WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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7/21/2021 12:25:08 PM

Office of West Virginia
Secretary Of State

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: Pharmacy TITLE-SERIES: 15-08

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: 15-08 Controlled Substances Monitoring Program

PRIMARY CONTACT

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CITE STATUTORY AUTHORITY: 30-5-7, 60A-9-6, 60A-9-9

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

This amendment is needed due to a statutory change from 2021 session.

IS THIS FILING SOLELY FOR THE SUNSET PROVISION REQUIREMENTS IN W. VA. CODE §29A-3-19(e)? No

IF YES, DO YOU CERTIFY THAT THE ONLY CHANGES TO THE RULE ARE THE FILING DATE, EFFECTIVE DATE AND AN EXTENSION OF THE SUNSET DATE? No

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 6/11/2021

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/12/2021

COMMENTS RECEIVED: No

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

None other than posting on WVSOS

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

This rule establishes requirements for the recordation and retention in a single repository of information regarding the prescribing, dispensing and consumption of certain controlled substances, drugs of concern, and opioid antagonists. The amendment requires a pharmacist to check the CSMP in certain instances.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

A bill passed last session requiring pharmacists to check the CSMP in certain instances. This amendment simply mirrors that change.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

0

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

0

C. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

0

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2021 Increase/Decrease (use "-")	2022 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services	0	0	0
Current Expenses	0	0	0
Repairs and Alterations	0	0	0
Assets	0	0	0
Other	0	0	0
2. Estimated Total Revenues	0	0	0

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

na

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Ryan L Hatfield -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 8
CONTROLLED SUBSTANCES MONITORING PROGRAM

§15-8-1. General.

1.1. Scope. -- This rule establishes requirements for the recordation and retention in a single repository of information regarding the prescribing, dispensing and consumption of certain controlled substances, drugs of concern, and opioid antagonists.

1.2. Authority. -- W. Va. Code §§ 30-5-7, 60A-9-6, and 60A-9-9.

1.3. Filing Date. -- ~~May 11, 2021~~

1.4. Effective Date. -- ~~June 11, 2021~~

1.5. Sunset Date. -- This rule shall terminate and have no further force or effect upon ~~June 11, 2031.~~

§15-8-2. Definitions.

2.1. The definitions applicable to the Uniform Controlled Substances Act set forth in West Virginia Code § 60A-1-101 apply to this Series.

2.2. The following words and phrases have the following meanings:

2.2.a. "Central repository" means the repository designated by the board for the collection of the transmitted information, which may be a vendor designated by the board and under contract with the board to act as the central repository.

2.2.b. "Controlled Substances Monitoring Program" or "CSMP" means the database maintained through the central repository for the information required to be transmitted by this rule.

2.2.c. "Date sold" means, for purposes of American Society for Automation in Pharmacy (ASAP) standard prescription drug monitoring program reporting formats, the date a prescription is delivered to the patient or the patient's caregiver or agent on behalf of the patient For prescriptions delivered by mail or other common carrier, it is the date placed in the mail or for delivery.

2.2.d. "Deliver" or "delivery" means the actual, constructive or attempted transfer from one person to another of: (1) A controlled substance, whether or not there is an agency relationship; (2) a counterfeit substance; or (3) an imitation controlled substance.

2.2.e. "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery. Dispensing has not occurred for purposes of this definition until the controlled substance is actually delivered to the recipient or recipient representative.

2.2.f. "Drugs of concern" means prescription drugs which are not controlled substances but which have a high potential for abuse.

2.2.g. "Authorized agent" means an individual, who is an employee of any of the covered persons or entities permitted to have access to the central repository pursuant to Rule 15-8-7.3 of this rule, who is specifically designated by the covered person or authorized representative of the covered entity to access the central repository on behalf of the covered person or entity.

2.2.h. "Electronic access" means the ability to connect with and view the information in the central repository maintained by the board using electronic means permits real-time connectivity to the central repository.

2.2.i. "Government-issued photo identification card" means an identification card of an individual that provides a photograph of him or her and is issued by a State or the Federal Government of the Unitesd States of America, or a document that, with respect to identification, is considered acceptable for purposes of sections 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B) of title 8, Code of Federal Regulations (2020).

2.2.j. "Internet" means an interconnected system of networks that connects computers around the world via the Transmission Control Protocol (TCP) and the Internet Protocol (IP) established by the Internet Society (ISOC).

2.2.k. "Intranet" means a privately maintained computer network that can be accessed only by authorized persons, especially members or employees of the organization that owns it.

2.2.l. "Medical Services Provider" means a licensed practitioner with the legal authority to dispense controlled substances.

2.2.m."Opioid antagonist or opiate antagonist" means drugs approved by the federal Food and Drug Administration for treatment of drug overdose which have a high affinity for opiate receptors but do not activate these receptors, and which block the effects of exogenously administered opioids such as morphine, heroin, meperidine, and methadone, or of endogenously released endorphins and enkephalins.

2.2.n. "Patient" means an individual who:

2.2.n.1. has a valid ongoing practitioner-patient relationship; or

2.2.n.2. has not yet established an ongoing practitioner-patient relationship, but:

2.2.n.2.A. has requested to establish such a relationship with the practitioner; or

2.2.n.2.B. has been referred to that practitioner for evaluation or care by another practitioner.

2.2.o. "Recipient" means the patient, ultimate user or research subject for whom a controlled substance is dispensed or filled.

2.2.p. "Recipient representative" means an individual to whom a controlled substance is dispensed or filled if the recipient is either less than 18 years of age or unavailable to receive the controlled substance.

2.2.q. "Reporter" means a medical services provider, health care facility, pharmacist, or pharmacy

that is required to submit the information outlined in section 4 of this rule.

2.2.r. "Schedule II, III, IV, or V Controlled Substance" means a controlled substance classified in those categories under W. Va. Code §§60A-2-206, 208, 210, and 212.

2.2.s. "Security prescription blank" means a prescription blank that complies with the requirements of §15-1-2~~7~~3 of the West Virginia Code of State Rules.

2.2.t. "Universal Claim Form" means a nationally recognized standard form developed by the National Council for Prescription Drug Programs used for billing drug claims to insurance plans.

§15-8-3. Prescription Monitoring Program.

3.1. Each time a Schedule II, III, IV, or V Controlled Substance, drug of concern, or opioid antagonist is dispensed for out-patient use, the medical services provider, health care facility, or pharmacy that dispensed the controlled substance, drug of concern, or opioid antagonist shall transmit to the central repository the information required by West Virginia Code § 60A-9-4 in the appropriate American Society for Automation in Pharmacy format used by the central repository for reporting to it. This includes the following:

3.1.a. The name, address, pharmacy prescription number and Drug Enforcement Administration controlled substance registration number of the dispensing pharmacy or the dispensing medical services provider;

3.1.b. The full legal name, address and birth date of the recipient. When reporting the full legal name, address, and date of birth of the recipient, the reporter shall include any middle name or initial and any suffix (e.g., Jr., II, III) as listed on the patient's government-issued photo identification card If the patient does not have such an identification card, such as a minor, then the reporter shall obtain and input the information to the best of his or her knowledge and ability based upon the information available to it from the prescription, the patient profile or record, and any other information known to the reporter. Examples of acceptable forms of ID include, but are not limited to: driver's licenses, non-driver identification cards, passports, and military IDs;

3.1.c. The Drug Enforcement Administration controlled substances registration number of the practitioner writing the prescription. By providing this registration number, the Controlled Substances Monitoring Program database will extract the prescriber's name and address required by statute; therefore, the reporters do not need to additionally supply the prescriber's name and address in addition to the prescriber's DEA number;

3.1.d. The national drug code number of the Schedule II, III, IV, or V controlled substance, drug of concern, or opioid antagonist dispensed. By providing this NDC number, the Controlled Substances Monitoring Program database will extract the name and dosage or strength of the controlled substance required by the statute such that the reporters do not need to additionally supply the name and dosage;

3.1.e. The quantity of the Schedule II, III, IV, or V controlled substance, drug of concern, or opioid antagonist dispensed;

3.1.f. The date the prescription was written and the date filled;

3.1.g. The number of refills, if any, authorized by the prescription;

3.1.h. If the prescription being dispensed is being picked up by a recipient representative on behalf of the recipient, the first and last name of the recipient representative as set forth on the person's government-issued photo identification card, the appropriate code for the type of ID, the ID number, the appropriate code indicating the relationship of the recipient representative to the patient, and the appropriate code for the issuing jurisdiction of the ID; and

3.1.i. The source of payment for the controlled substance, drug of concern, or opioid antagonist dispensed.

3.2 The board and the central repository shall provide for the electronic transmission of the information required to be provided by and through the use of a toll-free telephone line or other Internet connection.

§15-8-4. Information To Be Transmitted Within 24 Hours.

4.1. The information may be transmitted at any time, but shall be transmitted at least within twenty-four hours of the dispensing. If the dispensing is done by mail or other postal, courier, or logistics services such as United Parcel Service or Federal Express, then the information shall be submitted at least within forty-eight hours of the time the dispensing is placed in the mail for delivery. If a reporter is closed for a holiday, or week-end day, the reporter shall make the required report as soon as is practicable upon reopening, or within forty-eight hours, whichever occurs first. If there are no dispensings of any Schedule II, III, IV, or V controlled substances, drug of concern, or opioid antagonists, then the reporter shall submit a daily "zero" report If there are no such dispensings within up to seven days of the last report, the reporter may submit a weekly "zero" report no later than seven days after the last date and time reported on the previous report. If a reporter is unable to make the required reporting in a timely manner due to an emergency, the reporter shall inform the board of the emergency and provide the board with information on when the reporter believes it will return to full compliance. Such notification may be taken into consideration by any agency, licensing board, or court, when determining if the reporter is in compliance with reporting requirements of West Virginia Code §60A-9-3 and section three of this rule, and any penalties that may attach for any violation thereof.

4.2. If a reporter does not possess for the purpose of dispensing any Schedule II, III, IV, or V controlled substances, drug of concern, or opioid antagonists, the dispenser may notify the board in writing by requesting a waiver from reporting on a form supplied by the board. If the waiver is granted by the board, the reporter is not required to submit a zero report unless and until the reporter possesses a Schedule II, III, IV, or V controlled substance or opioid antagonist for the purpose of dispensing.

§15-8-5. Accuracy of Information Transmitted.

5.1. Information shall be reported accurately. If the reporting individual or entity discovers that information contained in the central repository is not accurate, he or she shall make the necessary corrections and resubmit the correct information as soon as possible, but in no event longer than 7 days after the discovery of the inaccurate reporting.

§15-8-6. Central Repository; Designation; Powers and Duties.

6.1. The central repository shall maintain a database for the information required to be transmitted by this rule. This database shall be referred to as the "Controlled Substances Monitoring Program", or the "CSMP".

6.2. The central repository shall provide the board with continuous 24-hour a day, on-line access.

6.3. The central repository shall secure the information collected and the database maintained against

access by unauthorized persons.

6.4. If the relationship between the board and the central repository is terminated by statute, the central repository shall provide to the board within a reasonable time, all collected information and the database maintained.

6.5. The board may accept a designated grant, public and private financial assistance, and licensure fees to provide funding for the central repository.

§15-8-7. Confidentiality.

7.1. The board shall carry out a program to protect the confidentiality of the information received by the central repository.

7.2. The board may disclose confidential information received by the central repository to a person who is engaged in receiving, processing, or storing the information.

7.3. The board may release confidential information received by the central repository to the following persons:

7.3.a. An authorized agent of a board in this state or another state that licenses practitioners authorized to prescribe Schedule II, III, IV, or V controlled substances who is engaged in an investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance;

7.3.b. Members of the West Virginia State Police expressly authorized by the superintendent of the West Virginia State Police to have access to the information;

7.3.c. An authorized agent of a local law-enforcement agency who is acting as a member of a Federally affiliated drug task force engaged in an investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance;

7.3.d. Authorized agents of the Drug Enforcement Administration who is engaged in an investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance;

7.3.e. Authorized agents of the West Virginia Bureau for Medical Services;

7.3.f. The Chief Medical Examiner for the State of West Virginia or his or her authorized agent for use in post-mortem examinations;

7.3.g. Authorized agents of the West Virginia Office of Health Facility Licensure and Certification for use in certification, licensure and regulation of health facilities;

7.3.h. A dean of a medical school located in this State or his or her designee 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;

7.3.i. 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;

7.3.j. A chief medical officer of a hospital, or a physician designated by the chief executive officer of a hospital which does not have a chief medical officer, to monitor prescriber level information of prescribing practices of prescribers who have admitting privileges to the hospital;

7.3.k. A person with an enforceable court order or regulatory agency administrative subpoena;

7.3.l. Inspectors and agents of the board to carry out the lawful purposes of the CSMP program, for purposes of a pharmacy inspection or drug inventory, or who are engaged in an investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance;

7.3.m. Prescribing practitioners or their authorized agents for purposes of treating a patient;

7.3.n. Pharmacists or a registered pharmacy technician as the agent of the pharmacist for purposes of treating a patient; and

7.3.o. A person using the data for compilation of educational, scholarly, or statistical purposes so long as the individually identifiable data of the persons or entities stored in the central repository remains confidential.

7.4. All information released by the board shall be related to a specific patient or a specific individual or entity under investigation by any of the persons set forth in subsection 7.3 (a) through (n) of this section except that practitioners who prescribe or dispense controlled substances may also request specific data related to all dispensings reported to the database as prescribed and/or dispensed under their drug enforcement administration controlled substance registration number or for the purpose of providing treatment to a patient.

7.4.a. A practitioner or practitioner's delegate may, prior to affirmatively accepting a patient into the practitioner's practice, obtain confidential information from the CSMP related to that patient for the purpose of determining whether or not to accept the patient and provide treatment.

7.4.b. If the patient is a newborn child or child being fed human breast milk, a practitioner or practitioner's delegate may obtain confidential information from the CSMP related to the child's mother, wet nurse, or other direct source of human breast milk, as the practitioner believes may be relevant for the purpose of providing treatment to that child-patient.

7.5. Access to the data collected by the central repository shall be limited to regular business hours of the board's office unless an individual authorized to receive the information proves that an immediate danger to the public exists and immediate access is necessary to prevent further harm The board may permit access at any time to authorized users through the use of a secure connection and through the use of proper security features designed to protect the integrity and confidentiality of the information from unauthorized access or disclosure.

7.6. A person or entity having access to the central repository and who is permitted to designate an authorized agent to have access to the central repository pursuant to this rule shall make the designation on a form to be supplied by the board. It is the responsibility of the designating individual to ensure that the designated agent maintains the confidentiality of the information in the central repository as required. If the designating individual remove the authority of the designated agent to act as the authorized agent, or should the designated agent leave the employment of the designating individual or entity then the designating individual shall immediately notify the board, at which time the designee's access to the central repository shall be removed.

7.7. A practitioner may file or store copies of a patient-specific report obtained from the CSMP in the patient's confidential medical file or chart maintained by the practitioner. The practitioner may share the information contained in the report with other practitioners providing treatment to the patient, the patient, or the patient's authorized guardian or representative for the purpose of providing treatment. If the information held in the patient file or chart is not subject to discovery in a civil or criminal matter absent a court order. The information is obtainable from the practitioner in a proper regulatory agency administrative matter through a regulatory agency administrative subpoena.

7.8. The board shall review records in the CSMP in accordance with parameters set by the Advisory Committee to identify abnormal or unusual practices of patients who exceed those parameters and are therefore outliers in the CSMP data. The board shall issue reports of the results of these searches to the Review Committee for its regular review and action. The board shall communicate with prescribers and dispensers of the patients who exceed the parameters to inform them of each practitioner's patient's activities as demonstrated in the CSMP reports. Reports and communications produced by the board shall be kept confidential by the board and the Review Committee.

7.9. The Review Committee may query the CSMP based on parameters established by the advisory committee to identify abnormal or unusual practices of patients who are outliers in the data according to their controlled substance prescribing, dispensing, or usage patterns or other indicators available in the system. The Review Committee may also query the CSMP based on parameters established by the advisory committee to identify abnormal prescribing and/or dispensing patterns of practitioners indicated by outliers in the system. The Review Committee may also query the CSMP for any relevant prescribing or dispensing records of involved patients or practitioners as it carries out its duty to review notices provided by the chief medical examiner pursuant to West Virginia Code § 61-12-10(h) and determine on a case-by-case basis whether a practitioner who prescribed or dispensed a controlled substance may have resulted in or contributed to the drug overdose, and, if so, if the practitioner may have breached professional or occupational standards or committed a criminal act when prescribing the controlled substance at issue to the decedent. The Review Committee, in accordance with parameters established by the Advisory Committee, may provide any pertinent information in its discretion from the CSMP to the relevant practitioner, the practitioner's licensing board, or law enforcement as permitted by West Virginia Code § 60A-9-5(b). The Review Committee, in accordance with parameters established by the Advisory Committee, may also communicate with pertinent practitioners or patients to make them aware of the practitioner's own prescribing or dispensing patterns or history, or the patient's own usage patterns or history as reflected in the CSMP in an effort to reduce inappropriate use of prescription drugs in accordance with West Virginia Code § 60A-9-5(a)(3)(C). The information obtained and developed by or on behalf of the Review Committee may not be shared except as provided in West Virginia Code § 60A-9-5(b) and as provided specifically in subsection 7.8 and this subsection of this section.

§15-8-8. Pharmacist Requirement to Check the Controlled Substances Monitoring Program Database.

8.1. A pharmacist shall access the West Virginia Controlled Substances Monitoring Program Database for information regarding specific patients in the following scenarios:

8.1.a. upon initially dispensing any Schedule II controlled substance, any opioid, or any benzodiazepine to a patient who is not suffering from a terminal illness; and

8.1.b. at least annually thereafter should the pharmacist continue to dispense the patient with a controlled substance.