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Office of the Secretary of State  
Building 1, Suite 157-K  
1900 Kanawha Blvd., East  
Charleston, West Virginia 25305

**Natalie E. Tennant**  
Secretary of State  
State of West Virginia

OFFICE OF THE SECRETARY OF STATE  
Telephone: (304) 558-6000  
Toll Free: 1-866-SOS-VOTE  
Fax: (304) 558-0900  
www.wvsos.com

September 14, 2016

NOTICE OF EMERGENCY RULE DECISION BY THE SECRETARY OF STATE

AGENCY: Health and Human Resources

RULE: New Rule, 69CSR11, Medication - Assisted Treatment- Opioid Treatment Program

DATE FILED AS AN EMERGENCY RULE: August 31, 2016

DECISION NO. 16-16

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

EMERGENCY RULE DECISION  
(ERD 16-16)

AGENCY: Health and Human Resources  
RULE: New Rule, 61CSR11, Medication - Assisted Treatment - Opioid Treatment Program  
FILED AS AN EMERGENCY RULE: August 31, 2016

- par. 1 The Health and 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) 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 DHHR filed this emergency rule with supporting documents with the Secretary of State August 31, 2016 and with the LRMRC August 31, 2016.
- 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 (B) Statutory Authority -- W. Va. Code §16-1-4©) reads:  
  
*The Legislature finds that an emergency exists and, therefore, the secretary shall file an 84 emergency rule to implement the provisions of this section pursuant to the provisions of section 85 fifteen, article three, chapter twenty-nine-a of this code.*
- 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) 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 DHHR are as follows:

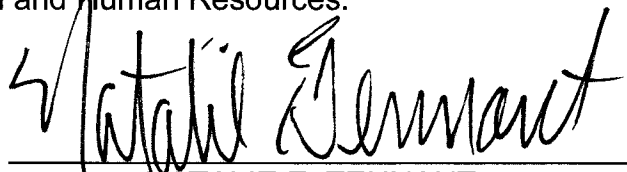
This rule applies to any publicly or privately owned medication-assisted treatment opioid treatment program in clinics or facilities that treats individuals with substance use disorders through the prescription, administration or dispensing of medication-assisted treatment medication in the form of opioid agonist, partial opioid agonist or other medication-assisted treatment medication as defined in W. Va. Code §16-5Y-2 and further described in this rule. The rule addresses licensure procedures and requirements; annual inspections; administrative organization and management; environment and operations; facility construction and renovations; life safety policies and procedures; for-cause inspections; complaints; plans of correction; waivers and variances; reports and records; staff training and credentialing; risk management; medication security, storage, administration and documentation; continuous quality improvement policies and diversion control plan; patient rights; patient records; pre-admission assessment; admission criteria and admission process; multiple program enrollments; controlled substances monitoring program database; orientation; required services; counseling; coordination of patient care; post-admission assessment and initial plan of care; physical and biopsychosocial assessments; individualized treatment plan of care; unsupervised take-home medications; detoxification program; administrative withdrawal; medical withdrawal; laboratory services and drug screens; special populations; advertisement disclosure; licensure denials, revocations and suspensions; penalties and equitable relief; administrative due process; and administrative appeals and judicial review.

Through the passage of SB 454 during the 2016 Regular Session of the West Virginia Legislature, the Legislature found that an emergency exists and, therefore, the secretary of the Department of Health and Human Resources is mandated to file an emergency rule to implement the provisions of W. Va. Code §16-5Y-1 et seq. establishing specific standards and procedures to provide for the licensure or registration and regulation of two types of medication-assisted treatment programs, including opioid treatment programs.

Facilities previously licensed and regulated under the opioid treatment program rule,

69CSR7, will be absorbed and thereafter licensed and regulated under W. Va. Code §§16-5Y-1, et seq. (2016) and this rule. The other type of medication-assisted treatment program authorized by SB 454, office-based medication-assisted treatment, will be addressed in a separate rule, 69 CSR 12.

- 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). . . "The Legislature finds that an emergency exists and, therefore, the secretary shall file an emergency rule to implement the provisions of W.Va Code 16-5Y-1 et seq
- par. 14 This decision shall be cited as Emergency Rule Decision 16-16 or ERD 16-16 and may be cited as precedent. This decision is available from the Secretary of State and has been filed with the Health and Human Resources.



NATALIE E. TENNANT  
Secretary of State

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