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Fast-Track Regulation Agency Background Document

Agency name	Department of Medical Assistance Services
Virginia Administrative Code (VAC) citation(s)	Addiction and Recovery Treatment Services (ARTS) (12 VAC 30 – 130- 5000 et seq.); Chapter 50 Amount, Duration, and Scope of Services: Inpatient Hospital Services (12 VAC 30-50-100); Outpatient Hospital, FQHCs and RHCs (12 VAC 30-50-110); EPSDT (12 VAC 30-50-130); Physician Services (12 VAC 30-50-140); Other Practitioners (12 VAC 30-50-150); Clinic Services (12 VAC 30-50-180); Substance Use Disorder Case Management (12 VAC 30-50-491); Expanded Pre-natal Care (12 VAC 30-50-510); Chapter 60: Utilization control Substance Use Treatment (12 VAC 30-60-181); Utilization control Case Management (12 VAC 30-60-185); Chapter 70 Inpatient Hospital Reimbursement (12 VAC 30-70-201, 12 VAC 30-70-415; 12 VAC 30-70-417); Chapter 80 Reimbursement for Other Provider Types: Substance abuse services (12 VAC 30-80-32); REPEALED: Chapter 50 Amount, Duration, and Scope of Services Community Substance Abuse Treatment Services (12 VAC 30-50-228); Chapter 60: Substance Abuse Treatment Services and Case Management Utilization Control (12 VAC 30-60-147 and 12 VAC 30-60-180); Chapter 130 Community Mental Health Mental Retardation Services (12 VAC 30-130-540 through 12 VAC 30-130-590)
Regulation title(s)	Amount, Duration, and Scope of Selected Services
Action title	Addiction and Recovery Treatment Services (ARTS)
Date this document prepared	November 14, 2016

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The Department of Medical Assistance Services is proposing a new program, called Addiction and Recovery Treatment Services (ARTS), which will provide a comprehensive continuum of addiction and recovery treatment services based on the American Society of Addiction Medicine (ASAM) Patient Placement Criteria. This will include: (i) inpatient withdrawal management services; (ii) residential treatment services; (iii) partial hospitalization; (iv) intensive outpatient treatment; (v) outpatient treatment including Medication Assisted Treatment (MAT); and (vi) peer recovery supports. Providers will be credentialed and trained to deliver these services consistent with ASAM's published criteria and using evidence-based best practices including Screening, Brief Intervention and Referral to Treatment (SBIRT) and Medication Assisted Treatment (MAT).

These new and revised services will be offered through Medicaid managed care organizations as well as via the fee-for-service delivery system to promote the full integration of coordinated physical health, traditional mental health, and addiction treatment services. DMAS will be administering these services under the authority of the State Plan for Medical Assistance and a federal demonstration waiver (the *Social Security Act* § 1115). DMAS submitted its waiver application to the Centers for Medicare and Medicaid Services on August 5, 2016.

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 Addiction and Recovery Treatment Services (ARTS) with the attached amended regulations Addiction and Recovery Treatment Services (ARTS) (12 VAC 30 – 130- 5000 et seq.); Chapter 50 Amount, Duration, and Scope of Services: Inpatient Hospital Services (12 VAC 30-50-100); Outpatient Hospital, FQHCs and RHCs (12 VAC 30-50-110); EPSDT (12 VAC 30-50-130); Physician Services (12 VAC 30-50-140); Other Practitioners (12 VAC 30-50-150); Clinic Services (12 VAC 30-50-180); Substance Use Disorder Case Management (12 VAC 30-50-491); Expanded Pre-natal Care (12 VAC 30-50-510); Chapter 60: Utilization control Substance Use Treatment (12 VAC 30-60-181); Utilization control Case Management (12 VAC 30-60-185); Chapter 70 Inpatient Hospital Reimbursement (12 VAC 30-70-201, 12 VAC 30-70-415; 12 VAC 30-70-417); Chapter 80 Reimbursement for Other Provider Types: Substance abuse services (12 VAC 30-80-32); REPEALED: Chapter 50 Amount, Duration, and Scope of Services Community Substance Abuse Treatment Services (12 VAC 30-50-228); Chapter 60: Substance Abuse Treatment Services and Case Management Utilization Control (12 VAC 30-60-147 and 12 VAC 30-60-180); Chapter 130 Community Mental Health Mental Retardation Services (12 VAC 30-130-540)

through 12 VAC 30-130-590) and adopt the action stated therein. I certify that this fast track regulatory action has completed all the requirements of the Code of Virginia § 2.2-4012.1, of the Administrative Process Act.

Date

Cynthia B. Jones, Director
Dept. of Medical Assistance Services

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 means the Addiction and Recovery Treatment Services.
- ASAM means the American Society of Addiction Medicine.
- BHSA (Magellan) means the Behavioral Health Services Administrator contracted with DMAS.
- CSB/BHA" means Community Services Board or Behavioral Health Authority.
- DSM means the Diagnostic and Statistical Manual.
- EPSDT means Early and Periodic Screening, Diagnosis and Treatment services.
- IMDs means Institutions for Mental Disease.
- FQHCs means Federally Qualified Healthcare Centers which are typically located in medically underserved areas of the Commonwealth.
- LOC means level of care.
- MAT means Medication Assisted Treatment
- NCQA means the National Committee for Quality Assurance.
- PCP means the primary care physician.
- SBIRT means Screening, Brief Intervention and Referral to Treatment.
- SUD means substance use disorder.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

The *Code of Virginia* (1950) as amended, § 32.1-325, grants to the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance. The *Code of Virginia* (1950) as amended, § 32.1-324, authorizes the Director of DMAS to administer and amend the Plan for Medical Assistance according to the Board's requirements. The Medicaid

authority as established by § 1902 (a) of the *Social Security Act* [42 U.S.C. 1396a] provides governing authority for payments for services.

The *2016 Acts of the Assembly*, Chapter 780, Item 306 MMMM directed:

1. "The Department of Medical Assistance Services, in consultation with the appropriate stakeholders, shall amend the state plan for medical assistance and/or seek federal authority through an 1115 demonstration waiver, as soon as feasible, to provide coverage of inpatient detoxification, inpatient substance abuse treatment, residential detoxification, residential substance abuse treatment, and peer support services to Medicaid individuals in the Fee-for-Service and Managed Care Delivery Systems. The department shall have the authority to implement this change effective upon passage of this Act, and prior to the completion of any regulatory process undertaken in order to effect such change."
2. "The Department of Medical Assistance Services shall make programmatic changes in the provision of all Substance Abuse Treatment Outpatient, Community Based and Residential Treatment services (group homes and facilities) for individuals with substance abuse disorders in order to ensure parity between the substance abuse treatment services and the medical and mental health services covered by the department and to ensure comprehensive treatment planning and care coordination for individuals receiving behavioral health and substance use disorder services. The department shall take action to ensure appropriate utilization and cost efficiency, and adjust reimbursement rates within the limits of the funding appropriated for this purpose based on current industry standards. The department shall consider all available options including, but not limited to, service definitions, prior authorization, utilization review, provider qualifications, and reimbursement rates for the following Medicaid services: substance abuse day treatment for pregnant women, substance abuse residential treatment for pregnant women, substance abuse case management, opioid treatment, substance abuse day treatment, and substance abuse intensive outpatient. The department shall have the authority to implement this change effective upon passage of this Act, and prior to the completion of any regulatory process undertaken in order to effect such change."
3. "The Department of Medical Assistance Services shall amend the State Plan for Medical Assistance and any waivers thereof to include peer support services to children and adults with mental health conditions and/or substance use disorders. The department shall work with its contractors, the Department of Behavioral Health and Developmental Services, and appropriate stakeholders to develop service definitions, utilization review criteria and provider qualifications. The department shall have the authority to implement this change effective upon passage of this Act, and prior to the completion of any regulatory process undertaken in order to effect such change."
4. "The Department of Medical Assistance Services shall amend the State Plan for Medical Assistance shall, prior to the submission of any state plan amendment or waivers to implement paragraphs MMMM 1, MMMM 2, and MMMM 3, submit a plan detailing the changes in provider rates, new services added and any other programmatic changes to the Chairmen of the House Appropriations and Senate Finance Committees."

Purpose

*Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. **Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens.** Discuss the goals of the proposal and the problems the proposal is intended to solve.*

The Commonwealth is currently experiencing a crisis of substance use of overwhelming proportions. More Virginians died from drug overdose in 2013 than from automobile accidents. In 2014, 80% of the people who died from drug overdoses (986 people) died from prescription opioid or heroin overdoses. Virginia's 1.1 million Medicaid/FAMIS members are affected disproportionately by this substance use epidemic as demonstrated by DMAS' claims history data showing 216,555 Medicaid members with a substance use diagnosis in state fiscal year 2015. This regulatory action has a direct, specific impact on the health, safety, and welfare of the Commonwealth's Medicaid individuals.

This action implements a comprehensive program of community-based addiction and recovery treatment services in response to the Governor's bipartisan Task Force on Prescription Drug and Heroin Addiction's numerous recommendations. A major recommendation of this Task Force was to increase access to treatment for opioid addiction for the Commonwealth's Medicaid members by increasing Medicaid reimbursement rates for these services, because data shows that these individuals are being disproportionately impacted by the substance use epidemic.

Rationale for using fast-track process

*Please **explain the rationale for using the fast-track process** in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?*

This regulatory action is being promulgated as a fast track action because public comments received about the general concept and features which have been specified to date have been positive. The comprehensive ARTS proposal is such a substantial improvement over the current fragmented approach to substance use treatment that the affected entities are actively participating with DMAS in its redesign and transformation efforts.

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 regulations affected by this action are the newly created Addiction and Recovery Treatment Services (ARTS) (12 VAC 30-130-5000 et seq.) Sections of the State Plan for Medical Assistance (and related regulations) recommended for modification or repeal are as follows

Chapter 50 Amount, Duration, and Scope of Services: Inpatient Hospital Services (12 VAC 30-50-100); EPSDT (12 VAC 30-50-130); Physician Services (12 VAC 30-50-140); Other Practitioners (12 VAC 30-50-150); Clinic Services (12 VAC 30-50-180); Axis I Case Management (12 VAC 30-50-491); Expanded Pre-natal Care (12 VAC 30-50-510); Chapter 60: Utilization control Freestanding Psychiatric Hospital services (12 VAC 30-60-25); Utilization control Substance Use Treatment (12 VAC 30-60-147); Utilization control Community Substance Use Treatment (12 VAC 30-60-180); Utilization control Case Management (12 VAC 30-60-185); Chapter 80: Inpatient Psychiatric Services in Residential Treatment Facilities under EPSDT (12 VAC 30-80-21); Reimbursement for Substance Abuse Services (12 VAC 30-80-32); Chapter 130 Community Mental Health Mental Retardation Services (12 VAC 30-130-540 through 12 VAC 30-130-590) (REPEALED).

CURRENT POLICY

DMAS covers approximately 1.1 million individuals: 80% of members receive care through contracted managed care organizations (MCOs) and 20% of members receive care through fee-for-service (FFS). The majority of members enrolled in Virginia's Medicaid and FAMIS programs include children, pregnant women, and individuals who meet the disability category of being aged, blind, or disabled. The 20% of the individuals receiving care through fee for service do so because they meet one of 16 categories of exception to MCO participation, for example: (i) inpatients in state mental hospitals, long-stay hospitals, nursing facilities, or ICF/IIDs; (ii) individuals on spend down; (iii) individuals younger than 21 years of age who are in residential treatment facility Level C programs; (iv) newly eligible individuals in their third trimester of pregnancy; (v) individuals who permanently live outside their area of residence; (vi) individuals receiving hospice services; (vii) individuals with other comprehensive group or individual health insurance; (viii) individuals eligible for Individuals with Disabilities Education Act (IDEA) Part C services; (ix) individuals whose eligibility period is less than 3 months or is retroactive, and; (x) individuals enrolled in the Virginia Birth-Related Neurological Injury Compensation Program.

Historically, Virginia funded only limited kinds of substance use treatment services to limited populations of Medicaid eligible individuals (for example, pregnant women and children). The Commonwealth now has compelling reasons to provide Medicaid coverage for the identification and treatment of substance use disorders: individuals with substance use disorders and comorbid medical conditions account for high Medicaid costs. Beyond health care risk, the economic costs associated with substance use disorders are significant. States and the federal government spend billions of tax dollars every year on the collateral impact associated with substance use disorders, including criminal justice, public assistance and lost productivity costs. From 1999 to 2013, the rate for drug poisoning deaths involving opioid analgesics nearly quadrupled across the nation.

Within the current system, non-traditional community-based addiction treatment services are "carved out" (excluded from coverage) of the MCOs and managed by Magellan, the Behavioral Health Service Administrator (BHSA) contractor for DMAS. For members enrolled in FFS, Magellan covers all traditional and non-traditional addiction treatment services. The non-traditional services include:

- Residential Treatment,
- Opioid Treatment (outpatient counseling with MAT),
- Day Treatment,
- Crisis Intervention,
- Intensive Outpatient Treatment, and
- Case Management.

The “carve out” of the community-based addiction treatment services from MCOs contributed to Virginia’s historically fragmented system in which poorly funded community-based addiction treatment services are delivered in distinct siloes separated from traditional mental health and physical health services. Providers who deliver these services have complained that the Medicaid reimbursement rates are lower than the cost of providing care and have struggled to understand who to bill for services. Patients have struggled to understand where to seek services.

Furthermore, the rate structure for addiction treatment services has not been adjusted since 2007 when DMAS first started reimbursing for addiction treatment services. Low reimbursement rates have severely limited the number of providers willing to provide these services to Medicaid and FAMIS members and resulted in inadequate access to treatment. DMAS only spent approximately \$2 million on community-based addiction treatment services in State Fiscal Year 2015 and served an average of 734 people per month, demonstrating the underutilization of these services considering the number of Virginians being seen in hospitals/emergency rooms with substance use diagnoses.

If DMAS continues reimbursing at the current low rates for substance use disorder treatment, low utilization of this benefit will continue and it will only be available to limited groups of members (children and pregnant women). If DMAS continues the current benefit package, it will continue to not provide coverage of peer support services for any members and would not cover inpatient and short-term residential detoxification and outpatient substance use disorder treatment for any non-pregnant adult members.

Medicaid, FAMIS and FAMIS MOMS members with diagnoses of substance use disorders (SUD) will continue to experience high rates of hospitalizations and hospital emergency department visits that could be prevented if adequate residential treatment, outpatient treatment, and peer supports were available and accessible.

RECOMMENDATIONS

To address the fragmentation of services and siloes, Virginia sought the authority to fully integrate physical and behavioral health services for individuals with SUD and to expand access to the full array of services for individuals with SUD. DMAS obtained approval from the Governor and General Assembly to “carve in” community-based SUD/ARTS treatment services into managed care plans for members who are already enrolled in MCOs. CMS recommends the use evidence based practice for the treatment of addictive, substance-related conditions as published by the American Society of Addiction Medicine (ASAM).

Since the MCOs already manage all the physical health services as well as the inpatient services, outpatient services, and medications for mental health and substance use, “carving in” the community-based ARTS services will allow the health plans to provide their enrolled members with the full array of all services based on members' levels of need. Magellan will continue to cover these services for those Medicaid members who are enrolled in FFS.

The ARTS waiver was necessary to provide Virginia the authority, and related federal financial participation, to provide coverage of short-term inpatient detox and residential substance use disorder in treatment facilities with greater than 16 beds. This will align Medicaid FFS residential treatment coverage with the CMS Medicaid and CHIP Managed Care Final Rule (CMS-2390-F). The expanded coverage of residential detoxification and residential substance use disorder treatment will be available for all Medicaid enrolled members and will be integrated with the full continuum of addiction treatment services. Seamless care transitions will occur from residential treatment to lower levels of care such as intensive outpatient and outpatient treatment with medications and long-term recovery supports available to all Medicaid enrolled members.

Addiction is a primary, chronic disease of the brain's reward, motivation, memory, and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social, and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and typically results in disability or premature death.

DMAS recommends the application of the ASAM Criteria which describe a wide range of levels and types of care for addiction and substance-related conditions and establish clinical guidelines for making the most appropriate treatment and placement recommendations for individuals who demonstrate specific signs, symptoms and behaviors of addiction. Application across the Commonwealth of this comprehensive system of multidimensional assessment, broad and flexible continuum of care, interdisciplinary team approach to care, and outcome-driven clinical treatment is expected to substantially reduce the consequences of the current addiction epidemic.

The comprehensive addiction treatment benefit approved previously by the Governor and General Assembly includes the following core components:

- v **Expanded coverage of inpatient detoxification and inpatient substance abuse treatment** (ASAM Level 4.0) for all Medicaid members (previously only available to children).
- v **Expanded coverage of residential detoxification and residential substance abuse treatment** (ASAM levels 3.1, 3.3, 3.5, and 3.7) for all Medicaid members (previously delivered using outdated, state-defined program rules).

- ▼ **Increased rates for existing substance abuse treatment services** currently covered by DMAS by 50% for Case Management and by 400% for Partial Hospitalization (ASAM Level 2.5), Intensive Outpatient (ASAM Level 2.1), and the counseling component (Opioid Treatment) of MAT to align with current industry standards.
- ▼ **Added coverage of Peer Supports for individuals with SUD and/or mental health conditions.** Reimbursement will be provided for peers certified by DBHDS who will provide intensive recovery coaching to individuals with SUD at all ASAM Levels of Care and to those who need recovery supports, which will be added to the Medicaid benefit in July 2017.

Major changes under this benefit are illustrated below.

Addiction Treatment Service	Children < 21	Adults*	Pregnant Women
Traditional Services			
Inpatient (ASAM Level 4.0)	X	Added	Added
Outpatient (ASAM Level 1.0)	X	X	X
Treatment using medication – medication component	X	X	X
Non-Traditional Services			
Residential (ASAM Levels 3.1, 3.3, 3.5, and 3.7)	X	Added	50% rate increase
Partial Hospitalization (ASAM Level 2.5)	400% rate increase	400% rate increase	400% rate increase
Intensive Outpatient (ASAM Level 2.1)	400% rate increase	400% rate increase	400% rate increase
Opioid Treatment – counseling component of treatment using medication (ASAM Level 1.0)	400% rate increase	400% rate increase	400% rate increase
Case Management	50% rate increase	50% rate increase	50% rate increase
Peer Recovery Coaching (DBHDS certified peers)	Added**	Added**	Added
<p>X = service was previously covered</p> <p>Added = service will be covered under the comprehensive addiction treatment benefit passed by the General Assembly starting on April 1, 2017. Rate increases were also included in addiction treatment benefit and will take effect on April 1, 2017.</p> <p>* Dual eligible individuals have coverage for inpatient and residential treatment services through Medicare.</p> <p>** Peer recovery support services for adults and family support partners for children and families will be added when DBHDS finalizes the peer certification standards and DMAS is able to ensure that CMS requirements are met for Peer Support Services.</p>			

The concept of medical necessity is used throughout DMAS' regulations as the basis for service coverage. Services that are not medically necessary are not covered (not reimbursed) by Medicaid. Because substance use, addictive and mental disorders are biopsychosocial in etiology

and expression, treatment and care management are most effective if they are also biopsychosocial and based on a multidimensional assessment rather than a single diagnosis. DMAS proposes to implement a system that takes into account the biopsychosocial nature of substance use, addiction and mental health disorders to result in a more holistic and evidence-based approach to service delivery and care.

Issues

Please identify the issues associated with the proposed regulatory action, 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, please indicate.

There are no disadvantages identified in providing the full continuum of treatment needed to address the substance use crisis and reverse the opioid epidemic in Virginia. The ARTS benefit and waiver are needed to ensure the success of Virginia's delivery system transformation in expanding access to the addiction treatment services that will save lives, improve patient outcomes, and decrease costs. There are no disadvantages to affected providers as their rates of reimbursement are recommended for increase.

The advantages to Medicaid-eligible individuals are discussed above.

Federal demonstration waivers have significant data reporting and evaluation components. CMS will require an independent evaluation of the ARTS waiver to demonstrate any improved outcomes for Medicaid members and cost savings from reducing Emergency Department visits and inpatient hospital utilization. This evaluation will help the Commonwealth demonstrate the impact of the ARTS benefit and waiver on the lives of its citizens, both Medicaid eligible and non-eligible, as well as on the Commonwealth's economy.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include 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 statement to that effect.

There are no requirements more restrictive than federal contained in these recommendations.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There will be no localities that are more affected than others as these requirements will apply statewide.

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) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of 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 proposed regulation.

This regulatory action is not expected to affect small businesses as it does not impose compliance or reporting requirements, nor deadlines for reporting, nor does it establish performance standards to replace design or operational standards.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

<p>Projected cost to the state to implement and enforce the proposed regulation, including: a) fund source / fund detail; and b) a delineation of one-time versus on-going expenditures</p>	<p>SFY 2017: \$2,602,412(GF); \$2,602,412(NGF); \$5,204,824 Total appropriations SFY 2018: \$8,376,259(GF); \$8,376,259(NGF); \$16,752,518 Total appropriations</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>The CSBs/BHAs will incur costs in educating their bachelor degree staff to enable such staff to apply for the CSAC exam/certification.</p>
<p>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</p>	<p>Inpatient hospitals, some physicians/nurse practitioners, case managers, residential treatment facilities, group homes, and outpatient clinics</p>
<p>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.</p>	<p>Case management.....152 Emergency Services/Crisis Intervention Service.....96 Managed Withdrawal - Medical Detox.....10 Medical Detox/Chemical Dependency Units.....5 MAT/Opioid Treatment</p>

	<p>Service.....29 MH Crisis Stabilization 23 MH/SA group home service 8 Outpatient Managed Withdrawal/Med Detox 1 Outpatient MH/SA Service.....422 Outpatient SA Service.....9 Partial hospitalization service.....3 Psychiatric Unit service.....28 Psychiatric Unit serv. Children 10 Residential Treatment SA Women with Child.....3 SA Case Management 26 SA Half Way House.....3 SA Intensive outpatient services.....99 SA Partial Hospitalization.....9 SA Residential Treatment.....17 SA Supervised Living Service.....28</p> <p>DMAS does not keep data on how many providers meet the definition of small businesses.</p>
<p>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	<p>Providers will be required to maintain the standard medical record documentation in order to support their claims that are submitted for reimbursement. No additional reporting requirements, record-keeping or administrative costs will be required for these regulatory changes.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>The beneficial impact will be the coverage by Medicaid, for eligible individuals, of addiction and recovery treatment services.</p>

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.

By meeting the CMS requirements, this comprehensive ARTS benefit package allows Virginia to amend the GAP 1115 waiver and apply for a Medicaid 1115 SUD waiver that waives the sixteen (16) bed limit in an Institution for Mental Disease (IMD) including inpatient and residential substance use treatment. This allows DMAS to draw down federal matching funds to support ARTS services delivered to Medicaid-eligible individuals in state psychiatric hospitals, replacing the current State General Fund supporting these services. The waiver would also draw down new federal matching funds that would incentivize providers to expand existing residential detox facilities beyond 16 beds, substantially increasing ARTS capacity. Many community-based providers currently restrict bed capacity to 16 beds specifically so they can bill Medicaid. By allowing community-based residential programs with greater than 16 beds to bill Medicaid, this waiver would substantially increase provider treatment capacity and access to treatment for all Virginians.

Stakeholders and the Governor's Taskforce on Prescription Drug and Heroin Abuse have documented the need for increased reimbursement rates for treatment services to address the prescription opiate and heroin epidemic in the Commonwealth. Opioid overdoses have become the most prevalent type of accidental death in the Commonwealth over the past five years. From 2007 to 2013, nearly 70% of all deaths from drugs/poisons were attributed to opioids. Since 2000, deaths from prescription opioid overdoses have more than doubled. In 2015, 809 Virginians died from prescription opioid and heroin overdoses. . Over the past two years, deaths from heroin overdoses have doubled. Increasing access to addiction treatment through the ARTS benefit and waiver is essential to reverse this epidemic.

Public participation notice

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.

Public comment has been positive and helped DMAS to identify key areas for substance use disorder treatment reform beginning in September 2015 until June 2016, using multiple modalities that included the Commonwealth's administrative record, the Virginia Regulatory Town Hall and a variety of electronic and face to face methods all of which were supported by electronic communications provided to interested stakeholders. DMAS held two public hearings on January 5, 2016 in the Richmond area and on January 7, 2016 in the far southwest region in Abingdon, Virginia.

In addition to the web based communication and public hearings, a comprehensive workgroup convened to develop the benefit program structure in collaboration with diverse stakeholders. The SUD/ARTS Workgroup (participant list attached) consisted of managed care organizations, the DMAS Behavioral Health Service Administrator, public and private behavioral health providers, health systems, provider associations, member advocacy organizations, peer support representatives, community service boards, hospital associations, Federally Qualified Health Centers, physician and psychiatric societies as well as staff from the Department of Behavioral Health and Developmental Services (DBHDS), the Virginia Department of Health Professions (DHP), the Virginia Department of Health (VDH) and DMAS. All workgroup activity has been summarized and posted to the DMAS website for review by stakeholders and interested individuals. Information on the workgroup and program design can be found on the DMAS website at: http://www.dmas.virginia.gov/Content_Pgs/bh-sud.aspx.

DMAS posted the draft concept paper on its website and provided notice through the Virginia Regulatory Town Hall on July 1, 2016:

<http://townhall.virginia.gov/L/ViewNotice.cfm?gnid=566>.

DMAS posted another public notice online through the Commonwealth's administrative record, the Virginia Regulatory Town Hall on July 1, 2016 as well as posted the notice on the DMAS website and distributed through the electronic distribution list. This notice further sought public comments for a 30 day period on the ARTS Waiver "Concept Paper" which incorporated feedback from the earlier public hearings. The ARTS Waiver "Concept Paper" was the draft application to amend the 1115 GAP Waiver. DMAS requested public comments on the entire Addiction and Recovery Treatment Services benefit delivery system design.

All feedback was considered and incorporated as appropriate in the 1115 Waiver amendment which was submitted to the Centers for Medicare and Medicaid Services (CMS) on August 5, 2016.

A summary of public comment and DMAS actions related to those comments is posted online at http://www.dmas.virginia.gov/Content_Pgs/bh-sud.aspx.

DMAS has not been notified of any concerns from providers, members, or the public.

Family Impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

These changes do not erode the authority or rights of parents in the education, nurturing, and supervision of their children; nor discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents.

The ARTS benefit may strengthen the authority or rights of parents in the education, nurturing and supervision of their children by increasing access to court-mandated addiction treatment that Medicaid-eligible parents may be required to obtain in order to be reunified with children in foster care. Access to addiction treatment may also encourage economic self-sufficiency, self-pride, and assumption of responsibility by individuals with substance use disorders who are able to enter recovery due to the ARTS program.

These changes do not erode the marital commitment. They may strengthen the marital commitment if Medicaid-eligible individuals experiencing strife in their marriage due to a substance use disorder are able to obtain treatment. These changes should not decrease disposable family income

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is 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 action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the pre-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
	12 VAC 30-130-5000		Creates new ARTS regulations
	12 VAC 30-130-5005		ARTS purpose and authority established.
	12 VAC 30-130-5020		New ARTS definitions.
	12 VAC 30-130-5050		New ARTS eligible individuals established.
	12 VAC 30-130-5100		New ARTS covered services established.
	12 VAC 30-130-5120		New ARTS covered clinic services (OTP); service components, staff requirements, risk management; care coordination; co-occurring enhanced programs.
	12 VAC 30-130-5121		New ARTS covered office-based opioid treatment clinic services

			(OBOT); service components, staff requirements, risk management; care coordination; co-occurring enhanced programs.
	12 VAC 30-130-5140		New ARTS covered practitioner services; service components, staff requirements, co-occurring enhanced programs. (ASAM 0.5)
	12 VAC 30-130-5141		New ARTS covered practitioner services; service components, staff requirements, co-occurring enhanced programs. (ASAM 1.0)
	12 VAC 30-130-5160		New ARTS covered community based intensive outpatient services; service components, staff requirements, co-occurring enhanced programs. (ASAM 2.1)
	12 VAC 30-130-5161		New ARTS covered community based care partial hospitalization services; service components, staff requirements, co-occurring enhanced programs. (ASAM 2.5)
	12 VAC 30-130-5180		New ARTS covered residential group home services; service components, staff requirements, co-occurring enhanced programs. (ASAM 3.1)
	12 VAC 30-130-5200		New ARTS covered residential treatment facility services; service components, staff requirements, co-occurring enhanced programs. (ASAM 3.3)
	12 VAC 30-130-5201		New ARTS covered medium/high intensity residential treatment facility services; service components, staff requirements, co-occurring enhanced programs. (ASAM 3.5)
	12 VAC 30-130-5202		New ARTS covered intensive inpatient residential treatment facility services; service components, staff requirements,

			co-occurring enhanced programs. (ASAM 3.7)
	12 VAC 30-130-5220		New ARTS covered intensive inpatient hospital services; service components, staff requirements, co-occurring enhanced programs. (ASAM 4.0)
	12 VAC 30-130-5500		New ARTS provider requirements; licensing standards.
12 VAC 30-50-100		Inpatient hospital services limits; enrolled providers.	New Incorporation by Reference added to link to new Chapter 130 regulations.
12 VAC 30-50-110		Outpatient hospital services; Federally Qualified Health Centers and Rural Health Clinics	New Incorporation by Reference added to link to new Chapter 130 regulations.
12 VAC 30-50-130		Early and Periodic Screening, Diagnosis and Treatment services	New Incorporation by Reference added to link to new Chapter 130 regulations.
12 VAC 30-50-140		Physician services limits.	New Incorporation by Reference added to link to new Chapter 130 regulations.
12 VAC 30-50-150		Other licensed practitioner services limits.	New Incorporation by Reference added to link to new Chapter 130 regulations.
12 VAC 30-50-180		Clinic services limits.	New Incorporation by Reference added to link to new Chapter 130 regulations.
12 VAC 30-50-228		Community substance abuse treatment services.	REPEALED as it is superseded by new ARTS program.
12 VAC 30-50-491		Case management for AXIS I disorders	Changes update existing text to new ARTS program.
12 VAC 30-50-510		Expanded pre-natal care services.	Residential substance abuse treatment and outpatient substance abuse treatment for pregnant and post-partum women is REPEALED as it is replaced by new ARTS program.
12 VAC 30-60-147		Utilization control: substance abuse treatment.	REPEALED as it is replace with new ARTS program.

12 VAC 30-60-180		Utilization control: substance abuse treatment.	REPEALED as it is replace with new ARTS program.
12 VAC 30-60-185		Utilization control: substance abuse case management	REPEALED as it is replace with new ARTS program.
12 VAC 30-80-32		Reimbursement for substance abuse treatment services.	Establishes reimbursement rules for ARTS services.
12 VAC 30-70-415		Reimbursement for freestanding psychiatric hospitals under EPSDT	Citation to new ARTS regulations added.
12 VAC 30-70-417		Reimbursement for inpatient psychiatric services in residential treatment facilities (Level C) under EPSDT	Citation to new ARTS regulations added.
12 VAC 30-130-540 thru -130-590		Community Mental Health Mental Retardation Services substance abuse treatment services.	REPEALED as it is replaced with new ARTS program.

ARTS WORKGROUP

Virginia Premier
Aetna Better Health
Anthem HealthKeepers Plus
Humana
Optima Family Care
Virginia Association of Health Plans
INTotal Health
Magellan of Virginia
Beacon Health Options
Richmond Behavioral Health Authority
Cumberland Mountain Community Services Board
Phoenix Houses of the Mid Atlantic
Caliber Virginia
Northwestern Community Services Board
Virginia Community Healthcare Association
Virginia Association of Community Services Boards
Community Care Network of Virginia IT Infrastructure Partnership
VOCAL
National Alliance for Mental Illness - Virginia

Department of Behavioral Health and Developmental Services
Virginia Department of Health
Department of Health Professions
Virginia Commonwealth University
Department of Medical Assistance Services