HOUSE BILL No. 4284

February 28, 2017, Introduced by Rep. Kosowski and referred to the Committee on Health Policy.

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~~ **A PRESCRIPTION DRUG MONITORING** 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~~ **INFORMATION** including, but not limited to, patient identifiers, ~~and~~ the name of the controlled substance dispensed, the date of

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dispensing, the quantity dispensed, the prescriber, and the dispenser. The department shall require a veterinarian, pharmacist, or dispensing prescriber to ~~utilize~~ **USE** the electronic ~~data~~ **INFORMATION** 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~~ **PRESCRIPTION DRUG** monitoring system or to incur any additional costs solely related to the transmission of ~~data~~ **INFORMATION** to the department. The rules promulgated under this subsection must exempt both of the following circumstances from the reporting requirements **UNDER THIS SECTION**:

(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.

(2) Notwithstanding any practitioner-patient privilege, the director of the department ~~may~~ **SHALL** provide ~~data~~ **INFORMATION** 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, **PRESCRIPTION DRUG DIVERSION, OR HEALTH CARE FRAUD.**

(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.~~**INFORMATION.**

(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.

(J) A PRESCRIPTION DRUG MONITORING SYSTEM IN ANOTHER JURISDICTION. THE DIRECTOR SHALL NOT TRANSMIT INFORMATION UNDER THIS SUBDIVISION UNLESS HE OR SHE HAS ENTERED INTO AN AGREEMENT WITH THE PRESCRIPTION DRUG MONITORING SYSTEM IN THE JURISDICTION. THE AGREEMENT MUST PROVIDE FOR THE MUTUAL EXCHANGE OF INFORMATION AND LIMIT THE USE OF THE INFORMATION ONLY AS AUTHORIZED IN AND SUBJECT TO THE SAME RESTRICTIONS OF THIS SECTION.

(3) Except as otherwise provided in this part, a person shall use information submitted under this section only for bona fide ~~drug-related~~ criminal, **CIVIL, OR ADMINISTRATIVE** investigatory or evidentiary purposes **RELATING TO DRUGS, PRESCRIPTION DRUG DIVERSION, OR HEALTH CARE FRAUD** 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~~ **INFORMATION** or any report under ~~subsection (2) containing any patient identifiers of the system~~ **THIS SECTION** from the department **THAT CONTAINS ANY PATIENT IDENTIFIERS** shall not provide ~~it~~ **THAT INFORMATION** to any other person except **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, PRESCRIPTION DRUG DIVERSION, OR HEALTH CARE FRAUD OR** by order of a court of competent jurisdiction.

(5) ~~Except as otherwise provided in this subsection, reporting~~ **REPORTING** under ~~subsection~~ **SUBSECTIONS** (1) **AND (11)** is mandatory for a veterinarian, pharmacist, **PRESCRIBER**, and dispensing prescriber, **AS APPLICABLE**. ~~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~~ **PRESCRIPTION DRUG** 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~~ **INFORMATION** 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~~ **INFORMATION** and any report containing any patient identifiers obtained from the ~~data~~ **INFORMATION** 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~~ **PRESCRIPTION DRUG** 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~~ **PRESCRIPTION DRUG** 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) As used in this section:~~

(11) THE DEPARTMENT SHALL INCLUDE IN THE PRESCRIPTION DRUG MONITORING SYSTEM ESTABLISHED UNDER SUBSECTION (1) A SYSTEM FOR MONITORING CONTROLLED SUBSTANCES PRESCRIBED IN THIS STATE AND, SUBJECT TO SUBSECTION (2)(J), SHARING THAT INFORMATION WITH PRESCRIPTION DRUG MONITORING SYSTEMS IN OTHER JURISDICTIONS. THE DEPARTMENT SHALL PROVIDE A FORMAT FOR PRESCRIBERS WHO PRESCRIBE CONTROLLED SUBSTANCES FOR REPORTING INFORMATION, INCLUDING, BUT NOT LIMITED TO, PATIENT IDENTIFIERS, THE NAME OF THE CONTROLLED SUBSTANCE PRESCRIBED, THE DATE OF PRESCRIBING, THE QUANTITY PRESCRIBED, AND THE PRESCRIBER. THE DEPARTMENT SHALL REQUIRE A PRESCRIBER TO USE THE ELECTRONIC INFORMATION TRANSMITTAL PROCESS DEVELOPED BY THE DEPARTMENT OR THE DEPARTMENT'S CONTRACTOR. THE DEPARTMENT SHALL NOT REQUIRE A PRESCRIBER TO PAY A NEW FEE

DEDICATED TO THE OPERATION OF THE REPORTING REQUIREMENTS UNDER THIS SUBSECTION OR TO INCUR ANY ADDITIONAL COSTS SOLELY RELATED TO THE TRANSMISSION OF INFORMATION TO THE DEPARTMENT. THE DEPARTMENT MAY PROMULGATE RULES IT CONSIDERS NECESSARY FOR THE IMPLEMENTATION AND ADMINISTRATION OF THIS SUBSECTION. IN ADDITION TO COMPLYING WITH ANY RULES PROMULGATED UNDER THIS SUBSECTION, A PRESCRIBER DESCRIBED IN THIS SUBSECTION SHALL USE THE ELECTRONIC INFORMATION TRANSMITTAL PROCESS AS FOLLOWS:

(A) BEFORE PRESCRIBING A CONTROLLED SUBSTANCE FOR THE FIRST TIME FOR A PATIENT, WHETHER THE PATIENT IS A NEW PATIENT OR AN EXISTING PATIENT.

(B) UNLESS A MORE FREQUENT UTILIZATION IS REQUIRED IN THIS SUBSECTION, AT LEAST ANNUALLY BEFORE PRESCRIBING A CONTROLLED SUBSTANCE FOR A PATIENT.

(C) AT LEAST ONCE DURING EVERY 12-WEEK PERIOD BEFORE PRESCRIBING A CONTROLLED SUBSTANCE FOR A PATIENT IF THE PRESCRIBER IS TREATING A PATIENT ON A PROTRACTED BASIS. AS USED IN THIS SUBDIVISION, "PROTRACTED BASIS" MEANS FOR A PERIOD IN EXCESS OF 12 WEEKS.

(D) BEFORE PRESCRIBING A CONTROLLED SUBSTANCE FOR A PATIENT REGARDLESS OF THE UTILIZATION REQUIRED UNDER SUBDIVISIONS (A) TO (C) IF THE PATIENT EXHIBITS BEHAVIORS OF CONCERN TO THE PRESCRIBER.

(12) IN ADDITION TO THE GENERAL DUTY REQUIREMENTS APPLICABLE TO A PRESCRIBER UNDER ARTICLE 15, A PRESCRIBER WHO BELIEVES OR HAS REASON TO BELIEVE THAT A PATIENT IS ABUSING OR DIVERTING CONTROLLED SUBSTANCES, BASED IN PART ON WHETHER THE PATIENT EXHIBITS BEHAVIORS OF CONCERN TO THE PRESCRIBER, SHALL USE SOUND CLINICAL JUDGMENT TO

DETERMINE WHETHER A CONTROLLED SUBSTANCE SHOULD BE PRESCRIBED FOR THE PATIENT UNDER THE CIRCUMSTANCES. A VIOLATION OF THIS SUBSECTION OR SUBSECTION (11) IS CONSIDERED A VIOLATION OF A GENERAL DUTY UNDER SECTION 16221(A). A PRESCRIBER WHO VIOLATES THIS SUBSECTION OR SUBSECTION (11) IS SUBJECT TO ANY PENALTY, REMEDY, OR ADMINISTRATIVE SANCTION APPLICABLE TO THAT VIOLATION UNDER ARTICLE 15.

(13) ~~(12)~~ As used in this section:

(A) "BEHAVIORS OF CONCERN" INCLUDES, BUT IS NOT LIMITED TO, ANY OF THE FOLLOWING:

(*i*) SELLING A PRESCRIPTION DRUG.

(*ii*) FORGING OR ALTERING A PRESCRIPTION FORM.

(*iii*) STEALING OR BORROWING A CONTROLLED SUBSTANCE.

(*iv*) INCREASING THE DOSAGE OF A CONTROLLED SUBSTANCE IN AN AMOUNT THAT EXCEEDS THE PRESCRIBED AMOUNT.

(*v*) HAVING A DRUG SCREEN RESULT THAT IS INCONSISTENT WITH THE TREATMENT PLAN OR REFUSING TO PARTICIPATE IN A DRUG SCREEN.

(*vi*) HAVING BEEN ARRESTED, HAVING BEEN CONVICTED, OR HAVING RECEIVED DIVERSION OR INTERVENTION INSTEAD OF CONVICTION FOR A DRUG-RELATED OFFENSE WHILE UNDER THE PRESCRIBER'S CARE.

(*vii*) RECEIVING CONTROLLED SUBSTANCES FROM MULTIPLE PRESCRIBERS.

(*viii*) HAVING A FAMILY MEMBER, FRIEND, LAW ENFORCEMENT OFFICER, OR HEALTH CARE PROFESSIONAL EXPRESS CONCERN RELATED TO THE PATIENT'S USE OF ILLEGAL DRUGS OR CONTROLLED SUBSTANCES.

(*ix*) HAVING A KNOWN HISTORY OF SUBSTANCE USE DISORDER AS THAT TERM IS DEFINED IN SECTION 100D OF THE MENTAL HEALTH CODE, 1974 PA

258, MCL 330.1100D.

(*x*) APPEARING IMPAIRED OR OVERLY SEDATED DURING AN OFFICE VISIT OR EXAMINATION.

(*xi*) REQUESTING CONTROLLED SUBSTANCES BY SPECIFIC NAME, STREET NAME, COLOR, OR IDENTIFYING MARKS.

(*xii*) FREQUENTLY REQUESTING EARLY REFILLS OF CONTROLLED SUBSTANCES.

(*xiii*) FREQUENTLY LOSING PRESCRIPTIONS FOR CONTROLLED SUBSTANCES.

(*xiv*) SHARING CONTROLLED SUBSTANCES WITH ANOTHER INDIVIDUAL.

(*xv*) RECURRING EMERGENCY DEPARTMENT VISITS TO OBTAIN CONTROLLED SUBSTANCES.

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

(C) ~~(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.