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SECRETARY OF STATE

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October 8, 2009

NOTICE OF EMERGENCY RULE DECISION BY THE SECRETARY OF STATE

AGENCY: Governor's Office of Health Enhancement and Lifestyle Planning

RULE: New Rule, 210CSR1,UPrescription Drug Advertising Expense Reporting

DATE FILED AS AN EMERGENCY RULE: September 22, 2009

DECISION NO. 27-09

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, appearing to read "Natalie E. Tennant".

NATALIE E. TENNANT
Secretary of State

EMERGENCY RULE DECISION
(ERD 27-09)

AGENCY: Governor's Office of Health Enhancement and Lifestyle Planning
RULE: New Rule, 210CSR1, Prescription Drug Advertising Expense Reporting

FILED AS AN EMERGENCY RULE: September 22, 2009

- par. 1 The Governor's Office of Health Enhancement and Lifestyle Planning (GOHELP) has filed the above new 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 GOHELP filed this emergency rule with supporting documents with the Secretary of State September 22, 2009 and with the LRMRC September 22, 2009.
- par. 7 It is the determination of the Secretary of State that the GOHELP 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 §16-29H-8(a) reads:

(a) The rule-making authority previously granted to the Pharmaceutical Cost Management Council in article three-c, chapter five-a of this code to require the reporting of pharmaceutical advertising costs is here transferred to the Governor's Office of Health Enhancement and Lifestyle Planning.
- par. 9 It is the determination of the Secretary of State that the GOHELP 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.

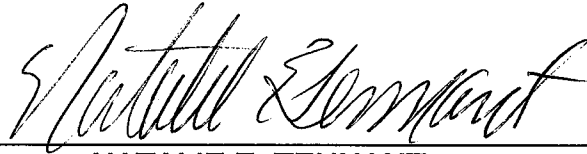
par. 12 The facts and circumstances as presented by the GOHELP are as follows:

On August 26, 2009, W.Va. Code § 16-29H-1 et seq. became effective. Article 29H established the Governor's Office of Health Enhancement and Lifestyle Planning ("GOHELP") and transferred the rule-making authority previously granted to the West Virginia Pharmaceutical Cost Management Council to GOHELP. The subject Article further mandates GOHELP to promulgate a legislative rule requiring certain entities to annually report pharmaceutical advertising costs. Until August 26, 2009, pharmaceutical advertising reporting was governed by a rule promulgated by the Pharmaceutical Cost Management Council (206CSR1). That rule had a calendar year reporting period. With the repeal of W. Va. Code § 5A-3C-1 et seq., the Pharmaceutical Cost Management Council existence was terminated resulting in the rescission of its rules. To prevent having a period of time in which pharmaceutical advertising reporting is not required by the state, a rule must be filed on an emergency basis. Reporting of drug advertising expenses allows the state to obtain an accurate view of the level and scope of drug advertising and marketing in West Virginia.

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). . . "preservation of public peace, health, safety and welfare" and ""prevent substantial harm to public interest"

par. 14

This decision shall be cited as Emergency Rule Decision 27-09 or ERD 27-09 and may be cited as precedent. This decision is available from the Secretary of State and has been filed with the Governor's Office of Health Enhancement and Lifestyle Planning, the Attorney General and the Legislative Rule Making Review Committee.



NATALIE E. TENNANT
Secretary of State

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