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Fast-Track Regulation Agency Background Document

Agency name	Department of Medical Assistance Services
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 30-130-5060, 12 VAC 30-60-181
VAC Chapter title(s)	Amount, Duration and Scope of Selected Services, Standards Established and Methods Used to Assure High Quality Care
Action title	Addiction and Recovery Treatment and Substance Use Disorder Services Updates
Date this document prepared	11/1/2021

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.

This regulatory action makes the following changes:

- Expands the substance use disorder service called “Preferred Office-Based Opioid Treatment” (which has been available only to individuals with a primary diagnosis of opioid use disorder) to individuals with a substance-related or addictive disorder, in accordance with the 2021 Appropriations Act, Item 313.PPPPP.
- Incorporates ARTS utilization review modifications that (1) were requested by the provider community; (2) document existing DMAS practices, rather than changes in practice; and (3)

align with the Board of Counseling’s scope of practice for CSAC-Supervisees. There are no costs associated with these changes.

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.

- ARTS=Addiction and Recovery Treatment Services
- CATP=Credentialed Addiction Treatment Professional
- DBHDS=Department of Behavioral Health and Developmental Services
- DMAS=Department of Medical Assistance Services
- ISP=Individual Service Plans
- OBAT=Office-Based Addiction Treatment
- OBOT=Office-Based Opioid Treatment

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.

I hereby approve the foregoing Regulatory Review Summary entitled “Addiction and Recovery Treatment and Substance Use Disorder Services Updates” and adopt the action stated therein. I certify that this final regulatory action has completed all the requirements of the Code of Virginia § 2.2-4012 of the Administrative Process Act.

November 1, 2021
Date

/signature/
Karen Kimsey, Director
Dept. of Medical Assistance 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.”

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

The Code of Virginia § 32.1 325, grants to the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance and to promulgate regulations. The Code of Virginia § 32.1-324, grants the Director of the Department of Medical Assistance Services the authority of the Board when it is not in session.

These regulatory changes are expected to be non-controversial. The full text of the 2021 Appropriations Act, Item 313.PPPPP requiring DMAS to expand the substance use disorder service “Preferred Office-Based Opioid Treatment” to individuals with a substance-related or addictive disorder is included in the Legal Basis section below. A state plan amendment has been approved by CMS and these changes will generally replicate the state plan text in the Virginia Administrative Code.

The ARTS utilization review regulation changes are expected to be non-controversial because they incorporate changes requested by the provider community, make changes that document existing DMAS practices, and make changes to align with the Board of Counseling’s scope of practice for CSAC-Supervisees.

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.

The Code of Virginia § 32.1 325, grants to the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance and to promulgate regulations. The Code of Virginia § 32.1-324, grants the Director of the Department of Medical Assistance Services the authority of the Board when it is not in session.

The 2021 Appropriations Act, Item 313.PPPPP states that: DMAS “shall seek federal authority through waiver and State Plan amendments under Titles XIX and XXI of the Social Security Act to expand the Preferred Office-Based Opioid Treatment (OBOT) model to include individuals with substance use disorders (SUD) that are covered in the Addiction and Recovery Treatment Services (ARTS) benefit.”

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.

The purpose of this action is to expand the substance use disorder service called “Preferred Office-Based Opioid Treatment,” in accordance with a General Assembly mandate and incorporate ARTS utilization review changes. These regulatory changes are essential to protect the health, safety, and welfare of Medicaid members.

The purpose of the General Assembly mandate is to expand the substance use disorder service called “Preferred Office-Based Opioid Treatment” (which has been available only to individuals with a primary diagnosis of opioid use disorder) to individuals with a substance-related or addictive disorder. In 2016, DMAS transformed the Medicaid substance use disorder benefit to address the opioid epidemic. According to data from the Virginia Department of Health, the number of fatal non-opioid illicit drug overdoses is increasing. This mandate allows DMAS to increase member access to preferred office-based addiction treatment to address other forms of substance-related or addictive disorders.

The purpose of the ARTS utilization review change to extend the time for CATPs to sign and date multidimensional assessments and ISPs from one to three days was requested by the provider community. The intent is to reduce the administrative burden on providers and provide more realistic timeframes for completion. The updates to the ARTS utilization review regulations that include: prohibiting health care entities with provisional licenses by DBHDS to be reimbursed as Medicaid providers; changing OBOT to OBAT; and, stating that prescriptions for naloxone must be included in providers’ documentation do not reflect changes in practice, but rather align DMAS regulations with the Department’s existing practices. Lastly, the ARTS utilization regulations are being revised to allow CSAC-Supervisees to complete multidimensional assessments and ISPs in accordance with the Board of Counseling’s scope of practice.

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 2021 Appropriations Act, Item 313.PPPPP, required DMAS to revise the state plan to expand the substance use disorder service called “Preferred Office-Based Opioid Treatment” (which has been available only to individuals with a primary diagnosis of opioid use disorder) to individuals with a substance-related or addictive disorder.

The ARTS utilization review regulation changes incorporate modifications that (1) were requested by the provider community; (2) document existing DMAS practices, rather than changes in practice; and (3) align with the Board of Counseling’s scope of practice for CSAC-Supervisees.

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.

These changes create no disadvantages to the public, the Agency, the Commonwealth, or the regulated community.

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.

There are no requirements in this regulation that are more restrictive than 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.

No state agencies, localities, or other entities are particularly affected by this change.

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: 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>	<p>For the 2021 Appropriations Act, Item 313.PPPPP, the General Assembly allocated the following funds for FY2022. General: \$881,306 Non-General: \$1,296,254 These costs are expected to be on-going expenditures. There is no anticipation that such costs can be absorbed within existing resources.</p> <p>There are no costs associated with the ARTS Utilization Review changes.</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</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>The benefit of the 2021 Appropriations Act, Item 313.PPPPP is expanded access to the substance use disorder service called</p>

	<p>“Preferred Office-Based Opioid Treatment” (which has been available only to individuals with a primary diagnosis of opioid use disorder) to individuals with a substance-related or addictive disorder.</p> <p>The benefits of the ARTS Utilization Review changes are to reduce the administrative burden on providers, and to align DMAS regulations with existing practices and with the Board of Counseling’s scope of practice for CSAC-Supervisees.</p>
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Impact on Localities

<p>Projected costs, savings, fees or revenues resulting from the regulatory change.</p>	<p>None</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The benefit of the 2021 Appropriations Act, Item 313.PPPPP is expanded access to the substance use disorder service called “Preferred Office-Based Opioid Treatment” (which has been available only to individuals with a primary diagnosis of opioid use disorder) to individuals with a substance-related or addictive disorder.</p> <p>The benefits of the ARTS Utilization Review changes are to reduce the administrative burden on providers, and to align DMAS regulations with existing practices and with the Board of Counseling’s scope of practice for CSAC-Supervisees.</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>Medicaid Preferred Office-Based Opioid Treatment providers being able to be reimbursed for providing services to members with primary substance use disorder diagnoses other than opioid use disorder.</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> <p>a) is independently owned and operated and;</p> <p>b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>Preferred Office Based Opioid Treatment Providers: 178 sites</p> <ul style="list-style-type: none"> • 52 sites are Community Services Boards • 8 sites are Federally Qualified Health Centers • Remaining are private providers/clinics.
<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> <p>a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses;</p>	<p>There are no costs associated with reporting/recordkeeping, development of real estate, fees, or purchases of equipment.</p>

<p>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>	
<p>Benefits the regulatory change is designed to produce.</p>	<p>The benefit of the 2021 Appropriations Act, Item 313.PPPPP is expanded access to the substance use disorder service called “Preferred Office-Based Opioid Treatment” (which has been available only to individuals with a primary diagnosis of opioid use disorder) to individuals with a substance-related or addictive disorder.</p> <p>The benefits of the ARTS Utilization Review changes are to reduce the administrative burden on providers, and to align DMAS regulations with existing practices and with the Board of Counseling’s scope of practice for CSAC-Supervisees.</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.

No alternative methods will accomplish the objectives of the General Assembly mandate to expand the substance use disorder service called “Preferred Office-Based Opioid Treatment” (which has been available only to individuals with a primary diagnosis of opioid use disorder) to individuals with a substance-related or addictive disorder. In 2016, DMAS transformed the Medicaid substance use disorder benefit to address the opioid epidemic. According to data from the Virginia Department of Health, the number of fatal non-opioid illicit drug overdoses is increasing. This mandate allows DMAS to increase member access to preferred office-based addiction treatment to address other forms of substance-related or addictive disorders.

No alternatives can achieve the purposes of the ARTS Utilization Review regulatory changes, which include (1) extending the time for CATPs to sign and date multidimensional assessments and ISPs from one to three days to reduce the administrative burden on providers and provide more realistic timeframes for completion, (2) documentation of existing DMAS practices that prohibit health care entities with provisional licenses by DBHDS to be reimbursed as Medicaid providers, change OBOT to OBAT, and require prescriptions for naloxone be included in providers’ documentation, and (3) allowing CSAC-Supervisees to complete multidimensional assessments and ISPs to align with the Board of Counseling’s scope of practice.

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.

No alternatives can achieve the objective of the General Assembly mandate, the purpose of the ARTS Utilization Review regulatory changes, or the purpose of incorporating the ARTS residential levels of care reimbursement methodology.

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.

As required by § 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.

DMAS 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 Meredith Lee, DMAS, 600 E. Broad Street, Richmond, VA 23219, 804-371-0552, Meredith.lee@dmas.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
12 VAC 30-60-181		No reference to CSAC-Supervisees.	Text changes are made to document existing DMAS practice that CSAC-Supervisees can complete multidimensional assessments and ISPs under supervision.
		References one business day.	Text changes are made to reflect an approved stakeholder request to extend the time for CATPs to sign and date multidimensional assessments and ISPs to three business days.
		No references to OBAT.	Text changes are made to change OBOT to OBAT.
		No reference to prescriptions for naloxone.	Text changes are made to document existing DMAS practice that requires prescriptions for naloxone be included in providers' documentation.
		No reference to provisional licenses.	Text changes are made to document existing DMAS practice that prohibits health care entities with provisional licenses by DBHDS to be reimbursed as Medicaid providers.
12 VAC 30-130-5060		No references to OBAT.	Text changes are made to expand the substance use disorder service "Preferred Office-Based Opioid Treatment" (which has been available only to individuals with a primary diagnosis of opioid use disorder) to individuals with a substance-related or addictive disorder.