WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION

Form #7

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2012 JUN -8 PM 4:06

OFFICE WEST VIRGINIA
SECRETARY OF STATE

Effective Date

NOTICE OF AN EMERGENCY RULE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY: WV Code Section 60A-9-6

EMERGENCY AMENDMENT TO AN EXISTING RULE: YES X NO ____

IF YES, SERIES NUMBER OF RULE BEING AMENDED: Series 8

TITLE OF RULE BEING AMENDED: Controlled Substances Monitoring

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: ____

TITLE OF RULE BEING PROPOSED: ____

THE ABOVE RULE IS BEING FILED AS AN EMERGENCY RULE TO BECOME EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 42ND DAY AFTER FILING, WHICHEVER OCCURS FIRST.

THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY ARE AS FOLLOWS:

SB 437 (2012), effective June 8, 2012, makes changes to the information required to be reported to the Controlled Substances Monitoring Program database, and gives the Board authority to require reporting within 24-hours of dispensing of controlled substances, rather than within 7 days. These rules are necessary to clarify the new requirements for information that must be reported, and to increase the frequency of reporting to the 24-hour time-frame desired by the Legislature and Governor's Office during debate over the Bill. The ongoing substance abuse issues in this State and our surrounding states require every effort we can reasonably and appropriately make to give prescribers, dispensers, agencies, and law enforcement the appropriate tools they need to fight illegal drug diversion, including more timely and accurate data required by the Bill. Without these clarifications, the reporting dispensers have questions about exactly they must report, and would only be required to report every 7 days, leaving unnecessary time lags for receipt and availability of that information to the users of the CSMP.

David E. Potters
Authorized Signature

Use additional sheets if necessary

Board Members
George Karos, Pres.
Lydia Main, Vice Pres.
Charles Woolcock, Sec.
Martin Castleberry
Rebekah E. Hott
Carl K. Hedrick, Jr.
Sam Kapourales

State of West Virginia
Board of Pharmacy

David E. Potters,
Executive Director &
General Counsel

Betty Jo Payne,
Asst. Exec. Director

Office
232 Capitol Street
Charleston, West Virginia 25301

Phone (304) 558-0558
Fax (304) 558-0572

APPROVAL OF FILING OF RULES

BE IT HEREBY KNOWN that the West Virginia Board of Pharmacy approves the filing of the following EMERGENCY RULES with the Secretary of State and the Legislative Rulemaking and Review Committee, which were considered and approved for filing by the Board at its meetings held on April 30, 2012, and May 30, 2012:

Title 15, Series 8, "CONTROLLED SUBSTANCES MONITORING"; and

Title 15, Series 11, "EPHEDRINE AND PSEUDOEPHEDRINE CONTROL".

Signed this **8th** day of **June, 2012.**

BY: George Karos

George Karos, President

EMERGENCY RULE QUESTIONNAIRE

DATE: June 8, 2012

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name, Address & Phone No.*) West Virginia Board of Pharmacy
106 Capitol Street, Suite 100, Charleston, West Virginia, 25301.
Phone: 304-558-0558

EMERGENCY RULE TITLE: Title 15, Series 8: "Controlled Substances Monitoring"

1. Date of filing June 8, 2012

2. Statutory authority for promulgating emergency rule:

SB 437, 2012 Regular Legislative Session changes necessitate rules modifications. West Virginia Code Section 60A-9-6 provides rule-making authority.

3. Date of filing of proposed legislative rule:

4. Does the emergency rule adopt new language or does it amend or appeal a current legislative rule? Amends current rule.

5. Has the same or similar emergency rule previously been filed and expired?

No.

6. State, with particularity, those facts and circumstances which make the emergency rule necessary for the **immediate** preservation of public peace, health, safety or welfare.

Senate Bill 437 (2012) makes changes to the information required to be reported to the Controlled Substances Monitoring Program database (the "CSMP"), and gives the Board authority to require the reporting within 24 hours of dispensing of controlled substances, rather than within 7 days. These rules are necessary to clarify the new requirements, and to increase the frequency of reporting to the 24-hour time-frame desired by the Legislature and Governor's Office per the Bill. The ongoing substance abuse issues require every effort we can make to give prescribers, dispenses, agencies,

7. If the emergency rule was promulgated in order to comply with a time limit established by the Code or federal statute or regulation, cite the Code provision, federal statute or regulation and time limit established therein.

SB 437 (2012) became effective June 8, 2012.

8. State, with particularity, those facts and circumstances which make the emergency rule necessary to prevent substantial harm to the public interest.

~~SB 437 is effective June 8, 2012. These rules are necessary to clarify the new~~ requirements for information reported to the CSMP, and to increase the reporting ~~frequency to within 24-hours. The ongoing substance abuse issues require every effort~~ we can make to give prescribers, dispenses, agencies, and law enforcement timely and ~~accurate data to use in the fight to curb illegal drug diversion. Without these~~ clarifications, the reporting dispensers have questions about what exactly they must report, and would only have to report every 7 days leaving unnecessary time lags.

Board Members
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BRIEF SUMMARY OF AND STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE PROPOSED EMERGENCY RULE

TITLE 15, SERIES 8 (WV CSR 15-8-1, et seq.)
CONTROLLED SUBSTANCES MONITORING

Summary and Statement of Circumstances: SB 437 (2012), effective June 8, 2012, makes changes to the West Virginia Controlled Substances Monitoring Program database (the "CSMP"). Among other things, it requires new fields of information to be reported, requires presentation of government-issued photo identification, and gives the Board authority to require reporting of the required information within 24-hours of dispensing of a controlled substance, rather than within 7 days. As such, these modifications add a definition of "Government-issued photo identification card", clarify reporting requirements for particular information fields, provide for "zero" reports and for obtaining appropriate waivers from reporting if no controlled substances are ever dispensed, and increase the frequency of reporting to within 24-hours of dispensing rather than every 7 days. These rules are necessary to clarify the new requirements for information that must be reported and make for more timely and accurate information. The ongoing substance abuse issues in this State and our surrounding states require every effort we can reasonably and appropriately make to give prescribers, dispensers, agencies, and law enforcement the appropriate tools they need to fight illegal drug diversion. Without these clarifications, the reporting dispensers have questions about what exactly they must report, and would only be required by rule to report every 7 days, leaving unnecessary time lags for receipt and availability of the information to the users of the CSMP.

For Further Information: Copies of the proposed rule may be obtained from the website of the West Virginia Secretary of State at www.wvsos.wv.gov, or interested parties may call the Administrative Law Division of the Office of the Secretary of State at (304) 558-6000.

Further information may be obtained by contacting the West Virginia Board of Pharmacy, David E. Potters, Executive Director and General Counsel, 106 Capitol Street, Suite 100, Charleston, West Virginia, 25301; telephone: (304) 558-0558.

Note: This is a proposed modification to existing rules, such that the changes are identified by strike-throughs and underlining in the proposed rule.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Title 15, Series 8: "Controlled Substances Monitoring"

Type of Rule: [X] Legislative [ ] Interpretive [ ] Procedural

Agency: West Virginia Board of Pharmacy

Address: 106 Capitol Street, Suite 100
Charleston, West Virginia 25301

Phone Number: 304-558-0558 Email: david.e.potters@wv.gov

Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

This rule will have no immediate impact on the Board of Pharmacy. However, the changes to the CSMP program as a whole necesitated by the new statutory requirements set forth in SB 437 (2012) were spelled out in the fiscal note prepared for SB 437. These include approximately $300,000.00 in upgrades to the CSMP database, increased funding for annual maintenance contracts for the improved CSMP database, ongoing annual funding for a new staff position at the Board as well as an upgraded staff position, and funding for new committees required by the Bill.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

FISCAL YEAR			
Effect of Proposal	Current Increase/Decrease (use "-")	Next Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0.00	0.00	0.00
Personal Services	0.00	0.00	0.00
Current Expenses	0.00	0.00	0.00
Repairs & Alterations	0.00	0.00	0.00
Assets	0.00	0.00	0.00
Other	0.00	0.00	0.00
2. Estimated Total Revenues	0.00	0.00	0.00

Title 15, Series 8: "Controlled Substances Monitoring"

Rule Title:

Rule Title: _____

3. **Explanation of above estimates (including long-range effect):**
Please include any increase or decrease in fees in your estimated total revenues.

These emergency rules merely clarify requirements of the new statutory provisions for the CSMP set forth in SB 437. This rule will have no immediate impact on the Board of Pharmacy. However, the changes to the CSMP program as a whole necesitated by the new statutory requirements set forth in SB 437 (2012) were spelled out in the fiscal note prepared for SB 437. These include approximately $300,000.00 in upgrades to the CSMP database, increased funding for annual maintenance contracts for the improved CSMP database, ongoing annual funding for a new staff position at the Board as well as an upgraded staff position, and funding for new committees required by the Bill.

MEMORANDUM

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

Date: June 8, 2012

Signature of Agency Head or Authorized Representative

David E. Potters

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 8
CONTROLLED SUBSTANCES MONITORING

§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.

1.2. Authority. -- W. Va. Code §60A-9-6.

1.3. Filing Date. -- ~~June 28, 2011~~June 8, 2012.

1.4. Effective Date. -- ~~July 1, 2011~~June 8, 2011.

§15-8-2. Definitions.

2.1. Except as otherwise indicated, 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 as used in this Rule have the following meanings:

2.2.1. "Central repository" refers to the central 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.

2.2.2. "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.

2.2.3 "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.

~~2.3~~ 2.2.4. "Duly 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 duly authorized representative of the covered person or entity to access the central repository on behalf of the covered person or entity.

~~2.4.~~2.2.5 "Electronic access" means the ability to connect with and view the information in the central repository maintained by the Board using the Internet or some other electronic means, such as an Intranet or satellite connection which permits real-time connectivity to the central repository the same as if connected through the Internet.

~~2.5. "Identification number" means any of the following:~~

~~(a) The birth date of the recipient.~~

2.2.6. "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 Unites 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. Examples of acceptable forms of ID include, but are not limited to: driver's licenses, non-driver identification cards, passports, and military IDs.

~~2.6~~2.2.7. "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).

~~2.7~~2.2.8. "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.

~~2.8. "Logo" means a symbol used by an individual, a pharmacy, professional practice, professional association or hospital.~~

2.2.9. "Medical Services Provider" means a licensed practitioner with the legal authority to dispense Controlled Substances.

~~2.10. "Practitioner" means:~~

~~(a) A physician, dentist, veterinarian, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state; and~~

~~(b) A pharmacy, hospital or other institution licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state.~~

~~2.11~~2.2.10. "Recipient" means an individual for whom a controlled substance is dispensed or filled.

~~2.12~~2.2.11. "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.

~~2.13~~2.2.12. "Reporter" means any medical services provider, health care facility, pharmacist, or pharmacy that is required to submit the information outlined in section 4 of this rule.

~~2.14~~2.2.13. "Schedule II, III, or IV Controlled Substance" means a controlled substance classified in those categories under W. Va. Code §§60A-2-206, 208 and 210.

~~2.15~~2.2.14. "Security prescription blank" means a prescription blank that complies with the requirements of Section 15-1-27 of the West Virginia Code of State Rules.

~~2.16~~2.2.15. "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, or IV Controlled Substance is dispensed ~~or filled~~ for out-patient use,

the medical services provider, health care facility, pharmacist or pharmacy that dispensed the controlled substance shall transmit to the central repository the ~~following~~ information required by West Virginia Code § 60A-9-4.~~:~~

~~(a) The name, address, pharmacy prescription number and Drug Enforcement Administration controlled substance registration number of the dispensing pharmacy;~~

~~(b) The name, including middle initial, address and birth date of the person for whom the prescription is written;~~

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

~~(d) The name and national drug code number of the Schedule II, III and IV controlled substance dispensed;~~

~~(e) The quantity and dosage of the Schedule II, III and IV controlled substance dispensed;~~

~~(f) The date the prescription was filled; and~~

~~(g) The number of refills, if any, authorized by the prescription.~~

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

(b) The full legal name, address and birth date of the person for whom the prescription is written. When reporting the full legal name, address, and date of birth of the person for whom the prescription is written, the reporter must 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. Provided that, if the patient does not have such an identification card, such as a minor, then the pharmacy shall report the information to the best of its 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;

(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;

(d) The national drug code number of the Schedule II, III and IV controlled substance 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;

(e) The quantity of the Schedule II, III and IV controlled substance dispensed;

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

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

(h) If the prescription being dispensed is being picked up by someone other than the patient on behalf of the patient, the full legal name, address and birth date of the person picking up the prescription as set forth on the person's government-issued photo identification card. When reporting the full legal name, address, and date of birth of the person picking up the prescription on behalf of the patient, the reporter must include any middle name or initial and any suffix (e.g., Jr., II, III) as listed on the person's government-issued photo identification card. If the reporter is unable to report this information to the central repository at the time of reporting the other required information, this information may be retained in either print or electronic form until such time as otherwise directed by rule promulgated by this Board; and

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

3.2. Any person reporting more than 20 controlled substance prescriptions in any given month shall transmit to the central repository the information outlined in section 4 of this rule using one of the following methods:

(a) An electronic device compatible with the receiving device of the central repository;
(b) A computer ~~diskette~~compact disc; or
(c) A magnetic tape.

3.3. Any person reporting less than 20 Schedule II, III, or IV ~~prescriptions~~ controlled substance dispensings in any given month may submit data using a Universal Claim Form or transmit the information using the methods outlined in subsection 3.2 of this section.

3.4. The Board may grant a waiver to a person who does not have an automated recordkeeping system capable of producing an electronic report in the established format. A person requesting a waiver shall make the request to the Board in writing and the Board shall grant the request if the dispenser agrees to report the data by submitting a completed Universal Claim Form.

3.5. 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 ~~Weekly~~ Within Twenty-Four Hours.

4.1. The information required to be submitted by the provisions of this rule may be transmitted at any time, but shall be transmitted at least ~~every week~~within twenty-four hours of the dispensing. Provided that, 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 must be submitted at least within forty-eight hours of the time the dispensing is placed in the mail for delivery. If there was no dispensing of any Schedule II, III, or IV controlled substances within up to seven days of the last report, the reporter must submit a "zero" report no later than seven days after the last date and time reported on the previous report. If a medical practitioner, pharmacy, or other reporter is closed for a holiday, or week-end day, the reporter must make the required report as soon as is practicable upon reopening, or within forty-eight hours, whichever occurs first. If a reporter is unable to make the required reporting in a timely manner due to an emergency, the reporter must 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 Section 60A-9-3 and Section 3 of this Series, and any penalties that may attach for any violation thereof.

4.2. If a dispenser does not possess for the purpose of dispensing any Schedule II, III, or IV controlled substances, the dispenser may notify the board of pharmacy in writing by requesting a waiver from reporting on a form supplied by the Board. If the waiver is properly filed with and granted by the Board, the dispenser is not required to submit a zero report unless and until the dispenser possesses for the purpose of dispensing a Schedule II, III, or IV controlled substance.

4.2. The Board may not penalize a reporter for failure to comply with the program if the Board or the central repository cannot secure adequate funding to implement the program and recover the cost.

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

The information required to be transmitted by this rule must be reported accurately. If the reporting individual or entity discovers that information contained in the central repository is not accurate, he or she must notify the Board of the inaccuracy and the necessary corrections in writing as soon as possible, but in no event longer than fourteen (14) days after the discovery of the inaccurate reporting, so that the Board may take the necessary steps to correct the error within the database.

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

6.1. The central repository shall create 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 to the database maintained by the central repository.

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

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 any 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:

(a) a duly authorized agent of a board in this state or another state that licenses practitioners authorized to prescribe Schedules II, III, and IV 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;

(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;

(c) an authorized agent of a local law-enforcement agency who is acting as a member of a ~~State recognized~~ Federally affiliated drug task force;

(d) authorized agents of the federal Drug Enforcement Administration;

(e) the Chief Medical Examiner for the State of West Virginia or his or her duly authorized agent for use in post-mortem examinations;

(f) a person with an enforceable court order or regulatory agency administrative subpoena;

(g) inspectors and agents of the Board;

(h) prescribing practitioners or their duly authorized agents;

(i) pharmacists or a registered pharmacy technician as the agent of the pharmacist; and

(j) 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 must 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 (i) of this section except that practitioners who prescribe 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.

7.5. All access to the data collected by the central repository shall be limited to regular business hours of the Board 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, Provided That 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. Any person or entity having access to the central repository and who is permitted to designate a duly authorized agent to have access to the central repository pursuant to this rule must make any such designation on a form to be supplied by the Board. It is the responsibility of the designating individual to insure that the designated agent maintains the confidentiality of the information in the central repository as required. Further, should the designating individual remove the authority of the designated agent to act as the duly authorized agent, or should the designated agent leave the employment of the covered person or entity such that he or she is no longer eligible to act as the duly authorized agent, then the designating individual must immediately notify the Board, at which time the designee's access to the central repository shall be removed.

15-8-8. Access Required. All practitioners who prescribe or dispense Schedule II, III, or IV controlled substances must have electronic access to the central repository in each of their individual places of practice by July 1, 2011.