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August 12, 2013

NOTICE OF EMERGENCY RULE DECISION BY THE SECRETARY OF STATE

AGENCY: West Virginia Board of Pharmacy

RULE: Amendments, 15CSR8, Controlled Substances Monitoring

DATE FILED AS AN EMERGENCY RULE: July 16, 2013

DECISION NO. 5-13

Following review under W. Va. Code §29A-3-15a, it is the decision of the Secretary of State that the above emergency rule is **approved**. A copy of the complete decision with required findings is available from this office.

A handwritten signature in cursive script that reads "Natalie E. Tennant".

NATALIE E. TENNANT
Secretary of State

EMERGENCY RULE DECISION
(ERD 5-13)

AGENCY: West Virginia Board of Pharmacy
RULE: Amendments, 15CSR8 Controlled Substances Monitoring
FILED AS AN EMERGENCY RULE: July 16, 2013

- par. 1 The West Virginia Board of Pharmacy (Board) has filed the above amendments to an existing rule as an emergency rule.
- par. 2 W. Va. Code §29A-3-15a requires the Secretary of State to review all emergency rules filed after March 8, 1986. This review requires the Secretary of State to determine if the agency filing such emergency rule: 1) has complied with the procedures for adopting an emergency rule; 2) exceeded the scope of its statutory authority in promulgating the emergency rule; or 3) can show that an emergency exists justifying the promulgation of an emergency rule.
- par. 3 Following review, the Secretary of State shall issue a decision as to whether or not such an emergency rule should be disapproved [§29A-3-15a].
- par. 4 (A) Procedural Compliance: W. Va. Code §29A-3-15 permits an agency to adopt, amend or repeal, without hearing, any legislative rule by filing such rule, along with a statement of the circumstances constituting the emergency, with the Secretary of State and forthwith with the Legislative Rule-Making Review Committee (LRMRC).
- par. 5 If an agency has accomplished the above two required filings with the appropriate supporting documents by the time the emergency rule decision is issued or the expiration of the forty-two day review period, whichever is sooner, the Secretary of State shall rule in favor of procedural compliance.
- par. 6 The Board filed this emergency rule with supporting documents with the Secretary of State July 16, 2013 and with the LRMRC July 16, 2013.
- par. 7 It is the determination of the Secretary of State that the Board has complied with the procedural requirements of W. Va. Code §29A-3-15 for adoption of an emergency rule.
- par. 8 (B) Statutory Authority -- W. Va. Code §60-9-4(a)(8) reads:

(8) If the prescription being dispensed is being picked up by someone other than the patient on behalf of the patient, the full legal name, address and birth date of the person picking up the prescription as set forth on the person's government-issued photo identification card shall be retained in either print or electronic form until such time as otherwise directed by rule promulgated by the board of pharmacy;

- par. 9 It is the determination of the Secretary of State that the Board has not exceeded its statutory authority in promulgating this emergency rule.
- par. 10 (C) Emergency -- W. Va. Code §29A-3-15(f) defines "emergency" as follows:
- (f) For the purposes of this section, an emergency exists when the promulgation of a rule is necessary for the immediate preservation of the public peace, health, safety or welfare or is necessary to comply with a time limitation established by this code or by a federal statute or regulation or to prevent substantial harm to the public interest.*
- par. 11 There are essentially three classes of emergency broadly presented with the above provision: 1) immediate preservation; 2) time limitation; and 3) substantial harm. An agency need only document to the satisfaction of the Secretary of State that there exists a nexus between the proposal and the circumstances creating at least one of the above three emergency categories.
- par. 12 The facts and circumstances as presented by the Board are as follows:
- 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.
- par. 13 It is the determination of the Secretary of State that this proposal qualifies under the definition of an emergency as defined in §29A-3-15(f). . ."immediate preservation of public peace, health, safety or welfare" and "prevent substantial harm to the public interest"

par. 14

This decision shall be cited as Emergency Rule Decision 5-13 or ERD 5-13 and may be cited as precedent. This decision is available from the Secretary of State and has been filed with the West Virginia Board of Pharmacy, the Attorney General and the Legislative Rule Making Review Committee.



NATALIE E. TENNANT
Secretary of State

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