



Virginia  
Regulatory  
Town Hall

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## Emergency Regulation Agency Background Document

<b>Agency name</b>	State Mental Health, Mental Retardation and Substance Abuse Services Board
<b>Virginia Administrative Code (VAC) citation</b>	12 VAC 35-105-10 et seq.
<b>Regulation title</b>	Rules and Regulations for the Licensing of Facilities and Providers of Mental Health, Mental Retardation and Substance Abuse Services
<b>Action title</b>	To add standards for the evaluation of the need and appropriateness of issuance of new licenses for providers of treatment for persons with opioid addiction
<b>Document preparation date</b>	

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Preamble

*The APA (Code of Virginia § 2.2-4011) states that an “emergency situation” is: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date.*

- 1) *Please explain why this is an “emergency situation” as described above.*
- 2) *Summarize the key provisions of the new regulation or substantive changes to an existing regulation.*

Chapter 7 of the 2005 Virginia Acts of Assembly (SB 753) directs the State Mental Health Mental Retardation Substance Abuse Services Board to adopt regulations to establish standards for the issuance of new licenses to providers of treatment for persons with opioid addiction. This legislation also requires that the provisions of the Act become effective within 280 days of its enactment and imposes a moratorium on the issuance of licenses to such providers until standards are in place. The Board is adopting these emergency regulations to comply with the Act.

The emergency regulations amend the existing Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services 12VAC35-105-10 et seq., by inserting

a new section that provides specific standards for evaluating the need and appropriateness for the issuance of new licenses for providers of treatment of persons with opioid addiction through the use of methadone or other opioid replacements. As required by the legislation, these standards include consideration of demographic and geographic factors, the availability of qualified staff and support services, the suitability of the service site, and several other related attributes of a proposed service provider.

**Legal basis**

*Other than the emergency authority described above, please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) the promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.*

The State Mental Health, Mental Retardation and Substance Abuse Service Board has the statutory authority to adopt the proposed emergency regulations under Virginia Code § 37.2-203 (formerly § 37.1-10) and Chapter 7 of the 2005 Acts of Assembly. The authority to adopt these regulations is mandatory.

**Substance**

*Please detail any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of Virginians.*

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
N/A	12VAC35-105-925	N/A	This new section of the regulation requires applicants requesting an initial license for the treatment of opioid addiction to supply specific information to demonstrate the need for and appropriateness of the proposed service. The regulations require applicants to identify a geographic service area for the service, which for the purpose of demonstrating need, must be located entirely in Virginia. The regulations require the applicants to submit admission policies for the proposed service that give priority to Virginia residents in its designated service area. Applicants are also required to document contact with the local community services board or behavioral health authority to discuss its proposed operation and to

			<p>develop joint agreements, as appropriate.</p> <p>The regulations also establish specific standards for the Department to use in evaluating the information supplied by the applicant with regard to the need for the service in the applicant’s designated service area.</p> <p>The regulation also requires applicants to provide documentation that qualified staff and support are available for the proposed service and that the designated building and local conditions are suitable to establish the service.</p>
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These regulatory provisions are considered essential to protect the health, safety and welfare of individuals who receive services. They will provide a framework to ensure that new providers have the necessary resources and support to provide an acceptable standard of treatment.

**Alternatives**

*Please describe all viable alternatives to the proposed regulatory action that have been considered to meet the essential purpose of the action.*

There are no viable alternatives to this regulatory action. The agency is required to adopt emergency regulations to implement the provisions of Chapter 7 of the 2005 Virginia Acts of Assembly. The agency developed the regulations in collaboration with consumers, providers, local officials and residents of many Virginia localities. As part of the process, the agency held several public meetings in localities throughout Virginia to seek public comment on initial drafts of the regulations. The final emergency regulations reflect views and information from many interested individuals.

The agency in collaboration with the stakeholders considered several alternative approaches to meeting the requirements of the legislation. The agency intends to continue to work with these stakeholders over the next year to adopt permanent regulations to replace the emergency regulations.

**Family impact**

*Please assess the impact of the emergency regulatory action on the institution of the family and family stability.*

This regulatory action will implement standards for the Department of Mental Health, Mental Retardation and Substance Abuse Services to evaluate the need and appropriateness of issuing licenses to new providers of services for the treatment of opioid addiction. These standards provide a means for regulatory oversight consistent with population needs in Virginia localities. This should have a positive impact on families affected by opioid addiction by promoting the quality of services and accountability of service providers.