COMMITTEE ON HEALTH, HOSPITALS AND HUMAN SERVICES

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BILL NO. 35-0295

Thirty-Fifth Legislature of the Virgin Islands

July 15, 2024

An Act amending title 19 Virgin Islands Code, part III, chapter 29 requiring the Virgin Islands Department of Health to establish and administer the "Virgin Islands Prescription Drug Monitoring Program" to provide prescription drug monitoring, and for other related purposes

PROPOSED BY: Senator Donna A. Frett-Gregory

Be it enacted by the Legislature of the Virgin Islands:

SECTION 1. Title 19 Virgin Islands Code, part III, chapter 29 is amended by adding subchapter IA to read as follows:

"Subchapter IA. Prescription Drug Monitoring Program

§ 635. Short title

This subchapter may be cited as the "Virgin Islands Prescription Drug Monitoring Program Act".

§ 635a. Definitions

As used in this subchapter:

(a) "Certified law enforcement prescription drug diversion investigator" means a law enforcement officer assigned by a qualified law enforcement agency to investigate prescription

drug diversion and who has completed a certification course in prescription drug diversion approved by the Prescription Drug Monitoring Program Advisory Committee.

(b) "Commissioner" means the Commissioner of the Virgin Islands Department of Health.

(c) "Controlled substance" means a drug, substance, or immediate precursor in Schedules II, III, IV, or V of 19 V.I.C § 595.

(d) "Department" means the Virgin Islands Department of Health.

(e) "Dispense" means to deliver a controlled substance to an ultimate user by or pursuant to the lawful order of a practitioner, including the packaging, labeling, or compounding necessary to prepare the controlled substance for that delivery.

(f) "Dispenser" means a practitioner who dispenses. "Dispenser" does not include:

(1) A licensed hospital pharmacy when it is distributing controlled substances for the purpose of outpatient services, inpatient hospital care, or at the time of discharge from a hospital, except for a pharmacy owned by a hospital that has a retail pharmacy permit when the pharmacy is distributing controlled substances directly to the public;

(2) A wholesale distributor of Schedules II-V controlled substances; or

(3) A practitioner or other authorized person who administers a controlled substance.

(g) "Exchangeability" means the ability of the prescription drug monitoring program to electronically share reported information with another state's prescription drug monitoring program if the information concerns the dispensing of a controlled substance either:

(1) To a patient who resides in the other state; or

(2) Prescribed by a practitioner whose principal place of business is in the other state.

(h) "Investigation" means an active inquiry that is being conducted with a reasonable, good-faith belief that the inquiry:

(1) could lead to the filing of administrative, civil, or criminal proceedings; or

(2) is ongoing and continuing and a reasonable, good-faith anticipation exists for securing an arrest or prosecution in the foreseeable future.

(i) "Licensing board" means the board that regulates and licenses practitioners or dispensers who prescribe or dispense medications.

(j) "Opioid" means a drug or medication that relieves pain, including:

(1) Hydrocodone;

(2) Oxycodone;

(3) Morphine;

(4) Codeine; and

(5) Fentanyl.

(k) "Patient" means the person or animal who is the ultimate user of a controlled substance for whom a lawful prescription is issued and for whom a controlled substance is lawfully dispensed.

(l) "Practitioner" means:

(1) A physician, dentist, veterinarian, advanced practice nurse, physician assistant, pharmacist, scientific investigator, or other person licensed, registered, or otherwise permitted to prescribe, distribute, dispense, conduct research with respect to, or to administer a controlled substance during professional practice or research in the Territory; and

(2) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance during professional practice or research in the Territory.

(m) "Prescribe" means to issue a direction or authorization, by prescription, permitting a patient lawfully to obtain a controlled substance.

(n) "Prescriber" means a practitioner who prescribes a controlled substance.

(o) "Prescription" means a controlled substance lawfully prescribed and subsequently dispensed.

(p) "Prescription drug monitoring database" or "PDMD" means the electronic prescription drug monitoring database established under the Virgin Islands Drug Monitoring Program established in section 635b (a)(1).

(q) "Prescription drug monitoring program" means a program that collects, manages, analyzes, and provides information regarding controlled substances.

(r) "Prescription Drug Monitoring Program Advisory Committee" or "Committee" means the Prescription Drug Monitoring Program Advisory Committee established in section 635c.

(s) "Qualified law enforcement agency" means a law enforcement agency that has a certified law enforcement prescription drug diversion investigator and a commissioner or chief officer who has successfully completed a certification course in prescription drug diversion approved by the Committee.

(t) "Schedule II" means controlled substances placed in Schedule II under 19 V.I.C. § 595(c).

(u) "Schedule III" means controlled substances placed in Schedule III under 19 V.I.C. § 595(c).

(v) "Schedule IV" means controlled substances placed in Schedule IV under 19 V.I.C. § 595(c).

(w) "Schedule V" means controlled substances placed in Schedule V under 19 V.I.C. § 595(c).

(x) "Ultimate user" means a person who lawfully possesses a controlled substance for:

(1) The person's own use;

(2) The use of a member of the person's household; or

(3) Administering to an animal owned by a person or by a member of the person's household.

(y) "Virgin Islands Prescription Drug Monitoring Program" or "Program" means the prescription drug monitoring program established in section 635b.

§ 635b. Establishment of Program; requirements

(a) The Department shall establish and administer the Virgin Islands Prescription Drug Monitoring Program. Under the Program, the Department shall:

(1) establish, maintain, and administer an electronic prescription drug monitoring database system to collect and store controlled substance dispensing information;

(2) provide dispensers with a basic file layout to enable electronic transmission of the information required under this subchapter; and

(3) establish and maintain a process for verifying the credentials of and authorizing the use of prescription information in the PDMD by those individuals and entities listed in sections 635d. and 635e.

(b) Each dispenser shall submit, by electronic means, information to the PDMD regarding each controlled substance dispensed that includes:

(1) the dispenser's identification number;

(2) the date the prescription was filled;

(3) the prescription number;

(4) whether the prescription is new or is a refill;

(5) the National Drug Code for the controlled substance that is dispensed;

(6) the quantity of the controlled substance dispensed;

(7) the number of days' supply dispensed;

(8) the number of refills ordered;

(9) a patient identifier that is not a social security number or a driver's license number;

(10) the patient's name;

(11) the patient's address;

(12) the patient's date of birth;

(13) the patient's gender;

(14) the prescriber's identification number;

(15) the date the prescription was issued by the prescriber; and

(16) the source of the payment for the prescription.

(c) Each dispenser shall submit the prescription information set forth in subsection (b) every 24 hours. If a dispenser is temporarily unable to comply with this subsection due to an equipment failure or other circumstances, the dispenser shall immediately notify the Department.

(d) The Department may issue a waiver to a dispenser that is unable to submit prescription information by electronic means acceptable to the Department. The waiver may permit the dispenser to submit prescription information to the Department by paper form or other means, provided all information required in subsection (b) is submitted in this alternative format and in accordance with the frequency requirements established in subsection (c). Requests for waivers must be submitted in writing to the Department.

(e) Except as required in subsection (f), a practitioner is encouraged to access or check the information in the PDMD before prescribing, dispensing, or administering medications.

(f)(1) Except as provided in paragraph (2), a practitioner shall consult the PDMD to review a patient's controlled substance dispensing history every time when prescribing, dispensing, or administering an opioid from Schedule II or Schedule III or a benzodiazepine medication to a patient.

(2) (A) Paragraph (1) does not apply to a prescriber or dispenser if the medication is prescribed or otherwise provided to a patient:

(i) currently receiving hospice or palliative care;

(ii) during an inpatient hospital admission or at discharge;

(iii) in a nursing home or residential care facility that uses a sole source pharmacy; or

(iv) at the scene of an emergency, in a licensed ground ambulance or in an air ambulance.

(B) Paragraph (1) does not apply to situations in which the PDMD is not accessible due to technological or electrical failure.

(g) A prescriber who has reviewed information from the PDMD shall make or cause to be made a notation in the patient's medical record stating the date and time upon which the inquiry was made and identifying the prescriber or designee's name who made the search and review. If the PDMD does not allow access to such individual, a notation to that effect shall also be made containing the same information of date, time, and individual's name.

(h) The Department may amend, by regulation, the exemptions listed in subsection (f)(2) upon a recommendation from the Committee and a showing that the exemption or lack of exemption is unnecessarily burdensome or has created a hardship.

(i) A licensed oncologist shall check the PDMD when prescribing any drug listed in subsection (f)(1) to a patient on an initial malignant episodic diagnosis and every three months following the diagnosis while continuing treatment.

(j) A licensing board shall adopt regulations requiring practitioners who have the authority to prescribe, dispense, or administer medications to check the information in the PDMD as provided in subsection (f).

(k) The Department, by regulation, shall create a process for patients to address errors, inconsistencies, and other matters in their record, including cases of breach of privacy and security.

(l) The Department shall develop algorithms within the PDMD that alert a practitioner if the practitioner's patient is being prescribed opioids by more than two practitioners within any thirty-day period.

(m) The Department shall purge prescription information from the PDMD after four years have elapsed from the date the prescription was dispensed.

§ 635c. Prescription Drug Monitoring Program Advisory Committee; Creation

(a) There is established within the Office of the Commissioner of Health the Prescription Drug Monitoring Program Advisory Committee to consult with and advise the Department on matters related to the establishment, maintenance, operation, and evaluation of the Program.

(b) The Committee consists of five voting members and the Commissioner, or a designee, who shall serve as a non-voting chairperson. The voting members of the Committee are:

(1) a mental health provider or certified drug and alcohol counselor; and

(2) one representative designated by each of the following organizations:

(A) Virgin Islands Board of Medical Examiners;

(B) Virgin Islands Board of Pharmacy;

(C) Virgin Islands Department of Justice; and

(D) Virgin Islands Territorial Public Defender Office.

(c) Each member shall serve a three-year term or until the appointment of the member's successor.

(d) Three voting members of the Committee constitute a quorum. Actions of the Committee are adopted when a majority of the members vote in favor of the action.

(e) The Committee shall hold not less than four meetings per year, or more often upon the call of a meeting by the chairperson or the majority of the members.

(f) Members may attend meetings in person, remotely by audiovisual means, or by audio-only.

(g) The Department shall provide staff assistance to the Committee.

(h) Members receive no compensation but must be reimbursed for their actual and necessary expenses incurred in the performance of their duties.

§ 635d. Direct access to the PDMD

(a) The following persons are provided direct access to information in the PDMD:

(1) a prescriber or dispenser or a designee for the sole purpose of providing medical or pharmaceutical care to a specific patient. The delegating prescriber or dispenser may be held civilly liable and criminally responsible for the misuse of the prescription information obtained by the designee;

(2) employees of the Department; and

(3) a certified law enforcement prescription drug diversion investigator who has complied with subsections (b) and (c).

(b) To be granted access to the PDMD, a certified law enforcement prescription drug diversion investigator shall provide the following information to the Department:

(1) the identification credentials assigned by the Department and the case number of the investigation; and

(2) an annual report from a qualified law enforcement agency.

(c) A qualified law enforcement agency shall submit to the Department an annual report of the data accessed by all certified law enforcement prescription drug diversion investigators in the qualified law enforcement agency, including written verification that the inquiries were part of a lawful prescription drug diversion investigation and providing the case number and the disposition of the investigation. The Department shall prepare a verification form and make the form available annually to the qualified law enforcement agency. The qualified law enforcement agency shall return the completed verification form to the Department not later than 30 days after its receipt. The certified law enforcement prescription drug diversion investigator's failure to timely submit the verification form results in the immediate suspension of access to the PDMD until the verification form has been submitted and the DOH has the opportunity, not to exceed seven days, to review the information on the verification form.

(d) The Department shall limit access to the Database to only those employees whose access is reasonably necessary to carry out this subchapter.

§ 635e. Access to PDMD information

(a) The following persons or entities may not directly access the PDMD, but may request information in the PDMD from the Department:

(1) a law enforcement officer pursuant to a criminal investigation but only after the law enforcement officer obtains a search warrant signed by a judge that demonstrates

probable cause to believe that a violation of federal or Virgin Islands criminal law has occurred, and that specified information contained in the PDMD would assist in the investigation of the crime, and that the specified information should be released to the law enforcement officer;

(2) a regulatory body engaged in the supervision of licensing or regulatory boards of practitioners authorized to prescribe or dispense controlled substances;

(3) a person or entity investigating a case of breaches of privacy of the PDMD or its records;

(4) medical examiners as authorized by law to investigate causes of deaths for cases under investigation pursuant to his official duties and responsibilities;

(5) the Department of Human Services if:

(A) the purpose of the PDMD information is related to an investigation under title 5 Virgin Islands Code, chapter 201, subchapter IV and not pursuant to a criminal investigation by a law enforcement officer; and

(B) the Department of Human Services has obtained a court order pursuant to 5 V.I.C. § 2556 to access the information;

(6) a patient or authorized agent of a patient, who requests his own prescription monitoring information; or

(7) a parent or legal guardian of a minor child who requests the minor child's information.

§ 635f. Confidentiality

(a) The PDMD and all information contained in the PDMD and any records maintained by the Department, or by an entity contracting with the Department, that is submitted to,

maintained, or stored as a part of the PDMD is confidential and not subject to disclosure under the Virgin Islands Public Records Act, 3 V.I.C. §881 et. seq.

(b) The Department shall establish regulations to ensure that the privacy and confidentiality of patients are maintained and that patient information collected, recorded, transmitted, and stored is protected and not disclosed to persons except as provided for in this subchapter.

§ 635g. Review of database information by the Department

(a) The Department shall review the PDMD information monthly, including a review to identify information that appears to indicate whether a patient is obtaining prescriptions in a manner that may represent misuse or abuse of controlled substances, based on prescribing criteria determined by the Commissioner upon consultation with the Committee. The prescribing criteria must be posted on the website of the Department and be available in print upon request.

(b) (1) If the PDMD information appears to indicate misuse or abuse may have occurred, the Department shall notify the prescribers and dispensers who have prescribed or dispensed the prescriptions and provide three consecutive monthly reports to the prescribers and dispensers.

(2) If after three months of providing reports to the prescribers and dispensers, the information continues to suggest that misuse or abuse may be occurring, the Department shall send a report to the licensing boards.

(3) If misuse or abuse is identified, the Department shall notify the practitioners and dispensers who prescribed or dispensed the prescriptions and the United States Diversion Control Division of the United States Drug Enforcement Administration.

§ 635h. Unlawful acts and penalties

(a) A dispenser who knowingly and intentionally fails to submit prescription monitoring information as required in section 635b. or knowingly and intentionally submits incorrect prescription information is guilty of a felony and, upon conviction, shall be sentenced to a term of imprisonment of not more than five years, or to payment of a fine not to exceed $50,000, or both, and the conviction shall be reported to the licensing board for action to be taken against the dispenser's license.

(b) A practitioner who purposely fails to access the PDMD as required by section 635b(f)(1) is subject to disciplinary action by the licensing board.

(c) An individual authorized to access prescription information in the PDMD who negligently uses, releases, or discloses the information in a manner or for a purpose in violation of this subchapter is guilty of a misdemeanor. Any person who is convicted of negligently using, releasing, or disclosing the information in violation of this subchapter shall, upon a subsequent conviction, be guilty of a felony and shall be sentenced to a term of imprisonment of not more than three years, or to payment of a fine not to exceed $5,000, or both.

(d)(1) An individual authorized to access prescription information in the PDMD who knowingly obtains or discloses the information in a manner or for a purpose in violation of this subchapter is guilty of a felony and, upon conviction, shall be sentenced to a term of imprisonment of not more than five years, or to payment of a fine not to exceed $50,000, or both.

(2) Any person who knowingly obtains, attempts to obtain, or discloses prescription information in the PDMD under false pretenses is guilty of a felony and, upon conviction, shall be sentenced to a term of imprisonment of not more than five years, or to payment of a fine not to exceed $100,000, or both.

(3) Any person who obtains or discloses prescription information in the PDMD with the intent to sell, transfer, or use the information for commercial advantage, personal gain, or malicious harm is guilty of a felony and, upon conviction, shall be sentenced to a term of imprisonment for not less than two years but not more than ten years, or to payment of a fine not to exceed $250,000, or both.

(e) The penalties provided in this section are intended to be cumulative of other penalties which may be applicable and are not intended to repeal other penalties.

§ 635i. Information exchange with other prescription drug monitoring programs

(a) The Department may provide prescription monitoring information to federal prescription drug monitoring programs or other states' prescription drug monitoring programs, and the information may be used by those programs consistent with this subchapter, provided the program or system, as determined by the Department, contains legal, administrative, technical, and physical safeguards that meet or exceed the security measures of the Department for the operation of the PDMD.

(b) The Department may request and receive prescription monitoring information from federal prescription drug monitoring programs or other states' prescription drug monitoring programs and may use information consistent with this subchapter.

(c) The Department may develop the capability to transmit information to other prescription drug monitoring programs and receive information from other prescription drug monitoring programs employing the standards of exchangeability.

(d) The Department may enter into written agreements with federal prescription drug monitoring programs or other states' prescription drug monitoring programs for the purpose of describing the terms and conditions for sharing prescription information.

§ 635j. Authority to contract and seek funding

(a)(1) The Department may contract to establish and administer the Program and may make application for, receive, and administer grant funding from public or private sources for this purpose.

(2) A contractor shall comply with the provisions regarding confidentiality of prescription information as outlined in this subchapter and is subject to the penalties specified in this subchapter for unlawful acts.

(b) A fee may not be levied against practitioners for the purpose of funding or complying with the Program.

§ 635k. Annual report on performance measures

The Department shall prepare and submit an annual report on performance measures of the Program to the Governor and the Chairperson of the Committee on Health, Hospitals and Human Services of the Legislature of the Virgin Islands by December 1st of each calendar year. Performance measures include outcomes relating to the reduction of the rate of inappropriate use of controlled substances through monitoring efforts and the reduction of the quantity of controlled substances obtained by individuals attempting to engage in fraud and deceit.

§ 635l. Regulations

The Department shall promulgate regulations necessary to effectuate the purposes of this subchapter."

SECTION 2. Title 5 Virgin Islands Code, subtitle 2, chapter 201, subchapter IV is amended by adding section 2556 to read as follows:

"§ 2556. Access to information in the prescription drug monitoring database

(a) The Department of Human Services may petition the court to allow an investigator investigating child abuse and neglect matters to request information from the prescription drug monitoring database established in 19 V.I.C. § 635b.

(b) The court may grant a petition under this section if the Department of Human Services demonstrate probable cause that:

(1) the person was or is in possession of one or more prescription drugs;

(2) the person gave birth to a baby; and

(3) the person or the baby tested positive for one or more prescription drugs at the time of the birth of the baby."

SECTION 3. This bill becomes effective 180 days after the enactment date of this act.

BILL SUMMARY

Section 1 of this bill amends title 19 of the Virgin Islands Code, part III, chapter 29 to: require the Virgin Islands Department of Health ("DOH") to establish and administer the Virgin Islands Prescription Drug Monitoring Program ("Program") that includes the development of an electronic prescription drug monitoring database ("PDMD") to collect and store controlled substance dispensing information; establish the Prescription Drug Monitoring Program Advisory Committee to consult with and advise the DOH on matters related to the establishment, maintenance, operation, and evaluation of the Program; require a dispenser to submit information to the PDMD regarding each controlled substance dispensed to a patient; require a practitioner, unless exempted, to consult the PDMD when prescribing, dispensing, or administering an opioid from Schedule II or Schedule III or a benzodiazepine medication to a patient and to make a notation of the inquiry in the patient's medical record; authorize certain persons or entities to directly access the PDMD or to request information from the PDMD;

establish that information in the PDMD is confidential and not subject to disclosure under the Virgin Islands Public Records Act, 3 V.I.C. §881 et. seq.; require the DOH to establish regulations to ensure that the privacy and confidentiality of patients are maintained; establish unlawful acts and penalties as it relates to the use of the PDMD; allow the DOH to provide prescription monitoring information to federal prescription drug monitoring programs or other states' prescription drug monitoring programs; allow the DOH to contract to develop, implement, maintain, or enhance the Program and seek funding for that purpose; and require the DOH to submit an annual report on performance measures of the Program to the Governor and the Chairperson of the Committee on Health, Hospitals and Human Services of the Legislature of the Virgin Islands by December 1st. Section 2 of this bill amends title 5 Virgin Islands Code, subtitle 2, chapter 201, subchapter IV to establish criteria necessary to allow the Department of Human Services to request information in the PDMD. Section 3 of this bill makes the provisions of this bill effective 180 days after enactment.

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