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Proposed Regulation Agency Background Document

Agency name	Department of Behavioral Health and Developmental Services (DBHDS)
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC35-46
VAC Chapter title(s)	Regulations for Children's Residential Facilities
Action title	Amend the Children's Residential Licensing Regulations to align with the ASAM Criteria
Date this document prepared	August 4, 2021

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), 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.

The Department of Behavioral Health and Developmental Services (DBDHS) was directed by the 2020 General Assembly within [Item 318.B](#) of the 2020 *Appropriation Act* to utilize emergency authority to promulgate licensing regulations that align with the American Society of Addiction Medicine (ASAM) Levels of Care Criteria or an equivalent set of criteria to ensure the provision of outcome-oriented and strengths-based care in the treatment of addiction. The goal of this regulatory action is to amend the licensing regulations, Regulations for Children's Residential Facilities [12VAC35-46], to align with the ASAM Levels of Care Criteria, which ensure individualized, clinically driven, participant-directed and outcome-informed treatment.

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.

ASAM - American Society of Addiction Medicine

DBHDS - Department of Behavioral Health and Developmental Services

State Board - State Board of Behavioral Health and Developmental Services

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 Executive Order 14 (as amended, July 16, 2018), “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.”

The 2020 General Assembly directed DBDHS to promulgate emergency regulations to become effective within 280 days or less from the enactment of the *Appropriation Act*. This regulatory action is being utilized to codify permanent regulations following the emergency regulations.

In addition to being mandated by the General Assembly, the regulatory change is necessary as substance use disorders affect individuals, their families, the workplace, and the general community, therefore DBHDS must incorporate best practices within its licensing regulations in order to promote recovery from the disease of addiction. This is especially a concern with the increase of substance use in general. According to the Monitoring the Futures Survey of 2019, there has been an increase in adolescent marijuana vaping from 2018 to 2019. This increase ranked among the largest single-year increases ever observed by this survey in the past 45 years among all outcomes ever measured. In 2019 the percentage of adolescents who had vaped marijuana in the last 12 months was 21% in 12th grade, 19% in 10th grade, and 7% in 8th grade.

According to the Middle School Virginia Youth Survey conducted by the Virginia Department of Health (VDH), in 2017 approximately 3% of respondents indicated that they used marijuana before age 11 and almost 10% drank alcohol before age 11. That same VDH survey of high school students illustrated that over 30% of this population in 2017 reported using alcohol in the past 30 days. The survey also indicated that 25% of respondents binge drank, 20% reported using marijuana, and approximately 3% used heroin in a 30 day period.

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.

DBDHS was directed by the 2020 General Assembly within Item 318.B. of the 2020 *Appropriation Act* to utilize emergency authority to promulgate regulations which align with a set of criteria to ensure the provision of outcome oriented and strengths-based care in the treatment of addiction. This regulatory action is being utilized to codify permanent regulations following the emergency regulations. Section 37.2- 203 of the Code of Virginia gives the Board of Behavioral Health and Developmental Services the authority to adopt regulations that may be necessary to carry out the provisions of Title 37.2 of the Code and other laws of the Commonwealth administered by the DBHDS commissioner. The State Board of Behavioral Health and Developmental Services voted to adopt this regulatory action on July 28, 2021.

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's intended to solve.

Substance related disorders affect the individual, their families, the workplace, and the general community, therefore the department must incorporate best practices in licensing regulations in order to promote remission and recovery from the disease of addiction. Regulations that promote remission and recovery from the disease of addiction are essential to protect the health and welfare of citizens.

Substance use disorders (SUDs) among children, adolescents, and their families pose particular challenges for the community. Given the differences in developmental and emotional growth between youth and adults, the complex needs of this population are remarkably different from those of the traditional adult treatment population, requiring different expertise and guidance. In addition, many adolescents who abuse drugs have a history of physical, emotional, or sexual abuse, or other trauma.

Behavioral therapies, delivered by trained clinicians, can help an adolescent stay off drugs by strengthening his motivation to change. The ASAM criteria is designed to provide specific substance use disorder treatment guidance to counselors, clinicians, and case managers. Level 3.5 programming is specifically designed for youth and adults that require 24 hour care and treatment to begin and sustain a recovery process. This type of guidance can significantly improve the treatment outcomes of youth in need of residential services.

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.

This regulatory action amends the Regulations for Children’s Residential Facilities [12VAC35-46] to align with the ASAM Levels of Care Criteria, which ensures individualized, clinically driven, participant-directed and outcome-informed treatment. The regulatory action provides the necessary definitions for the newly aligned services to be provided and creates staff, program admission, discharge, and co-occurring enhanced program criteria for ASAM levels of care 3.5 and 3.1.

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 of the regulatory change to the Regulations for Children’s Residential Facilities is that citizens of the Commonwealth will receive more effective treatment of substance use disorders. This is an advantage to the public, the agency, and the Commonwealth. The primary disadvantage is that some providers may experience a financial burden in order to comply with the new regulations. There are no known disadvantages to the agency or the Commonwealth.

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.

No requirements within the regulation exceed applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Identify any other state agencies, localities, or other entities particularly affected by the regulatory change. “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:

The Department of Medical Assistance Services (DMAS) may be particularly affected by the regulatory action as DMAS is a payor to many of the DBHDS providers affected by the regulatory action. DBHDS collaborated with DMAS on the development of this regulatory action.

Localities Particularly Affected:

No locality is particularly affected to the knowledge of DBHDS.

Other Entities Particularly Affected:

Providers of substance abuse services may be particularly affected by the regulation in order come into compliance with the regulations.

Economic Impact

Pursuant to § 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 change versus the status quo.

Impact on State Agencies

<p><i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including:</p> <ul style="list-style-type: none"> 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 	<p>DBHDS will incur costs related to the promulgation of regulations, training for providers, and conducting additional inspections. Specifically, DBHDS will issue conditional licenses for six months and conduct an inspection to ensure regulatory compliance. DBHDS anticipates needing to conduct ~ 250 initial inspections after the first six month period. The outcome of those inspections will determine if an additional inspection is required later that year.</p> <p>Additionally, the agency will need to provide technical assistance to providers, to include issuing Corrective Action Plans and confirming their implementation. DBHDS will require one additional full-time specialist to absorb the increased workload associated with this ASAM regulatory change.</p>
<p><i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</p>	<p>None known.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>The citizens of the Commonwealth will receive more effective treatment of substance related conditions.</p>

Impact on Localities

<p>Projected costs, savings, fees or revenues resulting from the regulatory change.</p>	<p>None known.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The citizens of the Commonwealth will receive more effective treatment of substance related conditions.</p>

Impact on Other Entities

<p>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.</p>	<p>DBHDS providers that provide substance abuse services. Individuals served by those providers. No other entities will be affected by these regulations.</p>
<p>Agency's best estimate of the number of such entities that will be affected. Include an estimate</p>	<p>DBHDS estimates the number of entities that will be affected is 63. There is no way to estimate the</p>

<p>of the number of small businesses affected. Small business means a business entity, including its affiliates, that:</p> <ul style="list-style-type: none"> 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. 	<p>number of small businesses within the pool of all providers.</p>
<p>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:</p> <ul style="list-style-type: none"> 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. 	<p>Children’s residential providers will need to obtain an updated license from DBHDS at no cost.</p> <p>These changes bring DBHDS’ regulations into alignment with the current requirements of the Department of Medical Assistance Services (DMAS). DMAS has required third-party administrative verification that providers were in compliance with the ASAM criteria for payment. Therefore, any provider utilizing Medicaid as a payor should be in compliance with these regulations and not incur any costs. However, a physical DBHDS inspection could reveal that providers currently billing Medicaid need to make changes to ensure ASAM is being implemented properly.</p> <p>Providers who do not participate in Medicaid <i>and</i> whose services do not meet these requirements may incur some costs related to hiring and training staff in the use of the ASAM criteria.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The citizens of the Commonwealth will receive more effective treatment of substance related conditions.</p>

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.

As this regulatory action is the result of a General Assembly mandate. There are no viable alternatives.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B 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 consistent with health, safety, environmental and economic welfare that will accomplish the objectives of the General Assembly mandate. The proposed regulatory changes align the Regulations for Children’s Residential Facilities with the ASAM criteria as directed. There are no exemptions of small business providers from all or any part of the requirements contained in the regulatory change.

**Periodic Review and
Small Business Impact Review Report of Findings**

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable.

In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency’s consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (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. Also, discuss why the agency’s decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

Neither a periodic review nor a small business impact review was conducted related to this action.

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

No public comment was received during the public comment period.

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.

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, (ii) any alternative approaches, (iii) the potential impacts of the regulation, and (iv) the agency’s regulatory flexibility analysis stated in that section of 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, Phone Number: 804-371-2709, 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.

A public hearing will not be held following the publication of this stage of this regulatory action.

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
12VAC35-46-10. Definitions.		Provides current definitions for the Children’s Residential Licensing Regulations	Change: Adding the following definitions for terms utilized within the ASAM criteria: <ul style="list-style-type: none"> • Allied health professional [NOTE FOR PROPOSED: ‘professionals’ changed to ‘professional’ in the singular]; • ASAM; • Clinically managed, low-intensity residential care; • Clinically managed, medium intensity residential care; • DSM; • Medication assisted treatment; and • Motivational enhancement. Impact: Clear regulations.
	12VAC35-46-1150. (Reserved).		Intent: Space saver section.
	12VAC35-46-1160. Clinically managed, medium intensity		Intent: Provide clear staff requirements within clinically-managed, medium intensity residential care programs, which provide 24 hour supportive treatment. The individuals served by clinically managed medium-intensity

	residential services staff criteria		<p>residential care are individuals who are not sufficiently stable to benefit from outpatient treatment regardless of intensity of service.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth.</p>
	12VAC35-46-1170. Clinically managed medium-intensity residential services program criteria		<p>Intent: Provide clear program requirements within clinically-managed, medium-intensity residential care programs, which provide 24 hour supportive treatment. The individuals served by clinically-managed, medium intensity residential care are individuals who are not sufficiently stable to benefit from outpatient treatment regardless of intensity of service.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth.</p>
	12VAC35-46-1180. Clinically managed, medium intensity residential services admission criteria.		<p>Intent: Provide clear admission requirements within clinically-managed, medium-intensity residential service programs.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth which is appropriately administered.</p> <p>professional [NOTE FOR PROPOSED: in B.1. changed to DSM abbreviation.]</p>
	12VAC35-46-1190. Clinically managed medium intensity residential services discharge criteria.		<p>Intent: Provide clear discharge requirements within clinically-managed medium-intensity residential service programs.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth which is appropriately administered.</p>
	12VAC35-46-1200. Clinically managed medium intensity residential services co-occurring enhanced programs		<p>Intent: Provide additional licensing requirements for medium-intensity residential services programs which treat individuals with co-occurring disorders.</p> <p>Impact: Clarity of the regulations. Clear requirements for providers treating individuals with co-occurring disorders.</p>

	<p>12VAC35-46-1210. Clinically managed low-intensity residential services staff criteria</p>		<p>Intent: Provide clear staff requirements within clinically managed low-intensity residential service program, which provide ongoing therapeutic environment for individuals requiring some structured support.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth.</p>
	<p>12VAC35-46-1220. Clinically-managed low-intensity residential services program criteria</p>		<p>Intent: Provide clear program requirements within clinically managed low-intensity residential service programs, which provide ongoing therapeutic environment for individuals requiring some structured support.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth.</p>
	<p>12VAC35-46-1230. Clinically managed low-intensity residential services admission criteria.</p>		<p>Intent: Provide clear admission requirements within clinically managed low-intensity residential service programs.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth which is appropriately administered.</p>
	<p>12VAC35-46-1240. Clinically-managed low-intensity residential services discharge criteria.</p>		<p>Intent: Provide clear discharge requirements within clinically managed low – intensity residential service programs.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth which is appropriately administered.</p>
	<p>12VAC35-46-1250. Clinically-managed low-intensity residential services co-occurring enhanced programs.</p>		<p>Intent: Provide additional licensing requirements for clinically managed low-intensity residential service programs which treat individuals with co-occurring disorders.</p> <p>Impact: Clarity of the regulations. Clear requirements for providers treating individuals with co-occurring disorders.</p>