WEST VIRGINIA CODE CHAPTER 60A ARTICLE 9

§60A-9-1. Short title.

This article shall be referred to as the West Virginia Controlled Substances Monitoring Act.

§60A-9-2. Establishment of program; purpose.

There is continued a West Virginia controlled substances monitoring act the purpose of which is to require the recordation and retention in a single repository of information regarding the prescribing, dispensing and consumption of certain controlled substances. A veterinarian is exempt from the requirements of this article.

§60A-9-3. Reporting system requirements; implementation; central repository requirement.

(a) The Board of Pharmacy shall implement a program wherein a central repository is established and maintained which shall contain such information as is required by the provisions of this article regarding Schedule II, III, and IV controlled substance prescriptions written or filled in this state. In implementing this program, the Board of Pharmacy shall consult with the West Virginia State Police, the licensing boards of practitioners affected by this article and affected practitioners.

(b) The program authorized by subsection (a) of this section shall be designed to minimize inconvenience to patients, prescribing practitioners and pharmacists while effectuating the collection and storage of the required information. The board shall allow reporting of the required information by electronic data transfer where feasible, and where not feasible, on reporting forms promulgated by the board. The information required to be submitted by the provisions of this article shall be required to be filed no more frequently than within twenty-four hours.

(c) (1) The board shall provide for the electronic transmission of the information required to be provided by this article by and through the use of a toll-free telephone line.

(2) A dispenser, who does not have an automated record-keeping system capable of producing an electronic report in the established format may request a waiver from electronic reporting. The request for a waiver shall be made to the board in writing and shall be granted if the dispenser agrees in writing to report the data by submitting a completed "Pharmacy Universal Claim Form" as defined by legislative rule.

§60A-9-4. Required information.

(a) The following individuals shall report the required information to the Controlled Substances Monitoring Program Database when:

(1) A medical services provider dispenses a controlled substance listed in Schedule II, III, IV, or V;

(2) A prescription for the controlled substance or opioid antagonist is filled by:

(A) A pharmacist or pharmacy in this state;

(B) A hospital, or other health care facility, for outpatient use; or

(C) A pharmacy or pharmacist licensed by the Board of Pharmacy, but situated outside this state for delivery to a person residing in this state; and

(3) A pharmacist or pharmacy sells an opioid antagonist.

(b) The above individuals shall, in a manner prescribed by rules promulgated by the 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, IV, and V controlled substance or opioid antagonist dispensed;

(5) The quantity and dosage of the Schedule II, III, IV, and V 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, information about 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 controlled substance dispensed.

(c) Whenever a medical services provider treats a patient for an overdose that has occurred 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 who is being treated, including any known ancillary evidence of the overdose. The Board of Pharmacy shall coordinate with the Division of Justice and Community Services and the Office of Drug Control Policy regarding the collection of overdose data.

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

(e) Products regulated by the provisions of §60A-10-1 *et seq*. of this code shall be subject to reporting pursuant to the provisions of this article to the extent set forth in said article.

(f) 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. 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 72 hours with no greater than two 72-hour cycles dispensed in any 15-day period of time: *Provided*, That an advanced practice registered nurse who is participating in a clinical trial, with institutional review board approval, for the rural expansion of medication-assisted treatment for opioid use disorder may exceed the 3-day supply for the time frame of the clinical trial, after registering with the Board of Pharmacy: *Provided, however*, That this exemption only permits one program to participate once in CTN-0102-XR, which is also the same program as provided for in §30-7-15a of this code.

(g) The Board of Pharmacy shall notify a physician prescribing buprenorphine or buprenorphine/naloxone within 60 days of the availability of an abuse deterrent or a practitioner-administered form of buprenorphine or buprenorphine/naloxone if approved by the Food and Drug Administration as provided in FDA Guidance to Industry. Upon receipt of the notice, a physician may switch his or her patients using buprenorphine or buprenorphine/naloxone to the abuse deterrent or a practitioner-administered form of the drug.

§60A-9-4a. Verification of identity.

Prior to releasing a Schedule II, III, or IV controlled substance sold at retail, a pharmacist or pharmacy shall verify the full legal name, address and birth date of the person picking up the controlled substance dispensed by requiring the presentation of a valid government-issued photo identification card. This information shall be reported in accordance with the provisions of this article.

§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 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 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 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 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, 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*. 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.

§60A-9-6. Promulgation of rules.

The state Board of Pharmacy shall promulgate legislative rules to effectuate the purposes of this article in accordance with the provisions of chapter twenty-nine-a of this code.

§60A-9-7. Criminal penalties; and administrative violations.

(a) Any person who is required to submit information to the state Board of Pharmacy pursuant to the provisions of this article who fails to do so as directed by the board is guilty of a misdemeanor and, upon conviction thereof, shall be fined not less than $100 nor more than $500.

(b) Any person who is required to submit information to the state Board of Pharmacy pursuant to the provisions of this article who knowingly and willfully refuses to submit the information required by this article is guilty of a misdemeanor and, upon conviction thereof, shall be confined in a county or regional jail not more than six months or fined not more than $1,000, or both confined and fined.

(c) Any person who is required by the provisions of this article to submit information to the state Board of Pharmacy who knowingly submits thereto information known to that person to be false or fraudulent is guilty of a misdemeanor and, upon conviction thereof, shall be confined in a county or regional jail not more than one year or fined not more than $5,000, or both confined and fined.

(d) Any person granted access to the information required by the provisions of this article to be maintained by the state Board of Pharmacy, who shall willfully disclose the information required to be maintained by this article in a manner inconsistent with a legitimate law-enforcement purpose, a legitimate professional regulatory purpose, the terms of a court order or as otherwise expressly authorized by the provisions of this article is guilty of a misdemeanor and, upon conviction thereof, shall be confined in a county or regional jail for not more than six months or fined not more than $1,000, or both confined and fined.

(e) Unauthorized access or use or unauthorized disclosure for reasons unrelated to the purposes of this article of the information in the database is a felony punishable by imprisonment in a state correctional facility for not less than one year nor more than five years or fined not less than $3,000 nor more than $10,000, or both imprisoned or fined.

(f) Any practitioner who fails to register with the West Virginia Controlled Substances Monitoring Program and obtain and maintain online or other electronic access to the program database as required in subsection (a), section five-a, article nine of this chapter, shall be subject to an administrative penalty of $1,000 by the licensing board of his or her licensure. All such fines collected pursuant to this subsection shall be remitted by the applicable licensing board to the Fight Substance Abuse Fund created under section eight of this article. The provisions of this subsection shall become effective on July 1, 2016.

(g) Any practitioner or dispenser who is required to access the information contained in the West Virginia Controlled Substances Monitoring Program database as set forth in subsection (a), section five-a of this article and fails to do so as directed by the rules of his or her licensing board shall be subject to such discipline as the licensing board deems appropriate and on or after July 1, 2016, be subject to a $100 administrative penalty per violation by the

applicable licensing board. All such fines collected pursuant to this subsection shall be transferred by the applicable licensing board to the Fight Substance Abuse Fund created under section eight of this article.

(h) Lack of available internet connectivity is a defense to any action brought pursuant to subsections (d) or (f) of this section.

§60A-9-8. Creation of Fight Substance Abuse Fund.

There is created a special revenue account in the state treasury, designated the Fight Substance Abuse Fund, which shall be an interest-bearing account. The fund shall consist of all moneys received from whatever source to further the purpose of this article. The fund shall be administered by the West Virginia Bureau for Public Health to provide funding for substance abuse prevention, treatment, treatment coordination, recovery and education. Any moneys remaining in the fund at the close of a fiscal year shall be carried forward for use in the next fiscal year. Fund balances shall be invested with the state's consolidated investment fund and any and all interest earnings on these investments shall be used solely for the purposes that moneys deposited in the fund may be used pursuant to this article. There is created within the Office of the Secretary of the Department of Health and the Department of Human Services the Grant Writer Pilot Project. The Secretary shall hire a person as a grant writer, who shall be placed within the Office of the Secretary. This person shall identify, application and monitoring policies and procedures to increase grant applications and improve management and oversight of grants. The grant writer shall focus his or her abilities on obtaining grants concerning the prevention and treatment of substance abuse. The grant writer is not eligible for civil service. The department shall report to the Legislative Oversight Commission on Health and Human Resources Accountability on the implementation of the new grant policy; the number of grants obtained; and an analysis examining the costs associated with obtaining a grant verses the federal money received.

§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, information about 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.