



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	Department of Behavioral Health and Developmental Services
Virginia Administrative Code (VAC) citation(s)	12 VAC35-105-925
Regulation title(s)	Rules and Regulations for Licensing Providers by the Department of Behavioral Health and Developmental Services
Action title	Align language regarding geographic exceptions for DBHDS-licensed providers of treatment for persons with opiate addiction to the Code of Virginia
Date this document prepared	April 20, 2017

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

The intent of Chapter 480 of the 2016 General Assembly (SB556) was to support the operation of programs that use opioid replacement therapy other than methadone, regardless of where the program is located. Specifically, qualifying language was added to Code of Virginia §37.2-406 stating that DBHDS may license programs using nonmethadone opioid replacements that are within half-mile of a K-12 school or licensed day care center if the opioid replacement has been approved by the U.S. Food and Drug Administration for the treatment of opioid addiction.

The purpose of this fast-track regulatory action is to align Section 925 of the Licensing regulations with changes in the Code of Virginia § 37.2-406.

Background

The previous statute governing opioid replacement program licensing was considered too restrictive. The use of opioid replacement therapy is an essential component of medication assisted treatment for opioid addiction, is recognized as an evidence-based treatment by the Substance Abuse and Mental Health Services Administration (SAMHSA), and was endorsed by the Governor’s Task Force on Prescription Drug and Heroin Abuse.

Virginia is experiencing an epidemic of deaths due to opioid misuse and addiction, the volume of which currently exceeds the number of deaths from highway fatalities. Improved access to treatment is critical to reducing these deaths. Medication-assisted treatment, when combined with counseling and other supports, is an evidence-based practice endorsed by the Governor’s Task Force on Prescription Drug and Heroin Abuse.

Federal law requires that methadone be administered only in a clinic. However, federal law permits physicians who have completed specialized training and received a special “waiver” from the U.S. Drug Enforcement Agency (DEA) to utilize another highly effective opioid replacement medication, buprenorphine (Subutex®, Suboxone®), in the privacy of their own office. Community services boards (CSBs) and private providers strive to offer geographically accessible programs to individuals needing care, but many CSB and private provider facilities are located in settings which were prohibited from using this medication due to this geographic restriction. Exempting non-methadone programs from the half-mile limit (which still applies to methadone clinics) permits these programs to utilize these effective medications in the treatment of this deadly disease.

In addition, two planning districts in the state have code-authorized exceptions to the half-mile restriction.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the “Definition” section of the regulations.

“State Board” means the State Board of Behavioral Health and Developmental Services.

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.

Section 37.2-203 of the Code of Virginia, authorizes the State Board of Behavioral Health and Developmental Services to adopt regulations that may be necessary to carry out the provisions of Title 37.2 and other laws of the Commonwealth administered by the Commissioner and the Department. The State Board voted at its regular meeting on April 5, 2017, to approve this fast-track action to Section 925 of 12 VAC35-105, Rules and Regulations for Licensing Providers by the Department of Behavioral Health and Developmental Services.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a

specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person’s overall regulatory authority.

Section 37.2-203 of the Code of Virginia, authorizes the State Board of Behavioral Health and Developmental Services to adopt regulations that may be necessary to carry out the provisions of Title 37.2 and other laws of the Commonwealth administered by the Commissioner and the Department.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation 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.

The purpose of this fast-track regulatory action is to align Section 925 of the Licensing regulations with changes in the Code of Virginia § 37.2-406. Specifically, in the code there are three exceptions to the geographic restriction on DBHDS-licensed providers of treatment for persons with opiate addiction through the use of opioid replacements that are within half-mile of a K-12 school or licensed day care center for the treatment of opioid addiction. The history of the exemptions is:

- Chapter 845 of the 2004 Acts of Assembly added Planning District 8.
- Chapter 415 of the 2014 Acts of Assembly added Planning District 23.
- Chapter 480 of the 2016 Acts of Assembly added using nonmethadone opioid replacements if the opioid replacement has been approved by the U.S. Food and Drug Administration for the treatment of opioid addiction.

This fast-track action would update the existing regulation to reflect these, and any future, changes to state law. By deleting all language in Section 925 B., the remaining language would simply cross-reference to § 37.2-406.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

The language already exists in the Code of Virginia; thus, providers must already comply with the language. No new language is proposed.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the “Detail of changes” section below.

This fast-track action would update the existing regulation to reflect these, and any future, changes to state law. By deleting all language in Section 925 B. except the language simply cross-referencing to § 37.2-406.



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.

This action will make it clearer to providers what is required regarding where to locate services for DBHDS-licensed providers of treatment for persons with opiate addiction. Rather than attempting to replicate language in the Code of Virginia, which was and could become updated faster than the regulatory language, this amendment will direct providers directly to the appropriate source in the Code.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is 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 no restrictions that are more restrictive.

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 particularly affected by the proposed regulation.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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.

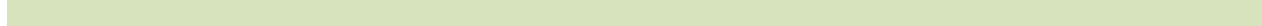
Because this amendment is updating existing regulatory language to comply with the Code of Virginia, there is no alternative to this regulatory change.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

The fiscal impact statement from the 2016 Session stated there would be no fiscal impact. That document may be viewed here:
<http://lis.virginia.gov/cgi-bin/legp604.exe?161+oth+SB556FER122+PDF>.

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	None.
Projected cost of the new regulations or changes to existing regulations on localities.	None.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	<ul style="list-style-type: none"> • Programs licensed by the Department of Behavioral Health and Developmental Services (DBHDS) that provide services to individuals who are addicted to opioids. • Individuals who are served by such programs.
Agency’s best estimate of the number of such 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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	Any impact was absorbed in 2016.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	This regulatory update merely provides facilities, CSBs, and private providers licensed by DBHDS to offer another medication option for individuals suffering from opioid abuse. Therefore, it does not have a fiscal impact on the operations of the system.
Beneficial impact the regulation is designed to produce.	Clarification to providers of exactly what is required by the Code of Virginia regarding location of programs licensed by the Department of Behavioral Health and Developmental Services (DBHDS) that provide services to individuals who are addicted to opioids.



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.

Because this amendment is updating language to comply with the Code of Virginia, there is no alternative to this regulatory change.

Public participation notice

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

This language went through the legislative process during the 2016 Session of the General Assembly, which allows for citizen input.

Periodic review and small business impact review report of findings

If this fast-track is the result of a periodic review/small business impact review, use this form to report the agency's findings. Please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review and (2) indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Commenter	Comment	Agency response

This amendment is not the result of a periodic review or small business impact review. It is merely complying with existing language in the Code of Virginia.

Family impact

Please assess the impact of this 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 regulation will have no impact on the institution of the family or family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

For changes to existing regulation(s), please use the following chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12 VAC 35-105-925		The current requirement only references one exception to the geographic location.	By deleting all language in Section 925 B., the remaining language would simply cross-reference to § 37.2-406.

If an existing regulation or regulations (or parts thereof) are being repealed and replaced by one or more new regulations, please use the following chart:

Current chapter-section number	Proposed new chapter-section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements

If a new regulation is being promulgated, that is not replacing an existing regulation, please use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements