



Proposed Regulation Agency Background Document

Agency name	State Mental Health, Mental Retardation and Substance Abuse Services Board
Virginia Administrative Code (VAC) citation	12 VAC 35-105 et seq.
Regulation title	Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services
Action title	Addition of standards new providers of services for the treatment of opioid addiction
Date this document prepared	April 14, 2006

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*.

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

This action will 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.

The agency adopted these provisions as emergency regulations that became effective in December 2005. This agency is taking this action to adopt these provisions on a permanent basis.

Legal basis

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) promulgating entity, i.e., the 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.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

In December 2005, the agency adopted emergency regulations to establish standards for issuance of new licenses to providers of treatment for persons with opioid addiction. This action was necessary to comply with the new legislation and to ensure that decisions to license new providers were rational based on the specific considerations established by the legislation. The agency is now taking action to adopt these standards on a permanent basis. The regulations are intended to ensure that essential services are available to persons who need them and that new providers are responsive to the needs of the population.

These standards for new providers are considered essential to protect the health, safety, and welfare of individuals who receive services. They provide a framework to ensure that new providers have the necessary resources and support to provide an acceptable standard of treatment. These standards also were developed to consider the diverse needs and varying circumstances of localities in Virginia where the new service is provided.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

This action will amend the existing Regulations, 12 VAC 35-105-10 et seq., to provide standards to evaluate the need and appropriateness for the issuance of new licenses to providers of treatment for persons with opiate addiction through the use of methadone or other opioid replacements. These standards include criteria for (i) determining need for new providers by considering (a) the number of persons residing in the service area who are known or reasonably estimated to be in need of this treatment; (b) the availability or relevant staff in the service area; and (c) the suitability of the building or space to be used to provide the service; (ii) assessing the availability of counseling or other services necessary for effective treatment of persons with opiate addiction; (iii) reviewing existing access to such treatment, including through physicians offices; (iv) evaluating the reasonable parameters, both

geographic and demographic of a clinic’s service area; and (v) reviewing the proposed clinic’s plan of operation, including security and accountability measures.

Issues

Please identify the issues associated with the proposed regulatory action, including:
 1) *the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
 2) *The primary advantages and disadvantages to the agency or the Commonwealth; and*
 3) *other pertinent matters of interest to the regulated community, government officials, and the public.*

If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

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- (1) This regulatory action should help promote the quality of services and provide accountability to the public. These standards provide a means for regulatory oversight consistent with population needs in Virginia localities. The Department will monitor such providers and be available to provide technical assistance to resolve any deficiencies. The standards also provide a means to ensure that providers to have necessary support and financial resources to provide a satisfactory standard of care.
 - (2) The Department’s existing Office of Licensing is responsible for applying the new standards and licensing service providers in accordance with the regulations. This is a cost-efficient and effective means to implement the new licensing requirements because this Office has the administrative support and experience to perform the required functions. Therefore, these regulations should be advantageous to the Department, providers of opioid addiction services, and the public.
 - (3) This action poses no known disadvantages to the public or the Commonwealth. The agency developed the proposed amendment in collaboration with consumers, providers and local government officials from various localities throughout Virginia through a series of public hearings and meetings. The groups assisted the agency to draft reasonable effective standards to implement the statutory requirements pursuant to Chapter 7 of the 2005 Acts of Assembly.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which are more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are federal regulations that apply to opioid treatment services but federal regulations do not require providers to demonstrate the need or appropriateness of the services prior establishing the service. Therefore, these requirements exceed the federal requirements. The General Assembly has mandated the additional requirements because of concerns about the impact of these service providers in Virginia, and the impact they may have on communities.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There is no locality that is particularly affected by these regulations that will bear a disproportionate material impact that would not be experienced by other localities. These regulatory provisions will apply to any provider seeking a license to operate in any locality in Virginia.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so by mail, email or fax to Leslie Anderson, Virginia Department of Mental Health, Mental Retardation, and Substance Abuse Services, P. O. Box 1097, Richmond, Virginia, 23228, (804) 371-6885, (804) 692-0066, leslie.anderson@co.dmhmrzas.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

A public hearing will be held and notice of the public hearing may appear on the Virginia Regulatory Town Hall website (www.townhall.virginia.gov) and can be found in the Calendar of Events section of the Virginia Register of Regulations. Both oral and written comments may be submitted at that time.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

<p>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</p>	<p>There is negligible additional cost to the state. The regulations will be implemented and enforced by the Department's existing Office of Licensing.</p>
<p>Projected cost of the regulation on localities</p>	<p>There is negligible additional cost to localities.</p>
<p>Description of the individuals, businesses or other entities likely to be affected by the regulation</p>	<p>This will impact opioid treatment clinics currently operating in Virginia and applicants that request new licenses to provide opioid treatment services.</p>
<p>Agency's best estimate of the number of such</p>	<p>There are 17 clinics in Virginia that provide services</p>

<p>entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>for persons with opioid addiction. All of them would be impacted by some of the regulations. Only new providers seeking licenses would be impacted by the regulations pertaining to determining need. All of the providers have fewer than 500 full-time employees although two are part of national corporations.</p>
<p>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</p>	<p>Applicants will have to collect data to document the need for the service and this will require time and effort on their part. The regulations may require some additional record keeping, but providers may consolidate that record keeping with record keeping they currently do. Therefore, there may be some additional administrative staff costs for providers but this cost should be negligible</p>

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

There are no appropriate alternatives to this regulatory action. The agency is required to adopt regulations to implement the provisions of the Chapter 7 of the Virginia 2005 Acts of Assembly. The agency has developed the regulations in collaboration with a stakeholder group, which included representatives of providers, consumers and local government officials. Some of these stakeholders represented current providers and consumers receiving treatment for opioid addiction. This group considered various alternatives for meeting the requirements of the legislation. The agency also reviewed standards developed by other states for evaluating similar service providers. The agency and stakeholders determined that the provisions of this regulation provide the least intrusive and least costly means of meeting the intent of the legislation.

Regulatory flexibility analysis

Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

All the affected entities are small businesses and are equally impacted by these regulations. Providers of opioid treatment services participated in the development of these regulations. As a result, the requirements were developed with consideration to the limitations of small business. The statute requires

establishment of specific standards criteria to evaluate the “need and appropriateness for the issuance of new licenses.” The statute does not provide authority to exempt any providers from complying with all or some of the standards.

The regulations require providers to demonstrate the need for and appropriateness of the proposed services by submitting specific documentation or information to the agency. When it developed standards, the agency identified sources of relevant data and information to ensure such information would be accessible to affected providers. The standards are written to reflect available information and to facilitate compliance with documentation requirements. It was determined that providers have reasonable access to alternative data sources that will enable them to demonstrate compliance with the standards.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
Mark W. Perrino	There is a great need for treatment services. The commenter recommends the Department consider the impact the regulations will have on access to treatment. Specifically, there is a requirement that individuals be assessed every six months for continued treatment. Individuals in treatment have been addicted for years and tried other alternatives, and this is re-evaluation is not required of individuals with diabetes or chronic depression. In addition, the federal government has promulgated standards, which are evidence-based and apply to all Virginia programs.	The Department will review the impact of the emergency regulations on access for treatment as it prepares the permanent regulations and the requirement for six-month reassessments. The Department will also consider this recommendation in conjunction with any other related comments that are submitted during the public comment period. The General Assembly has mandated additional regulation and that is the reason for going beyond the current federal requirements. The Department will review the Treatment Improvement Protocol.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

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. These services are intended to assist persons with opioid addiction to achieve their personal recovery goals which may promote economic self-sufficiency, self pride, and the assumption of family responsibilities.

This action should not have any adverse impact on the authority of parent’s rights, marital commitment, or disposable family income.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

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	<p>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 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</p>

			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.
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