convicted of a felony under a state or federal law relating to a controlled substance.

(4) If the disciplinary subcommittee suspends or revokes a license or if a license is void under subsection (6), all controlled substances owned or possessed by the licensee at the time of suspension or the effective date of the revocation order may be placed under seal or seized at the discretion of the disciplinary subcommittee. The department shall not dispose of controlled substances under seal or seizure until the time for taking an appeal has elapsed or until all appeals have been concluded, unless a court, upon application therefor, orders the sale of perishable controlled substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final or after a license becomes void under subsection (6) because the licensee's license to practice is revoked under article 15 and that revocation order becomes final, the disciplinary subcommittee may order all controlled substances under seal or seizure to be forfeited to this state.

(5) The disciplinary subcommittee shall promptly notify the bureau of all orders suspending or revoking a license and all forfeitures of controlled substances.

(6) A license under section 7306 to manufacture, distribute, prescribe, or dispense a controlled substance is automatically void if the licensee's license to practice is suspended or revoked under article 15.

(7) Subject to subsection (8), if the administrator or the disciplinary subcommittee finds that an applicant or licensee has been convicted of a misdemeanor or a felony under a state or federal law relating to a controlled substance, the applicant or licensee shall not have a direct financial interest in or be employed by a person who is licensed under this article to manufacture, distribute, prescribe, or dispense a controlled substance in a capacity in which the individual has direct access to controlled substances for a period of not less than 3 years after the date of conviction. An individual who violates this subsection is subject to a civil fine of not more than $25,000.00 in a proceeding in the circuit court.

(8) Subsection (7) 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 (7) does not apply to a conviction for a misdemeanor based upon an unintentional error or omission involving a clerical or record-keeping function.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1986, Act 174, Imd. Eff. July 7, 1986;—Am. 1988, Act 29, Eff. Aug. 26, 1988;—Am. 1988, Act 30, Eff. Aug. 26, 1988;—Am. 1993, Act 80, Eff. Apr. 1, 1994.

Compiler's note: Section 3 of Act 174 of 1986 provides: “This amendatory act shall only apply to contested cases filed on or after July 1, 1986.”

Popular name: Act 368

Administrative rules: R 338.493a et seq. and R 338.3101 et seq. of the Michigan Administrative Code.

333.7314 Denial, suspension, revocation, or limitation of license; order to show cause; service of order; conduct of proceedings; effect of proceeding on existing license; suspension of license on finding of imminent danger; duration of suspension; applicability of subsection (1).

Sec. 7314. (1) Before the disciplinary subcommittee suspends or revokes or limits a license or denies an application or a renewal of a license, the disciplinary subcommittee shall serve on the applicant or licensee an order to show cause why the application or license should not be denied, limited, revoked, or suspended, or why the renewal should not be denied. The order to show cause shall contain a statement of the basis for the

order and shall call upon the applicant or licensee to appear before the disciplinary subcommittee or a hearings examiner at a time and place not less than 30 days after the date of service of the order. A show cause order for a denial of renewal of a license shall be served not later than 30 days before expiration of the license. The proceedings described in this subsection shall be conducted without regard to any criminal prosecution or other proceeding. A proceeding to deny renewal of a license does not abate the existing license, which remains in effect pending the outcome of the administrative hearing.

(2) Pursuant to procedural guidelines adopted by the department, the department may suspend a license, without an order to show cause, simultaneously with the institution of proceedings under section 7311 or if renewal of licensure is refused, if the department finds that there is an imminent danger to the public health or safety that warrants this action. The suspension shall continue in effect until conclusion of the proceedings, including judicial review, unless sooner withdrawn by a hearings examiner or dissolved by a court of competent jurisdiction.

(3) Subsection (1) does not apply to the suspension or revocation of a license by the administrator pursuant to section 7311(6).

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1986, Act 174, Imd. Eff. July 7, 1987;—Am. 1993, Act 80, Eff. Apr. 1, 1994.

Compiler's note: Section 3 of Act 174 of 1986 provides: "This amendatory act shall only apply to contested cases filed on or after July 1, 1986."

Popular name: Act 368

333.7315 Reinstatement of license; application; hearing.

Sec. 7315. (1) An individual whose license is limited, suspended, or revoked under this part may apply to the board for a reinstatement of a revoked or suspended license or for removal of a limitation as to a particular controlled substance.

(2) In the case of a revoked license, an applicant shall not apply for reinstatement before the expiration of 5 years after the effective date of the revocation. The department shall return an application for reinstatement received before the expiration of the 5-year period.

(3) The department shall provide an opportunity for a hearing before final rejection of an application for reinstatement.

History: Add. 1988, Act 30, Eff. Aug. 26, 1988;—Am. 1993, Act 80, Eff. Apr. 1, 1994.

Popular name: Act 368

333.7316 Reinstatement of license; good moral character; public interest; disciplinary or corrective measure.

Sec. 7316. The administrator may reinstate a revoked or suspended license to an individual whose license has been suspended or revoked under this article or remove a limitation as to a particular controlled substance if, after a hearing, the administrator is satisfied that the applicant is of good moral character, has met the criteria in the rules promulgated under section 16245(6), and should be permitted in the public interest to have his or her license reinstated or the limitation removed. As a condition of reinstatement, the disciplinary subcommittee, upon the recommendation of the administrator, may impose a disciplinary or corrective measure authorized under this article. In determining the public interest, the administrator shall consider the factors set forth in section 7306(1)(a) to (g).

History: Add. 1988, Act 30, Eff. Aug. 26, 1988;—Am. 1993, Act 80, Eff. Apr. 1, 1994.

Popular name: Act 368

333.7321 Records; inventories; annual inventory; retention.

Sec. 7321. (1) Subject to subsection (2), a person licensed to manufacture, distribute, prescribe, or dispense controlled substances under this article shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of federal law and with any additional rules the administrator promulgates, unless exempted by those rules.

(2) Beginning May 1, 1989, and annually thereafter, each person licensed under this article to manufacture, distribute, prescribe, or dispense controlled substances shall inventory all schedule 2 to 5 controlled substances possessed by the person at the time of the inventory. A person described in this subsection may conduct the annual inventory required under this subsection not more than 30 days before May 1, but shall conduct the inventory not later than 60 days after May 1. A person described in this subsection shall retain the inventory required under this subsection for not less than 2 years after the date of the inventory's creation and shall make the inventory available for inspection by the department at the request of the department.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1988, Act 245, Eff. Sept. 1, 1988;—Am. 2016, Act 383, Eff. Mar. 28, 2017.

Popular name: Act 368

Administrative rules: R 338.471 et seq. and R 338.3101 et seq. of the Michigan Administrative Code.

333.7331 Authority to purchase schedule 1 or 2 controlled substance; order form.

Sec. 7331. (1) Only a practitioner who holds a license under this article to prescribe or dispense controlled substances may purchase from a licensed manufacturer or distributor a schedule 1 or 2 controlled substance. The authority granted under this subsection to purchase a schedule 1 or 2 controlled substance is not assignable or transferable.

(2) A purchase of a schedule 1 or 2 controlled substance under subsection (1) shall be made only pursuant to an order form which is in compliance with federal law.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1988, Act 10, Eff. Aug. 9, 1988.

Popular name: Act 368

333.7333 "Good faith" defined; dispensing controlled substance included in schedule 2; prescription form; electronic transmission under MCL 333.17754a; emergency; filling and refilling prescription; dispensing controlled substance included in schedule 3, 4, or 5; requirements and use of written prescription; class B dealer; animal control shelter or animal protection shelter; limited permit; administration of commercially prepared, premixed solution of sodium pentobarbital or animal tranquilizer; liability of veterinarian; "animal tranquilizer" and "class B dealer" defined.

Sec. 7333. (1) As used in this section, "good faith" means the prescribing or dispensing of a controlled substance by a practitioner licensed under section 7303 in the regular course of professional treatment to or for an individual who is under treatment by the practitioner for a pathology or condition other than that individual's physical or psychological dependence on or addiction to a controlled substance, except as provided in this article. Application of good faith to a pharmacist means the dispensing of a controlled substance pursuant to a prescriber's order which, in the professional judgment of the pharmacist, is lawful. The pharmacist shall be guided by nationally accepted professional standards including, but not limited to, all of the following, in making the judgment:

(a) Lack of consistency in the doctor-patient relationship.

(b) Frequency of prescriptions for the same drug by 1 prescriber for larger numbers of patients.

(c) Quantities beyond those normally prescribed for the same drug.

(d) Unusual dosages.

(e) Unusual geographic distances between patient, pharmacist, and prescriber.

(2) Except as otherwise provided in this section, a practitioner, in good faith, may dispense a controlled substance included in schedule 2 that is a prescription drug as determined under section 503(b) of the federal food, drug, and cosmetic act, 21 USC 353, or section 17708, on receipt of either of the following:

(a) A prescription of a practitioner licensed under section 7303 on a prescription form. More than 1 prescription for a controlled substance included in schedule 2 may be included on a single prescription form.

(b) A prescription that is electronically transmitted under section 17754a.

(3) In an emergency situation, as described in R 338.3165 of the Michigan Administrative Code, a controlled substance included in schedule 2 may be dispensed on the oral prescription of a practitioner if the prescribing practitioner promptly fills out a prescription form and forwards the prescription form to the dispensing pharmacy within 7 days after the oral prescription is issued. A prescription for a controlled substance included in schedule 2 must not be filled more than 90 days after the date on which the prescription was issued. A pharmacist, consistent with federal law and regulations on the partial filling of a controlled substance included in schedule 2, may partially fill in increments a prescription for a controlled substance included in schedule 2.

(4) A practitioner, in good faith, may dispense a controlled substance included in schedule 3, 4, or 5 that is a prescription drug as determined under section 503(b) of the federal food, drug, and cosmetic act, 21 USC 353, or section 17708, on receipt of any of the following:

(a) A prescription on a prescription form.

(b) An oral prescription of a practitioner.

(c) A prescription that is electronically transmitted under section 17754a.

(5) A prescription for a controlled substance included in schedule 3 or 4 must not be filled or refilled without specific refill instructions noted by the prescriber. A prescription for a controlled substance included in schedule 3 or 4 must not be filled or refilled later than 6 months after the date of the prescription or be refilled more than 5 times, unless renewed by the prescriber in accordance with rules promulgated by the administrator.

(6) A controlled substance included in schedule 5 must not be distributed or dispensed other than for a medical purpose, or in any manner except in accordance with rules promulgated by the administrator.

(7) If a prescription is required under this section, the prescription must contain the quantity of the controlled substance prescribed in both written and numerical terms. A prescription is in compliance with this subsection if, in addition to containing the quantity of the controlled substance prescribed in written terms, it contains preprinted numbers representative of the quantity of the controlled substance prescribed next to which is a box or line the prescriber may check.

(8) A prescribing practitioner shall not use a prescription form for a purpose other than prescribing. A prescribing practitioner shall not postdate a prescription form that contains a prescription for a controlled substance. Until the date on which section 17754a applies, a prescriber may transmit a prescription by facsimile of a printed prescription form and by electronic transmission of a printed prescription form, if not prohibited by federal law. If, with the patient's consent, a prescription is electronically transmitted under this subsection, it must be transmitted directly to a pharmacy of the patient's choice by the prescriber or the prescriber's authorized agent, and the data must not be altered, modified, or extracted in the transmission process.

(9) Notwithstanding subsections (1) to (6), a class B dealer may acquire a limited permit only for the purpose of buying, possessing, and administering a commercially prepared, premixed solution of sodium pentobarbital to perform euthanasia on injured, sick, homeless, or unwanted domestic pets and other animals, if the class B dealer does all of the following:

(a) Applies to the administrator for a permit in accordance with rules promulgated under this part. The application must contain the name of the individual in charge of the day-to-day operations of the class B dealer's facilities and the name of the individual responsible for designating employees who will be performing euthanasia on animals pursuant to this act.

(b) Complies with the rules promulgated by the administrator for the storage, handling, and use of a commercially prepared, premixed solution of sodium pentobarbital to perform euthanasia on animals. The class B dealer shall maintain a record of use and shall make the record available for inspection by the department of licensing and regulatory affairs, the department of agriculture and rural development, and the United States Department of Agriculture.

(c) Subject to subdivision (d), certifies that the class B dealer or an employee of the class B dealer has received, and can document completion of, a minimum of 16 hours of training, including at least 12 hours of content training and at least 4 hours of practical training, in the use of a commercially prepared, premixed solution of sodium pentobarbital and an animal tranquilizer to perform euthanasia on animals from a training program approved by the state veterinarian, in consultation with the Michigan board of veterinary medicine, and given by a licensed veterinarian pursuant to rules promulgated by the administrator. The training described in this subdivision must comply with the American Veterinary Medical Association's guidelines for the euthanasia of animals.

(d) Until December 31, 2021, ensures that the class B dealer or an employee of the class B dealer who received, and can document the completion of, the 8 hours of training required immediately before May 22, 2018 only administers a commercially prepared, premixed solution of sodium pentobarbital to perform euthanasia on the animals described in this subsection. Beginning January 1, 2022, the individuals described in this subdivision must have received, and be able to document the completion of, the training described in subdivision (c) to administer a commercially prepared, premixed solution of sodium pentobarbital or an animal tranquilizer to perform euthanasia on the animals described in this subsection.

(e) Certifies that only an individual described in subdivision (c) or (d) or an individual otherwise permitted to use a controlled substance pursuant to this article will administer the commercially prepared, premixed solution of sodium pentobarbital or an animal tranquilizer according to written procedures established by the class B dealer.

(f) Beginning January 1, 2022, certifies that the individual in charge of the day-to-day operations of the class B dealer's facilities has received, and can document the completion of, the training described in subdivision (c).

(g) Complies with all state and federal laws, rules, and regulations regarding the acquisition, use, and security of controlled substances.

(10) Notwithstanding subsections (1) to (6), an animal control shelter or animal protection shelter registered with the department of agriculture and rural development pursuant to 1969 PA 287, MCL 287.331 to 287.340, may acquire a limited permit only for the purpose of buying, possessing, and administering a commercially prepared, premixed solution of sodium pentobarbital, or an animal tranquilizer, to use exclusively as an adjunct in the process of performing euthanasia on injured, sick, homeless, or unwanted domestic pets and other animals, if the animal control shelter or animal protection shelter does all of the

following:

(a) Applies to the administrator for a permit in accordance with rules promulgated under this part. The application must contain the name of the individual in charge of the day-to-day operations of the animal control shelter or animal protection shelter and the name of the individual responsible for designating employees who will be performing euthanasia on animals pursuant to this act.

(b) Complies with the rules promulgated by the administrator for the storage, handling, and use of a commercially prepared, premixed solution of sodium pentobarbital or an animal tranquilizer to perform euthanasia on animals. The animal control shelter or animal protection shelter shall maintain a record of use and make the record available for inspection by the department of licensing and regulatory affairs and the department of agriculture and rural development.

(c) Subject to subdivision (d), certifies that an employee of the animal control shelter or animal protection shelter has received, and can document completion of, a minimum of 16 hours of training, including at least 12 hours of content training and at least 4 hours of practical training, in the use of a commercially prepared, premixed solution of sodium pentobarbital and an animal tranquilizer to perform euthanasia on animals from a training program approved by the state veterinarian, in consultation with the Michigan board of veterinary medicine, and given by a licensed veterinarian pursuant to rules promulgated by the administrator. The training described in this subdivision must comply with the American Veterinary Medical Association's guidelines for the euthanasia of animals.

(d) Until December 31, 2021, ensures that an employee of the animal control shelter or animal protection shelter who received, and can document the completion of, the training required immediately before May 22, 2018 only administers a commercially prepared solution of xylazine hydrochloride or a commercially prepared, premixed solution of sodium pentobarbital to perform euthanasia on the animals described in this subsection in accordance with his or her training. Beginning January 1, 2022, the employee described in this subdivision must have received, and be able to document the completion of, the training described in subdivision (c) to administer a commercially prepared, premixed solution of sodium pentobarbital or an animal tranquilizer to perform euthanasia on the animals described in this subsection.

(e) Certifies that only an individual described in subdivision (c) or (d) or an individual otherwise permitted to use a controlled substance pursuant to this article will administer a commercially prepared, premixed solution of sodium pentobarbital or an animal tranquilizer according to written procedures established by the animal control shelter or animal protection shelter.

(f) Beginning January 1, 2022, certifies that the individual in charge of the day-to-day operations of the animal control shelter or animal protection shelter has received, and can document the completion of, the training described in subdivision (c).

(g) Complies with all state and federal laws and regulations regarding the acquisition, use, and security of controlled substances.

(11) The application described in subsection (9) or (10) must include the names and addresses of all individuals employed by the animal control shelter or animal protection shelter or class B dealer who have been trained as described in subsection (9)(c), (d), and (f) or (10)(c), (d), and (f) and the name of the veterinarian who trained them. The list of names and addresses must be updated every 6 months.

(12) If an animal control shelter or animal protection shelter or class B dealer issued a permit pursuant to subsection (9) or (10) does not have in its employ an individual trained as described in subsection (9)(c) or (d) and (9)(f), or (10)(c) or (d) and (10)(f), the animal control shelter or animal protection shelter or class B dealer shall immediately notify the administrator and shall cease to administer a commercially prepared, premixed solution of sodium pentobarbital or an animal tranquilizer for the purposes described in subsection (9) or (10) until the administrator is notified that 1 of the following has occurred:

(a) An individual trained as described in subsection (9)(c), (d), or (f) or (10)(c), (d), or (f) has been hired by the animal control shelter or animal protection shelter or class B dealer.

(b) An individual employed by the animal control shelter or animal protection shelter or class B dealer has been trained as described in subsection (9)(c) or (f) or (10)(c) or (f).

(13) A veterinarian, including a veterinarian who trains individuals as described in subsection (9)(c), (d), or (f), or (10)(c), (d), or (f), is not civilly or criminally liable for the use of a commercially prepared, premixed solution of sodium pentobarbital or an animal tranquilizer by an animal control shelter or animal protection shelter or a class B dealer, unless the veterinarian is employed by or under contract with the animal control shelter or animal protection shelter or class B dealer and the terms of the veterinarian's employment or the contract require the veterinarian to be responsible for the use or administration of the commercially prepared, premixed solution of sodium pentobarbital or animal tranquilizer.

(14) A person shall not knowingly use or permit the use of a commercially prepared, premixed solution of sodium pentobarbital or an animal tranquilizer in violation of this section.

(15) This section does not require that a veterinarian be employed by or under contract with an animal control shelter or animal protection shelter or class B dealer to obtain, possess, or administer a commercially prepared, premixed solution of sodium pentobarbital or an animal tranquilizer pursuant to this section.

(16) Notwithstanding subsections (1) to (6), an animal control shelter registered with the department of agriculture and rural development pursuant to 1969 PA 287, MCL 287.331 to 287.340, may acquire a limited permit only for the purpose of buying, possessing, and administering an animal tranquilizer to sedate or immobilize an animal running at large that is dangerous or difficult to capture, if the animal control shelter does all of the following:

(a) Applies to the administrator for a permit in accordance with the rules promulgated under this part. The application must contain the name of the individual in charge of the day-to-day operations of the animal control shelter and the name of the individual responsible for designating employees who will be administering an animal tranquilizer pursuant to this act.

(b) Complies with the rules promulgated by the administrator for the storage, handling, and use of an animal tranquilizer. The animal control shelter shall maintain a record of use and shall make the record available for inspection by the department of licensing and regulatory affairs and the department of agriculture and rural development.

(c) Subject to subdivision (d), certifies that an employee of the animal control shelter has received, and can document completion of, both of the following in the following order:

(*i*) The training described in subsection (10)(c).

(*ii*) A minimum of 16 hours of training, including at least 12 hours of content training and at least 4 hours of practical training, in the use of animal tranquilizers to sedate or immobilize the animals described in this subsection from a training program approved by the state veterinarian, in consultation with the Michigan board of veterinary medicine, and given by a licensed veterinarian pursuant to rules promulgated by the administrator.

(d) Until December 31, 2021, ensures that an employee of the animal control shelter who received, and can document the completion of, the training required immediately before May 22, 2018 only administers a commercially prepared solution of xylazine hydrochloride to sedate or immobilize the animals described in this subsection. Beginning January 1, 2022, the employee described in this subdivision must have received, and be able to document the completion of, the training described in subdivision (c) to administer an animal tranquilizer to perform euthanasia on the animals described in this subsection.

(e) Certifies that only an individual described in subdivision (c) or (d) or an individual otherwise permitted to use a controlled substance pursuant to this article will administer an animal tranquilizer according to written procedures established by the animal control shelter.

(f) Beginning January 1, 2022, certifies that the individual in charge of the day-to-day operations of the animal control shelter has received, and can document the completion of, the training described in subdivision (c).

(g) Complies with all state and federal laws, rules, and regulations regarding the acquisition, use, and security of controlled substances.

(17) The application described in subsection (16) must include the names and business addresses of all individuals employed by the animal control shelter who have been trained as described in subsection (16)(c), (d), and (f) and must include documented proof of the training. The list of names and business addresses must be updated every 6 months.

(18) If an animal control shelter issued a permit pursuant to subsection (16) does not have in its employ an individual trained as described in subsection (16)(c) or (d) and (16)(f), the animal control shelter shall immediately notify the administrator and shall cease to administer an animal tranquilizer for the purposes described in subsection (16) until the administrator is notified that 1 of the following has occurred:

(a) An individual trained as described in subsection (16)(c), (d), or (f) has been hired by the animal control shelter.

(b) An individual employed by the animal control shelter has been trained as described in subsection (16)(c) or (f).

(19) A veterinarian, including a veterinarian who trains individuals as described in subsection (16)(c), (d), or (f), is not civilly or criminally liable for the use of an animal tranquilizer by an animal control shelter unless the veterinarian is employed by or under contract with the animal control shelter and the terms of the veterinarian's employment or the contract require the veterinarian to be responsible for the use or administration of an animal tranquilizer.

(20) As used in this section:

(a) "Animal tranquilizer" means a commercially prepared solution of xylazine hydrochloride, a commercially prepared solution of ketamine, or a commercially prepared compound containing tiletamine and

zolazepam.

(b) "Class B dealer" means a class B dealer licensed by the United States Department of Agriculture pursuant to the animal welfare act, 7 USC 2131 to 2160 and the department of agriculture and rural development pursuant to 1969 PA 224, MCL 287.381 to 287.395.

History: 1978, Act 368, Eff. Sept. 30, 1978;—Am. 1980, Act 414, Imd. Eff. Jan. 11, 1981;—Am. 1988, Act 28, Eff. Aug. 26, 1988;—Am. 1988, Act 60, Eff. Aug. 1, 1988;—Am. 1988, Act 240, Imd. Eff. July 11, 1988;—Am. 1989, Act 143, Imd. Eff. June 29, 1989;—Am. 1990, Act 30, Eff. Mar. 28, 1991;—Am. 1991, Act 186, Imd. Eff. Dec. 27, 1991;—Am. 1993, Act 80, Eff. Apr. 1, 1994;—Am. 1993, Act 138, Imd. Eff. Aug. 2, 1993;—Am. 2001, Act 231, Eff. Jan. 6, 2003;—Am. 2006, Act 451, Imd. Eff. Dec. 14, 2006;—Am. 2010, Act 3, Imd. Eff. Feb. 4, 2010;—Am. 2017, Act 251, Eff. Mar. 27, 2018;—Am. 2018, Act 34, Eff. May 22, 2018;—Am. 2020, Act 136, Imd. Eff. July 8, 2020.

Compiler's note: Enacting section 2 of Act 231 of 2001 provides:

"Enacting section 2. Section 7333 of the public health code, 1978 PA 368, MCL 333.7333, as amended by this amendatory act, takes effect upon promulgation of the rules required under section 7333a(1) of the public health code, 1978 PA 368, MCL 333.7333a, as added by this amendatory act, and receipt by the secretary of state of written notice from the director of the department of consumer and industry services that the electronic monitoring system required by section 7333a of the public health code, 1978 PA 368, MCL 333.7333a, as added by this amendatory act, is operational. The notice to the secretary of state shall include a statement that the department of consumer and industry services is able to receive data from at least 80% of those required to report under section 7333a of the public health code, 1978 PA 368, MCL 333.7333a, as added by this amendatory act, and is able to respond to requests for data from persons authorized to make such requests and to review and utilize the data."

The rules required under section 7333a of the public health code, 1978 PA 368, MCL 333.7333a, pertaining to the operation of the electronic monitoring system, were promulgated on December 30, 2002. In addition, a written notice from the director of the department of consumer and industry services that the electronic monitoring system required by section 7333a of the public health code is operational was filed with, and received by, the secretary of state on January 6, 2003.

Popular name: Act 368

Administrative rules: R 338.471 et seq. and R 338.3101 et seq. of the Michigan Administrative Code.

333.7333a Electronic monitoring system; definitions.

Sec. 7333a. (1) The department shall establish, by rule, an electronic system for monitoring schedule 2, 3, 4, and 5 controlled substances dispensed in this state by veterinarians, and by pharmacists and dispensing prescribers licensed under part 177 or dispensed to an address in this state by a pharmacy licensed in this state. The rules must provide an appropriate electronic format for the reporting of data including, but not limited to, patient identifiers, and the name of the controlled substance dispensed, the date of dispensing, the quantity dispensed, the prescriber, and the dispenser. The department shall require a veterinarian, pharmacist, or dispensing prescriber to utilize the electronic data transmittal process developed by the department or the department's contractor. The department shall not require a veterinarian, pharmacist, or dispensing prescriber to pay a new fee dedicated to the operation of the electronic monitoring system or to incur any additional costs solely related to the transmission of data to the department. The dispensing of a controlled substance in any of the following is exempt from the reporting requirements:

(a) A hospital that is licensed under article 17 that administers the controlled substance to an individual who is an inpatient.

(b) A health facility or agency licensed under article 17 if the controlled substance is dispensed by a dispensing prescriber in a quantity adequate to treat the patient for not more than 48 hours.

(c) A veterinary hospital or clinic that administers the controlled substance to an animal that is an inpatient.

(2) Notwithstanding any practitioner-patient privilege, the director of the department may provide data obtained under this section to all of the following:

(a) A designated representative of a board responsible for the licensure, regulation, or discipline of a practitioner, pharmacist, or other person that is authorized to prescribe, administer, or dispense controlled substances.

(b) An employee or agent of the department.

(c) A state, federal, or municipal employee or agent whose duty is to enforce the laws of this state or the United States relating to drugs.

(d) A state-operated Medicaid program.

(e) A state, federal, or municipal employee who is the holder of a search warrant or subpoena properly issued for the records.

(f) A practitioner or pharmacist who requests information and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient.

(g) An individual with whom the department has contracted under subsection (7).

(h) A practitioner or other person that is authorized to prescribe controlled substances for the purpose of determining if prescriptions written by that practitioner or other person have been dispensed.

(i) The health care payment or benefit provider for the purposes of ensuring patient safety and investigating

fraud and abuse.

(3) Except as otherwise provided in this part, a person shall use information submitted under this section only for bona fide drug-related criminal investigatory or evidentiary purposes or for the investigatory or evidentiary purposes in connection with the functions of a disciplinary subcommittee or 1 or more of the licensing or registration boards created in article 15.

(4) A person that receives data or any report under subsection (2) containing any patient identifiers of the system from the department shall not provide it to any other person except by order of a court of competent jurisdiction.

(5) Except as otherwise provided in this subsection, reporting under subsection (1) is mandatory for a veterinarian, pharmacist, and dispensing prescriber. However, the department may issue a written waiver of the electronic reporting requirement to a veterinarian, pharmacist, or dispensing prescriber who establishes grounds that he or she is unable to use the electronic monitoring system. The department shall require the applicant for the waiver to report the required information in a manner approved by the department.

(6) The department, in consultation with the Michigan board of pharmacy, the Michigan board of medicine, the Michigan board of osteopathic medicine and surgery, the department of state police, and appropriate medical professional associations, shall examine the need for and may promulgate rules for the production of a prescription form on paper that minimizes the potential for forgery. The rules must not include any requirement that sequential numbers, bar codes, or symbols be affixed, printed, or written on a prescription form or that the prescription form be a state produced prescription form. In examining the need for rules for the production of a prescription form on paper that minimizes the potential for forgery, the department shall consider and identify the following:

(a) Cost, benefits, and barriers.

(b) Overall cost-benefit analysis.

(c) Compatibility with the electronic monitoring system required under this section.

(7) The department may enter into 1 or more contractual agreements for the administration of this section.

(8) The department, all law enforcement officers, all officers of the court, and all regulatory agencies and officers, in using the data for investigative or prosecution purposes, shall consider the nature of the prescriber's and dispenser's practice and the condition for which the patient is being treated.

(9) The data and any report containing any patient identifiers obtained from the data are not public records and are not subject to disclosure under the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246.

(10) The department may issue a written request to a health care payment or benefit provider to determine if the provider has accessed the electronic monitoring system as provided in subsection (2)(i) in the previous calendar year and, if so, to determine the number of inquiries the provider made in the previous calendar year and any other information the department requests in relation to the provider's access to the electronic monitoring system. A health care payment or benefit provider shall respond to the written request on or before the March 31 following the request. The department shall collaborate with health care payment or benefit providers to develop a reasonable request and reporting form for use under this subsection.

(11) Before dispensing or prescribing buprenorphine, or a drug containing buprenorphine or methadone, to a patient in a substance use disorder program, a prescriber shall obtain and review data concerning that patient from the department under subsection (2). A prescriber dispensing buprenorphine, or a drug containing buprenorphine or methadone, to a patient in a substance use disorder program shall also report the data required in subsection (1), if federal law does not prohibit the reporting of data concerning the patient, to the department. As used in this subsection:

(a) "Approved service program" means that term as defined in section 100a of the mental health code, 1974 PA 258, MCL 330.1100a.

(b) "Substance use disorder program" means a program as that term is defined in section 260 of the mental health code, 1974 PA 258, MCL 330.1260, an approved service program, a nonregulated substance use disorder services program, a federal certified substance use disorder services program, or a federally regulated substance use disorder services program.

(12) R 338.3162e of the Michigan Administrative Code is rescinded.

(13) As used in this section:

(a) "Department" means the department of licensing and regulatory affairs.

(b) "Health care payment or benefit provider" means a person that provides health benefits, coverage, or insurance in this state, including a health insurance company, a nonprofit health care corporation, a health maintenance organization, a multiple employer welfare arrangement, a Medicaid contracted health plan, or any other person providing a plan of health benefits, coverage, or insurance subject to state insurance regulation.

History: Add. 2001, Act 231, Imd. Eff. Jan. 3, 2002;—Am. 2011, Act 108, Imd. Eff. July 20, 2011;—Am. 2012, Act 44, Imd. Eff. Mar. 7, 2012;—Am. 2016, Act 383, Eff. Mar. 28, 2017;—Am. 2017, Act 252, Eff. Mar. 27, 2018.

Popular name: Act 368

Administrative rules: R 338.3101 et seq. of the Michigan Administrative Code.

333.7333b Treatment of patient for acute pain; prescription for opioid; limitation; "acute pain" defined.

Sec. 7333b. (1) Beginning July 1, 2018, if a prescriber is treating a patient for acute pain, the prescriber shall not prescribe the patient more than a 7-day supply of an opioid within a 7-day period.

(2) As used in this section, "acute pain" means pain that is the normal, predicted physiological response to a noxious chemical or a thermal or mechanical stimulus and is typically associated with invasive procedures, trauma, and disease and usually lasts for a limited amount of time.

History: Add. 2017, Act 251, Eff. Mar. 27, 2018.

Popular name: Act 368

333.7334 Repealed. 2001, Act 231, Eff. Jan. 6, 2003.

Compiler's note: The repealed section pertained to official prescription form.

Popular name: Act 368

333.7335 Repealed. 2013, Act 268, Imd. Eff. Dec. 30, 2013.

Compiler's note: Former MCL 333.7335, pertaining to marihuana controlled substances therapeutic research program, expired November 1, 1982, pursuant to Act 125 of 1979.
The repealed section pertained to marihuana controlled substances therapeutic research program.

Popular name: Act 368

333.7336 Repealed. 2013, Act 268, Imd. Eff. Dec. 30, 2013.

Compiler's note: Former MCL 333.7336, pertaining to patient qualification review board and certification of designated pharmacies for participation in marihuana distribution, expired November 1, 1982, pursuant to Act 125 of 1979.
The repealed section pertained to patient qualification review board.

Popular name: Act 368

333.7339 Dispensing, selling, or giving product to individual less than 18 years of age; violation as misdemeanor; penalty.

Sec. 7339. (1) A person shall not dispense, sell, or otherwise give a product described in section 7220(1)(c)(*ii*) to an individual less than 18 years of age. This section does not apply to a physician or pharmacist who prescribes, dispenses, administers, or delivers a product described in section 7220(1)(c)(*ii*) to an individual less than 18 years of age, to a parent or guardian of an individual less than 18 years of age who delivers the product to the individual, or to a person authorized by the individual's parent or legal guardian who dispenses or delivers the product to the individual.

(2) In the course of selling, offering for sale, or otherwise distributing a product described in section 7220(1)(c)(*ii*), a person shall not advertise or represent in any manner that the product causes euphoria, ecstasy, a "buzz" or "high", or an altered mental state, heightens sexual performance, or, because it contains ephedrine alkaloids, increases muscle mass.

(3) A person who violates this section is guilty of a misdemeanor punishable by imprisonment for not more than 93 days or a fine of not more than $100.00, or both.

History: Add. 1999, Act 144, Eff. Jan. 21, 2000.

Popular name: Act 368

333.7340 Selling, distributing, delivering, or furnishing product containing ephedrine or pseudoephedrine; prohibition; exceptions; violation as felony; penalty.

Sec. 7340. (1) A person shall not sell, distribute, deliver, or otherwise furnish a product that contains 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 an individual if the sale is transacted through use of the mail, internet, telephone, or other electronic means.

(2) This section does not apply to any of 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 the 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 person who dispenses a product described in subsection (1) pursuant to a prescription.

(e) A person who, in the course of his or her business, sells or distributes products described in subsection (1) to either of the following:

(*i*) A person licensed by this state to manufacture, deliver, dispense, or possess with intent to manufacture or deliver a controlled substance, prescription drug, or other drug.

(*ii*) A person who orders those products described in subsection (1) for retail sale pursuant to a license issued under the general sales tax act, 1933 PA 167, MCL 205.51 to 205.78.

(f) A manufacturer or distributor who donates product samples to a nonprofit charitable organization that has tax-exempt status pursuant to section 501(c)(3) of the internal revenue code of 1986, a licensed practitioner, or a governmental entity.

(3) A person who violates this section is guilty of a felony punishable by imprisonment for not more than 4 years or a fine of not more than $5,000.00, or both.

History: Add. 2006, Act 261, Eff. Oct. 1, 2006.

Popular name: Act 368

333.7340a Submission of information to NPLEx.

Sec. 7340a. (1) Before completing a sale under section 17766f, a retailer shall electronically submit the required information to the national precursor log exchange (NPLEx) administered by the national association of drug diversion investigators (NADDI). A retailer shall not be required to pay a fee for using the NPLEx system.

(2) If a retailer selling a nonprescription product containing ephedrine or pseudoephedrine experiences mechanical or electronic failure of the electronic sales tracking system and is unable to comply with the electronic sales tracking requirement, the retailer shall maintain a written log or an alternative electronic record-keeping mechanism until such time as the retailer is able to comply with the electronic sales tracking requirement.

(3) NADDI shall provide real-time access to NPLEx information through the NPLEx online portal to law enforcement in this state as authorized by state and federal law.

(4) The system described in subsection (1) shall be capable of generating a stop sale alert notifying the retailer that the person is prohibited from purchasing a nonprescription product containing ephedrine or pseudoephedrine due to a conviction reported under the methamphetamine abuse reporting act or that completing the sale will result in the seller's or purchaser's violating the quantity limits set forth in section 17766f. Except as otherwise provided by law, the seller shall not complete the sale if the system generates a stop sale alert. The 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.

(5) A person's failure to comply with the record-keeping or sales verification requirements of this section does not create a civil cause of action for damages to any other person arising out of that failure absent a direct and proximate cause, and the person is immune from civil liability for any damages arising out of that failure.

(6) A person who violates this section is guilty of a misdemeanor punishable by a fine of not more than $500.00.

History: Add. 2011, Act 84, Imd. Eff. July 15, 2011;—Am. 2014, Act 275, Eff. Jan. 1, 2015.

Popular name: Act 368

333.7340c Soliciting or attempting to solicit another person to obtain ephedrine or pseudoephedrine; violation; penalty; other violation; report to state police; definitions.

Sec. 7340c. (1) A person shall not solicit another person to purchase or otherwise obtain any amount of ephedrine or pseudoephedrine knowing that it is to be used for the purpose of illegally manufacturing methamphetamine.

(2) Except as provided in subsection (3), a person who violates this section is guilty of a felony punishable by imprisonment for not more than 10 years or a fine of not more than $10,000.00, or both.

(3) A person who attempts to violate subsection (1) is guilty of a misdemeanor punishable by imprisonment for not more than 1 year or a fine of not more than $1,000.00, or both.

(4) This section does not prohibit the person from being charged with, convicted of, or sentenced for any other violation of law committed by the person while violating this section.

(5) If a person is convicted of violating this section, the court shall report the violation to the department of state police.

(6) For purposes of this section:

(a) "Ephedrine" includes the salts and isomers and salts of isomers of ephedrine.

(b) "Pseudoephedrine" includes the salts and isomers and salts of isomers of pseudoephedrine.

History: Add. 2014, Act 217, Eff. Jan. 1, 2015;—Am. 2016, Act 125, Eff. Aug. 23, 2016.

Popular name: Act 368

333.7341 Definitions; factors in determining imitation controlled substance; prohibited conduct; violation; civil fine; misdemeanor; penalty; default in payment of civil fine or costs; collection; prohibited advertisement or solicitation; violation as misdemeanor; penalty; section inapplicable to certain persons; violation as felony; penalty.

Sec. 7341. (1) As used in this section:

(a) "Distribute" means the actual, constructive, or attempted transfer, sale, delivery, or dispensing from one person to another of an imitation controlled substance.

(b) "Imitation controlled substance" means a substance that is not a controlled substance or is not a drug for which a prescription is required under federal or state law, which by dosage unit appearance including color, shape, size, or markings, and/or by representations made, would lead a reasonable person to believe that the substance is a controlled substance. However, this subsection does not apply to a drug that is not a controlled substance if it was marketed before the controlled substance that it physically resembles. An imitation controlled substance does not include a placebo or registered investigational drug that was manufactured, distributed, possessed, or delivered in the ordinary course of professional practice or research. All of the following factors shall be considered in determining whether a substance is an imitation controlled substance:

(*i*) Whether the substance was approved by the federal food and drug administration for over-the-counter sales and was sold in the federal food and drug administration approved packaging along with the federal food and drug administration approved labeling information.

(*ii*) Any statements made by an owner or another person in control of the substance concerning the nature, use, or effect of the substance.

(*iii*) Whether the substance is packaged in a manner normally used for illicit controlled substances.

(*iv*) Whether the owner or another person in control of the substance has any prior convictions under state or federal law related to controlled substances or fraud.

(*v*) The proximity of the substance to controlled substances.

(*vi*) Whether the consideration tendered in exchange for the substance substantially exceeds the reasonable value of the substance considering the actual chemical composition of the substance and, if applicable, the price at which the over-the-counter substances of like chemical composition sell.

(c) "Manufacture" means the production, preparation, compounding, conversion, encapsulating, packaging, repackaging, labeling, relabeling, or processing of an imitation controlled substance, directly or indirectly.

(2) In addition to all logically relevant factors, the following factors as related to "representations made" shall be considered in determining whether a substance is an imitation controlled substance:

(a) Any express or implied representation made that the nature of the substance or its use or effect is similar to that of a controlled substance.

(b) Any express or implied representation made that the substance may be resold for an amount considerably in excess of the reasonable value of the composite ingredients and the cost of processing.

(c) Any express or implied representation made that the substance is a controlled substance.

(d) Any express or implied representation that the substance is of a nature or appearance that the recipient of the substance will be able to distribute the substance as a controlled substance.

(e) That the substance's package, label, or name is substantially similar to that of a controlled substance.

(f) The proximity of the substance to a controlled substance.

(g) That the physical appearance of the substance is substantially identical to a specific controlled substance, including any numbers or codes thereon, and the shape, size, markings, or color.

(3) Except as provided in subsection (7), a person shall not manufacture, distribute, or possess with intent to distribute, an imitation controlled substance.

(4) A person shall not use, or possess with intent to use, an imitation controlled substance, except under the direction of a person authorized pursuant to subsection (7). A person who violates this subsection is subject to

a civil fine of not more than $100.00 and costs. Upon a second or subsequent violation of this subsection, a person is guilty of a misdemeanor punishable by imprisonment for not more than 90 days, or a fine of not more than $100.00, or both.

(5) A default in the payment of a civil fine or costs ordered under subsection (4) or an installment thereof may be collected by any means authorized for the enforcement of a judgment under chapter 40 or chapter 60 of the revised judicature act of 1961, 1961 PA 236, MCL 600.4001 to 600.4065 and 600.6001 to 600.6098.

(6) A person shall not place an advertisement or solicitation in this state to be distributed by any electronic media in this state, or place an advertisement or solicitation in this state in any newspaper, magazine, handbill, or other publication; or post or distribute an advertisement or solicitation in any public place in this state, knowing or having reason to know that the purpose of the advertisement or solicitation is to promote the distribution of an imitation controlled substance. A person who violates this subsection is guilty of a misdemeanor, punishable by imprisonment for not more than 1 year, or a fine of not more than $5,000.00, or both.

(7) This section does not apply to any person who is authorized by the administrator or the federal food and drug administration to manufacture, distribute, prescribe, or possess an imitation controlled substance for use as a placebo for legitimate medical, therapeutic, or research purposes.

(8) Except as provided in subsections (4) and (6), a person who violates this section is guilty of a felony, punishable by imprisonment for not more than 2 years, or by a fine of not more than $10,000.00, or both.

History: Add. 1984, Act 347, Eff. Mar. 29, 1985;—Am. 2012, Act 180, Imd. Eff. June 19, 2012.

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