

Amendments to Medication for Opioid Use Disorder (MOUD): General Regulations 12VAC35-105

What You Need to Know



Hi! My name is Larisa Terwilliger, and I am the Training Coordinator with the Office of Licensing.

Welcome to the *Amendments to Medication for Opioid Use Disorder* presentation for the general regulations, Chapter 105 - What You Need to Know.

- Part 8 of Title 42 of the Code of Federal Regulations (CFR) includes the regulations that guide opioid treatment programs (OTPs), which initially took effect in 2001. The U.S. Department of Health and Human Services (HHS), through the Substance Abuse and Mental Health Services Administration (SAMHSA), revised these regulations and released the final rule in February 2024. The amendments updated the regulations with the intent to increase access to lifesaving, evidence-based medications for opioid use disorder (MOUD) and to advance treatment retention through the promotion of person-centered interventions. The revised federal rules went into effect on April 2, 2024.
- A fast-track action amends the Rules and Regulations for Licensing Providers by the Department of Behavioral Health and Developmental Services (12VAC35-105) (the "Licensing Regulations") to align with those federal changes where appropriate. Additionally, federal regulations grant flexibility to states in certain areas. In response to Virginia's opioid crisis, the fast-track action utilized this latitude to incorporate three regulatory amendments recommended by the DBHDS clinical team that are slightly more stringent than required by the federal rule.
- Providers licensed to provide these services will be affected. The regulatory changes represent a lessening of administrative burden and may result in a reduction in cost for providers which may be passed on to individuals receiving services.
- 13 regulations in Chapter 105 have been amended, and 6 regulations have been repealed.
- These updated regulations go into effect on December 1, 2025.

Let's talk about what is happening.

These Fast-Track Amendments for Medication for Opioid Use Disorder (MOUD) align with federal updates to Opioid Treatment Programs (OTPs) that became effective April 2, 2024.

These new amendments were designed to expand access, remove unnecessary barriers, and strengthen safeguards to protect the health, safety, and welfare of citizens across the Commonwealth. These regulatory changes represent a lessening of administrative burden and may result in a reduction in cost for providers which may be passed on to individuals receiving services.

13 regulations in Chapter 105 have been amended, and 6 regulations have been repealed.

These updated regulations go into effect on December 1, 2025.

This presentation will serve as a quick-reference tool for you to be informed of these changes.

1. This action is following a mandate by the federal government to incorporate federal regulatory changes. In response to Virginia's opioid crisis, this action increases flexibilities related to take-home medication, initial evaluations and telehealth for counseling while remaining slightly more stringent than the federal schedule and allowances.
2. These amendments are essential to the health, safety, and welfare of citizens because they will increase access to lifesaving, evidence-based MOUD and advance treatment retention through the promotion of person-centered interventions. These elements were identified as being essential to promoting effective treatment in OTPs that have evolved over the past 20 years.
3. The new federal final rule changes promote practitioner autonomy, remove outdated language which stigmatizes treatment for substance use disorder, support a patient-centered approach, and reduce barriers to receiving care. The changes also permanently codify COVID-19 flexibilities related to take-home medication and telehealth for counseling. SAMSHA found that increased flexibilities related to take-home medication during the pandemic improved outcomes without increasing rates of diversion, and that by reducing barriers, telehealth expanded access to care which increased engagement in treatment.

Let's now explore the reasons behind this in more detail to have a better understanding as to *why* this is happening.

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to receiving care. The changes also permanently codify COVID-19 flexibilities related to take-home medication and telehealth for counseling. SAMSHA found that increased flexibilities related to take-home medication during the pandemic improved outcomes without increasing rates of diversion, and that by reducing barriers, telehealth expanded access to care which increased engagement in treatment.

This action incorporates three regulatory changes more restrictive than applicable federal requirements. The DBHDS clinical team recommended the slightly more stringent standards in response to Virginia's opioid crisis and to protect the health, safety, and welfare of the Commonwealth's citizens.

12VAC35-105-960

- Currently, the regulations do not allow for the use of telemedicine or audio-only evaluations.
 - *The amendments allow the use of audio-visual evaluations and audio-only evaluations to take place when audio-visual evaluations are not available, but only if the individual is in the presence of a licensed practitioner who is registered to prescribe and dispense controlled medications. This is slightly stricter than the federal regulations which does not require an audio-visual evaluation to be attempted and unavailable or the presence of a licensed practitioner for evaluations for treatment with buprenorphine or naltrexone.*

The next few slides show areas where the DBHDS clinical team recommended slightly more stringent standards in response to Virginia's opioid crisis and to protect the health, safety, and welfare of the Commonwealth's citizens. Although the standards are more restrictive than Federal requirements, these changes still ease the regulatory requirements for providers.

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12VAC35-105-970

- Currently, 12VAC35-105-970 requires a provider conduct face-to-face counseling sessions at least every two weeks for the first year of an individual's treatment and every month in the second year of the individual's treatment. After two years, the number of face-to-face counseling sessions are based on the individual's progress in treatment. Currently, the Licensing Regulations do not allow counseling to occur via telehealth.
 - *The amendments allow for counseling to occur via telehealth however they require that an individual have one in-person counseling session every month during the first year of treatment and one in-person counseling session quarterly during the second year of treatment. This is stricter than federal regulations, which do not require in-person counseling and do not require a minimum number of counseling sessions.*

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**12VAC35-105-990**

- Currently, 12VAC35-105-990 allows a single take home dose for when a clinic is closed for business, a single dose each week during the first 90 days of treatment, two doses per week in the second 90 days of treatment, three doses per week in the third 90 days of treatment, a six-day supply in the remaining months of the first year of treatment, a two-week supply after one year of continuous treatment and a one month's supply after two years of continuous treatment.
 - *The amendments allow for one take home dose for the first seven days of treatment, a five-day consecutive supply of take-home doses from eight days of treatment to 30 days of treatment, a 14-day supply of take-home doses from 31 days of treatment to 60 days of treatment, and a 28-day consecutive supply of take-home medication after 60 days of treatment. This regulatory change is stricter than the federal criteria that allow up to seven days of take-home doses during the first 14 days of treatment, up to 14 take-home doses from 15 days of treatment, and up to 28 take-home doses from 31 days in treatment.*



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- ~~12VAC35-105-1070 Observation area.~~ (Repealed.)
- ~~12VAC35-105-1090. Minimum number of employees or contractors on duty.~~ (Repealed.)
- ~~12VAC35-105-1100. Documentation.~~ (Repealed.)
- ~~12VAC35-105-1110. Admission assessments.~~ (Repealed.)
- ~~12VAC35-105-1120. Vital signs.~~ (Repealed.)
- ~~12VAC35-105-1130. Light snacks and fluids.~~ (Repealed.)

First, let's look at the regulations that have been repealed, or removed, and are no longer applicable. Those regulations are shown here.

- [12VAC35-105-20. Definitions.](#)
- [12VAC35-105-30. Licenses.](#)
- [12VAC35-105-925. Standards for the evaluation of new license for providers of services to individuals with opioid addiction.](#)
- [12VAC35-105-930 Registration, certification, or accreditation.](#)
- [12VAC35-105-935. Criteria for patient admission.](#)
- [12VAC35-105-945. Criteria for patient discharge.](#)
- [12VAC35-105-960. Initial and periodic assessment services.](#)
- [12VAC35-105-970. Counseling sessions.](#)
- [12VAC35-105-980. Drug screens.](#)
- [12VAC35-105-990. Take- home medication.](#)
- [12VAC35-105-1000. Preventing duplication of medication services.](#)
- [12VAC35-105-1010. Guests.](#)
- [12VAC35-105-1020. Withdrawal management prior to involuntary discharge.](#)



Click
the links to
view details
for each
regulation!

This slide shows all the amended regulations. For your ease of use, each regulation here is linked directly to the slide in this presentation that provides all the details for that specific regulation. Click on any linked regulation to quickly jump to that regulation's details slide in this presentation. Now Mackenzie is going to dive into these amended regulations in more detail.

Key

- **Underlined Italics** : means that specific portion of text is newly added and is now included in the regulation
- ~~**Strike-Through**~~: means that specific portion of text has been removed and is no longer included in the regulation

For the purposes of this presentation, when you see Underlined and Italicized text on the slides, that means *that* specific portion of text is *newly added* and is now included in the regulation.

When you see Red Text with the Strikethrough line, that means *that* specific portion of text has been *removed* and is no longer included in the regulation

Changes to Definitions

- Update of the terms "state opioid treatment authority" and "Service;"
 - "State ~~methadone opioid treatment~~ authority" or "**SOTA**" means the Virginia Department of Behavioral Health and Developmental Services, which is authorized by the federal Center for Substance Abuse Treatment to exercise the responsibility and authority for governing the treatment of ~~opiate addiction with an~~ opioid ~~drug use disorder with MOUD~~.
 - "Service" means, as defined by § 37.2-403 of the Code of Virginia, (i) planned individualized interventions intended to reduce or ameliorate mental illness, developmental disabilities, or substance abuse (substance use disorders) through care, treatment, training, habilitation, or other supports that are delivered by a provider to individuals with mental illness, developmental disabilities, or substance abuse (substance use disorders). Services include outpatient services, intensive in-home services, ~~medication-assisted medication for~~ opioid ~~use disorder~~ treatment services, inpatient psychiatric hospitalization, community gero-psychiatric residential services, assertive community treatment and other clinical services; day support, day treatment, partial hospitalization, psychosocial rehabilitation, and habilitation services; case management services; and supportive residential, special school, halfway house, in-home services, crisis stabilization, and other residential services; and (ii) planned individualized interventions intended to reduce or ameliorate the effects of brain injury through care, treatment, or other supports provided in residential services for persons with brain injury.

Let's begin with 12VAC35-105-20. Definitions. Amendments here include the updating of the terms "state opioid treatment authority or SOTA" and some of the terminology in "Service" has been updated which now reflects MOUD

Changes to Definitions Continued

- Removal of the terms ~~"medical detoxification"~~ and ~~"medication assisted opioid treatment"~~
- Addition of the terms "medication for opioid use disorder," "opioid treatment practitioner," and "withdrawal management."
 - "Medication for opioid use disorder" or "MOUD" means medications, including opioid agonist medications, approved by the Food and Drug Administration for the use in the treatment of opioid use disorder. (added)
 - "Opioid treatment practitioner" means a health care professional who is appropriately licensed to prescribe or dispense medications in Virginia for opioid use disorders and, as a result, is authorized to practice within an opioid treatment program. (added)
 - "Withdrawal management" means the dispensing of MOUD in decreasing doses to an individual to alleviate adverse physical effects incident to withdrawal from the continuous or sustained use of an opioid and as a method of bringing the individual to an opioid-free state within such a period. Long-term withdrawal management refers to the process of medication tapering that exceeds 30 days. (added)
- Likely impact: Clearer regulations. Alignment with federal changes and current evidence-based practices and terminology to provide person- centered treatment.

Here we see additional amendments to Definitions, including removal of the terms “medical detoxification” and “medication assisted opioid treatment”, and the addition of the terms “medication for opioid use disorder,” “opioid treatment practitioner”, and “withdrawal management.”

These changes were made to hopefully provide clearer regulations. Also, they also align with federal changes, current evidence-based practices and terminology to provide person- centered treatment.

12VAC35-105-30 Licenses.

A. Licenses are issued to providers who offer services to individuals who have mental illness, a developmental disability, or substance abuse (substance use disorders) or have brain injury and are receiving residential services.

B. Providers shall be licensed to provide specific services as defined in this chapter or as determined by the commissioner. These services include:

18. Medication for opioid use disorder treatment;

As previously stated, there are 13 regulations that have been amended, and we'll review those now.

The first amended regulation is 12VAC-105-30.Licenses

This change updated the name of the license from “medication assisted opioid treatment” to “medication for opioid use disorder treatment.” This aligns with federal changes and current terminology.

**12VAC35-105-925.E. Standards for the evaluation of new licenses for providers of services to individuals with opioid addiction.**

E. Applicants shall submit information to demonstrate that there are sufficient personnel available to meet the following staffing requirements and qualifications:

1. The program sponsor means the person responsible for the operation of the opioid treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, behavioral health, or social services at the program at any of its medication units. The program sponsor is responsible for ensuring the program is in continuous compliance with all federal, state, and local laws and regulations.
2. The program director or manager shall be licensed or certified by the applicable Virginia health regulatory board or registered as eligible for this license or certification with relevant training, experience, or both, in the treatment of individuals with opioid addiction. The program director is responsible for the day-to-day management of the program.
3. The medical director shall be a physician licensed to practice medicine in the Commonwealth with relevant training or experience in the treatment of individuals with opioid addiction and:
 - a. Is responsible for ensuring all medical and behavioral health services offered by the medication for opioid use disorder treatment provider are conducted in compliance with federal regulations at all times; and
 - b. Shall be physically present at the program for a sufficient number of hours to ensure regulatory compliance and carry out those duties specifically assigned to the medical director by regulation.
4. A minimum of one health care professional who is appropriately licensed by the Commonwealth to prescribe and dispense medications for opioid use disorders.



12VAC35-105-925 Standards for the evaluation of new licenses for providers of services to individuals with opioid addiction.

There were no changes made to 925A-D.

As it relates to 925.E. Amendments here include updated staffing requirements to align with federal changes which reduce the burden on licensed providers. Terminology has been updated from “Medication Assisted Opioid Treatment” to “Medication for Opioid Use Disorder”

As it relates to 925.E.4. this is only licensed pharmacists and physicians in Virginia

In Virginia, Opioid Treatment Practitioners, at this time include the following:

- **ONLY Pharmacists can dispense**
- **ONLY LPN and RNs can administer**
- **ONLY Licensed Providers with a DEA license to prescribe controlled substances can Order Medications**

There were no changes related to 925.F-J.

12VAC35-105-925.K-L. Standards for the evaluation of new licenses for providers of services to individuals with opioid addiction.

- K. Applicants shall provide policies and procedures that shall address assessment, administration, and regulation of medication and dose levels appropriate to the individual. The policies and procedures shall at a minimum require that each individual served be assessed every six months by the treatment team to determine if that individual is appropriate for safe and voluntary medically supervised withdrawal from opioid analgesics, including methadone or buprenorphine, alternative therapies including other medication-assisted treatments, or continued federally approved pharmacotherapy treatment for opioid addiction.
- L. Applicants shall submit policies and procedures describing services the applicant will provide to individuals who wish to discontinue medication for opioid use disorder treatment services.

925.K-L These amendments align with federal changes and current terminology.

There were no changes related to 925.M and N

12VAC35-105-930 Registration, certification, or accreditation.

- A. The medication *for* opioid use disorder treatment service shall maintain current registration or certification with:
1. The federal Drug Enforcement Administration;
 2. The federal Department of Health and Human Services; and
 3. The Virginia Board of Pharmacy.
- B. A provider of medication *for* opioid use disorder treatment services shall maintain accreditation with an entity approved under federal regulations.

12VAC35-105-930 Registration, certification, or accreditation.

Again, terminology has been updated to reflect “Opioid Use Disorder”.

12VAC35-105-935 Criteria for patient admission.

A. Before a medication for opioid use disorder treatment provider may admit an individual, the individual shall meet the criteria for admission as defined by the provider's policies. The provider's policy regarding admission shall at a minimum require the individual to (i) meet diagnostic criteria for opioid use disorder as defined within the DSM; and (ii) meet the admission criteria of Level 1.0 of ASAM. The policies shall be consistent with subsections B through D of this section.

B. A medication for opioid use disorder treatment provider's qualified personnel shall assess individuals to determine if the individuals are appropriate for treatment by applying established diagnostic criteria documented in the provider's procedures.

C. A medication for opioid use disorder treatment provider shall maintain current procedures designed to ensure that individuals are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria, that the person currently has an addiction to an opioid drug. In addition, an opioid treatment practitioner shall ensure that each individual voluntarily chooses maintenance treatment, that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the individual, and that each individual provides informed written consent to treatment.

D. No individual younger than 18 years of age may be admitted to maintenance treatment without written consent from a parent, legal guardian, or responsible adult designated by the relevant state authority.

12VAC35-105-935 Criteria for patient admission.

Terminology has been updated from “Medication Assisted Opioid Treatment” to “Medication for Opioid Use Disorder” Eliminates the 1-year Opioid Addiction History Requirement, promotes priority treatment for individuals who are pregnant, and removes the requirement of 2 documented instances of unsuccessful treatment for people under age 18. This aligns with federal changes and removes unnecessary barriers to medication access by focusing on individual needs. These amendments add protections for vulnerable groups.

12VAC35-105-945 Criteria for patient discharge.

Before a medication for opioid use disorder treatment provider discharges or transfers, the individual shall meet the criteria for discharge or transfer as defined by the provider's policies, which shall include provisions for the discharge or transfer of individuals who have:

1. Achieved the goals of the treatment services and no longer require medication for opioid use disorder treatment level of care;
2. Been unable to achieve the goals of the individual's treatment but could achieve the individual's goals with a different type of treatment; or
3. Achieved the individual's original treatment goals but have developed new treatment challenges that can only be adequately addressed in a different type of treatment.

12VAC35-105-945 Criteria for patient discharge.

Terminology has been updated from “Medication Assisted Opioid Treatment” to “Medication for Opioid Use Disorder”. This aligns with federal changes and current terminology.

12VAC35-105-960.A&B. Initial and periodic assessment services.

A. The provider shall require each individual to undergo an initial medical examination. The initial medical examination is comprised of two parts:

1. A screening examination to ensure that the individual meets the criteria for admission in accordance with 12VAC35-105-935 and that there are no contraindications to treatment with MOUD; and

2. A full health history and examination, including a physical examination, to determine the individual's broader health status, with lab testing as determined by an appropriately licensed practitioner. An individual's refusal to undergo lab testing for co-occurring physical health conditions should not preclude access to treatment, provided such refusal does not have the potential to negatively impact treatment with medications. The individual's full health history and examination shall be completed within 14 days of admission.

B. Both the screening examination and the full health history and examination shall be completed by an appropriately licensed practitioner. When the initial medical examination is performed outside of the provider's service:

1. The written results, narrative of the initial medical examination, and available lab testing results must be transmitted, consistent with applicable privacy laws, to the provider and verified by an opioid treatment practitioner; and

2. If the original screening examination was not conducted by an opioid treatment practitioner, the screening shall occur not more than seven days prior to admission to the provider's service.

12VAC35-105-960.Initial and periodic assessment services.

Regarding A & B, the requirements for initial medical examinations have been updated. The amendments allow screening examinations to be performed by practitioners external to the Opioid Treatment Program under certain conditions.

12VAC35-105-960.C-I. Initial and periodic assessment services.

C. The provider shall maintain the report of the individual's initial medical examination in the individual's service record.

D. The provider shall have a policy to ensure that coordination of care is in place with any prescribing physician.

E. The provider shall coordinate treatment services for individuals who are prescribed benzodiazepines and prescription narcotics with the treating physician. The coordination shall be the responsibility of the provider's physician and shall be documented.

F. Serology testing and other testing as deemed medically appropriate by the provider's physician based on the screening and full health history and examination, drawn not more than 30 days prior to admission to the provider's service, may form part of the initial medical examination.

G. An evaluation of an individual for treatment shall occur in person or use audio-visual telemedicine platforms. When not available, a provider may use audio-only devices, but only when the individual is in the presence of a licensed practitioner who is registered to prescribe and dispense controlled medications. The licensed practitioner shall document being physically present during the audio-only evaluation through signature in the individual's record. The provider's physician shall review the initial medical examination results and order MOUD as indicated.

H. Qualified personnel shall review a consent-to-treatment form with the patient and shall document informed written consent prior to the individual receiving the first dose of MOUD.

I. Assuming no contraindications, an individual may begin MOUD treatment after the screening examination is completed.

960.C-I: These amendments allow the screening of individuals for admission via audio-only or audio-visual telehealth technology if certain requirements are met.

Telehealth is an evidence-based practice that has been shown to be safe and effective. Its use expands access to care.

12VAC35-105-970 Counseling sessions.

A. For the purposes of this section, "face-to-face" shall include telemedicine.

B. The provider shall conduct face-to-face counseling sessions (either individual or group) at a frequency tailored to each individual based on an individualized assessment and the individual's care plan that was created after shared decision-making between the individual and the clinical team. At a minimum, the provider shall conduct one in-person session once a month for the first year of the individual's treatment and quarterly during the second year. The failure of an individual to participate in counseling sessions shall be addressed as part of the overall treatment process.

12VAC35-105-970 Counseling sessions.

The amendments to this section are stricter than the federal requirements, however the amendments allow for telehealth counseling and reduce the required frequency of counseling sessions. These changes remove unnecessary barriers to treatment access by focusing on individual needs.

12VAC35-105-980 Drug screens.

- A. The provider shall perform at least eight random drug screens per year unless the conditions in subsection B of this section apply.
- B. Whenever an individual's drug screen indicates continued illicit drug use or when clinically and environmentally indicated, random drug screens shall be performed at a frequency that is in accordance with generally accepted clinical practice and as indicated by the individual's response to stability in treatment.
- C. Drug screens shall be analyzed for opiates, methadone (if ordered), benzodiazepines, cocaine, and buprenorphine. In addition, drug screens for other drugs that have the potential for addiction shall be performed when clinically and environmentally indicated.
- D. The provider shall implement a written policy on how the results of drug screens shall be used to direct treatment.

12VAC35-105-980 Drug screens.

The amendments for this regulation reduce the required drug screens per year. The amendments also change the frequency of drug screens when an individual's drug screen indicates continued illicit drug use from weekly, to a frequency determined by the clinician. This change is intended to reduce barriers for individuals receiving services and increase treatment retention.

12VAC35-105-990.A. Take-home medication.

A. Determinations for take-home approval shall be based on the clinical judgment of the provider's physician in consultation with the treatment team and shall be documented in the individual's service record. Prior to dispensing regularly scheduled take-home medication, the medical director or opioid treatment practitioner shall ensure the individual demonstrates that the therapeutic benefits of unsupervised doses outweigh the risk as evidenced by the following criteria:

1. Absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of harm as it relates to the potential for overdose, or the ability to function safely;
2. Regularity of attendance for supervised medication administration;
3. Absence of serious behavioral problems that endanger the individual, the public, or others;
4. Absence of known recent diversion activity;
5. Whether take-home medication can be safely transported and stored; and
6. Any other criteria that the medical director or opioid treatment practitioner considers relevant to the individual's safety and the public health.

The next few slides are related to 12VAC35-105-990. Take-home medication.

Let's start with 990.A

The provisions in Part A are aligned completely with federal regulations.

The amended regulations make the Covid 19 flexibilities permanent. These flexibilities demonstrated that wider access to methadone improves outcomes without increasing rates of diversion when paired with individualized treatment, clinical judgement, safeguards and education.

12VAC35-105-990.B-C. Take-home medication.

B. Any individual in comprehensive maintenance treatment who is assessed to be appropriate to handle take-home medication shall undergo continued assessment and management to ensure suitability.

C. If it is determined that an individual in comprehensive maintenance treatment is appropriate for handling take-home medication, including take-home medication for provider closures, the amount of take-home medication shall not exceed:

- 1. A single take-home dose for one day when the clinic is closed for business, including Sundays and state or federal holidays, for the first seven days of treatment.*
- 2. A maximum of a five-day consecutive supply of take-home doses from eight days of treatment to 30 days of treatment*
- 3. A maximum of a 14-day supply of take-home doses from 31 days of treatment to 60 days of treatment*
- 4. A maximum of a 28-day consecutive supply of take-home medication after 60 days of treatment*

990.B-C:

Amendments to these regulation align the criteria for assessment for suitability for take-home medication with federal regulations.

These changes update criteria for consideration of take-home doses of methadone and allow individuals to receive a single take-home dose from the first week of treatment, with additional flexibilities with continued treatment under certain conditions.

The amendments to this section are somewhat stricter than the federal requirements. Changes also reduce regulatory burden as a simplified take-home schedule will result in less administrative burden on providers.

12VAC35-105-990.D-G. Take-home medication.

D. Exceptions to the take-home schedule in subsection C of this section may be made if approved by the SOTA or designee.

E. No medication shall be dispensed to individuals in short-term withdrawal management treatment or interim maintenance treatment for unsupervised take-home use.

F. Medication for opioid use disorder treatment providers shall maintain current procedures adequate to identify the theft or diversion of take-home medications. These procedures shall require the labeling of containers with the medication for opioid use disorder treatment provider's name, address, and telephone number.

Providers shall ensure that the take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child proof containers.

G. The provider shall educate the individual on the safe transportation and storage of take-home medication.

990.D-G. Take-home medication.

Overall, amendments to 990 remove unnecessary barriers to treatment access and increases access to lifesaving, evidence-based, MOUD treatment, and increases treatment retention.

12VAC35-105-1000 Preventing duplication of medication services.

To prevent duplication of medication for opioid use disorder treatment services, the provider shall implement written policy and procedures for contacting every medication for opioid use disorder treatment service within a 50-mile radius before admitting an individual to the service.

12VAC35-105-1000 Preventing duplication of medication services
These changes align with federal changes and current terminology.

12VAC35-105-1010 Guests.

A. For the purposes of this section, a guest is a patient of a medication for opioid use disorder treatment service in another state or another area of Virginia, who is traveling and is not yet eligible for take-home medication. Guest dosing shall be approved by the individual's home clinic and the receiving clinic's physician or medical director.

B. The provider shall not dispense medication to any guest unless the guest has been receiving such medication services from another provider and documentation from that provider has been received prior to dispensing medication.

C. Guests may receive medication for up to 28 days. To continue receiving medication after 28 days, the guest must be admitted to the service. Individuals receiving guest medications as part of a residential treatment service may exceed the 28-day maximum time limit at the medication for opioid use disorder treatment service.

12VAC35-105-1010 Guests

A few clarifying edits were made, and the changes also align with federal changes and current terminology.

12VAC35-105-1020 Withdrawal management prior to involuntary discharge.

A. The provider shall give an individual who is being involuntarily discharged an opportunity to withdraw from opioid agonist medication not less than 10 days or not more than 30 days prior to the individual's discharge from the service, unless the SOTA has granted an exception.

B. Providers may immediately discharge an individual who has exhibited violent behavior if the provider has defined within its policies the circumstances under which such discharge would be appropriate.

12VAC35-105-1020 Detoxification Withdrawal management prior to involuntary discharge

Regulation title changed to replace the term “Detoxification” with “Withdrawal management”. Subsections A and B have been added. Updated “state methadone authority” to “State Opioid Treatment Authority”, or “SOTA”.

Clarifying edits were made that incorporates DBHDS policy into regulations by stating that providers may immediately discharge an individual who has exhibited violent behavior *if* the provider has defined the circumstances under which such discharge would be appropriate within their policies. This promotes a safer treatment environment for staff and individuals receiving services.

Now Larisa is going to review the required policies, procedures and plans.

Policies and Procedures	Applicable Regulation
Standards for the evaluation of new licenses for providers of services to individuals with opioid addiction (Plan)	12VAC35-105-925.D.7.
Standards for the evaluation of new licenses for providers of services to individuals with opioid addiction (Policy)	12VAC35-105-925.H.5.
Standards for the evaluation of new licenses for providers of services to individuals with opioid addiction (Policy)	12VAC35-105-925.K.
Standards for the evaluation of new licenses for providers of services to individuals with opioid addiction (Policy)	12VAC35-105-925.L.
Criteria for patient admission (Policy)	12VAC35-105-935.A.
Criteria for patient admission (Procedure)	12VAC35-105-935.B.
Criteria for patient admission (Procedure)	12VAC35-105-935.C.
Criteria for involuntary termination from treatment. (Procedure)	12VAC35-105-940
Criteria for patient discharge (Policy)	12VAC35-105-945

 Removed

 Amended

 No Change

The next two slides show all the MOUD regulations that require a policy, procedure or plan. As noted on the right side of the slide, removed regulations are highlighted in Red, updated regulations are highlighted in blue and those regulations with No changes are white.

Policies and Procedures	Applicable Regulation	
Service operation schedule. (Policy & Procedure)	12VAC35-105-950.B.	Removed
Initial and periodic assessment services (Policy)	12VAC35-105-960.D.	Amended
Drug screens (Policy)	12VAC35-105-980.D.	No Change
Take-home medication (Procedure)	12VAC35-105-990.F.	
Preventing duplication of medication services (Policy)	12VAC35-105-1000	
Withdrawal management prior to involuntary discharge (Policy)	12VAC35-105-1020.B.	
Emergency preparedness plan. (Plan)	12VAC35-105-1040	
Security of opioid agonist medication supplies. (Plan)	12VAC35-105-1050.D.	
12VAC35-105-1120 Vital signs. (Repealed)	12VAC35-105-1120	Removed

Again, here we see the remaining MOUD regulations that require a policy, procedure or plan.

As a reminder, providers are allowed to have more policies than the ones required but must have at least the minimum required. If a provider chooses to have additional policies and procedures beyond those that are required, then the provider must be following their own policies; so if it's in your policy manual, you must be using and following it.

***Providers may be cited for noncompliance in accordance with regulation 150.5 if they are not following their own policy**

Helpful Documents

[Virginia Regulatory Town Hall Show XML](#)

[Virginia Regulatory Town Hall View Stage](#)

[Q&A: MOUD Regulations Changes](#)

This concludes today's presentation. If you'd like more information related to the MOUD Amendments, please visit the links provided here.