HOUSE BILL No. 4811

August 18, 2015, Introduced by Reps. LaVoy, Zemke, Darany, Schor, Irwin, Hovey-Wright and Chirkun and referred to the Committee on Regulatory Reform.

A bill to amend 1978 PA 368, entitled

"Public health code,"

by amending section 7333a (MCL 333.7333a), as amended by 2012 PA 44.

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 ~~shall~~ **MUST** provide an appropriate electronic format for the reporting of ~~data~~ **INFORMATION** including, but not limited to, patient identifiers, the name of the controlled substance dispensed, date

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of dispensing, quantity dispensed, prescriber, and dispenser. The department shall require a veterinarian, pharmacist, or dispensing prescriber to utilize the electronic ~~data~~ **INFORMATION** transmittal process developed by the department or the department's contractor. ~~A~~ **THE DEPARTMENT SHALL NOT REQUIRE A** veterinarian, pharmacist, or dispensing prescriber ~~shall not be required~~ to pay a new fee dedicated to the operation of the ~~electronic~~ **PRESCRIPTION DRUG** monitoring system ~~and shall not~~ **OR TO** incur any additional costs solely related to the transmission of ~~data~~ **INFORMATION** to the department. The rules promulgated under this subsection ~~shall~~ **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 who 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~~ **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 (8).

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

(i) Until December 31, 2016, 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 ~~shall be used~~ 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 who 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 ~~or entity~~ 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 (12)** 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) In addition to the information required to be reported

annually under section 7112(3), the controlled substances advisory commission shall include in the report information on the implementation and effectiveness of the ~~electronic~~ **PRESCRIPTION DRUG** monitoring system.

(7) The department, in consultation with the controlled substances advisory commission, the Michigan board of pharmacy, the Michigan board of medicine, the Michigan board of osteopathic medicine and surgery, the Michigan 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 ~~shall~~ **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.

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

(9) 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.

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

(11) Beginning February 1, 2013 and through February 1, 2016, 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.

(12) 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 THE REPORTING OF INFORMATION, INCLUDING, BUT NOT LIMITED TO, PATIENT IDENTIFIERS, THE NAME OF THE CONTROLLED SUBSTANCE PRESCRIBED, DATE OF PRESCRIBING, QUANTITY PRESCRIBED, AND

PRESCRIBER. THE DEPARTMENT SHALL REQUIRE A PRESCRIBER TO UTILIZE 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 THE REQUIREMENTS IN RULES PROMULGATED UNDER THIS SUBSECTION, IF ANY, A PRESCRIBER DESCRIBED IN THIS SUBSECTION SHALL UTILIZE 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.

(13) 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 (12) IS CONSIDERED A VIOLATION OF A GENERAL DUTY UNDER SECTION 16221(A). A PRESCRIBER WHO VIOLATES THIS SUBSECTION OR SUBSECTION (12) IS SUBJECT TO ANY PENALTY, REMEDY, OR ADMINISTRATIVE SANCTION APPLICABLE TO THAT VIOLATION UNDER ARTICLE 15.

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

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

(*i*) SELLING PRESCRIPTION DRUGS.

(*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 IN LIEU 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~~ **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.