SUBSTITUTE FOR

SENATE BILL NO. 47

A bill to amend 1978 PA 368, entitled

"Public health code,"

by amending section 7333a (MCL 333.7333a), as amended by 2016 PA 383.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

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 ~~rules promulgated~~ **DEPARTMENT'S AUTHORITY TO PROMULGATE RULES** under this subsection ~~must exempt both of the following circumstances from the reporting requirements:~~

~~(a) The administration of a controlled substance directly to a patient.~~

~~(b) The dispensing from a health facility or agency licensed under article 17 of a controlled substance by a dispensing prescriber in a quantity adequate to treat a patient for not more than 48 hours.~~**IS SUBJECT TO BOTH OF THE FOLLOWING:**

(A) THE RULES PROMULGATED UNDER THIS SUBSECTION MUST EXEMPT FROM THE REPORTING REQUIREMENTS THE DISPENSING OF A CONTROLLED SUBSTANCE IN ANY OF THE FOLLOWING:

(*i*) A HOSPITAL THAT IS LICENSED UNDER ARTICLE 17 THAT ADMINISTERS THE CONTROLLED SUBSTANCE TO AN INPATIENT.

(*ii*) EXCEPT AS OTHERWISE PROVIDED IN SUBDIVISION (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.

(B) THE RULES PROMULGATED UNDER THIS SUBSECTION MUST REQUIRE A DISPENSING PRESCRIBER TO REPORT THE DATA REQUIRED BY THIS SECTION

IF THE DISPENSING PRESCRIBER DISPENSES BUPRENORPHINE, OR A DRUG CONTAINING BUPRENORPHINE AND METHADONE, IN A SUBSTANCE USE DISORDER PROGRAM AND THE PATIENT PROVIDES CONSENT IN A MANNER CONSISTENT WITH SECTION 262 OF THE MENTAL HEALTH CODE, 1974 PA 258, MCL 330.1262, OR FEDERAL LAW, TO HAVE THE DATA REPORTED INTO THE ELECTRONIC MONITORING SYSTEM FOR THE PURPOSES DESCRIBED IN THIS SECTION. A DISPENSING PRESCRIBER WHO RECEIVES THE CONSENT DESCRIBED IN THIS SUBDIVISION SHALL MAINTAIN THE PATIENT'S CONSENT FORM AND MAKE IT AVAILABLE TO THE DEPARTMENT UPON THE DEPARTMENT'S REQUEST. AS USED IN THIS SUBDIVISION:

(*i*) "APPROVED SERVICES PROGRAM" MEANS THAT TERM AS DEFINED IN SECTION 100A OF THE MENTAL HEALTH CODE, 1974 PA 258, MCL 330.1100A.

(*ii*) "PROGRAM" MEANS THAT TERM AS DEFINED IN SECTION 260 OF THE MENTAL HEALTH CODE, 1974 PA 258, MCL 330.1260.

(*iii*) "SUBSTANCE USE DISORDER PROGRAM" MEANS A PROGRAM, 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.

(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) R 338.3162E OF THE MICHIGAN ADMINISTRATIVE CODE IS RESCINDED.

(12) ~~(11)~~ 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.

Enacting section 1. This amendatory act takes effect 90 days after the date it is enacted into law.