WEST VIRGINIA LEGISLATURE

2017 REGULAR SESSION

Committee Substitute

for

Committee Substitute

for

Senate Bill 333

BY SENATORS TAKUBO, PALUMBO, STOLLINGS, ROMANO,

CLINE AND MARONEY

[Originating in the Committee on the Judiciary;

reported on March 25, 2017]

A BILL to amend and reenact §60A-9-4, §60A-9-5 and §60A-9-5a of the Code of West Virginia, 1931, as amended; and to amend said code by adding thereto a new section, designated §60A-9-9, all relating to the Controlled Substances Monitoring Program database; requiring reporting instances of an overdose or a suspected overdose to the database; setting out elements to be reported; allowing access to the database to deans of the state's medical schools or their designees for monitoring prescribing practices of prescribing faculty and residents; allowing access to designated physician reviewers for medical provider employers and hospital chief medical officers; allowing the Board of Pharmacy to require that drugs of concern be reported to the database; exempting reporting requirements for drugs of concern from criminal penalties; allowing agents for the Office of Health Facility Licensure and Certification to access the database; allowing the Board of Pharmacy to develop administrative penalties for not reporting drugs of concern; providing for rulemaking; requiring the licensing boards to report to the Board of Pharmacy when notified of unusual prescribing habits of a licensee; and making technical corrections.

Be it enacted by the Legislature of West Virginia:

That §60A-9-4, §60A-9-5 and §60A-9-5a of the Code of West Virginia, 1931, as amended, be amended and reenacted; and that said code by amended by adding thereto a new section, designated §60A-9-9, all to read as follows:

ARTICLE 9. CONTROLLED SUBSTANCES MONITORING.

§60A-9-4. Required information.

(a) Whenever a medical services provider dispenses a controlled substance listed in Schedule II, III or IV as established under the provisions of article two of this chapter or an opioid antagonist, or whenever a prescription for the controlled substance or opioid antagonist is filled by: (i) A pharmacist or pharmacy in this state; (ii) a hospital, or other health care facility, for outpatient use; or (iii) a pharmacy or pharmacist licensed by the Board of Pharmacy, but situated

outside this state for delivery to a person residing in this state, the medical services provider, health care facility, pharmacist or pharmacy shall, in a manner prescribed by rules promulgated by the ~~board under~~ Board of Pharmacy pursuant to this article, report the following information, as applicable:

(1) The name, address, pharmacy prescription number and Drug Enforcement Administration controlled substance registration number of the dispensing pharmacy or the dispensing physician or dentist;

(2) The full legal name, address and birth date of the person for whom the prescription is written;

(3) The name, address and Drug Enforcement Administration controlled substances registration number of the practitioner writing the prescription;

(4) The name and national drug code number of the Schedule II, III and IV controlled substance or opioid antagonist dispensed;

(5) The quantity and dosage of the Schedule II, III and IV controlled substance or opioid antagonist dispensed;

(6) The date the prescription was written and the date filled;

(7) The number of refills, if any, authorized by the prescription;

(8) If the prescription being dispensed is being picked up by someone other than the patient on behalf of the patient, the first name, last name and middle initial, address and birth date of the person picking up the prescription as set forth on the person's government-issued photo identification card shall be retained in either print or electronic form until such time as otherwise directed by rule promulgated by the ~~board~~ Board of Pharmacy; and

(9) The source of payment for the controlled substance dispensed.

(b) Whenever a medical services provider treats a patient and an overdose has occurred or is suspected as a result of illicit or prescribed medication, the medical service provider shall report the full legal name, address and birth date of the person for whom treatments for an

overdose or suspected overdose is provided, including any known ancillary evidence of the overdose or suspected overdose including, but not limited to, the source of the overdose or potential overdose, if known, any family history of substance use, positive drugs' screens and any other evidence of the overdose or suspected overdose.

~~(b)~~ (c) The ~~board~~ Board of Pharmacy may prescribe by rule promulgated ~~under this~~ pursuant to this article the form to be used in prescribing a Schedule II, III, and IV substance or opioid antagonist if, in the determination of the ~~board~~ Board of Pharmacy, the administration of the requirements of this section would be facilitated.

~~(c)~~ (d) Products regulated by the provisions of article ten of this chapter shall be subject to reporting pursuant to the provisions of this article to the extent set forth in said article.

~~(d)~~ (e) Reporting required by this section is not required for a drug administered directly to a patient by a practitioner. Reporting is, however, required by this section for a drug dispensed to a patient by a practitioner. ~~*Provided,* That the~~ The quantity dispensed by a prescribing practitioner to his or her own patient may not exceed an amount adequate to treat the patient for a maximum of seventy-two hours with no greater than two 72-hour cycles dispensed in any fifteen-day period of time.

~~(e)~~ (f) The Board of Pharmacy shall notify a physician prescribing buprenorphine or buprenorphine/naloxone within sixty days of the availability of ~~the~~ an abuse deterrent form of buprenorphine or buprenorphine/naloxone ~~is~~ if approved by the Food and Drug Administration as provided in FDA Guidance to Industry. Upon receipt of the notice, a physician may switch their patients using buprenorphine or buprenorphine/naloxone to the abuse deterrent form of the drug.

§60A-9-5. Confidentiality; limited access to records; period of retention; no civil liability for required reporting.

(a)(1) The information required by this article to be kept by the ~~board~~ Board of Pharmacy is confidential and not subject to the provisions of chapter twenty-nine-b of this code or obtainable

as discovery in civil matters absent a court order and is open to inspection only by inspectors and agents of the ~~board~~ Board of Pharmacy, members of the West Virginia State Police expressly authorized by the Superintendent of the West Virginia State Police to have access to the information, authorized agents of local law-enforcement agencies as members of a federally affiliated drug task force, authorized agents of the federal Drug Enforcement Administration, duly authorized agents of the Bureau for Medical Services, duly authorized agents of the Office of the Chief Medical Examiner for use in post-mortem examinations, duly authorized agents of the Office of Health Facility Licensure and Certification and regulation of health facilities, duly authorized agents of licensing boards of practitioners in this state and other states authorized to prescribe Schedules II, III and IV controlled substances, prescribing practitioners and pharmacists, a dean of any medical school or his or her designee located in this state to access prescribed level data to monitor prescribing practices of faculty members, prescribers and residents enrolled in a degree program at the school where he or she serves as dean, a physician reviewer designated by an employer of medical providers to monitor prescriber level information of prescribing practices of physicians, advance practice registered nurses or physician assistant in their employ, and a chief medical officer of a hospital or a physician designated by the chief executive officer of a hospital who does not have a chief medical officer, for prescribers who have admitting privileges to the hospital or prescriber level information, and persons with an enforceable court order or regulatory agency administrative subpoena. ~~*Provided*, That all~~ All law-enforcement personnel who have access to the Controlled Substances Monitoring Program database shall be granted access in accordance with applicable state laws and the ~~board's legislative~~ Board of Pharmacy's rules, shall be certified as a West Virginia law-enforcement officer and shall have successfully completed training approved by the ~~board~~ Board of Pharmacy. All information released by the ~~board~~ Board of Pharmacy must be related to a specific patient or a specific individual or entity under investigation by any of the above parties except that practitioners who prescribe or dispense controlled substances may request specific data related to their Drug Enforcement

Administration controlled substance registration number or for the purpose of providing treatment to a patient: *Provided*, That the West Virginia Controlled Substances Monitoring Program Database Review Committee established in subsection (b) of this section is authorized to query the database to comply with said subsection.

(2) Subject to the provisions of subdivision (1) of this subsection, the ~~board~~ Board of Pharmacy shall also review the West Virginia Controlled Substance Monitoring Program database and issue reports that identify abnormal or unusual practices of patients who exceed parameters as determined by the advisory committee established in this section. The ~~board~~ Board of Pharmacy shall communicate with practitioners and dispensers to more effectively manage the medications of their patients in the manner recommended by the advisory committee. All other reports produced by the ~~board~~ Board of Pharmacy shall be kept confidential. The ~~board~~ Board of Pharmacy shall maintain the information required by this article for a period of not less than five years. Notwithstanding any other provisions of this code to the contrary, data obtained under the provisions of this article may be used for compilation of educational, scholarly or statistical purposes, and may be shared with the West Virginia Department of Health and Human Resources for those purposes, as long as the identities of persons or entities and any personally identifiable information, including protected health information, contained therein shall be redacted, scrubbed or otherwise irreversibly destroyed in a manner that will preserve the confidential nature of the information. No individual or entity required to report under section four of this article may be subject to a claim for civil damages or other civil relief for the reporting of information to the ~~board~~ Board of Pharmacy as required under and in accordance with the provisions of this article.

(3) The ~~board~~ Board of Pharmacy shall establish an advisory committee to develop, implement and recommend parameters to be used in identifying abnormal or unusual usage patterns of patients in this state. This advisory committee shall:

(A) Consist of the following members: A physician licensed by the West Virginia Board of Medicine, a dentist licensed by the West Virginia Board of Dental Examiners, a physician licensed

by the West Virginia Board of Osteopathic Medicine, a licensed physician certified by the American Board of Pain Medicine, a licensed physician board certified in medical oncology recommended by the West Virginia State Medical Association, a licensed physician board certified in palliative care recommended by the West Virginia Center on End of Life Care, a pharmacist licensed by the West Virginia Board of Pharmacy, a licensed physician member of the West Virginia Academy of Family Physicians, an expert in drug diversion and such other members as determined by the ~~board~~ Board of Pharmacy.

(B) Recommend parameters to identify abnormal or unusual usage patterns of controlled substances for patients in order to prepare reports as requested in accordance with subdivision (2), subsection (a) of this section.

(C) Make recommendations for training, research and other areas that are determined by the committee to have the potential to reduce inappropriate use of prescription drugs in this state, including, but not limited to, studying issues related to diversion of controlled substances used for the management of opioid addiction.

(D) Monitor the ability of medical services providers, health care facilities, pharmacists and pharmacies to meet the 24-hour reporting requirement for the Controlled Substances Monitoring Program set forth in section three of this article, and report on the feasibility of requiring real-time reporting.

(E) Establish outreach programs with local law enforcement to provide education to local law enforcement on the requirements and use of the Controlled Substances Monitoring Program database established in this article.

(b) The ~~board~~ Board of Pharmacy shall create a West Virginia Controlled Substances Monitoring Program Database Review Committee of individuals consisting of two prosecuting attorneys from West Virginia counties, two physicians with specialties which require extensive use of controlled substances and a pharmacist who is trained in the use and abuse of controlled substances. The review committee may determine that an additional physician who is an expert

in the field under investigation be added to the team when the facts of a case indicate that the additional expertise is required. The review committee, working independently, may query the database based on parameters established by the advisory committee. The review committee may make determinations on a case-by-case basis on specific unusual prescribing or dispensing patterns indicated by outliers in the system or abnormal or unusual usage patterns of controlled substances by patients which the review committee has reasonable cause to believe necessitates further action by law enforcement or the licensing board having jurisdiction over the practitioners or dispensers under consideration. The licensing board having jurisdiction over the practitioner or dispenser under consideration shall report back to the Board of Pharmacy regarding any findings, investigation or discipline resulting from the findings of the review committee within thirty days of resolution of any action taken by the licensing board resulting from the information provided by the Board of Pharmacy. The review committee shall also review notices provided by the chief medical examiner pursuant to subsection (h), section ten, article twelve, chapter sixty-one of this code and determine on a case-by-case basis whether a practitioner who prescribed or dispensed a controlled substance resulting in or contributing to the drug overdose may have breached professional or occupational standards or committed a criminal act when prescribing the controlled substance at issue to the decedent. Only in those cases in which there is reasonable cause to believe a breach of professional or occupational standards or a criminal act may have occurred, the review committee shall notify the appropriate professional licensing agency having jurisdiction over the applicable practitioner or dispenser and appropriate law-enforcement agencies and provide pertinent information from the database for their consideration. The number of cases identified shall be determined by the review committee based on a number that can be adequately reviewed by the review committee. The information obtained and developed may not be shared except as provided in this article and is not subject to the provisions of chapter twenty-nine-b of this code or obtainable as discovering in civil matters absent a court order.

(c) The ~~board~~ Board of Pharmacy is responsible for establishing and providing administrative support for the advisory committee and the West Virginia Controlled Substances Monitoring Program Database Review Committee. The advisory committee and the review committee shall elect a chair by majority vote. Members of the advisory committee and the review committee may not be compensated in their capacity as members but shall be reimbursed for reasonable expenses incurred in the performance of their duties.

(d) The ~~board~~ Board of Pharmacy shall promulgate rules with advice and consent of the advisory committee, in accordance with the provisions of article three, chapter twenty-nine-a of this code. The legislative rules must include, but shall not be limited to, the following matters:

(1) Identifying parameters used in identifying abnormal or unusual prescribing or dispensing patterns;

(2) Processing parameters and developing reports of abnormal or unusual prescribing or dispensing patterns for patients, practitioners and dispensers;

(3) Establishing the information to be contained in reports and the process by which the reports will be generated and disseminated; and

(4) Setting up processes and procedures to ensure that the privacy, confidentiality, and security of information collected, recorded, transmitted and maintained by the review committee is not disclosed except as provided in this section.

(e) Persons or entities with access to the West Virginia Controlled Substances Monitoring Program database pursuant to this section may, pursuant to rules promulgated by the ~~board~~ Board of Pharmacy, delegate appropriate personnel to have access to said database.

(f) Good faith reliance by a practitioner on information contained in the West Virginia Controlled Substances Monitoring Program database in prescribing or dispensing or refusing or declining to prescribe or dispense a Schedule II, III, or IV controlled substance shall constitute an absolute defense in any civil or criminal action brought due to prescribing or dispensing or refusing or declining to prescribe or dispense.

(g) A prescribing or dispensing practitioner may notify law enforcement of a patient who, in the prescribing or dispensing practitioner's judgment, may be in violation of section four hundred ten, article four of this chapter, based on information obtained and reviewed from the controlled substances monitoring database. A prescribing or dispensing practitioner who makes a notification pursuant to this subsection is immune from any civil, administrative or criminal liability that otherwise might be incurred or imposed because of the notification if the notification is made in good faith.

(h) Nothing in the article may be construed to require a practitioner to access the West Virginia Controlled Substances Monitoring Program database except as provided in section five-a of this article.

(i) The ~~board~~ Board of Pharmacy shall provide an annual report on the West Virginia Controlled Substance Monitoring Program to the Legislative Oversight Commission on Health and Human Resources Accountability with recommendations for needed legislation no later than January 1 of each year.

§60A-9-5a. Practitioner requirements to access database and conduct annual search of the database; required rulemaking.

(a) All practitioners, as that term is defined in section one hundred one, article two of this chapter who prescribe or dispense Schedule II, III or IV controlled substances shall register with the West Virginia Controlled Substances Monitoring Program and obtain and maintain online or other electronic access to the program database: *Provided*, That compliance with the provisions of this subsection must be accomplished within thirty days of the practitioner obtaining a new license: *Provided, however,* That ~~no licensing board~~ the Board of Pharmacy may renew a practitioner's license without proof that the practitioner meet the requirements of this subsection.

(b) Upon initially prescribing or dispensing any pain-relieving controlled substance for a patient for whom they are providing pain-relieving controlled substances as part of a course of treatment for chronic, nonmalignant pain but who are not suffering from a terminal illness and at

least annually thereafter should the practitioner or dispenser continue to treat the patient with controlled substances, all persons with prescriptive or dispensing authority and in possession of a valid Drug Enforcement Administration registration identification number and, who are licensed by the Board of Medicine as set forth in article three, chapter thirty of this code, the Board of Registered Professional Nurses as set forth in article seven of said chapter, the Board of Dental Examiners as set forth in article four of said chapter and the Board of Osteopathic Medicine as set forth in article fourteen of said chapter shall access the West Virginia Controlled Substances Monitoring Program database for information regarding specific patients ~~for whom they are providing pain-relieving controlled substances as part of a course of treatment for chronic, nonmalignant pain but who are not suffering from a terminal illness~~. The information obtained from accessing the West Virginia Controlled Substances Monitoring Program database for the patient shall be documented in the patient's medical record maintained by a private prescriber or any inpatient facility licensed pursuant to the provisions of chapter sixteen of this code. A pain-relieving controlled substance shall be defined as set forth in section one, article three-a, chapter thirty of this code.

(c) The various boards mentioned in subsection (b) of this section shall promulgate both emergency and legislative rules pursuant to the provisions of article three, chapter twenty-nine-a of this code to effectuate the provisions of this section.

§60A-9-9. Drugs of concern designation.

(a) The Board of Pharmacy may designate certain drugs as drugs of concern which must be reported to the database established pursuant to this article. The designation of a drug of concern shall be reserved for drugs which have a high potential for abuse. Whenever a medical services provider dispenses a drug of concern or whenever a prescription for a drug of concern is filled by: (i) A pharmacist or pharmacy in this state; (ii) a hospital, or other health care facility, for outpatient use; or (iii) a pharmacy or pharmacist licensed by the Board of Pharmacy, but situated outside this state for delivery to a person residing in this state, the medical services

provider, health care facility, pharmacist or pharmacy shall, in a manner prescribed by rules promulgated by the Board of Pharmacy under this article, report the following information, as applicable:

(1) The name, address, pharmacy prescription number and Drug Enforcement Administration controlled substance registration number of the dispensing pharmacy or the dispensing physician or dentist;

(2) The full legal name, address and birth date of the person for whom the prescription is written;

(3) The name, address and Drug Enforcement Administration controlled substances registration number of the practitioner writing the prescription;

(4) The name and national drug number of the drug of concern dispensed;

(5) The quantity and dosage of the drug of concern dispensed;

(6) The date the prescription was written and the date filled;

(7) The number of refills, if any, authorized by the prescription;

(8) If the prescription being dispensed is being picked up by someone other than the patient on behalf of the patient, the first name, last name and middle initial, address and birth date of the person picking up the prescription as set forth on the person's government-issued photo identification card shall be retained in either print or electronic form until such time as otherwise directed by rule promulgated by the Board of Pharmacy; and

(9) The source of payment for the drug of concern dispensed.

(b) The penalties set forth in section seven of this article shall not apply to drugs listed as drugs of concern. Failure to report may be considered a violation of the practice act of the prescriber and may result in discipline by the appropriate licensing board.

(c) The Board of Pharmacy may promulgate emergency rules pursuant to the provisions of section fifteen, article three, chapter twenty-nine-a of this code to effectuate the provisions of this section.