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

Form #3

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OFFICE WEST VIRGINIA SECRETARY OF STATE

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

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY: WV Code Section 30-5-7

AMENDMENT TO AN EXISTING RULE: YES X NO ____

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 8

TITLE OF RULE BEING AMENDED: Controlled Substances Monitoring

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: ____

TITLE OF RULE BEING PROPOSED: ____

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

David E. Potters

Authorized Signature

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: October 18, 2013

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

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

LEGISLATIVE RULE TITLE: Controlled Substances Monitoring

1. Authorizing statute(s) citation WV Code Sections 30-5-7 and 60A-9-6

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

   July 19, 2013

   b. What other notice, including advertising, did you give of the hearing?

   None. However, the Board of Pharmacy held public meetings discussing the changes during drafting and prior to filing. Further, the changes to this rule came due to requests from representatives of the industry to clarify the particular requirement addressed by the single change made, and the West Virginia Retailers Assoc., WV Pharmacists Association, and others were directly aware through discussions with the Board staff.

   c. Date of Public Hearing(s) ***or*** Public Comment Period ended:

   August 21, 2013, at 4:00 p.m.

   d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

   Attached _____ No comments received X

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

Filed Notice with the Secretary of State on October 18, 2013, for publication.

f. **Name, title, address and <u>phone/fax/e-mail numbers</u>** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

West Virginia Board of Pharmacy
David E. Potters
Executive Director & General Counsel
106 Capitol Street, Suite 100
Charleston, WV 25301
304-558-0558
304-558-0572(fax)
david.e.potters@wv.gov

g. **<u>IF DIFFERENT</u> FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

b. Date of hearing or comment period:

_____

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

_____

d. Attach findings and determinations and reasons:

Attached _____

Office
106 Capitol Street, Suite 100
Charleston, WV 25301

Website: www.wvbop.com

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

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, made changes to the West Virginia Controlled Substances Monitoring Program database (the "CSMP"). As such, the Board made rules revisions which became final through the 2013 Regular Legislative Session, final filed in June, 2013. The Board also continued with an ongoing project to upgrade the CSMP, which would also accommodate the new legislative mandates. Included in the changes, WV Code Section 60A-9-4 requires dispensers to report dispensing information to the Controlled Substances Monitoring Program (CSMP), including, among other things, the full legal name, address and birth date of anyone picking up a prescription on behalf of the actual patient. The old CSMP could not receive this information. As such, the Board has just turned on the new CSMP, revised in part due to this new 2012 code language. The new CSMP is updated to the ASAP 4.2 reporting format as required by national PMP standards and federal grants for the CSMP. However, due to ASAP 4.2 format restrictions, dispensers can only report the individual's first and last name, official government-issued photo identification card number, and the card's issuing authority. Dispensers fear that, without this proposed clarification, they will be deemed in violation of the Code and CSMP rules, despite reporting all information that can be put into the CSMP for these fields. As such, this immediate clarification by rule is required.

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: CONTROLLED SUBSTANCES MONITORING

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

Agency: West Virginia Board of Pharmacy

Address: 106 Capitol Street, Suite 100
Charleston, WV 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.

None. This is simply a clarification of a required reporting format.

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

Rule Title: CONTROLLED SUBSTANCES MONITORING

Rule Title: CONTROLLED SUBSTANCES MONITORING

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

No effect on the cost of the CSMP database. This is simply a clarification of a required reporting format.

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.

None. This is simply a clarification of a required reporting format.

Date: July 16, 2013

Signature of Agency Head or Authorized Representative

David E. Potters

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 §§ 30-5-7 and 60A-9-6.

1.3. Filing Date. -- ~~June 10, 2013~~_____.

1.4. Effective Date. -- ~~June 10, 2013~~_____.

§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 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. Dispensing has not occurred for purposes of this definition until the controlled substance is actually delivered to the recipient or recipient representative.

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.

2.2.5 "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.

2.2.6. "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.

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).

2.2.8. "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.

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

2.2.10. "Recipient" means the patient (ultimate user or research subject) for whom a controlled substance is dispensed or filled.

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.

2.2.12. "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.

2.2.13. "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.

2.2.14. "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.

2.2.15. "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 for out-patient use, the medical services provider, health care facility, or pharmacy that dispensed the controlled substance shall transmit to the central repository the information required by West Virginia Code § 60A-9-4. This includes the following:

(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;

(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, Provided that, 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 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.

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

(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 a recipient representative on behalf of the recipient, the full legal name, address and birth date of the recipient representative 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 shall 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 input this information to the central repository at the time of reporting, this information may be retained in either print or electronic form until such time as otherwise directed by rule promulgated by this board;~~, due to the CSMP formatting requirements and limitations of ASAP 4.2 to which the system is programed, this reporting shall be accomplished by reporting the individual's first name, last name, official government-issued photo identification card number and the card's issuing authority or jurisdiction (e.g., United States Military, State driver's license, Passport, Green Card, etc.). Investigators needing to identify the full legal name, address, and date of birth can then obtain those additional details using the ID information provided to access other databases at their disposal to provide the further details; 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 compact disc; or

(c) A magnetic tape.

3.3. Any person reporting less than 20 Schedule II, III, or IV 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 reporter who does not have an automated recordkeeping system capable of producing an electronic report in the established format. A reporter requesting a waiver shall make the request to the board in writing and the board shall grant the request if the reporter 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 Within 24 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 within 24 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 shall be submitted at least within 48 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 shall submit a "zero" report no later than seven days after the last date and time reported on the previous report. 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 48 hours, whichever occurs first. 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 Section 60A-9-3 and Section 3 of this Series, 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, or IV controlled substances, 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 properly filed with and granted by the board, the reporter is not required to submit a zero report unless and until the reporter possesses a Schedule II, III, or IV controlled substance for the purpose of dispensing.

4.3. 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 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 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 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 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 (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'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, 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 shall make the 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 designating individual or entity such that he or she is no longer eligible to act as the duly authorized agent, then the designating individual shall immediately notify the board, at which time the designee's access to the central repository shall be removed.

RESPONSES TO PUBLIC COMMENTS RECEIVED TO PROPOSED RULES

(Including explanation of any amendments made to the proposed rule as a result of comments)

TITLE 15, SERIES 8 (WV CSR 15-8-1, et seq.)
"Controlled Substances Monitoring"

The Board of Pharmacy met on September 15, 2013, to receive written public comments to the proposed rules filed with the Secretary of State on July 16, 2013, making amendments to Title 15, Series 8. No public comments were received by the Board, such that no responses were necessary. Therefore, the Board approved the rules for filing as previously proposed, without modification. The Board noted, however, that prior to drafting the rules changes, it received input requesting the changes from interested parties in the industry, and discussed the changes with the West Virginia Retailers Association and West Virginia Pharmacists Association. Further, the changes were discussed at a regular Board meeting prior to filing.

Prepared by:

David E. Potters

David E. Potters
Executive Director and General Counsel