SPONSOR: Sen. Bushweller & Sen. Hall-Long & Rep. Mitchell
Sens. Henry, Simpson, Sorenson; Reps. George, Barbieri, Lee, Ramone, Carson & Kovach

DELAWARE STATE SENATE
145th GENERAL ASSEMBLY

SENATE BILL NO. 235

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE CREATING THE DELAWARE PRESCRIPTION MONITORING ACT.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. This Act shall be cited as the "Delaware Prescription Monitoring Act."

Section 2. Amend Title 16, Chapter 47 of the Delaware Code by adding a new § 4798 to read as follows:

"§ 4798. The Delaware Prescription Monitoring Program. It is the intent of the General Assembly that the Delaware Prescription Monitoring Act established pursuant to this section serves as a means to promote public health and welfare and to detect the illegal use of controlled substances. The Delaware Prescription Monitoring Act shall have the dual purpose of reducing misuse and diversion of controlled substances in the State while promoting improved professional practice and patient care.

(a) Definitions.

(1) "Administer" or "administration" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or any other means.

(2) "Controlled substance" means any substance or drug defined, enumerated or included in Title 16, Chapter 47of the Delaware Code and Title 21, C.F.R. of the Federal Code.

(3) "Dispense" or "dispensing" means the interpretation, evaluation, and implementation of a prescription drug or, including the preparation and delivery of a drug to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

(4) "Dispenser" means a person authorized by this state to dispense or distribute to the ultimate user any controlled substance or drug monitored by the program, but shall not include any of the following:

A. A licensed health care facility pharmacy that dispenses or distributes any controlled substance or drug monitored by the program for the purposes of inpatient care, emergency department care for the immediate use of a controlled substance or when dispensing up to a 72 hour supply of a controlled substance or

a drug of concern monitored by the program at the time of discharge from such a facility.

(5) "Distribute" or "distribution" means the delivery of a drug other than by administering or dispensing.

(6) "Drug" means any of the following:

A. Any substance recognized as a drug in the official compendium, or supplement thereto, designated by the Office of Controlled Substances for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans.

B. Any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or pain in humans.

C. Any substance other than food intended to affect the structure or any function of the body of humans.

(7) "Drugs of concern" means drugs other than controlled substances as defined by rule which demonstrate a potential for abuse or diversion.

(8) "Patient" means the person who is the ultimate user of a controlled substance or drug monitored by the program for whom a prescription is issued and for whom a controlled substance or drug is dispensed.

(9) "Prescriber" means a licensed health care professional with the authority to write and issue prescriptions, except it shall not include:

A. A prescriber or other authorized person who administers such controlled substance or drug upon the lawful order of a prescriber.

B. A prescriber or other authorized person who, in providing emergency patient care in a healthcare facility, causes the administration of a controlled substance for immediate relief of symptoms arising from an acute condition.

C. A prescriber or other authorized person who prescribes up to a 72 hour supply of a controlled substance for on call services or emergency care.

D. A veterinarian who prescribes for the purpose of providing veterinary services.

(10) "Prescription monitoring information" means data submitted to and maintained by the prescription monitoring program established under this Act.

(11) "Prescription Monitoring Program" or "PMP" means the electronic program established by this Act.

(b) The Office of Controlled Substances shall establish and maintain a PMP program to monitor the prescribing and dispensing of all Schedule II, III, IV and V controlled substances by prescribers in this State, and to research the prescribing and dispensing of drugs of concern. The PMP shall not interfere with the legal use of a controlled substance or drug of concern. The PMP shall be:

(1) used to provide information to prescribers, dispensers, and patients to help avoid the illegal use of controlled substances;

(2) used to assist law enforcement to investigate illegal activity related to the prescribing, dispensing and consumption of controlled substances or drugs of concern; and

(3) designed to minimize inconvenience to patients and prescribing medical practitioners while effectuating the collection and storage of prescription monitoring information.

(c) A dispenser shall submit the required information regarding each prescription dispensed for a controlled substance, in accordance with the transmission methods and frequency established by regulation issued by the Office of Controlled Substances. When needed for bona fide research purposes and in accordance with applicable regulation, the Office of Controlled Substances may require a dispenser to submit the required information regarding each prescription dispensed for a drug of concern, but in no event should dispensers be required to submit such information any more frequently than that required for controlled substances. The following information shall be submitted for each prescription:

(1) pharmacy name;

(2) dispenser DEA registration number and name;

(3) date drug was dispensed;

(4) prescription number;

(5) whether prescription is new or a refill;

(6) NDC code for drug dispensed;

(7) quantity dispensed;

(8) approximate number of days supplied;

(9) patient name and date of birth;

(10) patient address;

(11) prescriber DEA registration number and name;

(12) date prescription issued by prescriber.

(d) A prescriber, or other person(s) authorized by the prescriber, shall obtain, before writing a prescription for a controlled substance listed in schedule II, III, IV or V for a patient, a patient utilization report regarding the patient for

the preceding 12 months from the computerized program established by the Office of Controlled Substances when the prescriber has a reasonable belief that the patient may be seeking the controlled substance, in whole or in part, for any reason other than the treatment of an existing medical condition. The prescriber shall review the patient utilization report to assess whether the prescription for the controlled substance is necessary.

(e) The Office of Controlled Substances may issue a waiver to a prescriber who is unable to access prescription information by electronic means. A prescriber who is unable to access prescription information by electronic means shall obtain a waiver from the OCS on annual basis until such time they can access the prescription information by electronic means.

(f) Unless a court of competent jurisdiction makes a finding of gross negligence, malice or criminal intent, the Office of Controlled Substances, any other state agency, any prescriber or dispenser, or any person or entity in proper possession of information pursuant to this statute is not subject to civil liability, administrative action or other legal or equitable relief for any of the following acts or omissions:

(1) Furnishing information pursuant to this section.

(2) Receiving, using or relying on, or not using or relying on, information received pursuant to this section.

(3) Information that was not furnished to the Office of Controlled Substances.

(4) Information that was factually incorrect or that was released by the Office of Controlled Substance to the wrong person or entity.

(g) Prescription information submitted to the PMP is protected health information, not subject to public or open records law, and not subject to disclosure, except as otherwise provided in this section.

(h) The Office of Controlled Substances shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted, and maintained is not disclosed, except as provided for in this section.

(1) If there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the Office of Controlled Substances shall notify the appropriate law enforcement or professional licensure, certification, or regulatory agency or entity and shall provide prescription information required for an investigation.

(2) The Office of Controlled Substances may provide data in the prescription monitoring program to the following persons:

(A) A prescriber, or other person authorized by the prescriber, or a dispenser, or other person authorized by the dispenser, who requests information and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide patient;

(B) An individual who requests the individual's own prescription monitoring information in accordance with procedures established pursuant to regulations;

(C) A designated representative of any Board or Commission pursuant to § 8735(a) of Title 29 responsible for the licensure, regulation, or discipline of prescribers, dispensers or other persons authorized to prescribe, administer, or dispense controlled substances and who is involved in a bona fide specific investigation involving a designated person;

(D) a local, state, or federal law enforcement or prosecutorial official engaged in the administration, investigation, or enforcement of the laws governing controlled substances and who is involved in a bona fide specific drug related investigation;

(E) the Delaware Department of Health and Social Services regarding Medicaid program recipients;

(F) a properly convened grand jury pursuant to a subpoena properly issued for the records;

(G) personnel of the Division of Professional Regulation for purposes of administration and enforcement of this section;

(H) qualified personnel for the purpose of bona fide research or education; however, data elements that would reasonably identify a specific recipient, prescriber or dispenser must be deleted or redacted from such information prior to disclosure; and further provided that, release of the information may be made only pursuant to a written agreement between qualified personnel and the Office of Controlled Substances in order to ensure compliance with this subsection.

(i) The Division of Professional Regulation may contract with another agency of this State or with a private vendor, as necessary, to ensure the effective operation of the prescription monitoring program. A contractor shall comply with the provisions regarding confidentiality of prescription information under this section is subject to the penalties specified in this section for any unlawful acts.

(j) The Office of Controlled Substances may promulgate regulations setting forth the procedures and methods for implementing this section.

(k) The Office of Controlled Substances shall design and implement an evaluation component to identify cost-benefits of the Prescription Monitoring Program, including its effect on diversion and abuse of controlled substances and drugs of concern, and other information relevant to policy, research and education involving controlled substances and drugs of concern monitored by the Prescription Monitoring Program.

(1) The Office of Controlled Substances shall report to the General Assembly the information obtained pursuant to this subsection on an annual basis.

(2) To the extent such information is made available to the Office of Controlled Substances, the report may include information and data, including surveys, polls, or other data from multi-disciplinary experts and stakeholders, relating to the negative or positive impact of the prescription monitoring program on appropriate prescribing practices of controlled substances and drugs of concern.

(l) A dispenser who fails to submit prescription monitoring information to the Office of Controlled Substances PMP as required by this section, or who knowingly submits incorrect prescription information, shall be subject to disciplinary sanction pursuant to Chapter 25 of Title 24.

(m) A person or persons authorized to have prescription monitoring information pursuant to this Act who knowingly discloses this information in violation of this section is guilty of a Class G felony and, upon conviction, shall be fined not more than five thousand dollars nor imprisoned more than 2 years, or both.

(n) A person or persons authorized to have prescription monitoring information pursuant to this Act who intentionally use(s) this information in the furtherance of other crimes is guilty of a Class E felony and, upon conviction, shall be fined not more than ten thousand dollars nor imprisoned more than 5 years, or both.

(o) A person or persons not authorized to have prescription monitoring information pursuant to this Act who obtain such information fraudulently is guilty of a Class E felony and, upon conviction, shall be fined not more than ten thousand dollars nor imprisoned more than 5 years, or both.”.

Section 3. The requirements of this Act shall be contingent upon the availability of appropriations, or of other adequate funding to implement and maintain the Prescription Monitoring Program in this Act.

SYNOPSIS

This Bill is the Delaware Prescription Monitoring Program Act. It provides for the establishment of a program for the monitoring of prescribing and dispensing Schedule II, III, IV, or V controlled substances and other drugs of concern by the Office of Controlled Substances of the Division of Professional Regulation. It requires dispensers to submit certain information regarding the dispensing of controlled substances. That information is compiled into a database that can be accessed by physicians and other prescribers to provide them additional information about their patient’s history of controlled substance use. That information can be used to lessen the diversion of controlled substances without interfering with their legitimate uses, such as chronic pain management. Information is also made available in certain circumstances to law enforcement and regulatory boards, to assist them in the investigation of unlawful use of controlled substances. Prescription monitoring information is protected health information, and the bill instructs the Office of Controlled Substances to maintain procedures to ensure the privacy and confidentiality of patient information. The bill also creates criminal penalties for unlawful disclosure of prescription information. The Office of Controlled Substances is required to provide the General Assembly with an annual evaluation of the program.

Author: Senator Bushweller