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August 9, 2012

NOTICE OF EMERGENCY RULE DECISION BY THE SECRETARY OF STATE

AGENCY: Health and Human Resources

RULE: New Rule, 69CSR7, <u>Regulations of Opioid Treatment Programs</u>

DATE FILED AS AN EMERGENCY RULE: July 31

DECISION NO. 17-12

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.

NATALIE E. TENNANT
Secretary of State

AGENCY: Health & Human Resources
RULE: New Rule, 69CSR7, <u>Regulations of Opioid Treatment Programs</u>
FILED AS AN EMERGENCY RULE: July 31, 2012

par. 1   The Health & Human Resources (DHHR) 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)   <u>Procedural Compliance</u>: 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 DHHR filed this emergency rule with supporting documents with the Secretary of State July 31, 2012 and with the LRMRC July 31, 2012.

par. 7   It is the determination of the Secretary of State that the DHHR has complied with the procedural requirements of W. Va. Code §29A-3-15 for adoption of an emergency rule.

par. 8   <u>(B) Statutory Authority</u> -- W. Va. Code §16-1-4(10)(D) reads:

(D) The secretary shall file revised emergency rules with the Secretary of State to regulate opioid treatment programs in compliance with the provisions of this section. Any opioid treatment program facility that has received a certificate of need pursuant to article two-d, of this chapter by the Health Care Authority shall be permitted to proceed to license and operate the facility.

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par. 9   It is the determination of the Secretary of State that the DHHR has not exceeded its statutory authority in promulgating this emergency rule.

par. 10   (C) <u>Emergency</u> -- 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 are as follows:

The provisions of W. Va. Code §16-1-4 require that the Secretary of the Department of Health and Human Resources regulate and license all opioid treatment centers in this state. The rules were previously known as Regulation of Opioid Treatment Programs, 64 CSR 90, effective April 11, 2008. After extensive amendments to W. Va. Code §16-1-4 during the 2012 Legislative Session, new rules were created that repeal and replace 64CSR90 and reflect the required changes. The rule establishes the administrative framework of an opioid treatment program and sets forth the requirements for ownership, staffing, operation and licensing. It specifies training criteria for medical and non-medical staff; provides minimum requirements for admission to an opioid treatment program; establishes the necessary steps for a patient to receive opioid treatment medications once admitted; and outlines the basic medical treatment, counseling and other opportunities available to a patient. The rule requires monthly drug testing for all patients; encourages a program where the amounts of drugs provided during medication therapy are reduced over time; and establishes individualized treatment plans of care for each patient. It also requires consultation and coordination with the prescription medication database maintained by the Board of Pharmacy, periodic medical assessments and reviews, and peer review analyses.

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 17-12 or ERD 17-12 and may be cited as precedent. This decision is available from the Secretary of State and has been filed with the Health & Human Resources, the Attorney General and the Legislative Rule Making Review Committee.

NATALIE E. TENNANT
Secretary of State

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