



Mac Warner
Secretary of State
State of West Virginia

Office of the Secretary of State
State Capitol
Charleston, West Virginia 25305

FILED

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Telephone: (304) 558-6000
Toll Free: 1-866-SOS-VOTE
Fax: (304) 558-0900
www.wvsos.gov

July 20, 2017

NOTICE OF EMERGENCY RULE DECISION BY THE SECRETARY OF STATE

AGENCY: Pharmacy

RULE: 15CSR8, Amendments, Controlled Substances Monitoring Program

DATE FILED AS AN EMERGENCY RULE: June 15, 2017

DECISION NO. 9-17

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.

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EMERGENCY RULE DECISION
(ERD 9-17)

- par. 1 Pharmacy 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 Pharmacy filed this emergency rule with supporting documents with the Secretary of State and with LRMRC June 15, 2017.
- par. 7 It is the determination of the Secretary of State that Pharmacy 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 §60A-9-5a©) reads:

©) The various boards mentioned in subsection (b) of this section shall promulgate both emergency and legislative rules pursuant to the provisions of article three, chapter twenty-nine-a of this code to effectuate the provisions of this section.
- par. 9 It is the determination of the Secretary of State that Pharmacy 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 Pharmacy are as follows:

SB 333 (2017), which becomes effective July 7, 2017, made changes to the West Virginia Controlled Substances Program (the including creation of new Section 60A-9-9 which grants emergency rulemaking authority for the Board to designate substances as drugs of concern to be tracked by the CSMP. Data in West Virginia indicates that the drug Gabapentin has been involved in numerous overdose deaths in this State in the past several years, including 89 deaths in 2014, 110 deaths in 2015, and 104 deaths in 2016.

As such, the Board has by this rule change designated Gabapentin a drug of concern to be reported to the CSMP. Because it is a drug that is used in concert with opioids and benzodiazepines by drug abusers around the country, the State of Ohio has also similarly designated Gabapentin, and is tracking its dispensings in Ohio's prescription monitoring program as well.

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 "to prevent substantial harm to the public interest"

par. 14 This decision shall be cited as Emergency Rule Decision 9-17 or ERD 9-17 and may be cited as precedent. This decision is available from the Secretary of State and has been filed with Pharmacy.

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