NOTICE REQUIREMENTS FOR PRESCRIPTION MONITORING PROGRAMS

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Colorado

West's Colorado Revised Statutes Annotated (2012)
Title 12. Professions and Occupations
Health Care
Article 42.5. Pharmacists, Pharmacy Businesses, and Pharmaceuticals
Part 4. Electronic Monitoring of Prescription Drugs

§ 12-42.5-403. Prescription drug use monitoring program

(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) 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.

(3) 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.

(4) 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.

Kansas

Kansas Administrative Regulations (2012)
Agency 68. Board of Pharmacy
Article 21. Prescription Monitoring Program

68-21-4 Notice of requests for information.

Each dispenser who may access information maintained by the board on each drug of concern and schedule II through IV drug dispensed to one of the dispenser's patients for the purpose of providing medical or pharmaceutical care shall notify the patient of this access to prescription monitoring information by performing either of the following:

(a) Posting an easily viewable sign at the place where prescription orders are issued or accepted for dispensing; or

(b) providing written material about the dispenser's access to prescription monitoring information.

Minnesota

Minnesota Statutes Annotated (2012)
Health (Ch. 144-159)
Chapter 152. Drugs, Controlled Substances
Prescriptions

§ 152.126. Controlled substances prescription electronic reporting system

Subdivision 1. Definitions. For purposes of this section, the terms defined in this subdivision have the meanings given.

(a) "Board" means the Minnesota State Board of Pharmacy established under chapter 151.

(b) "Controlled substances" means those substances listed in section 152.02, subdivisions 3 to 5, and those substances defined by the board pursuant to section 152.02, subdivisions 7, 8, and 12.

(c) "Dispense" or "dispensing" has the meaning given in section 151.01, subdivision 30. Dispensing does not include the direct administering of a controlled substance to a patient by a licensed health care professional.

(d) "Dispenser" means a person authorized by law to dispense a controlled substance, pursuant to a valid prescription. For the purposes of this section, a dispenser does not include a licensed hospital pharmacy that distributes controlled substances for inpatient hospital care or a veterinarian who is dispensing prescriptions under section 156.18.

(e) "Prescriber" means a licensed health care professional who is authorized to prescribe a controlled substance under section 152.12, subdivision 1.

(f) "Prescription" has the meaning given in section 151. 01, subdivision 16.

Subd. 1a. Treatment of intractable pain. This section is not intended to limit or interfere with the legitimate prescribing of controlled substances for pain. No prescriber shall be subject to disciplinary action by a health-related licensing board for prescribing a controlled substance according to the provisions of section 152.125.

Subd. 2. Prescription electronic reporting system. (a) The board shall establish by January 1, 2010, an electronic system for reporting the information required under subdivision 4 for all controlled substances dispensed within the state.

(b) The board may contract with a vendor for the purpose of obtaining technical assistance in the design, implementation, operation, and maintenance of the electronic reporting system.

Subd. 3. Prescription Electronic Reporting Advisory Committee. (a) The board shall convene an advisory committee. The committee must include at least one representative of:

(1) the Department of Health;

(2) the Department of Human Services;

(3) each health-related licensing board that licenses prescribers;

(4) a professional medical association, which may include an association of pain management and chemical dependency specialists;

(5) a professional pharmacy association;

(6) a professional nursing association;

(7) a professional dental association;

(8) a consumer privacy or security advocate; and

(9) a consumer or patient rights organization.

(b) The advisory committee shall advise the board on the development and operation of the electronic reporting system, including, but not limited to:

(1) technical standards for electronic prescription drug reporting;

(2) proper analysis and interpretation of prescription monitoring data; and

(3) an evaluation process for the program.

Subd. 4. Reporting requirements; notice. (a) Each dispenser must submit the following data to the board or its designated vendor, subject to the notice required under paragraph (d):

(1) name of the prescriber;

(2) national provider identifier of the prescriber;

(3) name of the dispenser;

(4) national provider identifier of the dispenser;

(5) prescription number;

(6) name of the patient for whom the prescription was written;

(7) address of the patient for whom the prescription was written;

(8) date of birth of the patient for whom the prescription was written;

(9) date the prescription was written;

(10) date the prescription was filled;

(11) name and strength of the controlled substance;

(12) quantity of controlled substance prescribed;

(13) quantity of controlled substance dispensed; and

(14) number of days supply.

(b) The dispenser must submit the required information by a procedure and in a format established by the board. The board may allow dispensers to omit data listed in this subdivision or may require the submission of data not listed in this subdivision provided the omission or submission is necessary for the purpose of complying with the electronic reporting or data transmission standards of the American Society for Automation in Pharmacy, the National Council on Prescription Drug Programs, or other relevant national standard-setting body.

(c) A dispenser is not required to submit this data for those controlled substance prescriptions dispensed for:

(1) individuals residing in licensed skilled nursing or intermediate care facilities;

(2) individuals receiving assisted living services under chapter 144G or through a medical assistance home and community-based waiver;

(3) individuals receiving medication intravenously;

(4) individuals receiving hospice and other palliative or end-of-life care; and

(5) individuals receiving services from a home care provider regulated under chapter 144A.

(d) A dispenser must not submit data under this subdivision unless a conspicuous notice of the reporting requirements of this section is given to the patient for whom the prescription was written.

Subd. 5. Use of data by board. (a) The board shall develop and maintain a database of the data reported under subdivision 4. The board shall maintain data that could identify an individual prescriber or dispenser in encrypted form. The database may be used by permissible users identified under subdivision 6 for the identification of:

(1) individuals receiving prescriptions for controlled substances from prescribers who subsequently obtain controlled substances from dispensers in quantities or with a frequency inconsistent with generally recognized standards of use for those controlled substances, including standards accepted by national and international pain management associations; and

(2) individuals presenting forged or otherwise false or altered prescriptions for controlled substances to dispensers.

(b) No permissible user identified under subdivision 6 may access the database for the sole purpose of identifying prescribers of controlled substances for unusual or excessive prescribing patterns without a valid search warrant or court order.

(c) No personnel of a state or federal occupational licensing board or agency may access the database for the purpose of obtaining information to be used to initiate or substantiate a disciplinary action against a prescriber.

(d) Data reported under subdivision 4 shall be retained by the board in the database for a 12-month period, and shall be removed from the database no later than 12 months from the last day of the month during which the data was received.

Subd. 6. Access to reporting system data. (a) Except as indicated in this subdivision, the data submitted to the board under subdivision 4 is private data on individuals as defined in section 13.02, subdivision 12, and not subject to public disclosure.

(b) Except as specified in subdivision 5, the following persons shall be considered permissible users and may access the data submitted under subdivision 4 in the same or similar manner, and for the same or similar purposes, as those persons who are authorized to access similar private data on individuals under federal and state law:

(1) a prescriber or an agent or employee of the prescriber to whom the prescriber has delegated the task of accessing the data, to the extent the information relates specifically to a current patient, to whom the prescriber is prescribing or considering prescribing any controlled substance and with the provision that the prescriber remains responsible for the use or misuse of data accessed by a delegated agent or employee;

(2) a dispenser or an agent or employee of the dispenser to whom the dispenser has delegated the task of accessing the data, to the extent the information relates specifically to a current patient to whom that dispenser is dispensing or considering dispensing any controlled substance and with

the provision that the dispenser remains responsible for the use or misuse of data accessed by a delegated agent or employee;

(3) an individual who is the recipient of a controlled substance prescription for which data was submitted under subdivision 4, or a guardian of the individual, parent or guardian of a minor, or health care agent of the individual acting under a health care directive under chapter 145C;

(4) personnel of the board specifically assigned to conduct a bona fide investigation of a specific licensee;

(5) personnel of the board engaged in the collection of controlled substance prescription information as part of the assigned duties and responsibilities under this section;

(6) authorized personnel of a vendor under contract with the board who are engaged in the design, implementation, operation, and maintenance of the electronic reporting system as part of the assigned duties and responsibilities of their employment, provided that access to data is limited to the minimum amount necessary to carry out such duties and responsibilities;

(7) federal, state, and local law enforcement authorities acting pursuant to a valid search warrant; and

(8) personnel of the medical assistance program assigned to use the data collected under this section to identify recipients whose usage of controlled substances may warrant restriction to a single primary care physician, a single outpatient pharmacy, or a single hospital.

For purposes of clause (3), access by an individual includes persons in the definition of an individual under section 13.02.

(c) Any permissible user identified in paragraph (b), who directly accesses the data electronically, shall implement and maintain a comprehensive information security program that contains administrative, technical, and physical safeguards that are appropriate to the user's size and complexity, and the sensitivity of the personal information obtained. The permissible user shall identify reasonably foreseeable internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized disclosure, misuse, or other compromise of the information and assess the sufficiency of any safeguards in place to control the risks.

(d) The board shall not release data submitted under this section unless it is provided with evidence, satisfactory to the board, that the person requesting the information is entitled to receive the data.

(e) The board shall not release the name of a prescriber without the written consent of the prescriber or a valid search warrant or court order. The board shall provide a mechanism for a

prescriber to submit to the board a signed consent authorizing the release of the prescriber's name when data containing the prescriber's name is requested.

(f) The board shall maintain a log of all persons who access the data and shall ensure that any permissible user complies with paragraph (c) prior to attaining direct access to the data.

(g) Section 13.05, subdivision 6, shall apply to any contract the board enters into pursuant to subdivision 2. A vendor shall not use data collected under this section for any purpose not specified in this section.

Subd. 7. Disciplinary action. (a) A dispenser who knowingly fails to submit data to the board as required under this section is subject to disciplinary action by the appropriate health-related licensing board.

(b) A prescriber or dispenser authorized to access the data who knowingly discloses the data in violation of state or federal laws relating to the privacy of health care data shall be subject to disciplinary action by the appropriate health-related licensing board, and appropriate civil penalties.

Subd. 8. Evaluation and reporting. (a) The board shall evaluate the prescription electronic reporting system to determine if the system is negatively impacting appropriate prescribing practices of controlled substances. The board may contract with a vendor to design and conduct the evaluation.

(b) The board shall submit the evaluation of the system to the legislature by July 15, 2011.

Subd. 9. Immunity from liability; no requirement to obtain information. (a) A pharmacist, prescriber, or other dispenser making a report to the program in good faith under this section is immune from any civil, criminal, or administrative liability, which might otherwise be incurred or imposed as a result of the report, or on the basis that the pharmacist or prescriber did or did not seek or obtain or use information from the program.

(b) Nothing in this section shall require a pharmacist, prescriber, or other dispenser to obtain information about a patient from the program, and the pharmacist, prescriber, or other dispenser, if acting in good faith, is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for requesting, receiving, or using information from the program.

Subd. 10. Funding. (a) The board may seek grants and private funds from nonprofit charitable foundations, the federal government, and other sources to fund the enhancement and ongoing operations of the prescription electronic reporting system established under this section. Any funds received shall be appropriated to the board for this purpose. The board may not expend

funds to enhance the program in a way that conflicts with this section without seeking approval from the legislature.

(b) The administrative services unit for the health-related licensing boards shall apportion between the Board of Medical Practice, the Board of Nursing, the Board of Dentistry, the Board of Podiatric Medicine, the Board of Optometry, and the Board of Pharmacy an amount to be paid through fees by each respective board. The amount apportioned to each board shall equal each board's share of the annual appropriation to the Board of Pharmacy from the state government special revenue fund for operating the prescription electronic reporting system under this section. Each board's apportioned share shall be based on the number of prescribers or dispensers that each board identified in this paragraph licenses as a percentage of the total number of prescribers and dispensers licensed collectively by these boards. Each respective board may adjust the fees that the boards are required to collect to compensate for the amount apportioned to each board by the administrative services unit.

Oregon

West's Oregon Revised Statutes (2012)
Title 36. Public Health and Safety
Chapter 431. State and Local Administration and Enforcement of Health Laws
Prescription Monitoring Program
(Program)

§ 431.962. Prescription monitoring program

(1)(a) The Department of Human Services, in consultation with the Prescription Monitoring Program Advisory Commission, shall establish and maintain a prescription monitoring program for monitoring and reporting prescription drugs dispensed by pharmacies in Oregon that are classified in schedules II through IV under the federal Controlled Substances Act, 21 U.S.C. 811 and 812, as modified under ORS 475.035.

(b)(A) To fulfill the requirements of this subsection, the department shall establish, maintain and operate an electronic system to monitor and report drugs described in paragraph (a) of this subsection that are dispensed by prescription.

(B) The system must operate and be accessible by practitioners and pharmacies 24 hours a day, seven days a week.

(C) The department may contract with a state agency or private entity to ensure the effective operation of the electronic system.

(2) In consultation with the commission, the department shall adopt rules for the operation of the electronic prescription monitoring program established under subsection (1) of this section, including but not limited to standards for:

(a) Reporting data;

(b) Providing maintenance, security and disclosure of data;

(c) Ensuring accuracy and completeness of data;

(d) Complying with the federal Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) and regulations adopted under it, including 45 C.F.R. parts 160 and 164, federal alcohol and drug treatment confidentiality laws and regulations adopted under those laws, including 42 C.F.R. part 2, and state health and mental health confidentiality laws, including ORS 179.505, 192.517 and 192.518 to 192.529;

(e) Ensuring accurate identification of persons or entities requesting information from the database;

(f) Accepting printed or nonelectronic reports from pharmacies that do not have the capability to provide electronic reports; and

(g) Notifying a patient, before or when a drug classified in schedules II through IV is dispensed to the patient, about the prescription monitoring program and the entry of the prescription in the system.

(3) The department shall submit an annual report to the commission regarding the prescription monitoring program established under this section.

Oregon Administrative Rules Compilation (2012)
Chapter 410. Oregon Health Authority, Division of Medical Assistance Programs
Division 121. Pharmaceutical Services
Non-medicaid Rules Prescription Drug Monitoring Program

410-121-4015. Notification to Patients

Using language provided by the Authority, a pharmacy shall notify each patient receiving a controlled substance about the Prescription Drug Monitoring Program before or when the controlled substance is dispensed to the patient. The notification shall include that the prescription will be entered into the system.

Utah

Utah Code Annotated (2012)
Title 26. Utah Health Code
Chapter 1. Department of Health Organization

§ 26-1-36. Duty to establish program to reduce deaths and other harm from prescription opiates used for chronic noncancer pain

(1) As used in this section, "opiate" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability.

(2) In addition to the duties listed in Section 26-1-30, the department shall develop and implement a two-year program in coordination with the Division of Professional Licensing, the Utah Labor Commission, and the Utah attorney general, to:

(a) investigate the causes of and risk factors for death and nonfatal complications of prescription opiate use and misuse in Utah for chronic pain by utilizing the Utah Controlled Substance Database created in Section 58-37f-201;

(b) study the risks, warning signs, and solutions to the risks associated with prescription opiate medications for chronic pain, including risks and prevention of misuse and diversion of those medications;

(c) provide education to health care providers, patients, insurers, and the general public on the appropriate management of chronic pain, including the effective use of medical treatment and quality care guidelines that are scientifically based and peer reviewed; and

(d) educate the public regarding:

(i) the purpose of the Controlled Substance Database established in Section 58-37f-201; and

(ii) the requirement that a person's name and prescription information be recorded on the database when the person fills a prescription for a schedule II, III, IV, or V controlled substance.

(3) The department shall report on the development and implementation of the program required in Subsection (2) to the legislative Health and Human Services Interim Committee and the legislative Business and Labor Interim Committee no later than the November interim meetings in 2008 and 2009. Each report shall include:

(a) recommendations on:

(i) use of the Utah Controlled Substance Database created in Section 58-37f-201 to identify and prevent:

(A) misuse of opiates;

(B) inappropriate prescribing; and

(C) adverse outcomes of prescription opiate medications;

(ii) interventions to prevent the diversion of prescription opiate medications; and

(iii) medical treatment and quality care guidelines that are:

(A) scientifically based; and

(B) peer reviewed; and

(b)(i) a measure of results against expectations under the program as of the date of the report; and

(ii) an analysis of the application of the program, use of the appropriated funds, and the impact and results of the use of the funds.

(4) The report provided under Subsection (3) for the 2008 interim shall also provide a final cumulative analysis of the measurable effectiveness of the program implemented under this section.

Vermont

Vermont Statutes Annotated (2012)
Title Eighteen. Health
Part 5. Foods and Drugs
Chapter 84A. Vermont Prescription Monitoring System

Title 18 § 4283. Creation; implementation

(a) Contingent upon the receipt of funding, the department may establish an electronic database and reporting system for monitoring Schedules II, III, and IV controlled substances, as defined in 21 C.F.R. Part 1308, as amended and as may be amended, that are dispensed within the state of Vermont by a health care provider or dispenser or dispensed to an address within the state by a pharmacy licensed by the Vermont board of pharmacy.

(b) As required by the department, every dispenser who is licensed by the Vermont board of pharmacy shall report to the department in a timely manner data for each controlled substance in Schedules II, III, and IV, as amended and as may be amended, dispensed to a patient within Vermont. Reporting shall not be required for:

(1) a drug administered directly to a patient; or

(2) a drug dispensed by a health care provider at a facility licensed by the department, provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of 48 hours.

(c) Data for each controlled substance that is dispensed shall include the following:

(1) patient identifier, which may include the patient's name and date of birth;

(2) drug dispensed;

(3) date of dispensing;

(4) quantity and dosage dispensed;

(5) the number of days' supply;

(6) health care provider; and

(7) dispenser.

(d) The data shall be provided in the electronic format defined by the department. To the extent possible, the format shall not require data entry in excess of that required in the regular course of business. Electronic transmission is not required if a waiver has been granted by the department to an individual dispenser. The department shall strive to create VPMS in a manner that will enable real-time transmittal to VPMS and real-time retrieval of information stored in VPMS.

(e) It is not the intention of the department that a health care provider or a dispenser shall have to pay a fee or tax or purchase hardware or proprietary software required by the department specifically for the establishment, maintenance, or transmission of the data. The department shall seek grant funds and take any other action within its financial capability to minimize any cost impact to health care providers and dispensers.

(f) The department shall purge from VPMS all data that is more than six years old.

(g) The commissioner shall develop and provide advisory notices, which shall make clear that all prescriptions for controlled drugs in Schedules II, III, and IV are entered into a statewide database in order to protect the public. The notices shall be distributed at no cost to dispensers and health care providers who are subject to this chapter.

(h) A dispenser shall be subject to discipline by the board of pharmacy or by the applicable licensing entity if the dispenser intentionally fails to comply with the requirements of subsection (b), (c), or (d) of this section.

Vermont Administrative Code (2012)
Title 12. Agency of Human Services
Subtitle 5. Department of Health
General
Rule 21. Prescription Monitoring System

12-5-21:1. GENERAL PROVISIONS

Section 1.1 Purpose.

This rule implements the Vermont Prescription Monitoring System ("VPMS") created by 18 V.S.A. Chapter 84A, which authorizes the Department to establish an electronic database and reporting system for electronic monitoring of prescriptions of certain controlled substances to promote the public health through enhanced opportunities for treatment for and prevention of abuse of controlled substances, without interfering with the legal medical use of those substances.

Section 1.2 Authority.

This rule is adopted under the authority of 3 V.S.A. §§ 801(b)(11) and 3003(a) and 18 V.S.A. §§ 102 and 4287.

Section 1.3 Effective Date.

This rule shall be effective on June 1, 2008.

Section 1.4 Definitions.

The definitions of terms contained in these rules are the same as those contained in 18 V.S.A. § 4282. If any of such legislative definitions are amended, the amended definitions shall be the definitions of the terms contained in these rules.

Additional definitions for purposes of these rules:

1. "Commissioner" means the Commissioner of the Vermont Department of Health.

2. "Controlled substance" means a substance listed on Schedules II, III or IV as defined in 21 C.F.R. Part 1308, as amended and as may be amended.

3. "Report of Controlled Substances Dispensed" means the report generated by dispensers of required data on each reportable prescription dispensed pursuant to this rule.

4. "Department" means the Vermont Department of Health.

5. "Dispense" or "dispensing" shall have the same meaning as those terms are defined in 26 V.S.A. § 2022(5).

6. "Pharmacist-manager" shall have the same meaning as defined in the Vermont Board of Pharmacy Administrative Rules.

7. "Reportable prescription" means each controlled substance dispensed from any pharmacy to a patient within Vermont during the reporting period, except (1) a controlled substance administered directly to a patient; or (2) a controlled substance dispensed by a health care provider at a facility licensed by the Department of Health, provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of 48 hours.

8. "VPMS report" means a report released by the Department of information from the VPMS database to an individual or entity eligible to receive the information pursuant to a specific provision of law.

Section 1.5 Distribution of Advisory Notices.

Each dispenser shall provide to customers to whom a reportable prescription is dispensed the advisory notice developed and distributed by the Department by: 1) prominently displaying the advisory notice in a manner readily accessible to its customers, or 2) duplicating the complete text of the advisory notice in another format, such as by printing on customer receipts or on patient instructions or providing a written insert for delivery to the patient, or 3) both.

Section 1.6 Confidentiality.

All data submitted to the VPMS database pursuant to this rule are confidential, not subject to disclosure pursuant to public records law, and shall only be disclosed as provided in 18 V.S.A. § 4284 or this rule.

A person who receives information from the VPMS database shall only use that information as permitted by law and shall share that information only with other persons eligible by law to receive it. There is no restriction on the right of a patient to share his or her own data received from the VPMS database.

Section 1.7 Correction of Information in the VPMS Database.

A patient, health care provider, dispenser, or professional licensure board, or other individual having knowledge of what they believe to be an error in the VPMS database, may submit a request to correct information in writing to the Department that shall include:

1. A statement explaining in detail the basis for the requested correction;

2. The precise change requested;

3. Documentation of the error and of the correct information;

4. The requester's name, address, telephone number and original signature.

The Department will review all requests to correct information in the VPMS database and contact the reporting pharmacy that provided the data. If the reporting pharmacy concurs that the data should be corrected as requested, the Department will correct the data. If the reporting pharmacy does not concur, the Department will decline to make the change and refer the requester to the reporting pharmacy. Upon request by a health care provider, dispenser or professional licensure board or other individual, and as permitted by 18 V.S.A. § 4284 and Part III of this rule, the Department will notify the requester whether the requested correction has been made. Any patient who has requested a correction will be notified of whether the requested correction has been made.

Virginia

Virginia Administrative Code (2012)
Title 18. Professional and Occupational Licensing
Vac Agency No. 76. Department of Health Professions
Chapter 20. Regulations Governing the Prescription Monitoring Program

18 VAC 76-20-70. Notice of requests for information.

A. Any dispenser who intends to request information from the program for a recipient or prospective recipient of a Schedule II, III, or IV controlled substance shall post a sign that can be easily viewed by the public at the place where the prescription is accepted for dispensing and that discloses to the public that the pharmacist may access information contained in the program files on all Schedule II, III or IV prescriptions dispensed to a patient. In lieu of posting a sign, the dispenser may provide such notice in written material provided to the recipient, or may obtain written consent from the recipient.

B. Any prescriber who intends to request information from the program about a patient or prospective patient shall post a sign that can be easily viewed by the public that discloses to the public that the prescriber may access information contained in the program files on all Schedule II, III or IV prescriptions dispensed to a patient. In lieu of posting a sign, the prescriber may provide such notice in written material provided to the patient, or may obtain written consent from the patient.