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COLORADO REVISED STATUTE 12-280-4

SECTION 12-280-401 - LEGISLATIVE DECLARATION

(1) The general assembly finds, determines, and declares that:

(a) Prescription drug misuse occurs in this country to an extent that exceeds or rivals the abuse of illicit drugs;

(b) Prescription drug misuse occurs at times due to the deception of the authorized practitioners where patients seek controlled substances for treatment and the practitioner is unaware of the patient's other medical providers and treatments;

(c) Electronic monitoring of prescriptions for controlled substances provides a mechanism whereby practitioners can discover the extent of each patient's requests for drugs and whether other providers have prescribed similar substances during a similar period of time;

(d) Electronic monitoring of prescriptions for controlled substances provides a mechanism for law enforcement officials and regulatory boards to efficiently investigate practitioner behavior that is potentially harmful to the public.

SECTION 12-280-403 - PRESCRIPTION DRUG USE MONITORING PROGRAM - REGISTRATION REQUIRED

(1) The board shall develop or procure a prescription controlled substance electronic program to track information regarding prescriptions for controlled substances dispensed in Colorado, including the following information:

(a) The date the prescription was dispensed;

(b) The name of the patient and the practitioner;

(c) The name and amount of the controlled substance;

(d) The method of payment;

(e) The name of the dispensing pharmacy; and

(f) Any other data elements necessary to determine whether a patient is visiting multiple practitioners or pharmacies, or both, to receive the same or similar medication.

(2) (a) Each practitioner licensed in this state who holds a current registration issued by the federal drug enforcement administration and each pharmacist licensed in this state shall register and maintain a user account with the program.

(b) When registering with the program or at any time thereafter, a practitioner may authorize designees to access the program under section 12-280-404(3)(b) or (3)(d) on behalf of the practitioner, and a pharmacist may authorize designees to access the program under section 12-280-404(3)(f) if:

(I) (A) The authorized designee of the practitioner is employed by, or is under contract with, the same professional practice as the practitioner; or

(B) The authorized designee of the pharmacist is employed by, or is under contract with, the same prescription drug outlet as the pharmacist; and

(II) The practitioner or pharmacist takes reasonable steps to ensure that the designee is sufficiently competent in the use of the program; and

(III) The practitioner or pharmacist remains responsible for:

(A) Ensuring that access to the program by the practitioner's designee is limited to the purposes authorized in section 12-280-404(3)(b) or (3)(d) or that access to the program by the pharmacist's designee is limited to the purposes authorized in section 12-280-404(3)(f), as the case may be, and that access to the program occurs in a manner that protects the confidentiality of the information obtained from the program; and

(B) Any negligent breach of confidentiality of information obtained from the program by the practitioner's or pharmacist's designee when the designee accessed the program on behalf of the supervising practitioner or pharmacist.

(c) A practitioner or pharmacist is subject to penalties pursuant to section 12-280-406 for violating the requirements of subsection (2)(b) of this section.

(d) Any individual authorized as a designee of a practitioner or pharmacist pursuant to subsection (2)(b) of this section shall register as a designee of a practitioner or pharmacist with the program for program data access in accordance with section 12-280-404(3)(b), (3)(d), or (3)(f), as applicable, and board rules.

(3) Each practitioner and each dispensing pharmacy shall disclose to a patient receiving a controlled substance that his or her identifying prescription information will be entered into the program database and may be accessed for limited purposes by specified individuals.

(4) The board shall establish a method and format for prescription drug outlets to convey the necessary information to the board or its designee. The method must not require more than a one-time entry of data per patient per prescription by a prescription drug outlet.

(5) The division may contract with any individual or public or private agency or organization in carrying out the data collection and processing duties required by this part 4.

(6) (a) On or before December 1, 2021, the division shall fully enable the expansion, utilization, and adoption of the United States bureau of justice assistance RxCheck, both for interstate data sharing and for integrating the program into the electronic medical records of practitioners and health systems within the state. Practitioners and health systems, through public and private integration organizations that comply with the business associate requirements of the federal "Health Insurance Portability and Accountability Act of 1996", as amended, 42 U.S.C. sec. 1320d to 1320d-9, and its related privacy and security regulations, are authorized to directly connect to the program through RxCheck. In order to complete the required RxCheck enablement, the division may authorize public or private integration organizations to provide to the division reasonable and necessary program query audit reports should audit reporting functionality not be sufficient for the division through RxCheck. Notwithstanding the enablement of RxCheck described in this subsection (6), the program, whether developed by the board or procured, must allow direct application program interface connections to the program through public and private integration organizations that comply with the business associate requirements of the "Health Insurance Portability and Accountability Act of 1996", as amended, 42 U.S.C. sec. 1320d to 1320d-9, and its related privacy and security regulations.

(b) For the 2021-22 state fiscal year, the general assembly shall appropriate money from the marijuana tax cash fund created in section 39-28.8-501 (1) to the department for appropriation to the division for the purposes of this subsection (6).

(7) (a) Subject to available funding, the division shall solicit applications from public and private integration organizations and, on or before July 1, 2024, approve:

(I) Qualified integration organizations that practitioners and pharmacists may use to integrate access of and data entry into the program; and

(II) Qualified integration organizations that practitioners and pharmacists may use to integrate access of and data entry into a patient's electronic medical records.

(b) The division shall implement a process whereby practitioners and pharmacists who have not integrated their electronic medical records and the program may apply for and receive money from a qualified integration organization approved by the division to help defray all or a portion of the costs to integrate the program and electronic medical records.

(c) The board may promulgate rules to implement this subsection (7).

(d) (I) For the 2022-23 state fiscal year, the general assembly shall transfer two million forty-five thousand one hundred ninety-eight dollars for the administrative costs of this subsection (7) from the general fund to the prescription drug monitoring fund created in section 12-280-405. The division may use the money transferred to the prescription drug monitoring fund pursuant to this subsection (7) for the purposes of this subsection (7). Any money transferred pursuant to this subsection (7) not expended prior to July 1, 2023, shall remain in the fund for the same purpose through December 30, 2024.

(II) This subsection (7)(d) is repealed, effective December 31, 2024.

SECTION 12-280-404 - PROGRAM OPERATION - ACCESS - RULES - DEFINITIONS - REPEAL

(1) The board shall operate and maintain the program.

(2) (a) The board shall adopt all rules necessary to implement the program.

(b) The rules adopted pursuant to subsection (2)(a) of this section may:

(I) Identify prescription drugs and substances by using evidence-based practices, in addition to controlled substances, that have a substantial potential for abuse and must require pharmacists and prescription drug outlets to report those prescription drugs and substances to the program when they are dispensed to a patient; and

(II) Include a data retention schedule for the information obtained and stored by the program pursuant to this part 4 and the processes for the preservation of de-identified, aggregated data for a period of time as determined by the board.

(c) The board shall determine if the program should track all prescription drugs prescribed in this state. If the board makes such determination, the board shall promulgate rules on or before June 1, 2022, to include all prescription drugs in the program. If the board determines that one or more prescription drugs should not be tracked through the program, the board shall publicly note the justification for such exclusion during the rule-making process.

(3) The program is available for query only to the following persons or groups of persons:

(a) Board staff responsible for administering the program;

(b) Any practitioner with the statutory authority to prescribe controlled substances, or an individual designated by the practitioner to act on his or her behalf in accordance with section 12-280-403(2)(b), to the extent the query relates to a current patient of the practitioner. The practitioner or his or her designee shall identify his or her area of health care specialty or practice upon the initial query of the program.

(c) (I) Any veterinarian with statutory authority to prescribe controlled substances, to the extent the query relates to a current patient or to a client and if the veterinarian, in the exercise of professional judgment, has a reasonable basis to suspect the client has committed drug abuse or has mistreated an animal.

(II) As used in this subsection (3)(c):

(A) "Client" has the same meaning as set forth in section 12-315-104(4).

(B) "Mistreat" has the same meaning as set forth in section 35-42-103(9).

(C) "Patient" has the same meaning as set forth in section 12-315-104(13).

(d) A practitioner, or an individual designated by the practitioner to act on his or her behalf in accordance with section 12-280-403(2)(b), engaged in a legitimate program to monitor a patient's drug abuse;

(e) The medical director, or his or her designee, at a facility that treats substance use disorders with controlled substances, if an individual in treatment at the facility gives permission to the facility to access his or her program records;

(f) A pharmacist, an individual designated by a pharmacist in accordance with section 12-280-403(2)(b) to act on his or her behalf, or a pharmacist licensed in another state, to the extent the information requested relates specifically to a current patient to whom the pharmacist is dispensing or considering dispensing a controlled substance or prescription drug or a patient to whom the pharmacist is currently providing clinical patient care services;

(g) Law enforcement officials so long as the information released is specific to an individual patient, pharmacy, or practitioner and is part of a bona fide investigation, and the request for information is accompanied by an official court order or subpoena;

(h) The individual who is the recipient of a controlled substance prescription so long as the information released is specific to the individual;

(i) State regulatory boards within the division and the director, so long as the information released is specific to an individual practitioner and is part of a bona fide investigation, and the request for information is accompanied by an official court order or subpoena;

(j) A resident physician with an active physician training license issued by the Colorado medical board pursuant to section 12-240-128 and under the supervision of a licensed physician;

(k) The department of public health and environment for purposes of population-level analysis, but any use of program data by the department is subject to the federal "Health Insurance Portability and Accountability Act of 1996", Pub.L. 104-191, as amended, and implementing federal regulations, including the requirement to remove any identifying data unless exempted from the requirement;

(l) A medical examiner who is a physician licensed pursuant to article 240 of this title 12, whose license is in good standing, and who is located and employed in the state of Colorado, or a coroner elected pursuant to section 30-10-601; or a deputy coroner who is authorized by the coroner to act on behalf of the coroner in accordance with subsection (3.5) of this section, if:

(I) The information released is specific to an individual who is the subject of an autopsy or a death investigation conducted by the medical examiner, coroner, or deputy

(II) The medical examiner coroner, or deputy coroner has legitimate access to the individual's medical record; and

(III) The individual's death or injury occurred under unusual, suspicious, or unnatural circumstances.

(3.5) A coroner may authorize a deputy coroner to access the program on behalf of the coroner if:

(a) The coroner takes reasonable steps to ensure that the deputy coroner is sufficiently competent to use the program; and

(b) The coroner remains responsible for:

(I) Ensuring that access to the program is limited to the purposes specified in subsection (3)(l) of this section and that the access occurs in a manner that protects the confidentiality of program information; and

(II) Any negligent breach of the confidentiality of information obtained from the program by the deputy coroner.

(4) (a) Each practitioner or practitioner's designee shall query the program prior to prescribing the second fill for an opioid unless the patient receiving the prescription:

(I) Is receiving the opioid in a hospital, skilled nursing facility, residential facility, or correctional facility;

(II) Has been diagnosed with cancer and is experiencing cancer-related pain;

(III) Is undergoing palliative care or hospice care;

(IV) Is experiencing post-surgical pain that, because of the nature of the procedure, is expected to last more than fourteen days;

(V) Is receiving treatment during a natural disaster or during an incident where mass casualties have taken place; or

(VI) Has received only a single dose to relieve pain for a single test or procedure.

(a.5) Each practitioner or the practitioner's designee shall query the program before prescribing a benzodiazepine to a patient unless the benzodiazepine is prescribed to treat a patient in hospice or to treat epilepsy, a seizure or seizure disorder, a suspected seizure disorder, spasticity, alcohol withdrawal, or a neurological condition, including a posttraumatic brain injury or catatonia.

(b) The program must use industry standards to allow providers or their designees direct access to data from within an electronic health record to the extent that the query relates to a current patient of the practitioner.

(c) A practitioner or practitioner's designee complies with this subsection (4) if the practitioner or practitioner's designee attempts to access the program before prescribing an opioid or a benzodiazepine, and the program is not available or is inaccessible due to technical failure.

(d) A violation of this subsection (4) does not create a private right of action or serve as the basis of a cause of action. A violation of this subsection (4) does not constitute negligence per se or contributory negligence per se and does not alone establish a standard of care. Compliance with this subsection (4) does not alone establish an absolute defense to any alleged breach of the standard of care.

(e) Repealed

(5) The board shall not charge a practitioner or pharmacy who transmits data in compliance with the operation and maintenance of the program a fee for the transmission of the data.

(6) The board or the department of public health and environment, pursuant to a written agreement that ensures compliance with this part 4, may provide data to qualified personnel of a public or private entity for the purpose of bona fide research or education so long as the data does not identify a recipient of, a practitioner who prescribed, or a prescription drug outlet that dispensed, a prescription drug.

(7) (a) The board shall provide a means of sharing information about individuals whose information is recorded in the program with out-of-state health care practitioners and law enforcement officials that meet the requirements of subsection (3)(b), (3)(d), or (3)(g) of this section.

(b) The board may, within existing funds available for operation of the program, provide a means of sharing prescription information and electronic health records through a board-approved vendor and method with the health information organization network, as defined in section 25-3.5-103 (8.5), in order to work collaboratively with the statewide health information exchanges designated by the department of health care policy and financing. Use of the information made available pursuant to this subsection (7)(b) is subject to privacy and security protections in state law and the federal "Health Insurance Portability and Accountability Act of 1996", Pub.L.104-191, as amended, and any implementing regulations.

(8) The board shall develop criteria for indicators of misuse, abuse, and diversion of controlled substances and, based on those criteria, provide unsolicited reports of dispensed controlled substances to prescribing practitioners and dispensing pharmacies for purposes of education and intervention to prevent and reduce occurrences of controlled substance misuse, abuse, and diversion. In developing the criteria, the board shall consult with the Colorado dental board, Colorado medical board, state board of nursing, state board of optometry, Colorado podiatry board, and state board of veterinary medicine.

(9) Reports generated by the program and provided to prescribing practitioners for purposes of information, education, and intervention to prevent and reduce occurrences of controlled substance misuse, abuse, and diversion are:

(a) Not public records under the "Colorado Open Records Act", part 2 of article 72 of title 24;

(b) Not discoverable in any criminal or administrative proceeding against a prescribing practitioner; and

(c) Not admissible in any civil, criminal, or administrative proceeding against a prescribing practitioner.

SECTION 12-280-406 - VIOLATIONS - PENALTIES

A person who knowingly releases, obtains, or attempts to obtain information from the program in violation of this part 4 shall be punished by a civil fine of not less than one thousand dollars and not more than ten thousand dollars for each violation. Fines paid shall be deposited in the general fund in accordance with section 12-20-404(6).

SECTION 12-280-408 - EXEMPTION - WAIVER

(1) A hospital licensed or certified pursuant to section 25-1.5-103, a prescription drug outlet located within the hospital that is dispensing a controlled substance for a chart order or dispensing less than or equal to a twenty-four-hour supply of a controlled substance, and an emergency medical service provider certified or licensed pursuant to section 25-3.5-203 are exempt from the reporting provisions of this part 4. A hospital prescription drug outlet licensed pursuant to section 12-280-114 shall comply with the provisions of this part 4 for controlled substances dispensed for outpatient care that have more than a twenty-four-hour supply.

(2) A prescription drug outlet that does not report controlled substance data to the program due to a lack of electronic automation of the outlet's business may apply to the board for a waiver from the reporting requirements.