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

Form #3

Do Not Mark In This Box

FILED

2014 AUG -1 P 3:49

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: West Virginia Code Section 30-5-7

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 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: July 31, 2014

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name, Address & Phone No.*) West Virginia Board of Pharmacy
2310 Kanawha Boulevard East
Charleston, WV 25311

304-558-0558

LEGISLATIVE RULE TITLE: ~~Title 15, Series 8~~
Controlled Substances Monitoring

1. Authorizing statute(s) citation ~~WV Code Section 30-5-7~~

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

June 27, 2014

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

E-mailed copy to pharmacy stakeholders, including representatives of West Virginia Pharmacists Association, West Virginia Retailers Association, West Virginia Society of Health ~~System Pharmacies, National Association of Chain Drug Stores,~~ West Virginia University School of Pharmacy, Marshall University School of Pharmacy, and University of Charleston School of Pharmacy, as well as representatives of several chain pharmacies and others.

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

July 27, 2014

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)

~~July 31, 2014~~ August 1, 2014

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)

David E. Potters
Executive Director & General Counsel
West Virginia Board of Pharmacy
~~2310 Kanawha Boulevard East~~
Charleston, WV 25311
~~304-558-0558~~
304-558-0572
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
2310 Kanawha Boulevard East
Charleston, WV 25311

Website: www.wvbop.com

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

BRIEF SUMMARY OF AND STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE PROPOSED 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 and 2014 Regular Legislative Sessions. The Board also continued working with the CSMP Advisory Committee on changes or clarifications which would assist practitioners in working with the system. The Advisory Committee made several recommendations for rules changes which were approved by the Board for when users can run certain patient profiles on intake of a potential new patient or a newborn, and on storage and access to reports in the practitioner's patient medical chart or file. These are implemented in the modifications. Other changes are merely clarifications for ease of reading and enforcement of current law and practices.

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, 2310 Kanawha Boulevard East, Charleston, West Virginia, 25311; 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: 2310 Kanawha Boulevard East
Charleston, West Virginia 25311

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 should have no significant fiscal impact on state government. It simply makes changes recommended by the CSMP Advisory Committee and approved by the Board for when users can run certain patient profiles on intake of a potential new patient or a newborn, and on storage and access to reports in the practitioner's patient medical chart or file. Other changes are merely clarifications for ease of reading and enforcement of current law and practices.

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: Title 15,Series 1: "LICENSURE AND PRACTICE OF PHARMACY"

Rule Title: _____

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

This should have no significant fiscal impact on state government. It simply makes changes recommended by the CSMP Advisory Committee and approved by the Board for when users can run certain patient profiles on intake of a potential new patient or a newborn, and on storage and access to reports in the practitioner's patient medical chart or file. Other changes are merely clarifications for ease of reading and enforcement of current law and practices.

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.

See above.

Date: Jume 27, 2014

Signature of Agency Head or Authorized Representative

David E. Potter

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. -- ~~April 30, 2014~~_____, 2015.

1.4. Effective Date. -- ~~May 30, 2014~~_____, 2015.

§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. "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.~~2~~3. "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~~4 "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.~~2.2.5. "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 duly authorized representative of the covered entity to access the central repository on behalf of the covered person or entity.

2.2.~~5~~6 "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~~7. "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~~8. "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~~9. "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~~10. "Medical Services Provider" means a licensed practitioner with the legal authority to dispense controlled substances.

2.2.11. "Patient", for purposes of access to the CSMP, means an individual who:

(a) has a valid ongoing practitioner-patient relationship; or

(b) has not yet established an ongoing practitioner-patient relationship, but:

(1) has requested to establish such a relationship with the practitioner; or

(2) has been referred to that practitioner for evaluation or care by another practitioner.

2.2.~~10~~12. "Recipient" means the patient (ultimate user or research subject) for whom a controlled substance is dispensed or filled.

2.2.~~11~~13. "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~~14. "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~~15. "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~~16. "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~~17. "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 shall be retained in either print or electronic form. If the reporter electronically reports 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 State military, State driver's license, Passport, Green Card, etc.) into the central repository, the reporter shall retain the additional information in print or electronic form for a period of ninety (90) days. If the reporter does not file the listed information into the central repository, the information shall be retained in print or electronic form for a period of at least two (2) years; and

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

3.2. Any person reporting more than twenty (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 twenty (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 twenty-four (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 forty-eight (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 forty-eight (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~~ 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 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 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;

(d) Authorized agents of the federal 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;

(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 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;

(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 or dispense controlled substances may also request specific data related to any and 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.

(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.

(b) In addition, in the case that 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. 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.

7.7. A practitioner may file or store copies of any 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, or with the patient or the patient's properly authorized guardian or representative for the purpose of providing treatment. However, 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 and issue reports of the results of these searches to the Review Committee for its regular review and action. Further, 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. All such reports and communications produced by the board shall be kept confidential by the board and the Review Committee, and are not open to inspection except as provided for confidential records and reports of 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 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 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(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.

Office Address
2310 Kanawha Blvd, East
Charleston, WV 25311

www.wvbop.com

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

RESPONSE 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 did not receive any written public comments regarding the proposed rules filed with the Secretary of State on June 27, 2014, making amendments to Title 15, Series 8, relating to the West Virginia Controlled Substances Monitoring Program (CSMP). The Board met in open public meeting on June 29, 2014, just after filing the proposed rules, and, although interested parties had not likely had a chance to review them at that time, no questions or information was presented at that meeting. The public comment period ended on July 27, 2014, with no written comments being filed. However, on July 25, 2014, the CSMP Advisory Committee met and received a report on the pending rules. Board staff to the Advisory Committee discussed with the Committee that a definition of "patient" might be helpful to clarify when the CSMP may be accessed given the prior recommendations they had made to permit a practitioner to access the CSMP patient profile of an individual who had requested to come under the care of that practitioner, or who had been referred to that practitioner, but whom the practitioner had not yet accepted into his or her practice, which rules changes were approved by the Board and included in this proposed rule. The Advisory Committee recommended specific language to define the term "patient". The Board held a public meeting on July 29, 2014, moved to modify the proposed rule to add the definition of "patient" as recommended by the Advisory Committee, and authorized this response and the proposed rules to be filed with the Secretary of State and the Legislative Rule-Making and Review Committee.

Prepared by:

David E. Potters

David E. Potters
Executive Director & General Counsel