



## Final 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
<b>Regulation title</b>	Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation, Substance Abuse, the Individual and Family Developmental Disabilities Waiver, and Residential Brain Injury Services
<b>Action title</b>	Addition of standards for new providers of services for the treatment of opioid addiction
<b>Date this document prepared</b>	December 11, 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

*Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.*

This action will amend the existing Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation, Substance Abuse, the Individual and Family Developmental Disabilities Waiver, and Residential Brain Injury 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.

### Statement of final agency action

*Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.*

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On December 8, 2006 the State Mental Health, Mental Retardation and Substance Abuse Service Board adopted the amendment to the Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation, Substance Abuse Services, the Individual and Family Development Disabilities Waiver, and Residential Brain Injury Services, to comply with Chapter 7 of the 2005 Acts of Assembly.

### 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 numbers, if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.*

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The State Mental Health, Mental Retardation and Substance Abuse Service Board has the statutory authority to adopt the 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. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.*

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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 identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.*

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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 there are no disadvantages to the public or the Commonwealth, please 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.

**Changes made since the proposed stage**

*Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.*

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There have been no changes to the text of the regulation since the publication at the proposed stage.

**Public comment**

*Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.*

Commenter	Comment	Agency response
Janice Gold, Alexandria CSB	Questioned the rationale for the routine six-month assessment for the continuation of treatment. (12 VAC 35-925.M). Believes this is overly burdensome and not productive. Recommends annual assessments.	<p>Services that are licensed under these regulations are required to assess an individual's progress on a quarterly basis 12 VAC 35-105-660.H). This assessment must include a determination as to whether continued treatment is necessary. The six-month assessment should not require more documentation than is already occurring. The Department will issue documentation guidelines to assist providers to comply with this new provision.</p> <p>No changes have been made in response to this comment.</p>
Renee Nunn and Ed Ohlinger, CRC Health Corp.	Same comment as above. Stated individuals receiving services not ready for reassessment in six months after initiation of services and it would be counter-productive.	Same comment as above.
L. Michael Gilmore  Director, Alexandria CSB	Questioned whether the current CSB methadone program is exempt from regulatory requirements if the program relocates from its current site.	<p>Since the CSB service is located in Planning District 8 (Northern Virginia), it is exempt from the requirements pertaining to location as long as it remains in Planning District 8. Since the program is already licensed, it is exempt from the provisions that require a determination of the need for the service. It is not exempt from additional program quality requirements beginning with 12 VAC 35-105-925.I.</p> <p>No changes have been made in response to this comment.</p>

**All changes made in this regulatory action**

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

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 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>

**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.*

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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.

### 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.*

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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.