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Fast-Track Regulation Agency Background Document

Agency name	DEPT. OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) citation(s)	12VAC30-60-181 Utilization review of addiction and recovery treatment services 12VAC30-60-185 Utilization review of substance use case management 12VAC30-80-32 Reimbursement for substance use disorder services 12VAC30-130-5010 Addiction and recovery treatment services; purpose 12VAC30-130-5020 Definitions 12VAC30-130-5030 Eligible individuals 12VAC30-130-5040 Covered services: requirements; limits; standards 12VAC30-130-5050 Covered services: clinic services - opioid treatment services 12VAC30-130-5060 Covered services: clinic services - office-based opioid treatment 12VAC30-130-5070 Covered services: practitioner services - early intervention/screening brief intervention and referral to treatment (Level 0.5) 12VAC30-130-5080 Covered services: outpatient services - physician services (Level 1.0) 12VAC30-130-5090 Covered services: community based services - intensive outpatient services (Level 2.1) 12VAC30-130-5100 Covered services: community based care - partial hospitalization services (Level 2.5) 12VAC30-130-5110 Covered services: clinically managed low intensity residential services (Level 3.1) 12VAC30-130-5120 Covered services: clinically managed population - specific high intensity residential service (Level 3.3)

	<p>12VAC30-130-5130 Covered services: clinically managed high intensity residential services (adult) and clinically managed medium intensity residential services...</p> <p>12VAC30-130-5140 Covered services: medically monitored intensive inpatient services (adult) and medically monitored high intensity inpatient services (adolescent)...</p> <p>12VAC30-130-5150 Covered services: medically managed intensive inpatient services (Level 4.0)</p>
Regulation title(s)	Same as above
Action title	ARTS Updates
Date this document prepared	

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 (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

Brief Summary

Please 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 Addiction and Recovery Treatment Services (ARTS) program regulations became effective on April 1, 2017. Now, almost two years later, the regulations need modifications to address program needs, to answer questions that have been raised by providers, and to incorporate the requirements of guidance documents that have been published by CMS (requiring Medicaid agencies to assess Medicaid members to determine if medication assisted treatment is needed), the Virginia Board of Counseling (defining the scope of practice for certified substance abuse counselors, and including substance use disorder counseling within that scope), and DMAS (related to telemedicine requirements).

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the “Definition” section of the regulations.

- ARTS = Addiction and Recovery Treatment Services
- CATP = Credentialed Addiction Treatment Professional
- CMS = Centers for Medicare and Medicaid Services
- CSAC = certified substance abuse counselors
- DMAS = Department of Medical Assistance Services
- ISP = Individual Service Plan
- MAT = Medication Assisted Treatment

Statement of Final Agency Action

Please 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 “ARTS Updates” and adopt the action stated therein. I certify that this final regulatory action has completed all the requirements of the Code of Virginia § 2.2-4012.1, of the Administrative Process Act.

August 12, 2019
Date

/signature/
Jennifer S. Lee, M.D., Director
Dept. of Medical Assistance Services

Mandate and Impetus

Please 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, board decision, etc.). 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, please also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

These regulations are expected to be non-controversial. The initial ARTS regulations were non-controversial even though they implemented new substance use programs. These updates do not restrict services or negatively impact providers or Medicaid members. Instead, they provide clarification and help to answer questions raised by providers since the initial ARTS implementation.

Legal Basis

Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity’s overall regulatory authority.

Section 32.1-325 of the Code of Virginia authorizes the Board of Medical Assistance Services to administer and amend the State Plan for Medical Assistance and to promulgate regulations. Section 32.1-324 of the Code of Virginia grants the Director of the Department of Medical Assistance Services the authority of the Board when it is not in session. The Medicaid authority established by § 1902 (a) of the Social Security Act (42 USC § 1396a) provides governing authority for payments for services.

Purpose

Please 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.

These changes are essential to protect the health, safety, and welfare of citizens in that they clarify existing rules for the ARTS program, in order to make it easier for providers to understand program rules, and in order to make these services more accessible to Medicaid members.

Substance

Please 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 changes in this regulatory package seek to streamline, simplify, and clarify existing requirements for ARTS services and ARTS providers. The changes include:

- 1) Changing references from "the BHSA" to "DMAS or its contractor" because the BHSA contract will be ending.
- 2) Correcting outdated citations.
- 3) Clarifying the roles and responsibilities of credentialed addiction treatment professionals (CATPs), certified substance abuse counselors (CSACs), and certified substance abuse counselor-assistants (CSAC-As). CATPs are licensed or registered with various Boards through the Department of Health Professions, while CSACs and CSAC-As are lower-level staff who are certified through the Board of Counseling. Defining these roles allows lower-level staff to perform tasks appropriate to their skill level, which frees up CATPs to perform higher-level skills. The Board of Counseling recently posted a guidance document that reflects this change, and DMAS seeks to match its requirements to the requirements of the Board of Counseling: <https://www.dhp.virginia.gov/counseling/guidelines/115-11.docx>
- 4) Providing additional clarity on substance use disorder counseling, psychotherapy, and counseling. Substance use disorder counseling can be provided by CSACs as part of their scope of practice as defined by the Board of Counseling, while psychotherapy and counseling may only be provided by licensed staff.
- 5) Providing additional clarity about medication assisted treatment (MAT). CMS requires Medicaid agencies to assess members to determine if they need MAT, and requires MAT to be provided on-site or through referral in intensive outpatient, partial hospitalization and residential levels of care. The CMS guidance document can be accessed at: <https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf> and is entitled, "States Shall Demonstrate Sufficient Provider Capacity at Critical Levels of Care including for Medication Assisted Treatment for OUD."

- 6) Clarifying the telemedicine definition to include the requirements of a 2014 Medicaid memo to providers. The definition of “face to face” was broadened to include the use of telemedicine so that telemedicine can be used to provide ARTS services. The 2014 memo can be accessed at: <https://www.virginiamedicaid.dmas.virginia.gov/wps/portal/MedicaidMemostoProviders> by searching for the Memo dated May 13, 2014.
- 7) Removing the hard limits on intensive outpatient treatment in compliance with the Mental Health Parity and Addiction Equity Act. (Pub. L. 110-343.)
- 8) In response to a public comment received during the original implementation of the ARTS program, clarifying that drug screening may be conducted using urine or blood serums.

Issues

Please 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 these regulatory changes is that they streamline and simplify existing requirements for ARTS services and provide additional clarity to ARTS providers. There are no disadvantages to the public, the agency, or the Commonwealth as a result of these changes.

Requirements More Restrictive than Federal

Please 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

Please 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, please 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. Please keep in mind that this is change versus the status quo.

Impact on State Agencies

<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	None
<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.	None
<i>For all agencies:</i> Benefits the regulatory change is designed to produce.	Clarification and updates to existing policies.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	None
Benefits the regulatory change is designed to produce.	Clarification and updates to existing policies.

Impact on Other Entities

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.	ARTS Providers
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	As of February 2019, the following are numbers of providers by level of care: Level 1.0/Outpatient: 2,965 Level 2.1/Intensive Outpatient: 137 Level 2.5/Partial Hospitalization: 22 Level 3.1-3.7/Group Home-Residential-Inpatient: 96 Level 4.0/Acute Inpatient: 103 Opioid Treatment Programs: 39 Preferred Office-Based Opioid Treatment: 103 ARTS providers in Virginia, and it is estimated that a large majority of these are small businesses.

<p>All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please 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>None</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>Clarification and updates to existing policies.</p>

Alternatives

Please 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 alternatives would clarify and update the existing regulatory policies for the ARTS program.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please 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.

This regulatory change will affect ARTS providers, many of which are small businesses. No other alternatives are available to replace the regulations, which describe ARTS services and service requirements. However, these changes seek to simplify and streamline regulatory requirements in several ways. For example, the changes seek to allow ARTS providers to employ lower-level qualified staff to complete tasks not requiring a licensed practitioner, which could decrease provider expenditures.

Public Participation

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.

Detail of Changes

Please 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.

If the regulatory change will be a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory change. Delete inapplicable tables.

If the regulatory change is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below. Please include citations to the specific section(s) of the regulation that are changing.

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
All			Throughout this regulatory package: <ul style="list-style-type: none"> - References to the BHSA are changed to “DMAS or its contractor” because the BHSA contract will be ending in 2020. - The roles and responsibilities of credentialed addiction treatment professionals (CATPs), certified substance abuse counselors (CSACs), certified substance abuse counselor-assistants (CSAC-As), and certified substance abuse counselor – supervisees are clarified in accordance with a guidance document issued by the Virginia Board of Counseling, as detailed in the “Substance” section above. CATPs are licensed or registered, while CSACs, CSAC-As, and CSAC-supervisees are lower-level staff who are certified. Defining these roles allows lower-level staff to perform tasks appropriate to their skill level, which frees up CATPs to perform higher-level skills.

			- Outdated citations are corrected.
12 VAC 30-60-181 F		ISP requirements are established.	Medication assisted treatment is added as an item to be addressed in the ISP if needed by the individual. This is required by CMS, as detailed in the "Substance" section above.
12 VAC 30-60-181 G			Progress note requirements are clarified according to guidance from the OAG.
			Documentation of assessment and referral for medication assisted treatment is required if medically indicated, as required by a CMS guidance document as detailed in the "Substance" section above.
12 VAC 30-60-185			The term "face to face" is added to the definitions. The term includes services provided via telemedicine.
	12VAC30-70-418		A new section on reimbursement for residential and inpatient substance use treatment services.
12 VAC 30-80-32			The term "substance use disorder counseling" is added; it can be provided by CSACs. Counseling and psychotherapy are different in that they can only be provided by licensed individuals.
12 VAC 30-80-32 D			Rates for low-intensity residential services are added. These had been inadvertently omitted from the first version of the ARTS regulations.
12 VAC 30-130-5020			<p>Definition were added for "addiction-credentialed physician," "ARTS care coordinator," "biomedical," "CSAC," "CSAC-A," "CSAC-supervisee," "counseling," "evidence-based," "face to face," (now includes telemedicine) "induction phase," "licensed practical nurse," "medication assisted treatment," "program of assertive community treatment," "psychoeducation," "psychotherapy," "substance use disorder counseling," (referring to the definition set forth in regulations promulgated by the Board of Counseling) and "tolerance."</p> <p>Definitions were revised for "buprenorphine-waivered," (this term was updated with current requirements) "care coordination," "credentialed addiction treatment professional," (broadened to include physician extenders) "ISP," (to tailor the definition</p>

			<p>to ARTS services rather than borrowing a definition from community mental health services) “office-based opioid treatment,” “opioid treatment program,” “opioid treatment services,” “physician extender,” “registered nurse,” “SBIRT,” “substance use care coordinator,” “substance use disorder,” “tolerance” and “telemedicine.” (The definition of telemedicine clarifies what “via electronic means” includes, according to a 2014 Medicaid Memo to providers.)</p> <p>Definitions that were not used in the text were stricken.</p>
12 VAC 30-130-5030			<p>References to GAP enrollees were removed, as these individuals are now part of the Medicaid expansion population.</p>
12 VAC 30-130-5040 A 1 and 2			<p>Clarifying information was added about primary and secondary diagnoses.</p> <p>References to opioid treatment services were clarified</p>
12 VAC 30-130-5040 B			<p>Text about diagnoses was clarified.</p>
12 VAC 30-130-5050			<p>Staffing requirements incorporate a DBHDS guidance document.</p> <p>Text about what services can be provided simultaneously with opioid treatment programs was clarified.</p> <p>Staffing requirements for medication administration were clarified.</p> <p>Naloxone prescribing, pregnancy testing, and family planning were added to opioid treatment programs.</p> <p>Interdisciplinary team staff requirements were clarified.</p> <p>Requirements for drug screening were clarified, including that drug screening may be conducted using urine or blood serums.</p> <p>Education requirements were clarified.</p> <p>Requirements for testing for infectious diseases were clarified.</p>
12VAC30-130-5060			<p>Requirements for dispensing and prescribing naloxone were clarified.</p>

			<p>Clarified requirements for medication administration, pregnancy testing, and family planning.</p> <p>Requirements for drug screening were clarified, including that drug screening may be conducted using urine or blood serums.</p> <p>Clarifying that drug screening may be conducted using urine or blood serums.</p>
12VAC 30-130-5070			Clarifies that billing should occur through the licensed provider or agency.
12VAC30-130-5080			<p>Staff qualifications are clarified.</p> <p>The definition of “co-occurring disorders” is only used once, so the definition was added to this section where the term is used.</p>
12VAC30-130-5090			Intensive outpatient treatment – limits were softened to average limits in compliance with the Mental Health Parity and Addiction Equity Act. Additional services were added to the list of services that can be provided if included in the ISP. Staff requirements were broadened to include CSACs and physician extenders.
12VAC30-130-5100			Partial hospitalization services – changes adding substance use disorder counseling, MAT, CSACs, and physician extenders.
12VAC30-130-5110			Low-intensity residential services - changes adding substance use disorder counseling, MAT, CSACs, and physician extenders.
12VAC30-130-5120			<p>Specific high-intensity residential services – clarification of DBHDS licensure requirements, adding buprenorphine (as part of MAT), substance use disorder counseling, and CSACs.</p> <p>Clarifying that drug screening may be conducted using urine or blood serums.</p>
12VAC30-130-5130			Clinically managed high/medium intensity residential services - clarification of DBHDS licensure requirements, adding MAT, substance use disorder counseling, psychoeducational activities, and physician extenders.
12VAC30-130-5140			Medically monitored inpatient services - clarification of DBHDS licensure

			requirements, adding MAT, substance use disorder counseling, psychoeducational activities, telemedicine, physician extenders.
12VAC30-130-5150			Medically managed intensive inpatient - adding substance use disorder counseling and physician extenders.