Committee on Health
Amendment in Nature of Substitute
B20-127

A BILL

IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

To improve the District's ability to identify and reduce diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of controlled substances; and to enhance patient care by providing prescription monitoring information that will assure legitimate use of controlled substances in health care, including palliative care, research and other medical and pharmacological uses.

BE IT ENACTED BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, that this act may be cited as the "Prescription Drug Monitoring Program Act of 2013".

Sec. 2. Definitions.

For the purposes of this act, the term:

(1) "Administer" shall have the same meaning as in section 102 of the District of Columbia Uniform Controlled Substances Act of 1981, effective August 5, 1981 (D.C. Law 4-29; D.C. Official Code § 48-901.02)("Controlled Substances Act").

(2) "Controlled substance" shall have the same meaning as in section 102 of the Controlled Substances Act~~District of Columbia Uniform Controlled Substances Act of 1981, effective August 5, 1981 (D.C. Law 4-29; D.C. Official Code § 48-901.02)~~.

(3) "Covered substance" means all controlled substances included in the schedules set forth in sections 206, 208, 210 and 212 of the Controlled Substances Act~~District of Columbia Uniform Controlled Substances Act of 1981, effective August 5, 1981 (D.C. Law 4-29; D.C. Official Code § 48-901.01 *et seq.*)~~, in schedules II through V of section 202(c) of Title II of the ~~Federal Controlled Substances Act~~Comprehensive Drug Abuse Prevention and Control Act of 1970, approved October 27, 1970 (84 Stat.

1247; 21 U.S.C. § 812), and any other drug as specified by rulemaking, that is required to be reported to the Prescription Drug Monitoring Program pursuant to the Prescription Drug Monitoring Program Act of 2013, as introduced on February 7, 2013 (D.C. Bill 20-127)("act") .

(4) "Department" means the Department of Health.

(5) "Director" means the Director of the Department of Health.

(6) "Dispense" shall have the same meaning as in section 102 of the Controlled Substances Act~~District of Columbia Uniform Controlled Substances Act of 1981, effective August 5, 1981 (D.C. Law 4-29; D.C. Official Code § 48-901.02)~~.

(7) "Dispenser" means a practitioner who dispenses a covered substance to the ultimate user, or his or her agent, but shall not include:

(A) A licensed hospital or institutional facility pharmacy that distributes such substances for the purpose of inpatient hospital care or the dispensing of prescriptions for controlled substances at the time of discharge from such a facility;

(B) A practitioner or other authorized person who administers such a substance;

(C) A wholesale distributor of a covered substance; or

(D) A clinical researcher providing a covered substance to research subjects as part of a research study approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protections programs.

(8) "Drug" ~~shall have the same meaning as in section 102 of the District of Columbia Uniform Controlled Substances Act of 1981, effective August 5, 1981 (D.C. Law 4-29; D.C. Official Code § 48-901.02). It shall include~~means:

"(A) Any substance recognized as a drug, medicine, or medicinal chemical in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, or official Veterinary Medicine Compendium or other official drug compendium or any supplement to any of them;

"(B) Any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal;

"(C) Any chemical substance, ~~(~~other than food,~~)~~ intended to affect the structure or any function of the body of man or other animal; and

"(D) Any substance intended for use as a component of any items specified in subparagraph (A), (B), or (C) of this paragraph, but does not include medical devices or their components, parts, or accessories.

(9) "Health occupations board" means a board that, pursuant to section 408 of the District of Columbia Health Occupations Revision Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1204.08), licenses and regulates health professionals with the authority to prescribe or dispense covered substances.

(10) "Interoperability" means, with respect to a District of Columbia or state prescription drug monitoring program, the ability of that program to share electronically reported prescription information with another state, district, or territory of the United States' prescription drug monitoring program or a third party, approved by the Director, that operates interstate prescription drug monitoring exchanges.

(11) "Patient" means the person or animal who is the ultimate user of a controlled substance or other drug required to be submitted under this act for whom a lawful prescription is issued or for whom a controlled substance or such other drug is lawfully dispensed.

(12) "Practitioner" shall have the same meaning as in section 102 of the Controlled Substances Act~~District of Columbia Uniform Controlled Substances Act of 1981, effective August 5, 1981, (D.C. Law 4-29; D.C. Official Code § 48-901.02)~~.

(13) "Prescriber" means a practitioner or other authorized person who prescribes a controlled substance or other covered substance in the course of his or her professional practice.

(14) "Prescription drug monitoring program" means a program that collects, manages, analyzes, and provides information regarding covered substances or other drugs required to be submitted under this act or program established by a similar act in another state, district or territory of the United States.

(15) "Program" means the Prescription Drug Monitoring Program established by section 3 of this act.

(16) "Ultimate user" shall have the same meaning as in section 102 of the Controlled Substances Act~~District of Columbia Uniform Controlled Substances Act of 1981, effective August 5, 1981, (D.C. Law 4-29; D.C. Official Code § 48-901.02)~~.

Sec. 3. Program establishment; Director's regulatory authority.

(a) There is established the Prescription Drug Monitoring Program ("Program") within the Department. The Program shall:

(1) Establish, maintain, and administer an electronic system to monitor the dispensing of covered substances;

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

(3) Establish and maintain a process for verifying the credentials and authorizing the use of prescription information by those individuals and agencies listed in subsections (b) and (c) of section 6 of this act.

(b) The Director, in accordance with Title 1 of the District of Columbia Administrative Procedure Act, approved October 21, 1968 (82 Stat. 1204; D.C. Official Code § 2-501 *et seq.*) shall issue rules, including the establishment of criteria for granting waivers to the reporting requirements set forth in this act, as necessary to implement the Prescription Drug Monitoring Program.

(c) The Director may contract with another District agency or a private vendor as may be necessary for the implementation and maintenance of the Program. Any such contractor shall be bound to comply with the provisions regarding confidentiality of data in this act and shall be subject to the penalties specified in this act.

(d) The Director shall also establish a multi-discipline advisory committee, which shall function under the Department to assist in the implementation and evaluation of the Prescription Drug Monitoring Program.

Sec. 4. Reporting requirements; exceptions.

(a) Each dispenser shall submit to the Program the required reporting information for each prescription dispensed for a covered substance within 24 hours after the covered substance is dispensed, unless otherwise established by the Director through rulemaking,

but this does not include merely placing the covered substance prescription into a bin for pickup by the ultimate user or his or her agent. Any dispenser located outside the boundaries of the District of Columbia that is licensed or registered by the District of Columbia, shall submit the required reporting information to the Program for each prescription dispensed for a covered substance to an ultimate user who resides within the District of Columbia within 24 hours after the date that the covered substance is dispensed, unless otherwise established by the Director through rulemaking.

(b) The failure of any person subject to the reporting requirements of this act to report the dispensing of a covered substance, unless otherwise exempted under this act, or the willful failure to transmit accurate information shall constitute grounds for the revocation, suspension, or denial of a District controlled substances registration; disciplinary action by the relevant health occupations board pursuant to section 514(c) of the District of Columbia Health Occupations Revision Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1205.14(c)); and the imposition of civil fines pursuant to section 104 of the Department of Consumer and Regulatory Affairs Civil Infractions Act of 1985, effective October 5, 1985 (D.C. Law 6-42, D.C. Official Code § 2-1801.04).

(c) Upon dispensing a covered substance, a dispenser of such covered substance shall report the following information to the Program:

(1) Patient name;

(2) Patient address;

(3) Patient date of birth;

(4) Patient gender;

(5) Dispenser identification number;

(6) Prescriber identification number;

(7) Date prescription was issued by prescriber;

(8) Date prescription was dispensed;

(9) Prescription number;

(10) Prescription type, whether the prescription is new or is a refill;

(11) National Drug Code for the drug dispensed;

(12) Quantity dispensed;

(13) Number of days' supply dispensed;

(14) Number of refills ordered;

(15) Source of payment for the prescription; and

(16) Any other required information as specified in the regulations promulgated by the Director to implement this act, or as required in order for the Program to be eligible to receive federal funds.

(d) Each dispenser shall transmit the required reporting information in accordance with the manner, format, standards, and schedules established by the Director through rulemaking.

(e) The reporting requirements of this act shall not apply to the dispensing of covered substances when the dispensing is limited to the following:

(1) Administering covered substances;

(2) Dispensing covered substances within an appropriately licensed narcotic maintenance program;

(3) Dispensing covered substances to inpatients in hospitals or nursing facilities licensed by the Department or facilities that are otherwise authorized by law to operate as hospitals or nursing homes in the District;

(4) Dispensing covered substances to inpatients in hospices licensed by the Department; or

(5) Dispensing covered substances as otherwise provided in the Department's regulations.

Sec. 5. Authority to access database.

(a) Any prescriber or dispenser authorized to access the information in the possession of the Program pursuant to this act may, pursuant to regulations promulgated by the Director to implement the provisions of this section, delegate such authority to up to two health care professionals who are:

(1) Licensed, registered, or certified by a health occupations board; and

(2) Employed at the same facility and under the direct supervision of the prescriber or dispenser.

Sec. 6. Confidentiality of data; disclosure of information; discretionary authority of the Director.

(a) All data, records, and reports relating to the prescribing and dispensing of covered substances to patients and any abstracts from such data, records, and reports that are in the possession of the Program pursuant to this act and any materials relating to the operation or safety of the Program shall be confidential and shall be exempt from disclosure based on requests made pursuant to Title 2 of the District of Columbia

Administrative Procedure Act, approved October 21, 1968 (82 Stat. 1204; D.C. Official Code § 2-501 *et seq.*). Information obtained pursuant to the Program may only be disclosed as provided in this act.

(b) Upon receiving a request for information in accordance with the Department's regulations and in compliance with applicable District and federal laws and regulations, the Director shall disclose the following:

(1) Information relevant to a specific investigation of a specific patient or of a specific dispenser or prescriber to an agent designated by the Chief of the Metropolitan Police Department to conduct drug diversion investigations;

(2) Information relevant to an investigation or inspection of or allegation of misconduct by a specific person licensed, certified, or registered by or an applicant for licensure, certification, or registration by a health occupations board or the Department;

(3) Information relevant to a disciplinary proceeding before a health occupations board or in any subsequent hearing, trial or appeal of an action or board order to designated employees of the Department;

(4) Information relevant to the proceedings of any grand jury or additional grand jury that has been properly impaneled in accordance with D.C. Official Code § 11-1916; and

(5) Information relevant to a specific investigation of a specific dispenser or specific prescriber to an agent of the United States Drug Enforcement Administration with authority to conduct drug diversion investigations.

(c) In accordance with the Department's regulations and applicable federal law and regulations, the Director may, at the Director's discretion, disclose:

(1) Information in the possession of the Program concerning a patient who is over the age of 18 to that patient, or to the parent or legal guardian of a child aged 18 years or under, unless otherwise prohibited by District or federal law;

(2) Information on a specific patient to a prescriber for the purpose of establishing the treatment history of the specific patient when such patient is either under care and treatment by the prescriber or the prescriber is initiating treatment of such patient. The request shall be made and the information shall be provided in the manner specified by the Director through rulemaking. Notice shall be given to patients that such information may be requested by a prescriber participating with the Program.

(3) Information on a specific patient to a dispenser for the purpose of establishing a prescription history to assist the dispenser in determining the validity of a prescription when the patient is seeking a covered substance from the dispenser or the facility in which the dispenser practices. The request shall be made and the information shall be provided in the manner specified by the Director through rulemaking. Notice shall be given to patients that such information may be requested by a dispenser participating with the Program.

(4) Information relevant to an investigation or regulatory proceeding of a specific dispenser or prescriber to other regulatory authorities concerned with granting, limiting, or denying licenses, certificates, or registrations to practice a health profession when the regulatory authority licenses the dispenser or prescriber, or the dispenser or prescriber is seeking licensure by a regulatory authority;

(5) Information relevant to an investigation relating to a specific dispenser or prescriber who is a participating provider in the District Medicaid program, DC Health

Care Alliance, or any other public health care program; ~~or~~ information relating to an investigation relating to a specific patient who is currently eligible for and receiving, or who has been eligible for and has received medical assistance services; information relevant to the Medicaid Fraud Control Unit of the Office of the Inspector General, or to designated employees of the Department of Health Care Finance, as appropriate;

(6) Information relevant to the determination of the cause of death of a specific patient to the designated employees of the Office of the Chief Medical Examiner; and

(7) Information for the purpose of bona fide research or education to qualified personnel, however:

(A) Data elements that would reasonably identify a specific patient, prescriber, or dispenser shall be deleted or redacted from such information prior to disclosure; and

(B) Release of the information shall only be made pursuant to a written agreement between qualified personnel and the Director in order to ensure compliance with this act.

(d) Confidential information that has been received, maintained, or developed by a health occupations board or disclosed by the health occupations board pursuant to this act shall not be available for discovery or court subpoena or introduced into evidence in any medical malpractice suit or other action for damages arising out of the provision of or failure to provide services. However, this section shall not be construed to inhibit any investigation or prosecution conducted pursuant to this act.

Sec. 7. Interoperability; Information exchange with other prescription drug monitoring programs.

(a) The Director is authorized to enter into written agreements with other prescription drug monitoring programs, or a third party, approved by the Director, that operates an interstate prescription drug monitoring exchange, for the purpose of interoperability and the mutual exchange of information among prescription drug monitoring programs, and describing the terms and conditions for the sharing of prescription information under this section.

(b) The Director may provide prescription monitoring information pursuant to such agreements, which shall only use the information for the purposes allowed by this act.

(c) The Director may request and receive prescription drug monitoring information from other states' prescription drug monitoring programs and may use such information under the provisions of this act.

Sec. 8. Criteria for indicators of misuse; Director's authority to disclose information; intervention.

(a) The Director may establish through rulemaking:

(1) Criteria for indicators of misuse; and

(2) A method for analysis of data collected by the Program using the criteria for indicators of misuse.

(b) Upon the development of such criteria and data analysis, the Director may, in addition to the discretionary disclosure of information pursuant to this act, disclose information using the criteria that indicates potential misuse by recipients of covered

substances to their specific prescribers for the purpose of intervention to prevent such misuse.

Sec. 9. Immunity from liability.

(a) The Director and the employees of the Department shall not be liable for any civil damages resulting from the accuracy or inaccuracy of any information reported, compiled or maintained by the Program pursuant to this act.

(b) The Director and the employees of the Department shall not be liable for any civil damages resulting from the disclosure of or failure to disclose any information in compliance with this act and the Department's regulations.

(c) In the absence of gross negligence or willful misconduct, prescribers or dispensers complying in good faith with the reporting requirements of this act shall not be liable for any civil damages for any act or omission resulting from the submission of such required reports.

Sec. 10. Unlawful disclosure of information and acts; disciplinary action authorized; penalties.

(a) It shall be unlawful for any person having access to the confidential information in possession of the Program or any data or reports produced by the Program to disclose such confidential information except as provided in this act. Any person who discloses this confidential information in violation of the provisions of this act shall be guilty of a misdemeanor upon conviction.

(b) It shall be unlawful for any person who lawfully receives confidential information from the Program to redisclose or use such confidential information in any way other than the authorized purpose for which the request was made. Any person who

discloses confidential information in violation of this act shall be guilty of a misdemeanor upon conviction.

(c) Nothing in this section shall prohibit a person who prescribes or dispenses a covered substance required to be reported to the program from redisclosing information obtained from the Program to another prescriber or dispenser who has prescribed or dispensed a covered substance to the same patient.

(d) Unauthorized use or disclosure of confidential information received from the Program shall also be grounds for disciplinary action by the relevant health occupations board.

Sec. 11. Fiscal impact statement.

The Council adopts the fiscal impact statement in the committee report as the fiscal impact statement required by section 602(c)(3) of the District of Columbia Home Rule Act, approved December 24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(3)).

Sec. 12. Effective date.

This act shall take effect one year following approval by the Mayor (or in the event of veto by the Mayor, action by the Council to override the veto), a 30-day period of Congressional review as provided in section 602(c)(1) of the District of Columbia Home Rule Act, approved December 24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(1)), and publication in the District of Columbia Register.