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## Proposed Regulation Agency Background Document

<b>Agency name</b>	Department of Behavioral Health and Developmental Services (DBHDS)
<b>Virginia Administrative Code (VAC) Chapter citation(s)</b>	12VAC35-105
<b>VAC Chapter title(s)</b>	Rules and Regulations for Licensing Providers by the Department of Behavioral Health and Developmental Services
<b>Action title</b>	Amend the Licensing regulations to align with the ASAM Criteria
<b>Date this document prepared</b>	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 (DBHDS) 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 Levels of Care Criteria (ASAM) 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, Rules and Regulations for Licensing Providers by the DBHDS ("Licensing Regulations"), 12VAC35-105, to align with the ASAM Levels of Care Criteria which ensures 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.*

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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.”*

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The 2020 General Assembly directed DBHDS to promulgate emergency regulations to become effective within 280 days or less from the enactment of the Item 318.B. of the 2020 *Appropriation Act*. This regulatory action is being utilized to codify permanent regulations following the emergency regulations.

In addition to the mandate from the General Assembly, this regulatory action is needed to incorporate best practices into the Licensing Regulations in order to promote recovery from the disease of addiction, because substance-related disorders affect individuals, their families, the workplace and the general community. Executive Order 9 (2016) declared the opioid addiction crisis a public health emergency in Virginia. Since that time, DBHDS and a number of sister agencies have worked to make policy changes to address the crisis.

## 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.*

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DBHDS was directed by the 2020 General Assembly within the 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. Item 318 of the 2020 Acts of Assembly Chapter 1289 charges the Department to make the changes within this regulatory action. Section 37.2-203 of the Code of Virginia gives the State 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 of Virginia 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.*

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The purpose of this regulatory action is to align Virginia's licensing regulations with the ASAM levels of care criteria. This alignment is necessary to incorporate best practices into the 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 protecting the health and welfare of citizens of Virginia.

Substance related disorders affect individuals needing or receiving services, their families, the workplace, and the general community. An essential component of Virginia's efforts to address the opioid epidemic is ensuring that a range of quality, evidence-based, substance use related services that span the spectrum of levels of care are available throughout the Commonwealth. The alignment of Virginia's licensing regulations with the ASAM criteria will help advance that effort.

## 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.*

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This regulatory action amends the Licensing Regulations to align with the ASAM Levels of Care Criteria which ensures individualized, clinically driven, individual-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:

- 4.0 (Medically managed intensive inpatient services),
- 3.7 (Medically monitored intensive inpatient services),
- 3.5 (Clinically managed high-intensity residential services),
- 3.3 (Clinically managed population-specific high-intensity residential services),
- 3.1 (Clinically managed low-intensity residential services),
- 2.5 (substance abuse partial hospitalization services),
- 2.1 (Substance abuse intensive outpatient services),
- (Substance abuse outpatient services), and
- Medication assisted opioid treatment services.

## 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.*

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The primary advantage of the regulatory change is licensing regulations that incorporate best practices related to treatment of substance related conditions, which in turn will result in citizens receiving more effective treatment of substance related conditions. 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. The requirements regarding opioid treatment programs bring the Licensing Regulations into alignment with the federal regulations regarding Certification and Treatment Standards for Opioid Treatment Programs (42 CFR Part 8 Subpart C).

**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"> <li>a) fund source / fund detail;</li> <li>b) delineation of one-time versus on-going expenditures; and</li> <li>c) whether any costs or revenue loss can be absorbed within existing resources</li> </ul>	<p>DBHDS will incur costs related to the promulgation of regulations, training for providers, and conducting additional inspections. The costs shall be absorbed within existing resources.</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 of the number of small businesses affected. Small business means a business entity, including its affiliates, that:</p> <ul style="list-style-type: none"> <li>a) is independently owned and operated and;</li> <li>b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</li> </ul>	<p>DBDHS approximates that 283 entities will be affected. There is no way to estimate the 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"> <li>a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses;</li> <li>b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change;</li> <li>c) fees;</li> <li>d) purchases of equipment or services; and</li> <li>e) time required to comply with the requirements.</li> </ul>	<p>Approximately 250 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</p>

	<p>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 Licensing Regulations 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.*

Committer	Comment	Agency response
Loudoun MHSADS	<p><b>SA Intensive Outpatient Services 12VAC35-105-1740 Substance abuse intensive outpatient services program criteria</b></p> <ol style="list-style-type: none"> <li>1. Mention of programming in a “structured environment.” What does the agency identify or measure as a structured environment?</li> <li>3. In number 2 there is a requirement that consultation is available within 24 hours by telephone; however, in number 3, emergency consultation is required to be available 24 hours a day. I believe the emergency requirement is requiring instantaneous availability, but the language of number 2 convolutes the meaning of number 3 to a degree. If the intent is instantaneous availability, it would be clarifying to say so.</li> </ol> <p><b>12VAC35-105-1760 Substance abuse intensive outpatient services discharge criteria</b></p> <ol style="list-style-type: none"> <li>2. This point allows discharge when “unable to achieve the</li> </ol>	<p>Questions regarding the content of the regulations and methods to comply are best answered via direct contact with DBDHS rather than through the public comment forum. DBHDS encourages all providers who have questions regarding compliance to attend the Department’s ASAM trainings. Information regarding the Department’s trainings can be found: <a href="https://dbhds.virginia.gov/quality-management/Office-of-Licensing">https://dbhds.virginia.gov/quality-management/Office-of-Licensing</a></p> <p>The removal of the requirement for intensive case management as part of substance abuse outpatient services enhanced co-occurring would mean the service would no longer be in alignment with the ASAM Criteria and would be contradictory to the General Assembly mandate.</p>

	<p>goals of the individual's treatment but could achieve the individual's goals with a different type of treatment." Guidance requested as to how this should be measured and expectations regarding the identification of the individual's ability to achieve goals and identification of the alternative treatment. What about discharge when an individual no longer wishes to achieve the goals of treatment?</p> <p><b><u>12VAC35-105-1820 Substance abuse outpatient services co-occurring enhanced programs</u></b></p> <p>Recommend removing the requirement for intensive case management as part of enhanced co-occurring.</p>	
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**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](mailto: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.*

**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		<p>Provides current definitions for the Licensing Regulations.</p> <p>The following term is being amended: "Medication assisted opioid treatment (Opioid treatment service)" means an intervention strategy that combines outpatient treatment with the administering or dispensing of synthetic narcotics, such as methadone or buprenorphine (suboxone), approved by the federal Food and Drug Administration for the purpose of replacing the use of and reducing the craving for opioid substances, such as heroin or other narcotic drugs.</p>	<p>Change: Adding the following definitions for terms utilized within the ASAM criteria:</p> <ul style="list-style-type: none"> <li>• Allied health professionals;</li> <li>• ASAM;</li> <li>• Clinically managed high-intensity residential care;</li> <li>• Clinically managed low-intensity residential care;</li> <li>• Clinically managed population-specific high-intensity residential services;</li> <li>• Credentialed addiction treatment professional;</li> <li>• Diagnostic and Statistical Manual of Mental Disorders</li> <li>• Intensity of Service;</li> <li>• Medically managed intensive inpatient service;</li> <li>• Medically monitored intensive inpatient treatment</li> <li>• Medication assisted treatment;</li> <li>• Mental health intensive outpatient services;</li> <li>• Mental health outpatient service;</li> <li>• Mental health partial hospitalization service;</li> <li>• Motivational enhancement;</li> <li>• Substance abuse intensive outpatient service;</li> <li>• Substance abuse outpatient service; and</li> <li>• Substance abuse partial hospitalization services.</li> </ul> <p>Removing the following terms which will no longer be used due to alignment with ASAM:</p> <ul style="list-style-type: none"> <li>• Medically managed withdrawal services;</li> <li>• Outpatient service;</li> <li>• Partial hospitalization service;</li> <li>• Social detoxification service; and</li> <li>• Substance abuse intensive outpatient service.</li> </ul> <p>Amending the following terms:</p> <ul style="list-style-type: none"> <li>• Medical detoxification; and</li> <li>• Medication assisted opioid treatment</li> </ul>

<p>12VAC35-105-30. Licenses.</p>		<p>Provides the current list of specific services which require a license</p>	<p>Change: Adding the new ASAM license titles within the list of services which require a license including: Clinically-managed high-intensity residential care; clinically-managed low-intensity residential care; medically managed intensive inpatient service; medically monitored intensive inpatient treatment; medication assisted opioid treatment; mental health intensive outpatient; mental health outpatient; mental health partial hospitalization; specific high-intensity residential; substance abuse outpatient; and substance abuse partial hospitalization.</p> <p>Removal of terms which will not be utilized due to ASAM alignment including:</p> <ul style="list-style-type: none"> <li>• Managed withdrawal, including medical detoxification and social detoxification;</li> <li>• Opioid treatment/medication assisted treatment;</li> <li>• Outpatient; and</li> <li>• Partial hospitalization.</li> </ul> <p>Impact: Clear regulations, some providers may have their license type changed due to the new terminology</p>
<p>12VAC35-105-925. Standards for the evaluation of new licenses for providers of services to individuals with opioid addiction.</p>		<p>Provides the standards for providers of services to individuals with opioid addictions.</p>	<p>Change: Update the requirements of providers of services to individuals with opioid addictions, specifically requirements related to personnel, and minimum services provided.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth.</p>
<p>12VAC35-105-930. Registration certification or accreditation</p>		<p>Provides requirements for opioid treatment services with regard to registration, certification or accreditation</p>	<p>Change: Updating the terminology within the section to reflect the ASAM terminology. Specifically replacing the term “opioid treatment service” with “medication assisted opioid treatment service.”</p> <p>Impact: Clarity of the regulations.</p>
	<p>12VAC35-105-935. Criteria for patient admission.</p>		<p>Change: Adding the required patient admission criteria for providers of services to individuals with opioid addictions.</p>

			Impact: Robust, effective substance use disorder treatment within the Commonwealth.
12VAC35-105-940. Criteria for involuntary termination from treatment.		Provides requirements for opioid treatment services with regard to involuntary termination from treatment	Change: Minor corrections  Impact: Clarity of the regulations.
	12VAC35-105-940. Criteria for patient discharge.		Change: Adding the required patient discharge criteria for providers of services to individuals with opioid addictions.  Impact: Robust, effective substance use disorder treatment within the Commonwealth.
12VAC35-105-950. Service operation schedule.		Provides service operation schedule requirements for providers of opioid treatment services	Change: Adding a requirement that each provider must have a policy that addresses medication for new and at-risk patients within opioid treatment programs.  Impact: Robust, effective substance use disorder treatment within the Commonwealth. Alignment with federal regulations.
12VAC35-105-960. Initial and periodic assessment services.		Provides requirements for the physical examination of individuals receiving opioid treatment services.	Change: Clarifying that the report of the individual's physical examination shall be documented within the individual's service record. Adding the requirement for a consent to treatment form. Adding the requirement for additional coordination by providers to prevent medication duplication.  Impact: Robust, effective substance use disorder treatment within the Commonwealth. Alignment with federal regulations.
	12VAC35-105-965. Special services for pregnant individuals.		Change: Adding the required services for patients who are pregnant and being treatment for opioid addictions.  Impact: Robust, effective substance use disorder treatment within the Commonwealth. Alignment with federal regulations.
12VAC35-105-980. Drug screens.		Provides requirements for opioid treatment services regarding drug screens.	Change: Increasing the requirements to one drug screen per month.  Impact: Robust, effective substance use disorder treatment within the Commonwealth. Alignment with federal regulations.

<p>12VAC35-105-990. Take-home medication.</p>		<p>Provides requirements for opioid treatment services regarding take-home medication.</p>	<p>Change: Adding requirements regarding the determination for approval of take home medication. Adding the requirements regarding the amount of take home medication. Additionally adding that individuals within short-term detoxification are not qualified for unsupervised take home use. Finally requiring that providers maintain policies and procedures to identify the theft or diversion of take-home medication.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth. Alignment with federal regulations.</p>
<p>12VAC35-105-1000. Preventing duplication of medication services.</p>		<p>Requires opioid treatment service providers to take steps to prevent the duplication of opioid treatment services.</p>	<p>Change: Updating the terminology within the section to reflect the ASAM terminology. Specifically replacing the terms “opioid medication services” and “opioid treatment service” to “medication assisted opioid treatment services.”</p> <p>Impact: Clarity of the regulations.</p>
<p>12VAC35-105-1010. Guests</p>		<p>Provides the requirements for opioid treatment service providers with regards to guest medication.</p>	<p>Change: Updating the terminology within the section to reflect the ASAM terminology. Adding a definition of guest.</p> <p>Impact: Clarity of the regulations.</p>
	<p>12VAC35-105- 1420. (Reserved).</p>		<p>Intent: Space saver section.</p>
	<p>12VAC35-105-1430. Medically managed intensive inpatient staff criteria.</p>		<p>Intent: Provide clear staff requirements within medically managed intensive inpatient programs, which are programs provided within an acute care inpatient setting such as an acute care hospital.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth.</p>
	<p>12VAC35-105-1440. Medically managed intensive inpatient program criteria.</p>		<p>Intent: Provide clear program requirements within medically managed intensive inpatient programs which are programs provided within an acute care inpatient setting such as an acute care hospital.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth.</p>

	<p>12VAC35-105-1450. Medically managed intensive inpatient admission criteria.</p>		<p>Intent: Provide clear admission requirements within medically managed intensive inpatient programs.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth which is appropriately administered.</p>
	<p>12VAC35-105-1460. Medically managed intensive inpatient discharge criteria.</p>		<p>Intent: Provide clear discharge requirements within medically managed intensive inpatient programs.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth which is appropriately administered.</p>
	<p>12VAC35-105-1470. Medically managed intensive inpatient co-occurring enhanced programs.</p>		<p>Intent: Provide additional licensing requirements for medically managed intensive inpatient 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>12VAC35-105-1480. Medically monitored intensive inpatient services staff criteria.</p>		<p>Intent: Provide clear staff requirements within medically monitored intensive inpatient treatment programs, which provide 24 hour care in a facility under the supervision of medical personnel providing directed evaluation, observation, and medical monitoring.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth.</p>
	<p>12VAC35-105-1490. Medically monitored intensive inpatient services program criteria.</p>		<p>Intent: Provide clear program requirements within medically monitored intensive inpatient treatment programs, which provide 24 hour care in a facility under the supervision of medical personnel providing directed evaluation, observation, and medical monitoring.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth.</p>
	<p>12VAC35-105-1500. Medically monitored intensive inpatient admission criteria.</p>		<p>Intent: Provide clear admission requirements within medically monitored intensive inpatient programs.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth.</p>

			Commonwealth which is appropriately administered.
	12VAC35-105-1510. Medically monitored intensive inpatient discharge criteria.		<p>Intent: Provide clear discharge requirements within medically monitored intensive inpatient programs.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth which is appropriately administered.</p>
	12VAC35-105-1520. Medically monitored intensive inpatient co-occurring enhanced programs.		<p>Intent: Provide additional licensing requirements for medically monitored intensive inpatient 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>
	12VAC35-105-1530. Clinically managed high-intensity residential services staff criteria		<p>Intent: Provide clear staff requirements within clinically managed high intensity residential care programs, which provide 24 hour supportive treatment. The individuals served by clinically managed high-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>
	12VAC35-105-1540. Clinically managed high-intensity residential services program criteria.		<p>Intent: Provide clear program requirements within clinically managed high intensity residential care programs, which provide 24 hour supportive treatment. The individuals served by clinically managed high-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>
	12VAC35-105-1550. Clinically managed high-intensity residential services		<p>Intent: Provide clear admission requirements within clinically managed high-intensity residential service programs.</p> <p>Impact: Robust, effective substance use disorder treatment within the</p>

	admission criteria.		Commonwealth which is appropriately administered.
	12VAC35-105-1560. Clinically managed high-intensity residential services discharge criteria.		<p>Intent: Provide clear discharge requirements within clinically managed high-intensity residential service programs.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth which is appropriately administered.</p>
	12VAC35-105-1570. Clinically managed high-intensity residential services co-occurring enhanced programs.		<p>Intent: Provide additional licensing requirements for clinically managed high-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>
	12VAC35-105-1580. Clinically managed population-specific high-intensity residential services staff criteria.		<p>Intent: Provide clear staff requirements within high intensity residential services programs, which provide a structured recovery environment in combination with high-intensity clinical services provided in a manner to meet the functional limitations of the individuals served.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth.</p>
	12VAC35-105-1590. Clinically managed population-specific high-intensity residential services program criteria.		<p>Intent: Provide clear program requirements within high intensity residential services programs, which provide a structured recovery environment in combination with high-intensity clinical services provided in a manner to meet the functional limitations of the individuals served.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth.</p>
	12VAC35-105-1600. Clinically managed population-specific high-intensity residential services		<p>Intent: Provide clear admission requirements within high intensity residential services programs.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth which is appropriately administered</p>

	admission criteria.		
	12VAC35-105-1610. Clinically managed population-specific high intensity residential services discharge criteria.		<p>Intent: Provide clear discharge requirements within high intensity residential services programs.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth which is appropriately administered</p>
	12VAC35-105-1620. Clinically managed population-specific high-intensity residential services co-occurring enhanced programs.		<p>Intent: Provide additional licensing requirements for high 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>
	12VAC35-105-1630. Clinically managed low-intensity residential services staff criteria.		<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>
	12VAC35-105-1640. Clinically managed low-intensity residential services program criteria.		<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>
	12VAC35-105-1650. Clinically managed low-intensity residential services admission criteria		<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>
	12VAC35-105-1660.		<p>Intent: Provide clear discharge requirements within clinically managed</p>

	Clinically managed low-intensity residential services discharge criteria.		low – intensity residential service programs.  Impact: Robust, effective substance use disorder treatment within the Commonwealth which is appropriately administered.
	12VAC35-105-1670. Clinically managed low-intensity residential services co-occurring enhanced programs.		Intent: Provide additional licensing requirements for clinically managed low-intensity residential service programs which treat individuals with co-occurring disorders.  Impact: Clarity of the regulations. Clear requirements for providers treating individuals with co-occurring disorders.
	12VAC35-105-1680. Substance abuse partial hospitalization services staff criteria.		Intent: Provide clear staff requirements within partial hospitalization programs, which provide services for individuals who require a more intensive treatment experience than intensive outpatient treatment but who do not require residential treatment.  Impact: Robust, effective substance use disorder treatment within the Commonwealth.
	12VAC35-105-1690. Substance abuse partial hospitalization services.		Intent: Provide clear program requirements within partial hospitalization programs which provide services for individuals who require a more intensive treatment experience than intensive outpatient treatment but who do not require residential treatment.  Impact: Robust, effective substance use disorder treatment within the Commonwealth.
	12VAC35-105-1700. Substance abuse partial hospitalization admission criteria.		Intent: Provide clear admission requirements within partial hospitalization programs.  Impact: Robust, effective substance use disorder treatment within the Commonwealth which is appropriately administered.
	12VAC35-105-1710. Substance abuse partial hospitalization discharge criteria.		Intent: Provide clear discharge requirements within partial hospitalization programs.  Impact: Robust, effective substance use disorder treatment within the Commonwealth which is appropriately administered.

	12VAC35-105-1720. Substance abuse partial hospitalization co-occurring enhanced programs.		<p>Intent: Provide additional licensing requirements for partial hospitalization 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>
	12VAC35-105-1730. Substance abuse intensive outpatient staff criteria.		<p>Intent: Provide clear staff requirements within intensive outpatient service programs, which provide between 9 and 19 hours of structured treatment consisting primarily of counseling and education. Within this level of care an individual's needs for psychiatric and medical services are generally addressed through referrals.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth.</p>
	12VAC35-105-1740. Substance abuse intensive outpatient services program criteria.		<p>Intent: Provide clear program requirements within intensive outpatient programs, which provide between 9 and 19 hours of structured treatment consisting primarily of counseling and education.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth.</p>
	12VAC35-105-1750. Substance abuse intensive outpatient services admission criteria.		<p>Intent: Provide clear admission requirements within intensive outpatient service programs.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth which is appropriately administered.</p>
	12VAC35-105-1760. Substance abuse intensive outpatient services discharge criteria.		<p>Intent: Provide clear discharge requirements within intensive outpatient service programs.</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth which is appropriately administered.</p>
	12VAC35-105-1770. Substance abuse intensive outpatient		<p>Intent: Provide additional licensing requirements for intensive outpatient service programs which treat individuals with co-occurring disorders.</p>

	services co-occurring		Impact: Clarity of the regulations. Clear requirements for providers treating individuals with co-occurring disorders.
	12VAC35-105-1780. Substance abuse outpatient services staff criteria.		Intent: Provide clear staff requirements within outpatient service programs, which provide an organized nonresidential service for fewer than 9 contact hours a week.  Impact: Robust, effective substance use disorder treatment within the Commonwealth.
	12VAC35-105-1790. Substance abuse outpatient services program criteria.		Intent: Provide clear program requirements within outpatient programs, which provide an organized nonresidential service for fewer than 9 contact hours a week.  Impact: Robust, effective substance use disorder treatment within the Commonwealth.
	12VAC35-105-1800. Substance abuse outpatient services admission criteria.		Intent: Provide clear admission requirements within outpatient service programs.  Impact: Robust, effective substance use disorder treatment within the Commonwealth which is appropriately administered.
	12VAC35-105-1810. Substance abuse outpatient services discharge criteria.		Intent: Provide clear discharge requirements within outpatient service programs.  Impact: Robust, effective substance use disorder treatment within the Commonwealth which is appropriately administered.
	12VAC35-105-1820. Substance abuse outpatient services co-occurring enhanced programs.		Intent: Provide additional licensing requirements for outpatient service programs which treat individuals with co-occurring disorders.  Impact: Clarity of the regulations. Clear requirements for providers treating individuals with co-occurring disorders.

Table 3: Changes to the Emergency Regulation

Emergency chapter-section number	New chapter-section number, if applicable	Current <u>emergency</u> requirement	Change, intent, rationale, and likely impact of new or changed requirements since emergency stage
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<p>12VAC35-105-10. Definitions.</p>			<p>Change: Editing the term “medical detoxification” with clarifying language.</p> <p>Editing the term “medication assisted opioid treatment” to include naltrexone as an example of an FDA approved synthetic narcotic utilized for treatment.</p> <p>Impact: Clarity of the regulations.</p>
<p>12VAC35-105-925. Standards for the evaluation of new licenses for providers of services to individuals with opioid addiction.</p>			<p>Change: Aligning the regulations with the requirements within the federal regulations regarding Certification and Treatment Standards for Opioid Treatment Programs (42 CFR Part 8 Subpart C). Specifically incorporating the requirements regarding staffing and minimum program requirements. Due to the addition of the federal requirements to these sections the ASAM provisions regarding staffing and programmatic requirements of medication assisted opioid treatment services were also moved to this section.</p> <p>Impact: Clearer regulations.</p>
	<p>12VAC35-105-935. Criteria for patient admission.</p>		<p>Change: Moving the elements related to ASAM patient admission into the article related to medication assisted opioid treatment so all requirements can be in the same place in the regulations. Incorporating the requirements within the federal regulations regarding Certification and Treatment Standards for Opioid Treatment Programs (42 CFR Part 8 Subpart C).</p> <p>Impact: Clearer regulations. Robust, effective substance use disorder treatment within the Commonwealth which is appropriately administered.</p>
<p>12VAC35-105-940</p>			<p>Change: Correction of a minor typographical error. Clarifying that the signed criteria for involuntary termination from treatment shall be maintained in the individual’s service record. Adding that the individual be provided a copy of the grievance procedure at admission. Clarifying that “Individuals who fail to sign the authorization form shall be denied admission to the program.”</p>

			Impact: Clarity of the regulations.
	12VAC35-105-945. Criteria for patient discharge.		Change: Moving the elements related to ASAM patient discharge into the article related to medication assisted opioid treatment so all requirements can be in the same place in the regulations.  Impact: Clarity of the regulations.
12VAC35-105-950. Service operation schedule			Change: Updating the “state methadone authority” to the “state opioid treatment authority.” Adding the requirement that each program have a policy addressing medication for newly admitted patients and those deemed at risk. This incorporates a requirement within the federal regulations regarding Certification and Treatment Standards for Opioid Treatment Programs (42 CFR Part 8 Subpart C).  Impact: Clarity of the regulations. Robust, effective substance use disorder treatment within the Commonwealth which are aligned with federal requirements.
12VAC35-105-960. Physical examinations	12VAC35-105-960. Initial and periodic assessment services.		Change: Clarifying that physical examinations are exempt only for transfers within the Commonwealth. Adding that the report of the physical examinations shall be within the individual’s service record. Adding the requirement that the program physician shall review the consent to treatment form with the patient prior to treatment. Adding a requirement that the program have a policy to ensure coordination of care to prevent duplication of medications. This incorporates requirements within the federal regulations regarding Certification and Treatment Standards for Opioid Treatment Programs (42 CFR Part 8 Subpart C).  Impact: Clarity of the regulations. Robust, effective substance use disorder treatment within the Commonwealth which are aligned with federal requirements.
	12VAC35-105-965. Special services for		Change: Adding requirements for special services the provider must provide for pregnant individuals. This incorporates requirements within the federal regulations regarding

	pregnant individuals.		<p>Certification and Treatment Standards for Opioid Treatment Programs (42 CFR Part 8 Subpart C).</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth which are aligned with federal requirements.</p>
12VAC35-105-980. Drug screens.			<p>Change: Increasing the number of drug screens to one per month. This incorporates requirements within the federal regulations regarding Certification and Treatment Standards for Opioid Treatment Programs (42 CFR Part 8 Subpart C).</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth which are aligned with federal requirements.</p>
12VAC35-105-990. Take-home medication.			<p>Change: Adding the requirements regarding determinations for take home approval for medication and adding the amount of take home medication that a patient may receive based on their service history. Also adding the requirement that providers have procedures to identify theft or diversion of take home medications. These edits incorporate requirements within the federal regulations regarding Certification and Treatment Standards for Opioid Treatment Programs (42 CFR Part 8 Subpart C).</p> <p>Impact: Robust, effective substance use disorder treatment within the Commonwealth which are aligned with federal requirements.</p>
12VAC35-105-1000. Preventing duplication of medication services.			<p>Change: Additional of minor clarifying language.</p> <p>Impact: Clarity of the regulations.</p>
12VAC35-105-1010. Guests.			<p>Change: Minor clarifying language. Addition of a definition of guest.</p> <p>Impact: Clarity of the regulations.</p>
12VAC35-105-1430. Medically managed intensive inpatient staff criteria.			<p>Change: Clarifying that the interdisciplinary team may include a list of professionals.</p> <p>Impact: Clarity of the regulations.</p>

<p>12VAC35-105-1480. Medically monitored intensive inpatient services staff criteria.</p>			<p>Change: Clarifying that the interdisciplinary team may include a list of professionals.</p> <p>Impact: Clarity of the regulations.</p>
<p>12VAC35-105-1680. Substance abuse partial hospitalization services staff criteria.</p>			<p>Change: Clarifying that the interdisciplinary team may include a list of professionals.</p> <p>Impact: Clarity of the regulations.</p>
<p>12VAC35-105-1730. Substance abuse intensive outpatient services staff criteria.</p>			<p>Change: Clarifying that the interdisciplinary team may include a list of professionals.</p> <p>Impact: Clarity of the regulations.</p>