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Fast-Track Regulation
Agency Background Document

Agency name	Department of Behavioral Health and Developmental Services (DBHDS)
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC35-105
VAC Chapter title(s)	Rules and Regulations for Licensing Providers by the Department of Behavioral Health and Developmental Services ("Licensing Regulations")
Action title	Integration of the Final Federal Rule: Registration Requirements for Narcotic Treatment Programs with Mobile Components into the Licensing Regulations
Date this document prepared	~~June 20, 2023~~ April 25, 2024; Reposted 9/26/24

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

In June 2021, the federal Drug Enforcement Administration (DEA) published a final rule permitting DEA registrants who are authorized to dispense methadone for opioid use disorder to add a "mobile component" to their existing registrants. The Department of Behavioral Health and Developmental Services (DBHDS) is integrating these federal regulations into the Licensing Regulations due to provider interest in supplying these mobile medication assisted treatment (mobile MAT) services. The integration of the federal rules within the Licensing Regulations shall increase transparency and set administrative expectations for this service. The availability of mobile MAT is expected to help address the opioid crisis in Virginia.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

Drug Enforcement Administration (DEA)
Department of Behavioral Health and Developmental Services (DBHDS)
Mobile medication assisted treatment (mobile MAT)

Statement of Final Agency Action

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.

The State Board voted on December 7, 2022, to initiate the exempt stage titled "Integration of the final federal rule: Registration Requirements for Narcotic Treatment Programs with Mobile Components into the Licensing Regulations to amend the Rules and Regulations for Licensing Providers by the Department of Behavioral Health and Developmental Services [12VAC35-105]." The action was submitted to the Office of the Attorney General on December 8, 2022, to start the formal process for adoption.

On June 16, 2023, the Office of the Attorney General indicated that upon further review this action could not move forward as exempt because the agency has discretion on whether or not to adopt regulations to align with federal regulation. These changes are not controversial; therefore, a fast track action is appropriate. The language remains exactly the same as initially filed.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in the ORM procedures, "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

Consistent with Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track rulemaking process.

The Drug Enforcement Administration implemented the "Registration Requirements for Narcotic Treatment Programs with Mobile Components" within 21 CFR Parts 1300, 1301 and 1304" in June 2021.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the

promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Section 37.2-203 of the Code of Virginia authorizes the Board to adopt regulations that 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 and authorizes the Department to ensure the development of long-range programs and plans for mental health, developmental, and substance abuse services provided by the Department, community services boards, and behavioral health authorities.

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it is intended to solve.

The regulations are intended to make maintenance or detoxification treatments more widely available, while ensuring that safeguards are in place to reduce the likelihood of diversion.

Substance

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.

The regulations detail under what circumstances mobile components of medication assisted treatment programs would be able to transport and dispense controlled substances away from their registered locations within the same state as the medication assisted treatment programs. The regulations set forth requirements for security, recordkeeping, reporting, and inventory for those mobile components.

Issues

Identify the issues associated with the regulatory change, 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, include a specific statement to that effect.

The primary advantage to the public it the enhanced ability for medication assisted treatment programs to provide an expanded resource to those seeking and need of substance use disorder treatment. There are no known disadvantages to the public. The primary advantages to the agency or the Commonwealth are more substance use services and resources at a time when opioid involved deaths are increasing across the country.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and 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 specific statement to that effect.

This action incorporates federal requirements therefore there are no requirements more restrictive than federal.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected

There are no state agencies particularly affected.

Localities Particularly Affected

There is no locality particularly affected.

Other Entities Particularly Affected

There is no other entity particularly affected.

Economic Impact

Consistent with § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	There is no additional cost to implement and enforce the amendments.

For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There is no additional cost to any other state agency due to these amendments.
For all agencies: Benefits the regulatory change is designed to produce.	This regulatory requirements creates an opportunity for providers to provide an expanded resource to those seeking and need of substance use disorder treatment.

Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

Projected costs, savings, fees or revenues resulting from the regulatory change.	There is no additional cost to any other locality due to this amendment.
Benefits the regulatory change is designed to produce.	This change will help to ensure local citizens have an opportunity to access expanded resources for those seeking and in need of substance use disorder treatment.

Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Individuals receiving services and their families through the opportunity to access expanded resources for those seeking and in need of substance use disorder treatment.
Agency's best estimate of the number of such entities that will be affected. 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.	It is not possible to estimate the exact number of individuals receiving services that will be affected by this regulation
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	The regulations provide an opportunity for providers to provide an expanded resource to those seeking and need of substance use disorder treatment. However, the program is permissive not mandatory therefore any costs incurred would be at the provider's discretion and choice.

Benefits the regulatory change is designed to produce.	The enhanced ability for medication assisted treatment programs to provide an expanded resource to those seeking and need of substance use disorder treatment

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.

There is no alternative to this regulatory change.

If this analysis has been reported on the ORM Economic Impact form, indicate the tables on which it was reported. Information provided on that form need not be repeated here.

Regulatory Flexibility Analysis

Consistent with § 2.2-4007.1 B of the Code of Virginia, 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) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing 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 regulatory change.

There are no other alternative regulatory methods which will incorporate the federal regulations permitting the operation of mobile components of mobile medication assisted treatment program. The proposed regulatory changes align the Licensing Regulations with federal regulations. There are no exemptions of small business providers from all or any part of the requirements contained in the regulatory change as the regulatory change incorporates a permissive program that providers are not required to participate in.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

Consistent with § 2.2-4011 of the Code of Virginia, 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.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The Department of Behavioral Health and Developmental Services is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Susan Puglisi, 1220 Bank Street, Richmond, Virginia 23219, email: susan.puglisi@dbhds.virginia.gov In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
12VAC35-105-20		Definitions for the Licensing Regulations	Addition of the term “mobile medication assisted treatment program.” Likely impact: Clearer regulations
	12VAC35-105-1830		New section which requires that any mobile medication assisted treatment program operate as a component of a licensed medication assisted treatment location and be listed on the provider’s license addendum. Likely impact: Clear regulations.

	12VAC35-105-1840		New section which incorporates the federal physical security controls for mobile medication assisted treatment programs within the licensing regulations. The federal physical security control requirements are within 21 CFR Section 1301.72 (a)(1) and (e). Likely impact: Clear regulations.
	12VAC35-105-1850		New section which incorporates the federal security controls for mobile medication assisted treatment programs within the licensing regulations. The federal security control requirements are within 21 CFR 1301.74(j)(k)(l)(m) and (n). Likely impact: Clear regulations
	12VAC35-105-1860		New section which incorporates federal record requirements for mobile medication assisted treatment programs within the licensing regulations. The federal record requirements are within 21 CFR 1304.24. Likely impact: Clear regulations.
	12VAC35-105-1870		New section which exempts mobile medication assisted treatment programs from the physical plant requirements of the licensing regulations. Likely impact: Clear regulations.