WEST VIRGINIA LEGISLATURE 2021 REGULAR SESSION

ENROLLED

House Bill 2262

BY DELEGATES ROHRBACH, J. PACK, SUMMERS, G. WARD, SMITH, STEELE, ESPINOSA AND WORRELL

[Passed March 2, 2021; in effect ninety days from passage.]

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AN ACT to amend and reenact §60A-9-5 and §60A-9-5a of the Code of West Virginia, 1931, as amended, all relating to the controlled substances monitoring database; removing the requirement that a veterinarian monitor the controlled substance monitoring database; adding the requirement that a pharmacist licensed by the West Virginia Board of Pharmacy monitor the controlled substance database; and updating the code to reflect previous changes.

Be it enacted by the Legislature of West Virginia:

ARTICLE 9. CONTROLLED SUBSTANCES MONITORING.

§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 of Pharmacy is confidential and not subject to the provisions of §29B-1-1 et seq. 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 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 for use in certification, licensure, 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, IV, and V controlled substances, prescribing practitioners and pharmacists, a dean of any medical school or his or her designee located in this state to access prescriber 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

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level information of prescribing practices of physicians, advance practice registered nurses, or physician assistants 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. All lawenforcement personnel who have access to the Controlled Substances Monitoring Program Database shall be granted access in accordance with applicable state laws and the 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 of Pharmacy. All information released by the 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 §60A-9-5(b) of this code is authorized to query the database to comply with §60A-9-5(b) of this code.

(2) Subject to the provisions of §60A-9-5(a)(1) of this code, the Board of Pharmacy shall also review the West Virginia Controlled Substances Monitoring Program Database and issue reports that identify abnormal or unusual practices of patients and practitioners with prescriptive authority who exceed parameters as determined by the advisory committee established in this section. The 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 of Pharmacy shall be kept confidential. The 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 §60A-9-4 of this code may be subject to a claim for civil damages or other civil relief for the reporting of information to the Board of Pharmacy as required under and in accordance with the provisions of this article.

- (3) The 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 and practitioners with prescriptive authority 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 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 §60A-9-5(a)(2) of this code.
- (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,

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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 §60A-9-3 of this code, 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 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 30 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 §61-12-10(h) 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 §29B-1-1 *et seq.* of this code or obtainable as discovering in civil matters absent a court order.

- (c) The 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 of Pharmacy shall promulgate rules with advice and consent of the advisory committee, after consultation with the licensing boards set forth in §60A-9-5(d)(4) of this code and in accordance with the provisions of §29A-3-1 *et seq.* 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;
 - (4) Dissemination of these reports at least quarterly to:
 - (A) The West Virginia Board of Medicine codified in §30-3-1 et seq. of this code;
 - (B) The West Virginia Board of Osteopathic Medicine codified in §30-14-1 *et seq.* of this code;
 - (C) The West Virginia Board of Examiners for Registered Professional Nurses codified in §30-7-1 et seq. of this code;
 - (D) The West Virginia Board of Dentistry codified in §30-4-1 et seq. of this code; and
 - (E) The West Virginia Board of Optometry codified in §30-8-1 et seq. of this code; and
 - (5) 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 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, IV, or V 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 §60A-4-410 of this code, based on information obtained and reviewed from the Controlled Substances Monitoring

Program 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 §60A-9-5 of this code.
- (i) The Board of Pharmacy shall provide an annual report on the West Virginia Controlled Substances 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 §60A-2-201 of this code who prescribe or dispense Schedule II, III, IV or V 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 30 days of the practitioner obtaining a new license: *Provided*, *however*, That the Board of Pharmacy may renew a practitioner's license without proof that the practitioner meet the requirements of this subsection.
- (b) 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 §30-3-1 *et seq.* of this code, the Board of Registered Professional Nurses as set forth in §30-7-1 *et seq.* of this code, the Board of Dental Examiners as set forth in §30-4-1 *et seq.* of this code, the Board of Osteopathic Medicine as set forth in §30-14-1 *et seq.* of this code, the West Virginia Board of Optometrists as set forth in §30-8-1 *et seq.* of this code, and a pharmacist licensed by the West Virginia Board of Pharmacy as set forth in §30-5-1 *et seq.*

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upon initially prescribing or dispensing any Schedule II controlled substance, any opioid or any benzodiazepine to a patient who is not suffering from a terminal illness, and at least annually thereafter should the practitioner or dispenser continue to treat the patient with a controlled substance, shall access the West Virginia Controlled Substances Monitoring Program Database for information regarding specific patients. 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 16 of this code. A pain-relieving controlled substance shall be defined as set forth in §30-3A-1 of this code.

(c) The various boards mentioned in §60A-9-5(b) of this code shall amend its legislative rules pursuant to the provisions of §29A-3-1 *et seq.* of this code to effectuate the provisions of this article.

The Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.

Chairman, House Committee Chairman, Senate Committee
Originating in the House.
In effect ninety days from passage. Clerk of the House of Delegates Clerk of the Senate Speaker of the House of Delegates Character Clerk of the House of Delegates Character Speaker of the House of Delegates
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