

OFFICE OF THE SECRETARY OF STATE
STATE OF WEST VIRGINIA



Betty Ireland
Secretary of State

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

July 19, 2005

NOTICE OF EMERGENCY RULE DECISION BY THE SECRETARY OF STATE

AGENCY: Health and Human Resources

RULE: New Rule, 64CSR90, Regulation of Opioid Treatment Programs

DATE FILED AS AN EMERGENCY RULE: June 8, 2005

DECISION NO. 5-05

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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Secretary of State

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EMERGENCY RULE DECISION
(ERD 5-05)

AGENCY: Health and Human Resources
RULE: New Rule, 64CSR90, Regulation of Opioid Treatment Programs
FILED AS AN EMERGENCY RULE: June 8, 2005

- par. 1 The Department of 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 June 8, 2005 and with the LRMRC June 8, 2005.
- 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:

§16-1-4. Proposal of rules by the secretary.

The secretary may propose rules, in accordance with the provisions of article three, chapter twenty-nine-a of the code, that are necessary and proper to effectuate the purposes of this chapter. The secretary may appoint or designate advisory councils of professionals in the areas of hospitals, nursing homes, barbers and beauticians, postmortem examinations, mental health and mental retardation centers and any other areas necessary to advise the secretary on rules.

The rules may include, but are not limited to, the regulation of:

(a) Land usage endangering the public health: Provided, That no rules may be promulgated or enforced restricting the subdivision or development of any parcel of land within which the individual tracts, lots or parcels exceed two acres each in total surface area and which individual tracts, lots or parcels have an average frontage of not less than one hundred fifty feet even though the total surface area of the tract, lot or parcel equals or exceeds two acres in total surface area, and which tracts are sold, leased or utilized only as single family dwelling units. Notwithstanding the provisions of this subsection, nothing in this section may be construed to abate the authority of the department to: (1) Restrict the subdivision or development of a tract for any more intense or higher density occupancy than a single family dwelling unit; (2) propose or enforce rules applicable to single family dwelling units for single family dwelling unit sanitary sewerage disposal systems; or (3) restrict any subdivision or development which might endanger the public health, the sanitary condition of streams, or sources of water supply;

(b) The sanitary condition of all institutions and schools, whether public or private, public conveyances, dairies, slaughterhouses, workshops, factories, labor camps, all other places open to the general public and inviting public patronage or public assembly, or tendering to the public any item for human consumption, and places where trades or industries are conducted;

© Occupational and industrial health hazards, the sanitary conditions of streams, sources of water supply, sewerage facilities and plumbing systems and the qualifications of personnel connected with any of those facilities, without regard to whether the supplies or systems are publicly or privately owned; and the design of all water systems, plumbing systems, sewerage systems, sewage treatment plants, excreta disposal methods and swimming pools in this state, whether publicly or privately owned;

(d) Safe drinking water, including:

(1) The maximum contaminant levels to which all public water systems must conform in order to prevent adverse effects on the health of individuals, and, if appropriate, treatment techniques that reduce the contaminant or contaminants to a level which will not adversely affect the health of the consumer. The rule shall contain provisions to protect and prevent contamination of wellheads and well fields used by public water supplies so that contaminants do not reach a level that would adversely affect the health of the consumer;

(2) The minimum requirements for: Sampling and testing; system operation; public notification by a public water system on being granted a variance or exemption or upon failure to comply with specific requirements of this section and rules promulgated under this section; record keeping; laboratory certification; as well as procedures and conditions for granting variances and exemptions to public water systems from state public water systems rules; and

(3) The requirements covering the production and distribution of bottled drinking water and may establish requirements governing the taste, odor, appearance and other consumer acceptability parameters of drinking water;

(e) Food and drug standards, including cleanliness, proscription of additives, proscription of sale and other requirements in accordance with article seven of this chapter, as are necessary to protect the health of the citizens of this state;

(f) The training and examination requirements for emergency medical service attendants and emergency medical care technician-paramedics; the designation of the health care facilities, health care services, and the industries and occupations in the state that must have emergency medical service attendants and emergency medical care technician-paramedics employed, and the availability, communications, and equipment requirements with respect to emergency medical service attendants and to emergency medical care technician-paramedics: Provided, That any regulation of emergency medical service attendants and emergency medical care technician-paramedics shall not exceed the provisions of article four-c of this chapter;

(g) The health and sanitary conditions of establishments commonly referred to as bed and breakfast inns. For purposes of this article, "bed and breakfast inn" means an establishment providing sleeping accommodations and, at a minimum, a breakfast for a fee: Provided, That the secretary may not require an owner of a bed and breakfast providing sleeping accommodations of six or fewer rooms to install a restaurant style or commercial food service facility: Provided, however, That the secretary may not require an owner of a bed and breakfast providing sleeping accommodations of more than six rooms to install a restaurant-type or commercial food service facility if the entire bed and breakfast inn or those rooms numbering above six are used on an aggregate of two weeks or less per year;

(h) Fees for services provided by the bureau for public health including, but not limited to, laboratory service fees, environmental health service fees, health facility fees and permit fees;

(I) The collection of data on health status, the health system and the costs of health care;

(j) Opioid treatment programs duly licensed and operating under the requirements of chapter twenty-seven of this code. The secretary shall promulgate emergency rules to govern such programs: Provided, That there shall be a moratorium on the licensure of new opioid treatment programs that do not have a certificate of need as of the effective date of this subsection until such time as the secretary files emergency rules with the secretary of state to regulate such programs. All existing opioid treatment programs shall be in compliance within one hundred eighty days of the effective date of this rule; and

(k) Other health-related matters which the department is authorized to supervise and for which the rule-making authority has not been otherwise assigned.

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 new rule was developed at the request of the 2004 West Virginia legislature in order to better regulate the proliferation of medication-assisted opioid treatment programs in West Virginia. Since 2001, the number of programs licensed by the state of West Virginia as Behavioral Health Centers (64CSR11) has grown from zero to eight with at least five more in development and pending approval by the WV Health Care Authority in the coming year. More than 4,000 individuals are being treated by the licensed methadone programs at the present time. The behavioral health regulations do not adequately address the specific treatment needs of the opioid dependent population and the potential dangers of medication-assisted treatment. This rule brings West Virginia standards into compliance with federal standards for care, allows the DHHR to ensure that programs are in compliance with both state and federal standards of care, and in some cases, provides standards which are more stringent than those provided by the federal government in order to meet local demands for increased attention to the health and safety of consumers and the public at large.

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 the Legislature gave specific instructions to file as an emergency rule.

par. 14 This decision shall be cited as Emergency Rule Decision 5-05 or ERD 5-05 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, the Attorney General and the Legislative Rule Making Review Committee.


BETTY IRELAND
Secretary of State

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