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: West Virginia Code Sections 30-5-19 and 60A-9-6

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

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

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

APPROVAL OF FILING OF REGULATIONS

BE IT HEREBY KNOWN that the West Virginia Board of Pharmacy approves the filing of the following modified rules and responses to public comment with the Secretary of State and the Legislative Rulemaking and Review Committee:

(1) Series 1, "Board of Pharmacy Rule Regarding Licensure and the Practice of Pharmacy"; and

(2) Series 8, "Controlled Substances Monitoring", proposing changes to effectuate SB 365, 2010 Regular Session.

Signed this 26th day of July, 2010,

BY: _____
George Karos, President

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: 7/29/2010

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

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

(304) 558-0558

LEGISLATIVE RULE TITLE: Controlled Substances Monitoring

1. Authorizing statute(s) citation West Virginia Code Sections 30-5-19 and 60A-9-6

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

Filed with Secretary of State on June 17, 2010, at 1:38 p.m.

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

N/A

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

Public Comment Period ended on July 18, 2010, at 4:30 p.m.

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

Attached X No comments received _____

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

Filed with Secretary of State on July 29, 2010.

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
232 Capitol Street
Charleston, West Virginia 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)

N/A

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 _____

BRIEF SUMMARY OF AND STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE PROPOSED LEGISLATIVE RULE

Controlled Substances Monitoring

15 CSR 8

Summary and Statement of Circumstances: SB 365 passed during the Regular Session, 2010, and duly enacted into law, among other things, permits the Office of the Chief Medical Examiner to have access to the Controlled Substances Monitoring Program database (the "CSMP") maintained by the Board of Pharmacy, permits certain individuals or entities having access to the CSMP to designate duly authorized agents to access it on their behalf, and requires all practitioners who prescribe or dispense Schedule II, III, or IV controlled substances to have online access to the CSMP in their places of practice. West Virginia Code Section §60A-9-4 directs the West Virginia Board of Pharmacy to promulgate rules to implement the provisions of this Article 9. These proposed rules allow the Chief Medical Examiner's Office's access to the CSMP, set forth the requirements for designation of duly authorized agents for access, and require electronic access by practitioners.

For Further Information: Copies of the proposed rule may be obtained from the website of the West Virginia Secretary of State at www.wvsos.com, 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, 232 Capitol Street, Charleston, West Virginia, 25301, telephone (304) 558-0558.

Note: This is a proposed change to an existing series, such that there are strike-throughs and underlining of the language changes 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: 232 Capitol Street
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 program has been in existence in its current form since 2002, with modifications in 2005 and 2006. The changes required by this modification of the rules should not have any additional impact over what has been in place to date.

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.

This program has been in existence in its current form since 2002, with modifications in 2005 and 2006. The changes required by this modification of the rules should not have any additional impact over what has been in place to date.

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.

This program has been in existence in its current form since 2002, with modifications in 2005 and 2006. The changes required by this modification of the rules should not have any additional impact over what has been in place to date.

Date: 7/29/2010

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 §60A-9-6.

1.3. Filing Date. -- ~~June 23, 2003~~ _____.

1.4. Effective Date. -- ~~June 23, 2003~~ _____.

§15-8-2. Definitions.

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. "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 "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. "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.

~~2.3~~2.5. "Identification number" means any of the following:

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

2.6. "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. "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.

~~2.4~~2.8. "Logo" means a symbol used by an individual, a pharmacy, professional practice, professional association or hospital.

~~2.5~~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.

~~2.6~~2.11. "Recipient" means an individual for whom a controlled substance is dispensed or filled.

~~2.7~~2.12. "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.

~~2.8~~2.13. "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.

~~2.9~~2.14. "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.

~~2.10~~2.15. "Security prescription blank" means a prescription blank that complies with the requirements of Section ~~5 of this rule~~15-1-27 of the West Virginia Code of State Rules.

~~2.11~~2.16. "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 ~~information outlined in section 4 of this rule.~~ following information:

(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.

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; or

(c) A magnetic tape.

3.3. Any person reporting less than 20 Schedule II, III, or IV prescriptions 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.

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.

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

§15-8-5. ~~Prescription Forms.~~Accuracy of Information Transmitted.

~~5.1. The purpose of this section is to establish minimum requirements that will decrease the potential for forgery or alteration of a prescription or a prescription blank for a controlled substance.~~

~~5.2. After June 1, 2003, the Board of Pharmacy recommends that a written prescription for a controlled substance in Schedules II, III or IV be on a security prescription blank.~~

~~5.3. Minimum Requirements of a Security Prescription Blank.~~

~~5.3.1. A prescription for a controlled substance should contain the following security features:~~

~~(a) A latent, repetitive "void" pattern screened and printed across the entire front of the prescription blank. If the prescription is photocopied, the word "void" shall appear in a pattern across the~~

entire front of the prescription;

(b) A watermark printed on the backside of the prescription blank so that it is only seen at a forty-five (45) degree angle;

(c) An opaque "Rx" symbol or an "Rx" symbol printed in disappearing ink shall appear in the upper part of the blank. The symbol shall disappear if the prescription copy is lightened;

(d) Six (6) quantity check-off boxes printed on the form and the following quantities shall appear:

(1) ! 1-24;

(2) ! 25-49;

(3) ! 50-74;

(4) ! 75-100;

(5) ! 101-150; and

(6) ! 151 and over:

Provided, That if the blank has the quantity prescribed electronically printed in both numeric and word format, then the quantity check-off boxes would not be necessary;

(e) The following statement printed on the bottom of the prescription blank: "Prescription is void if more than one (1) controlled substance prescription is written per blank"; and

(f) Refill options in the following order: Refill NR 1 2 3 4 5: Provided, That if the blank has the refill amount electronically printed in both numeric and word format, then the quantity check-off boxes would not be necessary.

5.3.2. A prescription shall bear the preprinted, stamped, typed, or manually printed name, address and telephone number of the prescribing practitioner.

5.3.3. A prescription blank for a controlled substance shall not contain:

(a) An advertisement on the front or the back of the prescription blank;

(b) The preprinted name of a controlled substance; or

(c) The written, typed or rubber-stamped name of a controlled substance until the prescription blank is signed, dated and issued to a patient.

5.3.4. A prescription blank for a controlled substance shall provide space for the patient's name and address, the practitioner's signature and the practitioner's DEA registration number.

5.3.5. Only one (1) controlled substance prescription blank shall be written per prescription blank.

5.3.6. A quantity check-off box that corresponds to the quantity prescribed shall be marked or the quantity electronically printed in both numeric and word format.

~~5.3.7. If a prescribed drug is a schedule II, III or IV controlled substance, a refill option shall be marked or the refill amount electronically printed in both numeric and word format.~~

~~5.3.8. If a prescription for a schedule II, III or IV controlled substance will be transmitted to a pharmacy by facsimile, the practitioner or the practitioner's agent shall, prior to transmission, write or stamp "FAXED" on the face of the original prescription along with the date and the person's initials.~~

~~5.3.9. If a prescription for a schedule II, III or IV controlled substance has been transmitted to a pharmacy by facsimile, the transmitting practitioner shall file the original prescription in the patient's record.~~

~~5.3.10. A pharmacist shall not be required to use a security prescription blank to record an oral prescription or a transferred prescription for a Schedule II, III or IV controlled substance.~~

~~5.3.11. The requirements of this section do not apply to prescriptions for controlled substances that are electronically transmitted from a prescriber to a pharmacy: Provided, That all electronically transmitted prescriptions for controlled substances shall comply with all federal requirements."~~

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~~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 ~~and~~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) ~~A person with an enforceable court order or regulatory agency administrative subpoena;~~ an authorized agent of a local law-enforcement agency who is acting as a member of a State recognized drug task force;

(d) authorized agents of the federal ~~d~~Drug ~~e~~Enforcement ~~agency~~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;

(~~e~~g) inspectors and agents of ~~the board~~the board; ~~and~~

(~~f~~h) prescribing practitioners or their duly authorized agents ~~and pharmacists.~~;

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

(j) a person using the date 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 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.

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

State of West Virginia
Board of Pharmacy

Office
232 Capitol Street
Charleston, West Virginia 25301

RESPONSES TO COMMENTS RECEIVED TO PROPOSED RULES

(Including explanation of 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
Pertaining to SB 365 and Access to the West Virginia Controlled Substances Monitoring Program

The Board of Pharmacy received written public comments to the proposed rules filed with the Secretary of State on June 17, 2010, making amendments to Title 15, Series 8. The Board reviewed those comments at a public meeting on July 21, 2010. Following are the Board's responses to those comments.

1. The Board received a comment from the West Virginia State Medical Association ("WVSMA"), identifying a single issue with the proposed language of Section 15-8-2.2.9. They ask that the Board directly track the language of West Virginia Code Section 60A-9-5 and require that all practitioners "who prescribe or dispense Schedule II, III, or IV controlled substances" have electronic access to the West Virginia Controlled Substances Monitoring Program database. The Board accepts their comment and will add that language to Section 15-8-2.2.9 as requested to clarify the rule and make it directly in line with the statute. This was an unintentional oversight in drafting the rule, and the Board appreciates the WVSMA bringing it to the Board's attention.

2. The Board received a comment from the National Association of Chain Drug Stores ("NACDS") raising several points of concern with proposed rule.

   A. First, NACDS states that the proposed amendments to Section 15-8-3 would add a new requirement for pharmacies to report the middle initial of the patients in the data reported to the Controlled Substances Monitoring Program (CSMP). The language added to 15-8-3 was directly copied from the West Virginia Code, but the middle initial added due to problems the Board has recognized over the years with individuals sharing the same first and last name, and even sharing the same date of birth, such that their records get merged

in the CSMP. The facility in the system to provide the middle initial was added some time ago, and some pharmacies already provide it. It is possible that much of this information is already in place in the pharmacies patient profiles for use in submitting claims for third-party payment and other issues. Patients routinely provide this information to receive medical services, and should not be resistant to providing it when they already provide medical cards, insurance cards, photo identification, and other such personal information to receive prescriptions. Given that most medical providers track full names, this does not seem to be an unreasonable request in the Board's view. Nonetheless, given the assertion by NACDS that the pharmacy computer systems would be burdened by this change, the Board will seek input on the national guidelines for Prescription Monitoring Program reporting formats. In speaking with one national corporation who reports into the CSMP, they reported to the Board's Executive Director, David Potters, that they simply needed enough lead-time to modify their reporting program, and had already undertaken to make the necessary changes to comply. Thus, at this time, the Board has determined that it will not make any changes based upon this comment at this time, and will proceed forward with this rule change as proposed.

B. NACDS next comments on the proposed changes to Section 15-8-5. By way of background, the Board has experienced situations where certain patient or prescriber records are not correct in the CSMP because the pharmacy reported dispensing information inaccurately. In order to correct the information in the database, the pharmacy needs to notify the Board of the inaccuracy. The Board always requests that they do so in writing so that the Board has verification of the issue and documentation of why it went into the CSMP and made a change to what was reported. The Board does not make any such changes without such verification. While NACDS does not take issue with having to report the inaccuracies so that they can be corrected, they request that more time be given to report them, up to 14 days from discovery. The Board accepts this comment and has changed the language to strike the word "immediately" and add "as soon as possible, but in no event longer than fourteen (14) days after the discovery of the inaccurate reporting". Next, NACDS asks that "inconsequential inaccuracies such as misspellings or typos for nonessential information" not need to be reported. However, all of the information reported to the CSMP has been deemed by the Legislature in West Virginia Code Section 60A-9-4 to be essential, and is not inconsequential. The system searches by name and date of birth, or by prescriber, depending on the type of search. If the name is not spelled correctly, or the prescriber's DEA number is not entered accurately, the system will not recognize it, will nit filter it properly, and it will not show up in a search run by that name or DEA number. Likewise, if the national drug code is not entered accurately to identify the name and strength of the controlled substance dispensed, then the system will not recognize it, and it will not appear on the patient's or prescriber's profile. Even the patient's address is not "inconsequential" as that is used to further identify the patient to make sure it is the correct individual being investigated or reviewed. Thus, the Board will not make any changes to the proposed rule based upon this portion of the comment at this time.

C. NACDS next comments on Section 15-8-7.3. It asks that that the Board insure that members of a drug task force who are given access to the CSMP by West Virginia Code Section 60A-9-5 be limited to "authorized agents of local law enforcement agencies as a member of a drug task force." The Board believes this proposed change is directly in line with the language of West Virginia Code Section 60A-9-5, and will modify Section 15-8-

7.3 by striking the words "a member" at the beginning of the affected clause, and inserting the words "an authorized agent". In addition, NACDS asks the Board to have some sort of criteria or procedure for assuring that all investigations done by such drug task force agents are done only on a specific patient or individual or entity under investigation as required by West Virginia Code Section 60A-9-5. The Board notes that the statute and Rule Section 15-8-7.4 already limit the searches as stated in the comment, and the Code provides criminal penalties under 60A-9-7 for inappropriate access to or sharing of the information obtained. This would open the agent up to potential civil suit as well. Further, if an individual learns that the information was not accessed appropriately in a criminal case, then the evidence obtained as a result would be subject to a motion to suppress which would jeopardize any criminal prosecution. The Board does not have the staff or funding to audit each and every transaction into the CSMP, and must rely on these systems in place. Further, the system itself tracks what searches were done under any given password so that the information could be available for an audit or use in an administrative or court proceeding. That said, the Board notes that the West Virginia State Police Drug Diversion Unit investigators voluntarily make and keep a log of their searches, including their reasonable articulable suspicion for running a search in the CSMP, to track and justify their investigations. The Board proposes that the Legislature consider whether such logs should be kept by all law enforcement, including drug task forces, who access the CSMP, including how long the logs should be kept. The Board notes that the CSMP requires at least five (5) years of data to be stored in the CSMP, and that any such logs could be required to be kept for that same time period. Such logs could then be available for audits or court proceedings.

Prepared by:

David E. Potters

David E. Potters
Executive Director and General Counsel

WEST VIRGINIA State Medical Association

RECEIVED ON

JUL 5

WV BOARD OF PHARMACY

Mr. David E. Potters
Executive Director
WV Board of Pharmacy
C/O Series 1 Public Comments
232 Capitol Street
Charleston, WV 25301

Dear Mr. Potters,

Thank you for the opportunity to provide written comment to the West Virginia Board of Pharmacy regarding your rule **15 CSR 8 Board of Pharmacy Rules Regarding Controlled Substances Monitoring**. In our review of this rule we have identified a just one issue that we would like to raise here and hope our comment is constructive as you finalize this document.

Per the statute authorizing this rule (§60A-9-5. (b)) there is a requirement that "all practitioners… who prescribe or dispense schedule II, III or IV controlled substances shall, on or before July 1, 2011 have online or other form of electronic access to the West Virginia Controlled Substances Monitoring Program database." The language effecting this provision in the rule is written more broadly and references "all practitioners" as that has been defined in section 15-8-2.2.9 of the rule.

The WVSMA requests that you modify the language in the rule to properly conform with the statute only requiring practitioners "who prescribe or dispense schedule II, III, or IV controlled substances" to have electronic access to the central repository.

We thank you for your consideration of our comments, please do not hesitate to contact us regarding and questions you may have regarding this letter.

Sincerely,

Carlos C. Jimenez, MD
President

West Virginia State Medical Association
4307 MacCorkle Avenue, SE
P. O. Box 4106 • Charleston, West Virginia 25364
Phone: 304-925-0342 • Toll Free 800-257-4747 • Fax: 304-925-0345
www.wvsma.com

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

July 16, 2010

Sent via Certified U.S. Mail and facsimile (304.558.0572)

David E. Potters, Executive Director and General Counsel
West Virginia Board of Pharmacy
232 Capitol Street
Charleston, WV 25301

RE: Board of Pharmacy Rules regarding West Virginia Controlled Substances Monitoring -- CO Series 8 Public Comments

Dear Executive Director and General Counsel Potters:

On behalf of our members operating pharmacies in the state of West Virginia, the National Association of Chain Drug Stores is submitting comments on the proposed rules regarding controlled substances monitoring, Sections 15-8-1 to 15-8-7.

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We have fourteen members operating approximately 272 pharmacies in the State of West Virginia. NACDS members operating in West Virginia include RiteAid, CVS Caremark, Wal-mart, Fruth Pharmacies, Health Mart, Medicine Shoppe, Drug Emporium of West Virginia, Sears Holding, Target, Walgreen Company, Ahold, and Weis Markets.

NACDS members operating in West Virginia support controlled substance monitoring programs and routinely provide information to the West Virginia program. As the Board of Pharmacy moves forward with these proposed rules, we have several comments and ask for the Board's assistance in clarifying and amending certain provisions.

Section 15-8-3

The proposed regulation has added the requirement for pharmacies to provide the middle initial of the patient, along with the name, address and birth date. We have concerns with this requirement for several reasons. Prescribers do not provide the middle initial on prescriptions. Patients may not agree to provide the middle initial and pharmacies would not be able to force patients to provide that information. The middle initial should not be necessary as pharmacies report the patient name and date of birth.

We note that the implementing statute Code of West Virginia Section 60A-9-1(b) provides that the program "shall be designed to minimize inconvenience to patients, prescribing practitioners and pharmacists." Pharmacy computer systems for the most part do not have the ability to store this information, and we are not aware of other

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state controlled substance monitoring programs asking for this information. It would be burdensome and costly for pharmacies to have to change their computer systems.

For these reasons, we ask that section 15-8-3 be changed to not require submission of the middle initial.

Section 15-8-5

This section of the proposed rule adds the requirement that if the reporter discovers that the information contained in the central repository is not accurate, that he or she must notify the Board of the inaccuracy and the necessary corrections in writing immediately so the Board may correct the error in the database.

While we understand the Board wanting to be notified if a pharmacy discovers an inaccuracy, we believe that this should be limited in scope to significant inaccuracies and that the process should be clarified. For example, does the Board want to be notified of inconsequential inaccuracies such as misspellings or typos for non-essential information? Also we have concerns about immediate reporting and ask that instead there be a reasonable time period of 14 days.

Section 15-8-7.3

Because of our concerns over the need for confidentiality of the information provided to the program, we ask for amendments to section 15-8-7.3(c) regarding the Board's provision of the controlled substance monitoring program information to a members of a state recognized drug task force.

First, the proposed rule provides that the information could be provided to "a member of a local law-enforcement agency who is acting as a member of a State recognized drug task force." However, the implementing statute provides that the person must be authorized agents of local law-enforcement agencies as a member of a drug task force. We ask for an amendment so that the person must be an authorized agent.

Second, because these are drug task forces, we believe that the utmost confidentiality of patient information should be maintained. We ask that the Board clarify in the proposed rule that the information provided to a drug task force is limited to a specific patient or individual or entity under investigation. We note that West Virginia Code section 60A-9-5 provides that all information released by the Board must be related to a specific patient or a specific individual or entity under investigation. Also, in the interest of confidentiality, we ask that the Board have criteria and a procedure for assuring these limitations.

For these reasons, we ask for the amendments shown below.

> The Board may release confidential information received by the central repository to the following persons:
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> . . .
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> (c) ~~A person with an enforceable court order or regulatory agency administrative subpoena; a member of~~ *an authorized agent of* a local law enforcement agency who is acting as a member of a State recognized drug task force *who is limited to receiving information that is related to a specific investigation or prosecution as determined by Board of Pharmacy criteria and procedure*;

Thank you for your consideration of our comments. Should you have any questions or need any further information, please do not hesitate to contact us.

Sincerely,

Diane L. Darvey

Diane L. Darvey, Pharm.D., JD
Director, Public Policy, Government Affairs