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WEST VIRGINIA LEGISLATURE 2002 OCT 24 A 9: 32
Legislative Rule-Making Review Committee

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SECRETARY OF STATE

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October 23, 2002

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NOTICE OF ACTION TAKEN BY THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

TO: Joe Manchin, Secretary of State, State Register

TO: William T. Douglass, Jr.
Pharmacy, WV Board of
232 Capitol Street
Charleston, WV 25301

FROM: Legislative Rule-Making Review Committee

Proposed Rule: **Controlled Substances Monitoring, 15CSR8**

The Legislative Rule-Making Review Committee recommends that the West Virginia Legislature:

1. Authorize the agency to promulgate the Legislative rule
 - (a) as originally filed
 - (b) as modified by the agency
2. Authorize the agency to promulgate part of the Legislative rule; a statement of reasons for such recommendation is attached.
3. Authorize the agency to promulgate the Legislative rule with certain amendments; amendments and a statement of reasons for such recommendation is attached.
4. Authorize the agency to promulgate the Legislative rule as modified with certain amendments; amendments and a statement of reasons for such recommendation is attached.
5. Recommends that the Legislative rule be withdrawn; a statement of reasons for such recommendation is attached.

SCANNED

ANALYSIS OF PROPOSED LEGISLATIVE RULES

Agency: Board of Pharmacy

Subject: Controlled Substances Monitoring, 15CSR8

PERTINENT DATES

Filed for public comment: June 11, 2002
Public comment period ended: July 12, 2002
Filed following public comment period: July 17, 2002
Filed LRMRC: July 17, 2002
Filed as emergency: June 11, 2002

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Fiscal Impact: Cost increase of \$140,000 for first year, \$110,000 thereafter

ABSTRACT

The proposed rule amends a current legislative rule. The following is a synopsis of the substantive amendments.

Section 2 defines terms. Under the current rule, the term "Identification number" means the recipient's drivers license number or social security number, or if the recipient is an animal, the same information for the animal's owner. The proposed rule would define it as the birth date of the recipient. "Schedule III and IV" has been added to "Schedule II Controlled Substance". Finally a definition has been added for the term "Security subscription blank".

Section 3 relates to prescription monitoring program. Language has been deleted requiring a pharmacy to use its National Association of Boards of Pharmacy number to identify itself. Language has been added allowing the Board to grant a waiver to a person who does not have an automatic record keeping system capable of producing an electronic report in the established format. The

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dispenser must agree to report the data by submitting a completed Universal Claim Form.

The current rule requires the Board and central repository to pay for telephone access charges, line charges and switch charges for the transmission of data by reporters. Under the proposed rule, the Board would instead be required to provide a toll-free telephone line.

Section 4 relates to information to be transmitted. It has been amended to mirror the Code provisions regarding information which must be submitted by a reporter.

Section 5 relates to prescription forms. This new section establishes minimum requirements for prescription forms in order to decrease the potential for forgery or alteration. Unless a waiver is granted, all written prescriptions for a controlled substance must be on a security prescription blank after January 1, 2003. This section sets forth specific requirements for the actual prescription blank such as size, a latent repetitive void pattern, a watermark, etc. Special provisions are set forth for faxed prescriptions and oral or transferred prescriptions. It prohibits a pharmacist from filling a prescription that is not in compliance, except under certain circumstances. It also requires a pharmacist who continues to receive nonconforming prescriptions from the same practitioner to inform the Board. This section also states that it does not apply to prescriptions for controlled substances that are electronically transmitted, if the prescriptions comply with all federal requirements.

This section allows a practitioner or pharmacy to apply for a waiver from the requirements of this section. It also requires that the system or prescription blank proposed by the applicant provide a level of security equivalent to a security prescription blank.

Section 7 relates to confidentiality. The current rule lists those persons to whom confidential information received by the central repository may be released. The proposed rule adds authorized agents of the Federal Drug Enforcement Agency, inspectors and agents of the Board, and prescribing practitioners and pharmacists. This section would also allow practitioners who prescribe controlled substances to request specific data related to

their drug enforcement administration, controlled substance registration number or for the purpose of providing treatment to a patient.

AUTHORITY

Statutory authority: W.Va. Code, §60A-9-6, which provides as follows:

The board of pharmacy shall promulgate legislative rules to effectuate the purposes of this article in accordance with the provisions of chapter twenty-nine-a of this code.

ANALYSIS

I. HAS THE AGENCY EXCEEDED THE SCOPE OF ITS STATUTORY AUTHORITY IN APPROVING THE PROPOSED LEGISLATIVE RULE?

No.

II. IS THE PROPOSED LEGISLATIVE RULE IN CONFORMITY WITH THE INTENT OF THE STATUTE WHICH THE RULE IS INTENDED TO IMPLEMENT, EXTEND, APPLY, INTERPRET OR MAKE SPECIFIC?

Yes.

III. DOES THE PROPOSED LEGISLATIVE RULE CONFLICT WITH OTHER CODE PROVISIONS OR WITH ANY OTHER RULE ADOPTED BY THE SAME OR A DIFFERENT AGENCY?

No.

IV. IS THE PROPOSED LEGISLATIVE RULE NECESSARY TO FULLY ACCOMPLISH THE OBJECTIVES OF THE STATUTE UNDER WHICH THE PROPOSED RULE WAS PROMULGATED?

Yes.

V. IS THE PROPOSED LEGISLATIVE RULE REASONABLE, ESPECIALLY AS IT AFFECTS THE CONVENIENCE OF THE GENERAL PUBLIC OR OF PERSONS AFFECTED BY IT?

Possibly. The National Association of Chain Drug Stores feels that the requirement to submit information weekly is unreasonable in that no other state requires information to be submitted that frequently. The majority of the states require monthly reporting. The Board feels that the benefits obtained from timely data outweigh the burden on the reporters.

VI. CAN THE PROPOSED LEGISLATIVE RULE BE MADE LESS COMPLEX OR MORE READILY UNDERSTANDABLE BY THE GENERAL PUBLIC?

No.

VII. WAS THE PROPOSED LEGISLATIVE RULE PROMULGATED IN COMPLIANCE WITH THE REQUIREMENTS OF CHAPTER 29A, ARTICLE 3 AND WITH ANY REQUIREMENTS IMPOSED BY ANY OTHER PROVISIONS OF THE CODE?

Yes.

VIII. OTHER

Counsel has technical modifications to suggest.