SUBSTITUTE FOR

SENATE BILL NO. 1247

A bill to amend 1978 PA 368, entitled "Public health code,"

by amending sections 7109 and 7333a (MCL 333.7109 and 333.7333a), section 7109 as amended by 2016 PA 383 and section 7333a as amended by 2017 PA 252.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

- 1 Sec. 7109. (1) "Person" means a person as defined in section
- 2 1106 or a governmental entity.
- 3 (2) "Poppy straw" means all parts, except the seeds, of the
- 4 opium poppy, after mowing.
- 5 (3) "Practitioner" means any of the following:
- 6 (a) A prescriber or pharmacist, a scientific investigator as
- 7 defined by rule of the administrator, or other person licensed,
- 8 registered, or otherwise permitted to distribute, dispense, conduct

- 1 research with respect to, or administer a controlled substance in
- 2 the course of professional practice or research in this state,
- 3 including an individual in charge of a dog pound or animal shelter
- 4 licensed or registered by the department of agriculture and rural
- 5 development under 1969 PA 287, MCL 287.331 to 287.340, or a class B
- 6 dealer licensed by the United States Department of Agriculture
- 7 under the animal welfare act, Public Law 89-544, 7 USC 2131 to
- 8 2147, 2149, and 2151 to 2159 and the department of agriculture and
- 9 rural development under 1969 PA 224, MCL 287.381 to 287.395, for
- 10 the limited purpose of buying, possessing, and administering a
- 11 commercially prepared, premixed solution of sodium pentobarbital to
- 12 practice euthanasia on animals.
- 13 (b) A pharmacy, hospital, or other institution or place of
- 14 professional practice licensed, registered, or otherwise permitted
- 15 to distribute, prescribe, dispense, conduct research with respect
- 16 to, or administer a controlled substance in the course of
- 17 professional practice or research in this state.
- 18 (4) "Prescriber" means that term as defined in section 17708.
- 19 (5) "Prescription form" means a printed form, that is
- 20 authorized and intended for use by a prescribing practitioner to
- 21 prescribe controlled substances or other prescription drugs and
- 22 that meets the requirements of rules promulgated by the
- 23 administrator, and all of the following requirements:
- 24 (a) Bears the preprinted, stamped, typed, or manually printed
- 25 name, address, and telephone number or pager number of the
- 26 prescribing practitioner.
- 27 (b) Includes the manually printed name of the patient, the

- 1 address of the patient, the prescribing practitioner's signature,
- 2 and the prescribing practitioner's drug enforcement administration
- 3 registration number.
- 4 (c) Includes the quantity of the prescription drug prescribed,
- 5 in both written and numerical terms.
- 6 (d) Includes the date the prescription drug was prescribed.
- 7 (e) Complies with any rules promulgated by the department
- 8 under section 7333a(6).7333A(8).
- 9 (6) "Production" means the manufacture, planting, cultivation,
- 10 growing, or harvesting of a controlled substance.
- 11 (7) "Sign" means to affix one's signature manually to a
- 12 document or to use an electronic signature.
- 13 (8) "Ultimate user" means an individual who lawfully possesses
- 14 a controlled substance for personal use or for the use of a member
- 15 of the individual's household, or for administering to an animal
- 16 owned by the individual or by a member of the individual's
- 17 household.
- 18 Sec. 7333a. (1) The department shall establish, by rule, an
- 19 electronic system for monitoring schedule 2, 3, 4, and 5 controlled
- 20 substances dispensed in this state by veterinarians, and by
- 21 pharmacists and dispensing prescribers licensed under part 177 or
- 22 dispensed to an address in this state by a pharmacy licensed in
- 23 this state. The rules must provide an appropriate electronic format
- 24 for the reporting of data including, but not limited to, patient
- 25 identifiers, and the name of the controlled substance dispensed,
- 26 the date of dispensing, the quantity dispensed, the prescriber, and
- 27 the dispenser. The department shall require a veterinarian,

- 1 pharmacist, or dispensing prescriber to utilize the electronic data
- 2 transmittal process developed by the department or the department's
- 3 contractor. The department shall not require a veterinarian,
- 4 pharmacist, or dispensing prescriber to pay a new fee dedicated to
- 5 the operation of the electronic monitoring system or to incur any
- 6 additional costs solely related to the transmission of data to the
- 7 department. The dispensing of a controlled substance in any of the
- 8 following is exempt from the reporting requirements:
- 9 (a) A hospital that is licensed under article 17 that
- 10 administers the controlled substance to an individual who is an
- 11 inpatient.
- 12 (b) A health facility or agency licensed under article 17 if
- 13 the controlled substance is dispensed by a dispensing prescriber in
- 14 a quantity adequate to treat the patient for not more than 48
- 15 hours.
- 16 (c) A veterinary hospital or clinic that administers the
- 17 controlled substance to an animal that is an inpatient.
- 18 (2) Notwithstanding any practitioner-patient privilege, the
- 19 director of the department may provide data obtained under this
- 20 section to all of the following:
- 21 (a) A designated representative of a board responsible for the
- 22 licensure, regulation, or discipline of a practitioner, pharmacist,
- 23 or other person that is authorized to prescribe, administer, or
- 24 dispense controlled substances.
- 25 (b) An employee or agent of the department.
- 26 (c) A—SUBJECT TO SUBSECTION (4), A state, federal, or
- 27 municipal employee or agent whose duty is to enforce the laws of

- 1 this state or the United States relating to drugs.
- 2 (d) A state-operated Medicaid program.
- 3 (e) A-SUBJECT TO SUBSECTION (4), A state, federal, or
- 4 municipal employee who is the holder of a search warrant or
- 5 subpoena properly issued for the records.
- 6 (f) A practitioner or pharmacist who requests information and
- 7 certifies that the requested information is for the purpose of
- 8 providing medical or pharmaceutical treatment to a bona fide
- 9 current patient.
- 10 (g) An individual with whom the department has contracted
- 11 under subsection (7). (9).
- 12 (h) A practitioner or other person that is authorized to
- 13 prescribe controlled substances for the purpose of determining if
- 14 prescriptions written by that practitioner or other person have
- 15 been dispensed.
- 16 (i) The health care payment or benefit provider for the
- 17 purposes of ensuring patient safety and investigating fraud and
- 18 abuse.
- 19 (3) Except as otherwise provided in this part, a person shall
- 20 use information submitted OBTAINED FROM THE DEPARTMENT under this
- 21 section SUBSECTION (2) only for bona fide drug-related criminal
- 22 investigatory or evidentiary purposes or for the investigatory or
- 23 evidentiary purposes in connection with the functions of a
- 24 disciplinary subcommittee or 1 or more of the licensing or
- 25 registration boards created in article 15.
- 26 (4) THE DIRECTOR OF THE DEPARTMENT SHALL PROVIDE A LAW
- 27 ENFORCEMENT OFFICER WHO IS EMPLOYED BY THE DEPARTMENT OF STATE

- 1 POLICE WITH ACCESS TO AN APPLICATION PROGRAM INTERFACE FOR
- 2 MONITORING SCHEDULE 2, 3, 4, AND 5 CONTROLLED SUBSTANCES FOR THE
- 3 PURPOSES OF THE LAW ENFORCEMENT ACCESS TO MICHIGAN AUTOMATED
- 4 PRESCRIPTION SYSTEM DATA ACT. PATIENT TREATMENT INFORMATION
- 5 PROVIDED THROUGH THE APPLICATION PROGRAM INTERFACE UNDER THIS
- 6 SUBSECTION MUST BE DEIDENTIFIED TO PROTECT THE IDENTITY AND PRIVACY
- 7 OF PATIENTS IN ACCORDANCE WITH FEDERAL AND STATE LAW, INCLUDING,
- 8 BUT NOT LIMITED TO, REGULATIONS PROMULGATED UNDER THE HEALTH
- 9 INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996, PUBLIC LAW
- 10 104-191, RELATED TO DEIDENTIFICATION AND PRIVACY STANDARDS BUT NOT
- 11 INCLUDING DATA BREACH NOTIFICATIONS OR ANY OTHER REQUIREMENT. THE
- 12 APPLICATION PROGRAM INTERFACE MUST DISCLOSE PRESCRIBER AND
- 13 DISPENSER DATA TO THE LAW ENFORCEMENT OFFICER.
- 14 (5) THE DEPARTMENT, IN CONSULTATION WITH THE DEPARTMENT OF
- 15 STATE POLICE, SHALL PROMULGATE RULES THAT IT CONSIDERS NECESSARY
- 16 THAT ENSURE THAT ANY DATA PROVIDED BY THE DIRECTOR OF THE
- 17 DEPARTMENT UNDER SUBSECTION (2) IS PROVIDED ONLY TO THE EXTENT
- 18 NECESSARY, THAT MINIMIZE THE INAPPROPRIATE USE OF THE DATA PROVIDED
- 19 UNDER SUBSECTION (2), AND THAT MINIMIZE THE RISK OF A BREACH OF THE
- 20 DATA IN THE ELECTRONIC MONITORING SYSTEM.
- 21 (6) (4)—A person that receives data or any report under
- 22 subsection (2) containing any patient identifiers of the system
- 23 from the department shall not provide it to any other person except
- 24 by order of a court of competent jurisdiction.
- 25 (7) (5) Except as otherwise provided in this subsection,
- 26 reporting under subsection (1) is mandatory for a veterinarian,
- 27 pharmacist, and dispensing prescriber. However, the department may

- 1 issue a written waiver of the electronic reporting requirement to a
- 2 veterinarian, pharmacist, or dispensing prescriber who establishes
- 3 grounds that he or she is unable to use the electronic monitoring
- 4 system. The department shall require the applicant for the waiver
- 5 to report the required information in a manner approved by the
- 6 department.
- 7 (8) (6) The department, in consultation with the Michigan
- 8 board of pharmacy, the Michigan board of medicine, the Michigan
- 9 board of osteopathic medicine and surgery, the department of state
- 10 police, and appropriate medical professional associations, shall
- 11 examine the need for and may promulgate rules for the production of
- 12 a prescription form on paper that minimizes the potential for
- 13 forgery. The rules must not include any requirement that sequential
- 14 numbers, bar codes, or symbols be affixed, printed, or written on a
- 15 prescription form or that the prescription form be a state produced
- 16 prescription form. In examining the need for rules for the
- 17 production of a prescription form on paper that minimizes the
- 18 potential for forgery, the department shall consider and identify
- 19 the following:
- 20 (a) Cost, benefits, and barriers.
- 21 (b) Overall cost-benefit analysis.
- (c) Compatibility with the electronic monitoring system
- 23 required under this section.
- 24 (9) (7) The department may enter into 1 or more contractual
- 25 agreements for the administration of this section.
- 26 (10) (8)—The department, all law enforcement officers, all
- 27 officers of the court, and all regulatory agencies and officers, in

- 1 using the data OBTAINED UNDER THIS SECTION for investigative or
- 2 prosecution purposes, shall consider the nature of the prescriber's
- 3 and dispenser's practice and the condition for which the patient is
- 4 being treated.
- 5 (11) (9) The data and any report containing any patient
- 6 identifiers obtained from the data OBTAINED UNDER THIS SECTION are
- 7 not public records and are not subject to disclosure under the
- 8 freedom of information act, 1976 PA 442, MCL 15.231 to 15.246.
- 9 (12) (10) The department may issue a written request to a
- 10 health care payment or benefit provider to determine if the
- 11 provider has accessed the electronic monitoring system as provided
- 12 in subsection (2)(i) in the previous calendar year and, if so, to
- 13 determine the number of inquiries the provider made in the previous
- 14 calendar year and any other information the department requests in
- 15 relation to the provider's access to the electronic monitoring
- 16 system. A health care payment or benefit provider shall respond to
- 17 the written request on or before the March 31 following the
- 18 request. The department shall collaborate with health care payment
- 19 or benefit providers to develop a reasonable request and reporting
- 20 form for use under this subsection.
- 21 (13) (11)—Before dispensing or prescribing buprenorphine, or a
- 22 drug containing buprenorphine or methadone, to a patient in a
- 23 substance use disorder program, a prescriber shall obtain and
- 24 review data concerning that patient from the department under
- 25 subsection (2). A prescriber dispensing buprenorphine, or a drug
- 26 containing buprenorphine or methadone, to a patient in a substance
- 27 use disorder program shall also report the data required in

- 1 subsection (1), if federal law does not prohibit the reporting of
- 2 data concerning the patient, to the department. As used in this
- 3 subsection:
- 4 (a) "Approved service program" means that term as defined in
- 5 section 100a of the mental health code, 1974 PA 258, MCL 330.1100a.
- 6 (b) "Substance use disorder program" means a program as that
- 7 term is defined in section 260 of the mental health code, 1974 PA
- 8 258, MCL 330.1260, an approved service program, a nonregulated
- 9 substance use disorder services program, a federal certified
- 10 substance use disorder services program, or a federally regulated
- 11 substance use disorder services program.
- 12 (12) R 338.3162e of the Michigan Administrative Code is
- 13 rescinded.
- 14 (14) $\frac{(13)}{(13)}$ As used in this section:
- (a) "Department" means the department of licensing and
- 16 regulatory affairs.
- 17 (b) "Health care payment or benefit provider" means a person
- 18 that provides health benefits, coverage, or insurance in this
- 19 state, including a health insurance company, a nonprofit health
- 20 care corporation, a health maintenance organization, a multiple
- 21 employer welfare arrangement, a Medicaid contracted health plan, or
- 22 any other person providing a plan of health benefits, coverage, or
- 23 insurance subject to state insurance regulation.
- 24 Enacting section 1. This amendatory act takes effect 90 days
- 25 after the date it is enacted into law.
- 26 Enacting section 2. This amendatory act does not take effect
- 27 unless Senate Bill No. 1245 of the 99th Legislature is enacted into

1 law.