



Virginia Department of Planning and Budget **Economic Impact Analysis**

12 VAC 35-105 Rules and Regulations for Licensing Providers by the Department of Behavioral Health and Developmental Services

Department of Behavioral Health and Developmental Services

Town Hall Action/Stage: 6152/10070

May 24, 2024

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 19. The analysis presented below represents DPB’s best estimate of the potential economic impacts as of the date of this analysis.¹

Summary of the Proposed Amendments to Regulation

The Board of Behavioral Health and Developmental Services (Board) proposes to amend this regulation to incorporate a 2021 federal rule pertaining to narcotic treatment programs with mobile components. The proposed amendments would allow currently licensed narcotic treatment programs, which are also called medication assisted treatment (MAT) programs, to voluntarily deploy mobile units with oversight from the Department of Behavioral Health and Developmental Services (DBHDS).

Background

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 voluntarily add a “mobile component” to their existing registrants.”² Although the federal

¹ Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the analysis should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5) the impact on the use and value of private property.

² See *Registration Requirements for Narcotic Treatment Programs with Mobile Components*: <https://www.govinfo.gov/content/pkg/FR-2021-06-28/pdf/2021-13519.pdf>.

regulation is already in effect, and licensed MAT providers are already registered with the DEA, adding a “mobile component” requires a significant investment to retrofit a vehicle to meet the requirements in the federal rule. DBHDS reports that MAT providers in Virginia requested the Board to incorporate mobile units as a voluntary option within the regulation so that they were explicitly authorized by both state and federal law, thus ensuring that their investment in the mobile unit was protected and that they were not operating in a legal grey area. Consequently, the agency seeks to amend the state regulation to align with the federal requirements.

The proposed changes are designed to “make maintenance or detoxification treatments more widely available, while ensuring that safeguards are in place to reduce the likelihood of diversion.”³ The most substantive requirements regarding security, recordkeeping, reporting, and inventory are identical to the requirements in the federal regulation.

- Section 20 (Definitions) would be amended to add a definition for “mobile medication assisted treatment program” or “mobile MAT program.”
- Section 1830 would be newly added to state that each mobile MAT program shall operate as a component of a licensed MAT location and be listed on the provider’s license addendum. This requirement would operationalize the federal requirement that providers operating mobile MATs must have an existing brick-and-mortar location with a DEA registration number.
- Section 1840 would be newly added to list the physical security control requirements for mobile MAT programs and storage areas.⁴ These requirements include installing a safe and limiting access to the controlled substance storage areas within the vehicle.
- Section 1850 would also be newly added to list the other security controls for mobile MATs.⁵ These requirements pertain to proper dosage, where individuals seeking treatment should wait, and restrictions on provider personnel.
- Section 1860 would be newly added to establish the record-keeping requirements for mobile MATs.⁶

³ ABD, page 2.

⁴ The federal physical security control requirements are within 21 CFR Section 1301.72 (a)(1) and (e): <https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2/section-1301.72>.

⁵ The federal security control requirements are within 21 CFR 1301.74(j)(k)(l)(m) and (n): <https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2/section-1301.74>.

⁶ The federal record requirements are within 21 CFR 1304.24: <https://www.ecfr.gov/current/title-21/chapter-II/part-1304/subject-group-ECFRd220d26113f6a5/section-1304.24>

- Lastly, Section 1870 would be newly added to exempt mobile MATs from meeting the physical plant requirements in this regulation since those requirements are intended for licensed entities with physical locations and would simply not apply to mobile units.

Estimated Benefits and Costs

The proposed amendments would benefit MAT providers and the individuals receiving their services. The amendments are intended to encourage MAT providers to invest in mobile units by providing legal recognition and ensuring that they would not be operating in a legal grey area. The deployment of mobile units would make MAT more accessible to individuals with opioid misuse disorder, thereby reducing drug overdoses and addressing the opioid crisis in Virginia.⁷

Businesses and Other Entities Affected

The proposed amendments would primarily benefit currently licensed MAT providers as well as providers seeking MAT licensure by providing them the legal authority to deploy mobile MAT units at the state level. DBHDS reports that there are currently 41 licensed MAT providers and that one of them is already building a mobile unit. An adverse impact is indicated if there is any increase in net cost or reduction in net benefit for any entity, even if the benefits exceed the costs for all entities combined.⁸ Because the proposed amendments create a voluntary option, and thus do not require any investments or actions by MAT providers, any increase in net cost or reduction in net benefit would be made by the provider at their discretion. Given that the changes would not directly require any action be taken by providers unless they choose to deploy a mobile unit, an adverse impact is not indicated.

⁷ See <https://curbthecrisis.com/> and <https://www.vdh.virginia.gov/drug-overdose-data/>.

⁸ Statute does not define “adverse impact,” state whether only Virginia entities should be considered, nor indicate whether an adverse impact results from regulatory requirements mandated by legislation. As a result, DPB has adopted a definition of adverse impact that assesses changes in net costs and benefits for each affected Virginia entity that directly results from discretionary changes to the regulation.

Small Businesses⁹ Affected:¹⁰

The proposed amendments would not adversely affect small businesses. MAT providers that are small businesses would benefit from being able to operate a mobile unit.

Localities¹¹ Affected¹²

The proposed amendments would particularly benefit localities that receive additional opioid treatment via mobile MAT programs once this regulation becomes effective. The proposed amendments would not create new costs for any local governments.

Projected Impact on Employment

The proposed amendments would slightly increase the employment of providers who would staff the mobile MAT units.

Effects on the Use and Value of Private Property

The value of licensed MATs that are private companies would increase if they invest in a mobile MAT unit that generates additional revenue. Real estate development costs would not be affected.

⁹ Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as “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.”

¹⁰ If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.

¹¹ “Locality” can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

¹² Virginia Code § 2.2-4007.04 defines “particularly affected” as bearing disproportionate material impact.