

COMMONWEALTH of VIRGINIA

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MEMORANDUM

To:	DBHDS Licensed Providers of Substance Use Services
From:	Jae Benz, Director, Office of Licensing
Cc:	Veronica Davis, Associate Director for State Licensure Operations Mackenzie Glassco, Associate Director of Quality & Compliance

Date:February 17, 2023Re:Changes from the Emergency ASAM Regulations to the Final ASAM Regulations

Purpose: The purpose of this memo is to alert licensed substance use providers that the American Society of Addiction Medicine Levels of Care Criteria (ASAM) regulations will become final and permanent on February 17, 2023, and to highlight changes made to the regulations from the emergency stage to the final stage.

The Department of Behavioral Health and Developmental Services (DBHDS) was directed by the 2020 General Assembly within the Appropriation Act to utilize emergency authority to promulgate licensing regulations that align with ASAM or an equivalent set of criteria to ensure the provision of outcome-oriented and strengths-based care in the treatment of addiction. The emergency regulations became effective on February 20, 2021. The final, permanent regulations will become effective on February 17, 2023.

Included in this memo is a chart highlighting all the areas in which the regulations changed from the emergency stage to the final stage. This chart is meant to be a tool to provide greater clarity; providers should review the regulations for full requirements.

The Office of Licensing offered several training opportunities to support providers in achieving and maintaining compliance with the ASAM criteria when the emergency regulations became effective. These trainings are still available via PowerPoint on the Office of Licensing's <u>website</u>. Please take this opportunity to review these materials if you have not already done so.

If you have any questions related to the content of this memorandum, please do not hesitate to reach out directly to your licensing specialist. For additional information on the final ASAM regulations, please visit the <u>Virginia Regulatory Town Hall</u>. Soon after becoming effective on February 17th, 2023, all changes will be incorporated within the online regulations <u>here</u>.

Regulation Number	Change From Emergency to Final Stage	Analysis
Throughout the regulation	Level of care numericals were added throughout the regulatory chapter where the service name is indicated.	The level of care numericals were added throughout the chapter at the request of providers. ASAM's level of care are usually referred in shorthand by their level of care number; therefore, this is a clarifying edit.
12VAC35-105-20	Addition of the term "Addiction"	Adding the definition of addiction is a clarifying edit, to ensure transparency of the regulations. The definition comes from the ASAM Criteria.
12VAC35-105-20	Amendment of the term "Credentialed addiction treatment professional" was made changing and combining the terms "a licensed clinical nurse specialist" and "a licensed psychiatric nurse practitioner" to a licensed nurse practitioner with experience or training in psychiatry or mental health.	This amendment more accurately reflects the title of these specialists within the Commonwealth of Virginia given recent changes made by the Department of Health Professions.
12VAC35-105-20	Edits were made to the definition of "medication assisted opioid treatment" and "medication assisted treatment"	These are clarifying edits requested by subject matter experts to simplify the definitions.
12VAC35-105-925	Updates made to the standards for providers of services to individuals with opioid addiction, specifically medication assisted opioid treatment (MAOT) programs due to changes in federal regulations. Adds that the program sponsor means the person responsible for the operation of the opioid treatment program and who assumes responsibility for all its employees. The program sponsor is responsible for ensuring the program is in compliance with all federal, state, and local laws and regulations.	These changes are required due to changes in the federal regulations regarding Certification and Treatment Standards for Opioid Treatment Programs (42 CFR Part 8 Subpart C).

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	Adds that the program director is responsible for the day-to-day management of the program.	
	Adds that the medical director is 1) responsible for ensuring all services are conducted in compliance with federal regulations; 2) physically present at the program for a sufficient number of hours to ensure regulatory compliance.	
	Adds that the program must have linkages or access to psychological, medical and psychiatric consultation; have access to emergency medical and psychiatric care through affiliations with more intensive levels of care; have the ability to conduct or arrange for appropriate laboratory and toxicology tests; that the program may provide peer recovery specialists who are professionally qualified by education and experience; and requires that the provider notify SAMHSA of changes in staff. Addition that the service is required to have the capability to provide: general services; HIV/AIDS education; initial medical examination services; special services for pregnant individuals; initial and periodic individualized, patient-centered assessment and treatment services, counseling services; drug abuse testing; and case management	
	services. Adds that applicants for new services shall provide policies and procedures that address	

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	assessment, administration and regulation of	
	medication and dose levels.	
12VAC35-105-935	Adds the federal requirements regarding the criteria for admission to MAOT programs and combines those requirements with the ASAM requirements regarding admission.The federal rules require that individuals be admitted by qualified personnel; that individuals with 2 or more unsuccessful detox episodes in a year be assessed for other forms of treatment; that programs shall not admit individuals to MAOT for more than two detoxification treatment episodes in one year; the program use accepted medical criteria for admission; admitted individuals be currently addicted to an opioid drug, the addiction has occurred at least one year before admission; each individual voluntarily chooses maintenance treatment; and each individual provides informed written consent to treatment.	These changes are required due to changes in the federal regulations regarding Certification and Treatment Standards for Opioid Treatment Programs (42 CFR Part 8 Subpart C).
	For individuals younger than 18 years of age the individual is required to have 2 documented unsuccessful attempts at short- term detoxification within a 12 month period to be eligible for MAOT and must have written parental or legal guardian consent or be determined as a responsible adult per state authority consents. The program may waive the requirement of a 1 year history of addiction for individuals	

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	released from penal institutions, pregnant	
	individuals and previously treated individuals.	
12VAC35-105-940	Adds the federal requirements regarding criteria for involuntary termination from treatment for MAOT providers. These require that the provider establish criteria for involuntary termination from treatment that describe the rights of the individual, and the responsibilities and rights of the provider. Further requires the provider establish a grievance procedure, which is given to the individual at admission.	These changes are required due to changes in the federal regulations regarding Certification and Treatment Standards for Opioid Treatment Programs (42 CFR Part 8 Subpart C).
	Finally requires that upon admission and yearly afterwards that the individual sign an authorization for disclosure of information to allow the provider access to the Virginia Prescription Monitoring System. Individuals who fail to sign the authorization shall be denied admission.	
12VAC35-105-950	Adds the federal requirements regarding the service operation schedule of MAOTP: if the service dispenses medication requiring daily doses the service shall operate every day except official state holidays and any additional closures shall require prior approval from the state methadone authority.	These changes are required due to changes in the federal regulations regarding Certification and Treatment Standards for Opioid Treatment Programs (42 CFR Part 8 Subpart C).
	The service may close on Sundays if: 1) the provider addresses recently admitted individuals, individuals not currently on a stable dose, those that present noncompliance behaviors and individuals who previously picked up take-home medications on Sundays,	

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	security of take-home medications doses, and health and safety of individuals receiving services.	
	2) the provider receives approval from the state opioid treatment authority (SOTA) and has policies which address the individuals listed within section (1) above;	
	3) the provider shall notify individuals in writing at least 30 days prior to closing on Sundays.	
	4) the provider shall establish procedures for access to dosing information 24/7.	
	Finally requires that dispensing hours include at least 2 hours each day outside of 9-5 working hours, and the SOTA may approve an alternative schedule if the SOTA determines that the schedule meets the needs of the population served by the provider.	
12VAC35-105-960	Adds that MAOT providers maintain the report of the individual's physical examination in the individual's service record, that the physician review a consent to treatment form with the individual prior to the individual receiving medication, require a policy to ensure coordination of care is in place with any prescribing physicians, including for individuals prescribed benzodiazepines and prescription narcotics.	These changes are required due to changes in the federal regulations regarding Certification and Treatment Standards for Opioid Treatment Programs (42 CFR Part 8 Subpart C).
12VAC35-105-965	Adds the requirement that MAOT providers ensure that every pregnant woman has the opportunity for prenatal care, prenatal	These changes are required due to changes in the federal regulations regarding Certification and Treatment Standards for Opioid

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	education and postpartum follow up. These	Treatment Programs (42 CFR Part 8 Subpart
	services can be provided on site or by referral.	C).
12VAC35-105-980	Adds the requirement that at least one random	These changes are required due to changes in
	drug screen per month occur within MAOT	the federal regulations regarding Certification
	programs unless a drug screen indicates	and Treatment Standards for Opioid
	continued illicit drug use, in which case a	Treatment Programs (42 CFR Part 8 Subpart
	random drug screen shall be performed	C).
	weekly. Requires that drug screens be	
	analyzed for 1) opiates, 2) methadone, 3)	
	benzodiazepines, 4) cocaine, and 5)	
	buprenorphine. Finally requires that the	
	provider implement a policy on how drug	
	screens shall be used to direct treatment.	
12VAC35-105-990	Adds the requirements regarding take-home	These changes are required due to changes in
	medications which include the approval shall	the federal regulations regarding Certification
	be based on clinical judgement of the	and Treatment Standards for Opioid
	physician in consultation with the treatment	Treatment Programs (42 CFR Part 8 Subpart
	team and be documents in the individual's	C).
	record; that an individual must demonstrate	
	current lifestyle stability as evidence by 8	
	benchmarks. Also lays out the limitations on	
	take home medication which corresponds with	
	the individual's length of treatment. Requires	
	that MAOT providers maintain procedures to	
	identify theft or diversion of take-home	
	medications and specifies requirements of	
	those procedures. Finally requires that	
	providers educate individuals on safe	
	transportation and storage of take home	
	medication to reduce the risk of accidental	
	ingestion, including child proof containers.	
12VAC35-105-1010	Adds requirements for guests of MAOT	These changes are required due to changes in
	services. Guests are patients of a MAOT	the federal regulations regarding Certification
	service in another state or area of Virginia	and Treatment Standards for Opioid
	who is traveling and is not yet eligible for	

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	take-home medication. Guests shall not receive medication until documentation from the home provider has been received and guests may not receive medication for more than 28 days. After 28 days, the guest must be admitted to the service.	Treatment Programs (42 CFR Part 8 Subpart C).
12VAC35-105-1430	A clarifying edit which states the interdisciplinary team serving ASAM Level of Care 4.0 <u>may</u> include addiction-credentialed physicians, nurse practitioners, physician assistants, nurses, counselors, psychologists, and social workers.	This edit was requested on the part of providers. Commenters were concerned that the interdisciplinary team was required to have one of each of the health professionals mentioned. This edit clarifies that the mentioned health care professionals are examples of the members of the interdisciplinary team.
12VAC35-105-1450	Amends that a provider of Level of Care 4.0 services must have admission criteria which at a minimum requires the individual to meet diagnostic criteria for a substance use disorder or a substance induced disorder.	This removes that an individual meet diagnostic criteria of addictive disorder of moderate to high severity, which aligns more closely with the ASAM Criteria.
12VAC35-105-1480	Adds that a licensed nurse practitioner, or a licensed physician assistant can also be the health profession that conducts the necessary in person assessment of the individual within 24 hours of admission of a Level of care 3.7 setting.	Aligns more closely with ASAM which also allows physician extenders to make the required assessment of an individual in person in a 3.7 setting.
	A clarifying edit which states the interdisciplinary team serving ASAM Level of Care 3.7 <u>may</u> include physicians, nurses, addiction counselors, and behavioral health specialists.	This edit was requested on the part of providers. Commenters were concerned that the interdisciplinary team was required to have one of each of the health professionals mentioned. This edit clarifies that the mentioned health care professionals are examples of the members of the interdisciplinary team.

Regulation Number	Change From Emergency to Final Stage	Analysis
	A clarifying edit that medication assisted	MAT is not appropriate for all individuals
	treatment (MAT) only need to be made	served.
	available for individuals with opioid or	
	alcohol use disorder.	
12VAC35-105-1490	Replacement of the term licensed mental health professional with credentialed addiction treatment professional.	Credentialed addiction treatment professional which was defined within the emergency action more accurately reflects the
1014 605 105 1500		professionals determining treatment services.
12VAC35-105-1500	Updating that the individual being admitted to a Level of Care 3.7 program shall meet the diagnostic criteria for moderate or severe substance use or addictive disorder.	This edit is made to more closely align to the ASAM Criteria.
12VAC35-105-1520	Replacement of the term licensed mental health professional with credentialed addiction treatment professional.	Credentialed addiction treatment professional which was defined within the emergency action more accurately reflects the professionals conducting behavioral health- focused assessments at the time of admission.
12VAC35-105-1530	Clarifying that Level of Care 3.5 settings shall be staffed by credentialed addiction treatment professionals in addition to other allied health professionals.	This provision caused confusion among providers. This edit was made at the request of providers to make the regulations clearer.
12VAC35-105-1540	Replacement of the term licensed professional with credentialed addiction treatment professional.	Credentialed addiction treatment professional which was defined within the emergency action more accurately reflects the professionals determining treatment services.
	A clarifying edit that medication assisted treatment (MAT) only need to be made available for individuals with opioid or alcohol use disorder.	MAT is not appropriate for all individuals served.
12VAC35-105-1590	Replacement of the term licensed professional with credentialed addiction treatment professional.	Credentialed addiction treatment professional which was defined within the emergency action more accurately reflects the professionals determining treatment services.

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	A clarifying edit that medication assisted treatment (MAT) only need to be made available for individuals with opioid or alcohol use disorder.	MAT is not appropriate for all individuals served.
12VAC35-105-1600	Amends that a provider of Level of Care 3.3 services must have admission criteria which at a minimum requires the individual to meet diagnostic criteria for moderate or severe substance use or addictive disorder.	This edit is made to more closely align to the ASAM Criteria.
12VAC35-105-1640	A clarifying edit that medication assisted treatment (MAT) only need to be made available for individuals with opioid or alcohol use disorder.	MAT is not appropriate for all individuals served.
12VAC35-105-1650	Amends that a provider of Level of Care 3.1 services must have admission criteria which at a minimum requires the individual to meet diagnostic criteria for moderate or severe substance use or addictive disorder.	This edit is made to more closely align to the ASAM Criteria.
12VAC35-105-1680	A clarifying edit which states the interdisciplinary team serving ASAM Level of Care 2.5 <u>may</u> include counselors, psychologists, social workers, and addiction- credentialed physicians.	This edit was requested on the part of providers. Commenters were concerned that the interdisciplinary team was required to have one of each of the health professionals mentioned. This edit clarifies that the mentioned health care professionals are examples of the members of the interdisciplinary team.
12VAC35-105-1690	Updating that the 20 hours of programming for Level of Care 2.5 settings must be skilled treatment services.	This edit more closely aligns with the ASAM Criteria.
	A clarifying edit that medication assisted treatment (MAT) only need to be made	MAT is not appropriate for all individuals served.

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	available for individuals with opioid or	
	alcohol use disorder.	
12VAC35-105-1730	A clarifying edit which states the	This edit was requested on the part of
	interdisciplinary team serving ASAM Level of	providers. Commenters were concerned that
	Care 2.1 may include counselors,	the interdisciplinary team was required to
	psychologists, social workers, and addiction-	have one of each of the health professionals
	credentialed physicians.	mentioned. This edit clarifies that the
		mentioned health care professionals are
		examples of the members of the
		interdisciplinary team.
12VAC35-105-1740	A clarifying edit that medication assisted	MAT is not appropriate for all individuals
	treatment (MAT) only need to be made	served.
	available for individuals with opioid or	
	alcohol use disorder.	