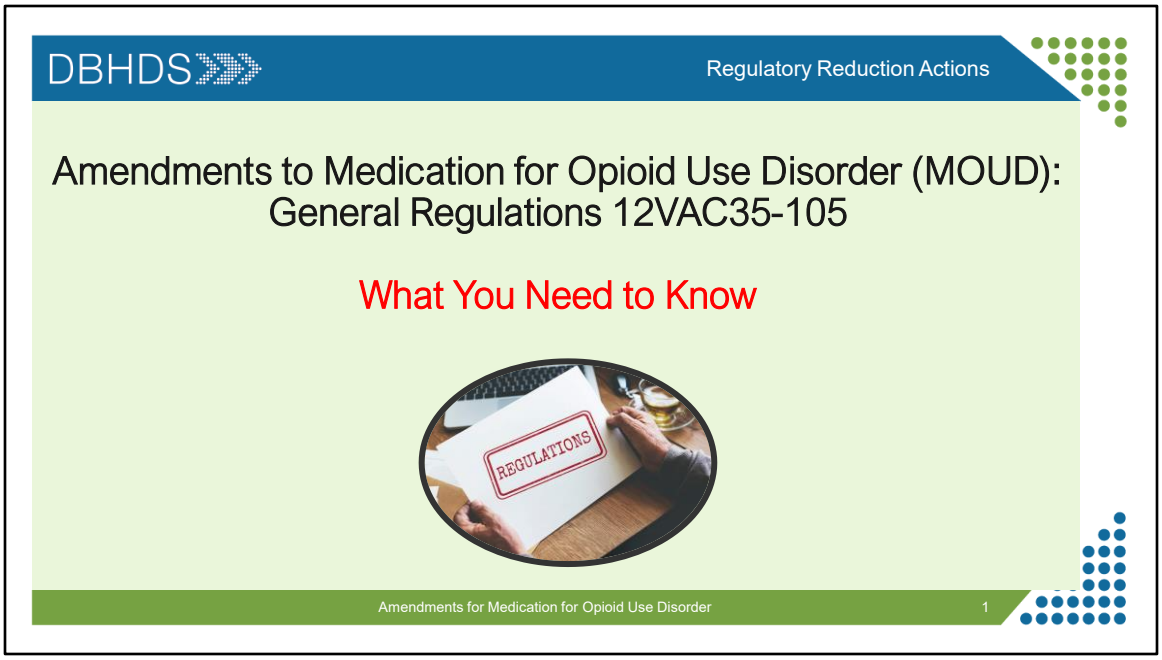
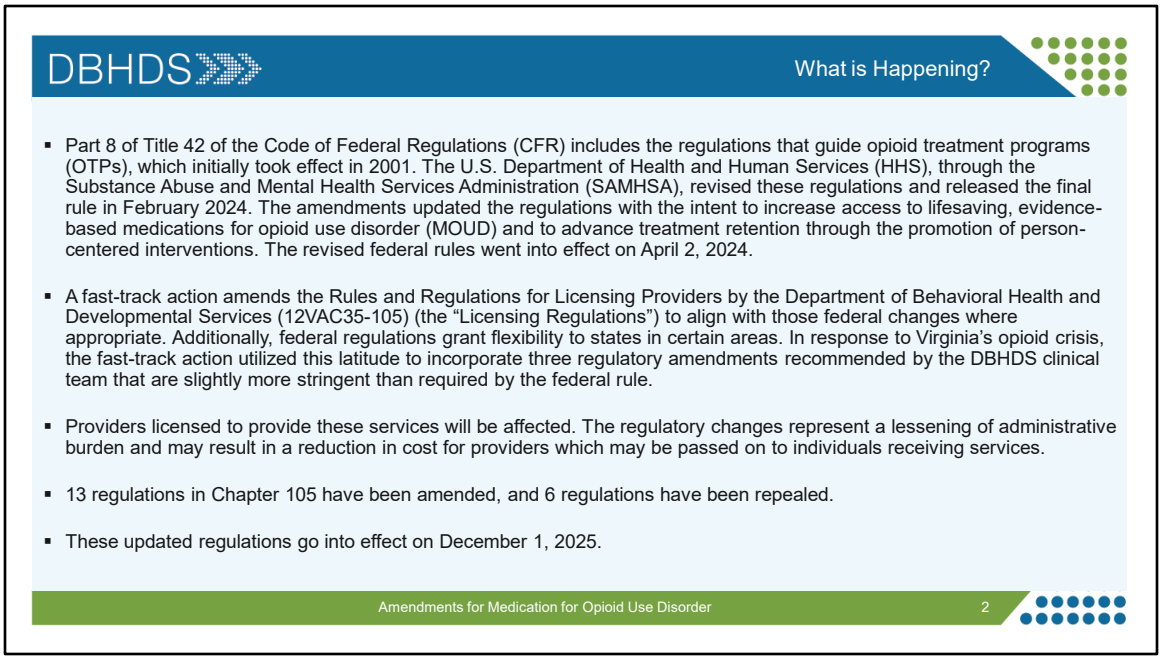


Hi! My name is Larisa Terwilliger, and I am the Training Coordinator with the Office of Licensing.

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



Let's talk about what is happening.

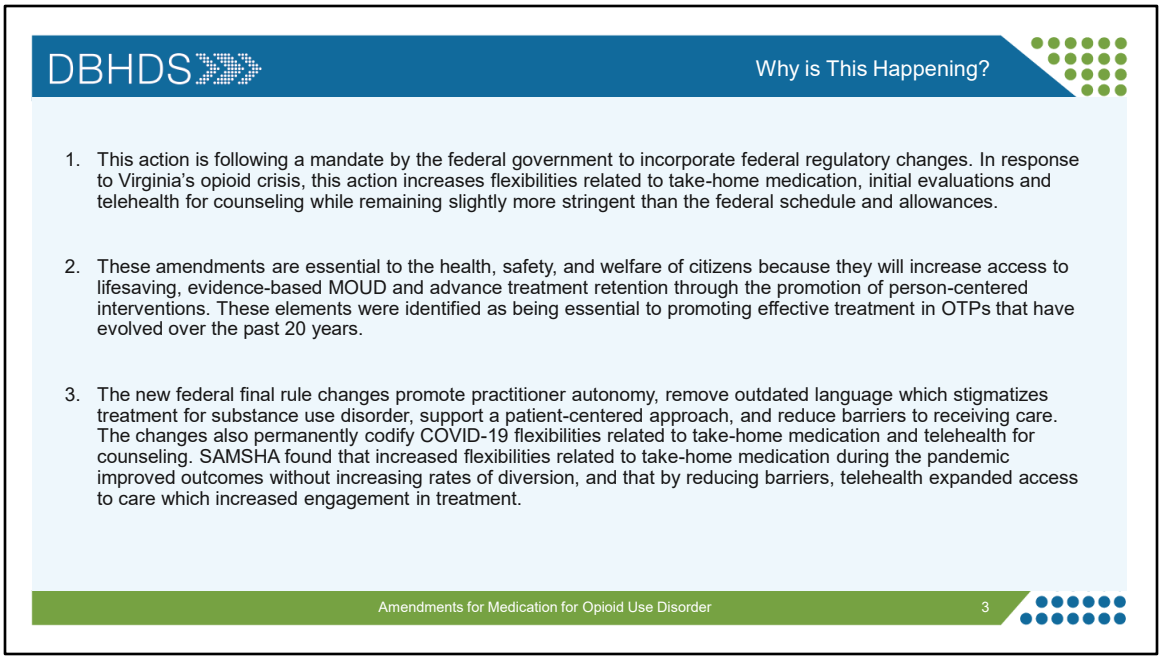
These Fast-Track Amendments for Medication for Opioid Use Disorder (MOUD) align with federal updates to Opioid Treatment Programs (OTPs) that became effective April 2, 2024.

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13 regulations in Chapter 105 have been amended, and 6 regulations have been repealed.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



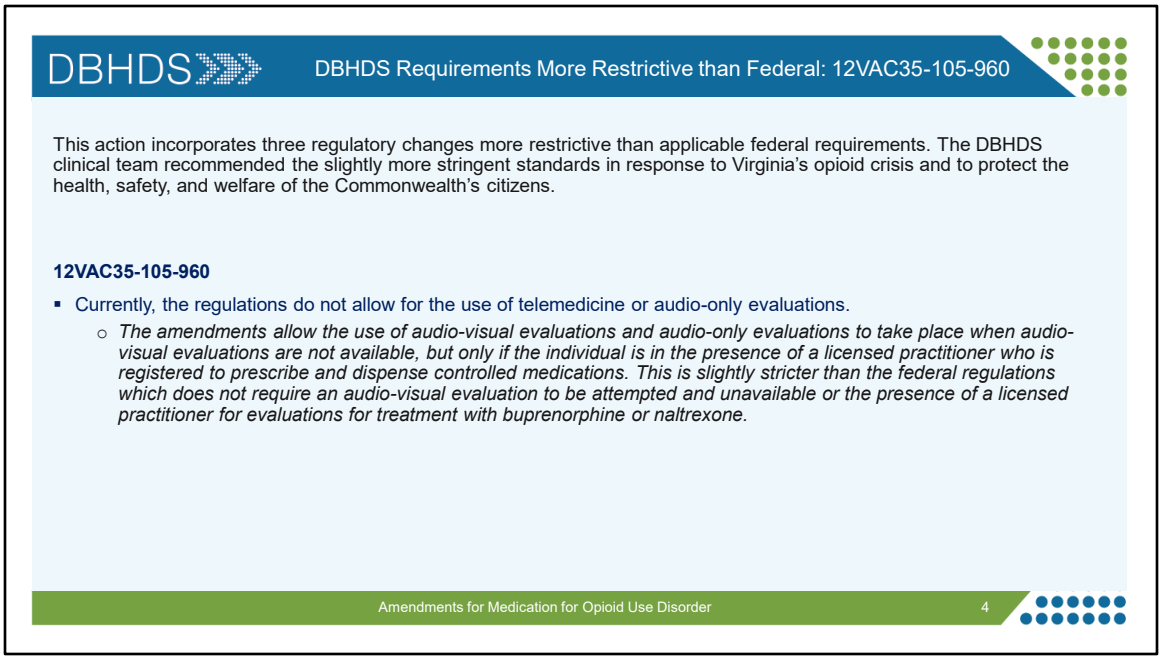
Let's now explore the reasons behind this in more detail to have a better understanding as to *why* this is happening.

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.

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.

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

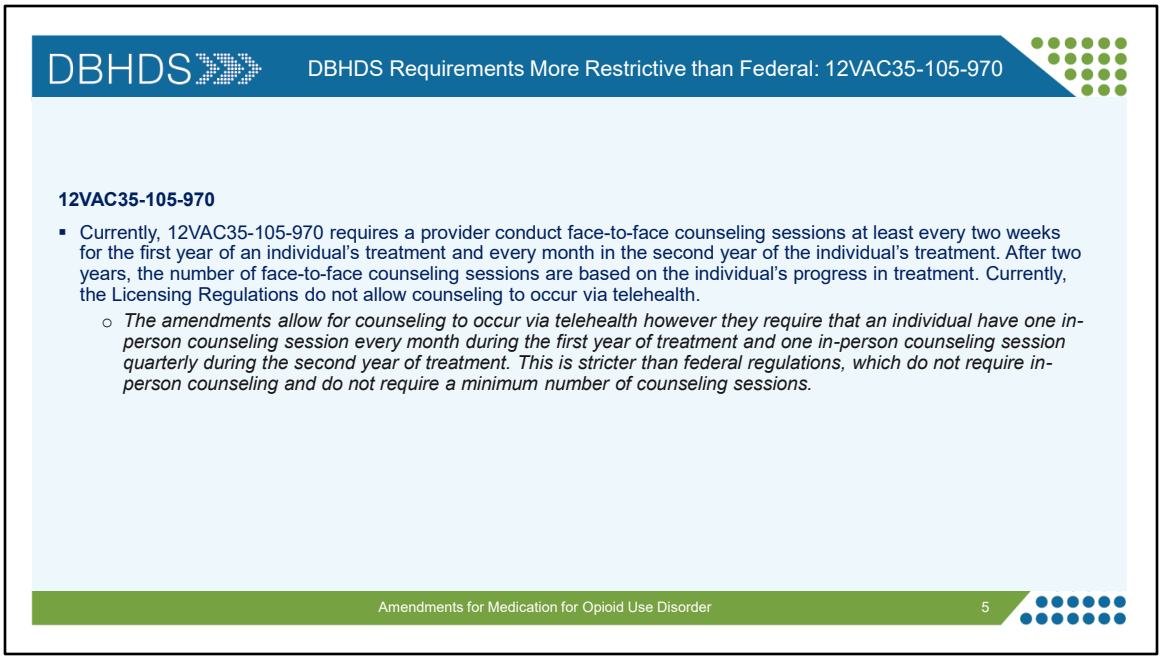
to receiving care. The changes also permanently codify COVID-19 flexibilities related to take-home medication and telehealth for counseling. SAMSHA found that increased flexibilities related to take-home medication during the pandemic improved outcomes without increasing rates of diversion, and that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



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.

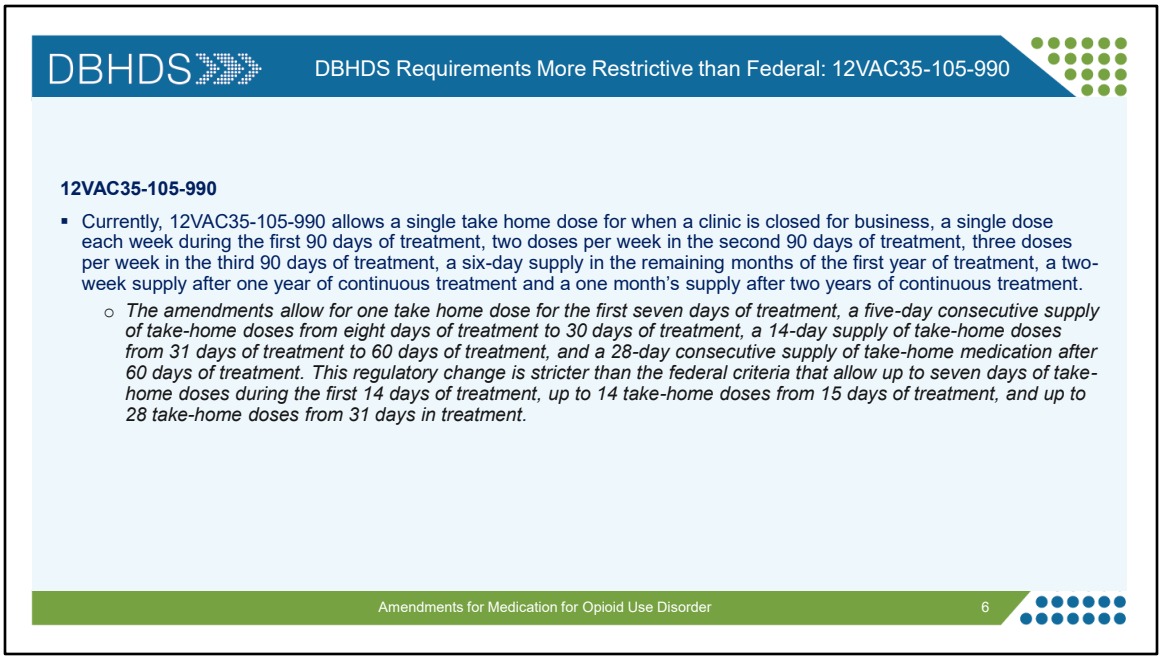
Currently, the regulations do not allow for the use of telemedicine or audio-only evaluations.

- **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**



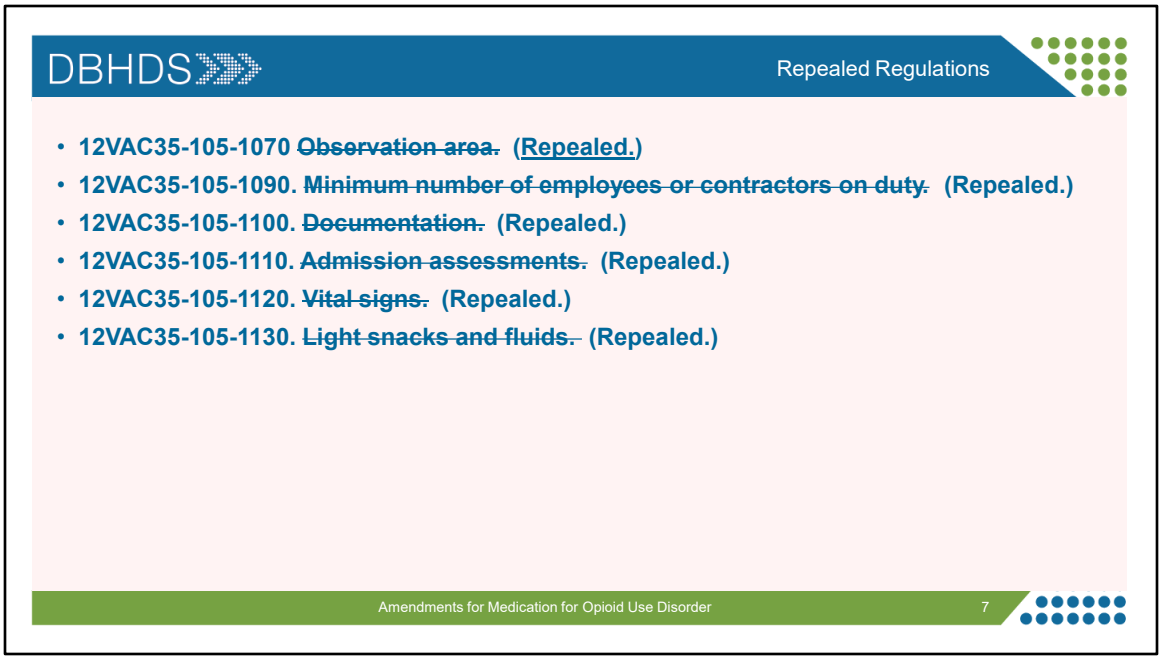
Currently, 12VAC35-105-970 requires a provider conduct face-to-face counseling sessions at least every two weeks for the first year of an individual's treatment and every month in the second year of the individual's treatment. After two years, the number of face-to-face counseling sessions are based 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.**

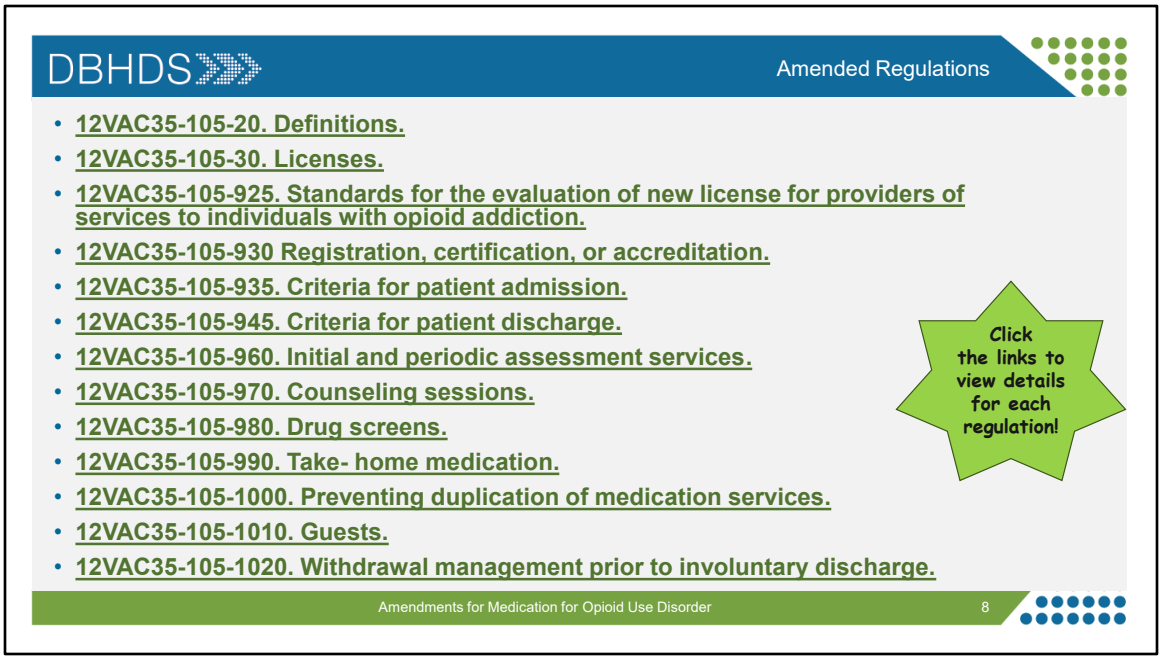


Currently, 12VAC35-105-990 allows a single take home dose for when a clinic is closed for business, a single dose each week during the first 90 days of treatment, two doses per week in the second 90 days of treatment, three doses per week in the third 90 days of treatment, a six-day supply in the remaining 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.

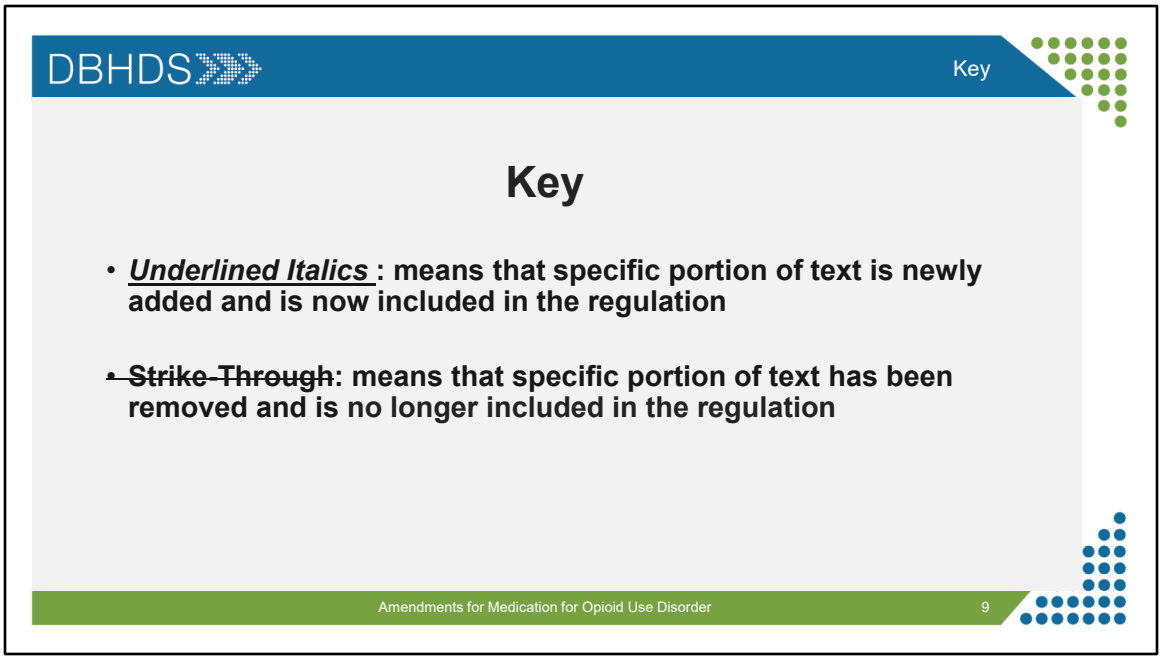
- **The amendments allow for one take home dose for the first seven days of treatment, a five-day consecutive supply of take-home doses from eight days of treatment to 30 days of treatment, a 14-day supply of take-home doses from 31 days of treatment to 60 days of treatment, and a 28-day consecutive 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.**



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

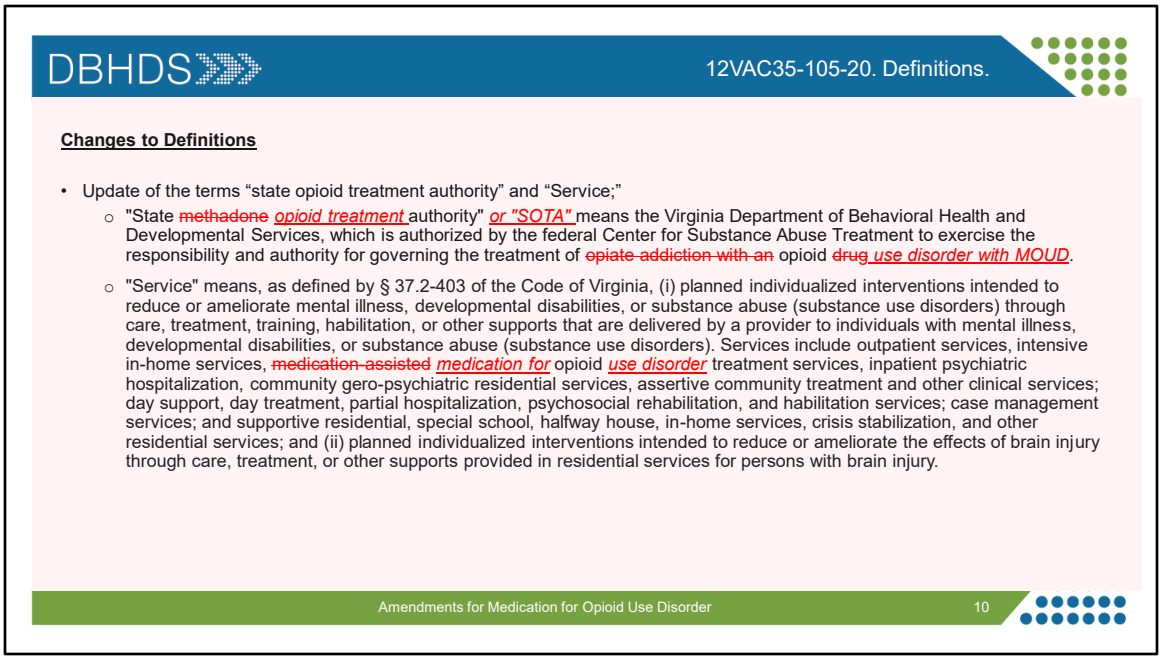


This slide shows all the amended regulations. For your ease of use, each regulation here is linked directly to the slide in this presentation that provides all the details for that specific regulation. Click on any linked regulation to quickly jump to that regulation's details slide in this presentation.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

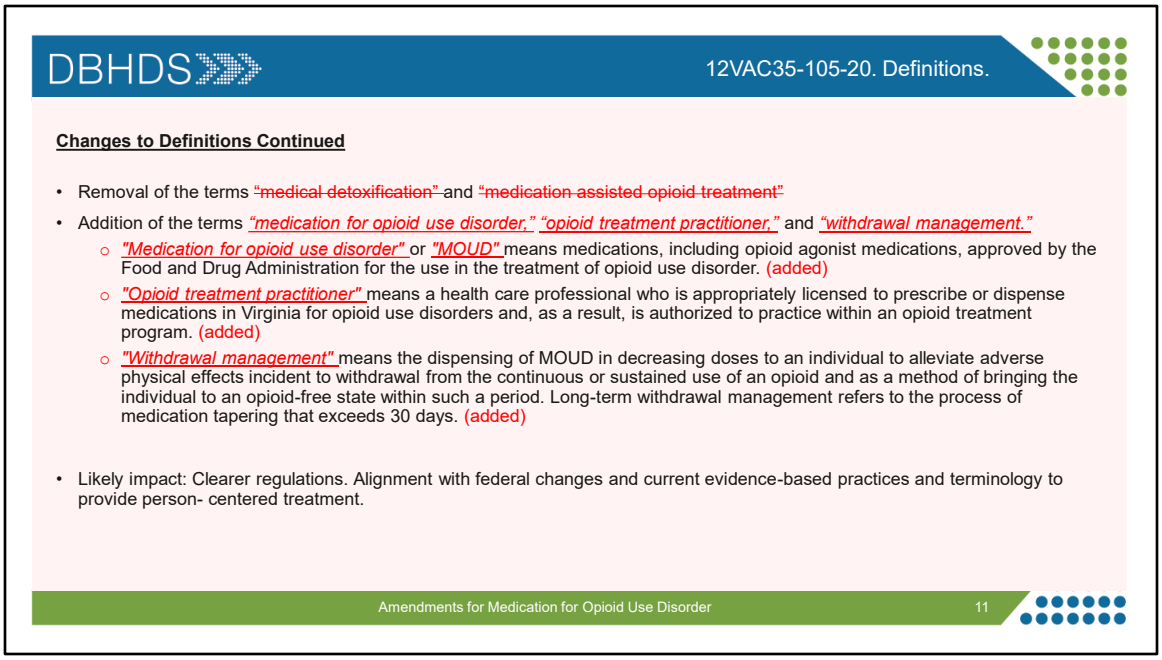


For the purposes of this presentation, when you see Underlined and Italicized text on the slides, that means *that* specific portion of text is *newly added* and is now included in the regulation.

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

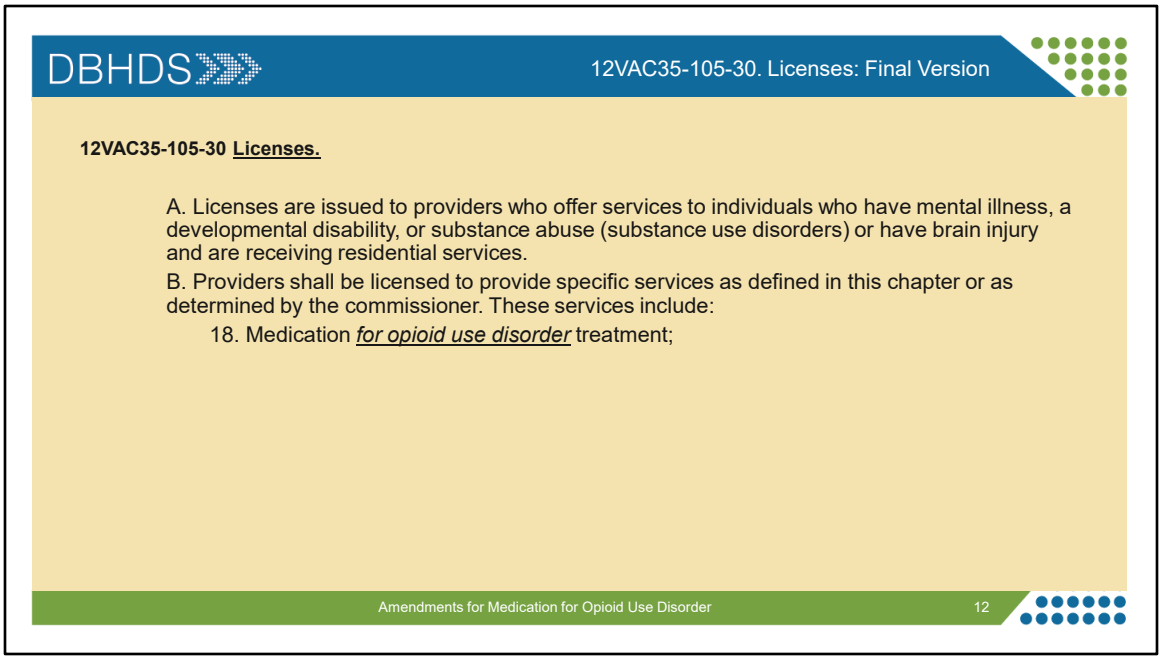


Let’s begin with 12VAC35-105-20. Definitions. Amendments here include the updating of the terms “state opioid treatment authority or SOTA” and some of the terminology in “Service” has been updated which now reflects MOUD



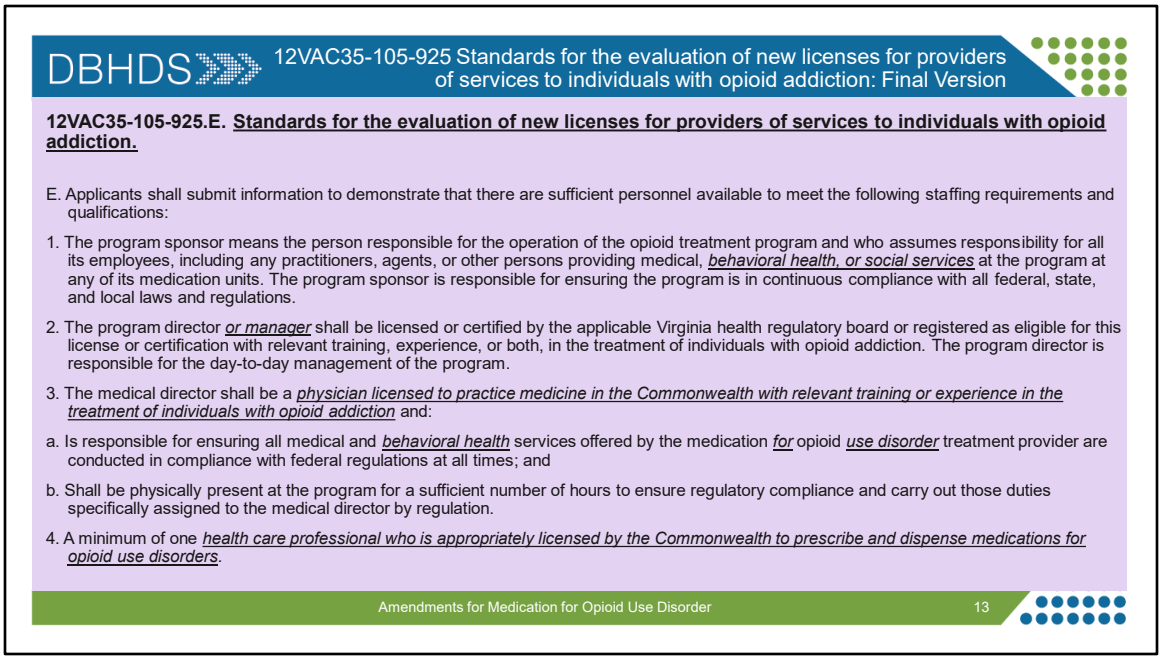
Here we see additional amendments to Definitions, including removal of the terms "medical detoxification" and "medication assisted opioid treatment", and the addition of the terms "medication for opioid use disorder," "opioid treatment practitioner", and "withdrawal management."

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.



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 Standards for the evaluation of new licenses for providers of services to individuals with opioid addiction.

There were no changes made to 925A-D.

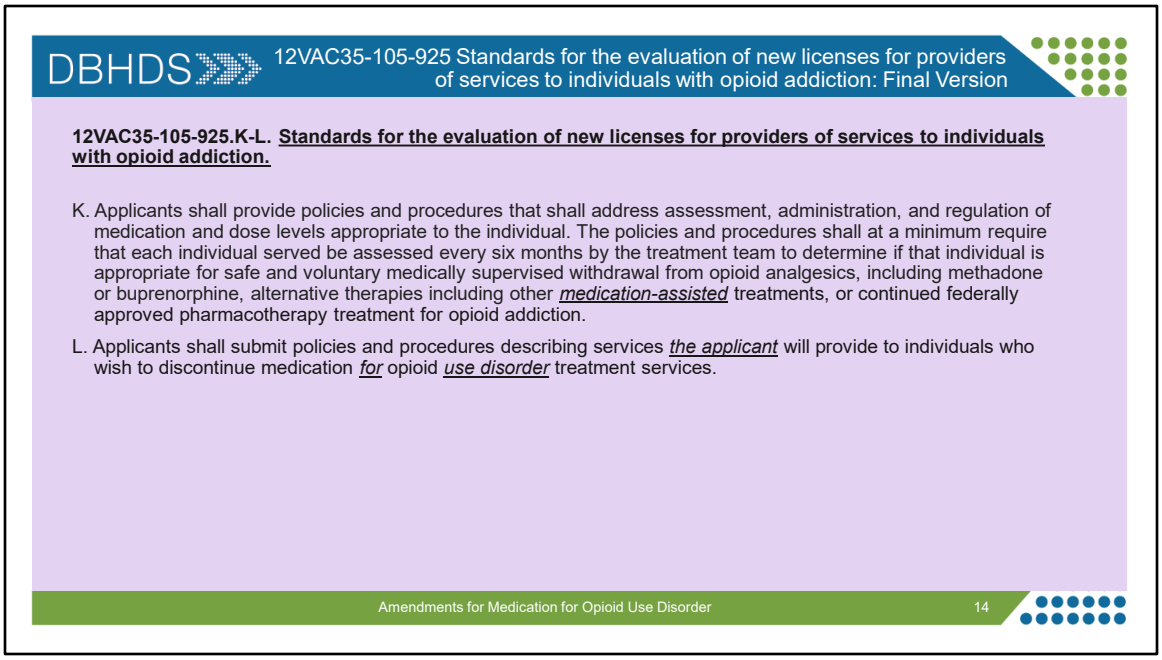
As it relates to 925.E. Amendments here include updated staffing requirements to align with federal changes which reduce the burden on licensed providers. Terminology has been updated from "Medication Assisted Opioid Treatment" to "Medication for Opioid Use Disorder"

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.

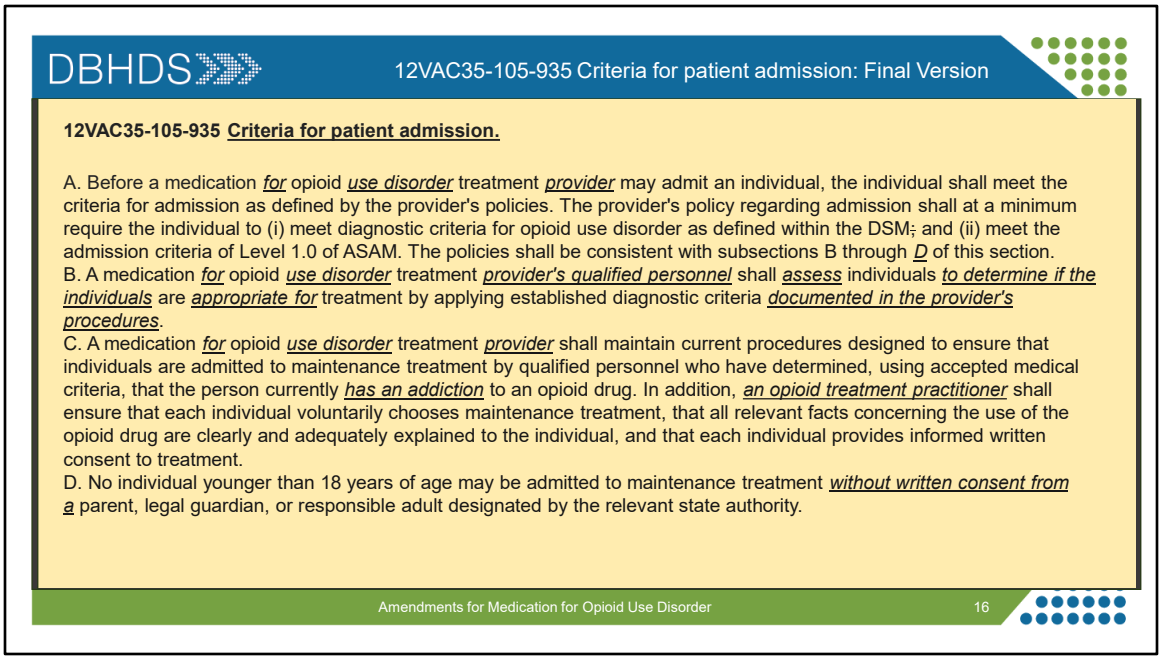


925.K-L These amendments align with federal changes and current terminology.

There were no changes related to 925.M and N

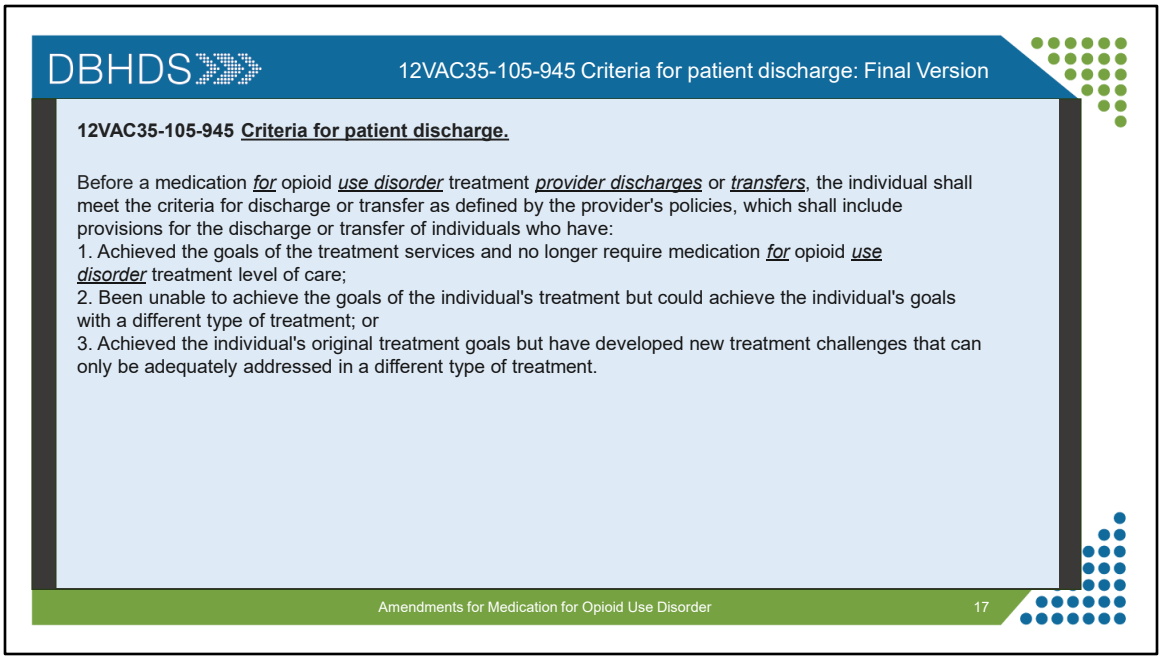
12VAC35-105-930 Registration, certification, or accreditation.

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



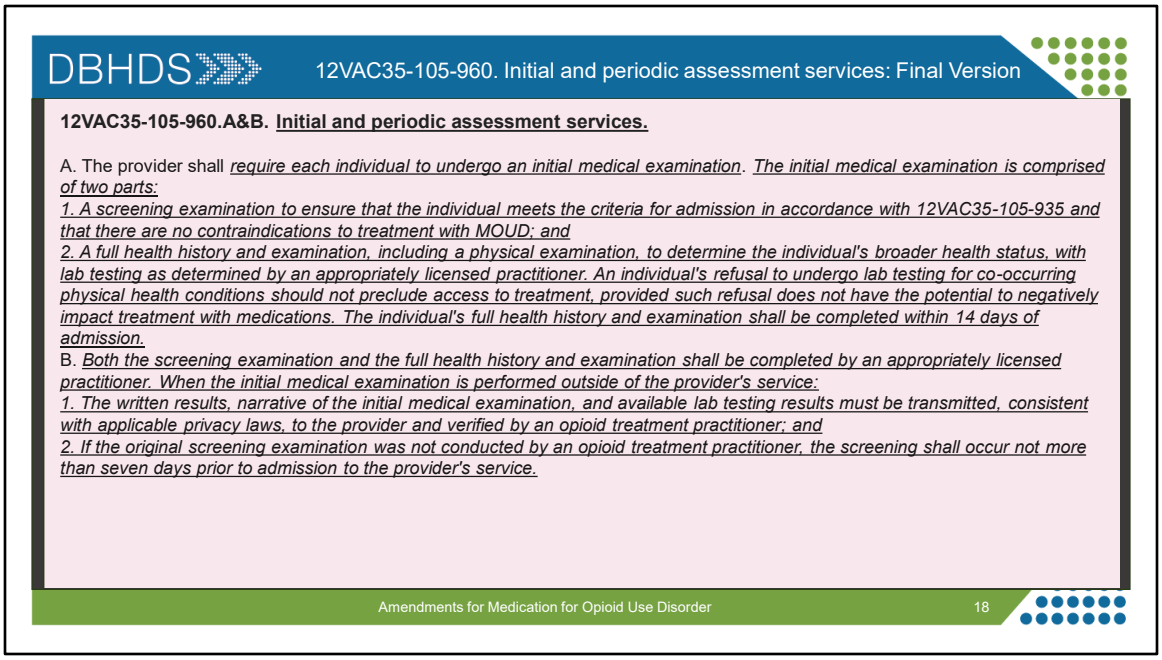
12VAC35-105-935 Criteria for patient admission.

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.

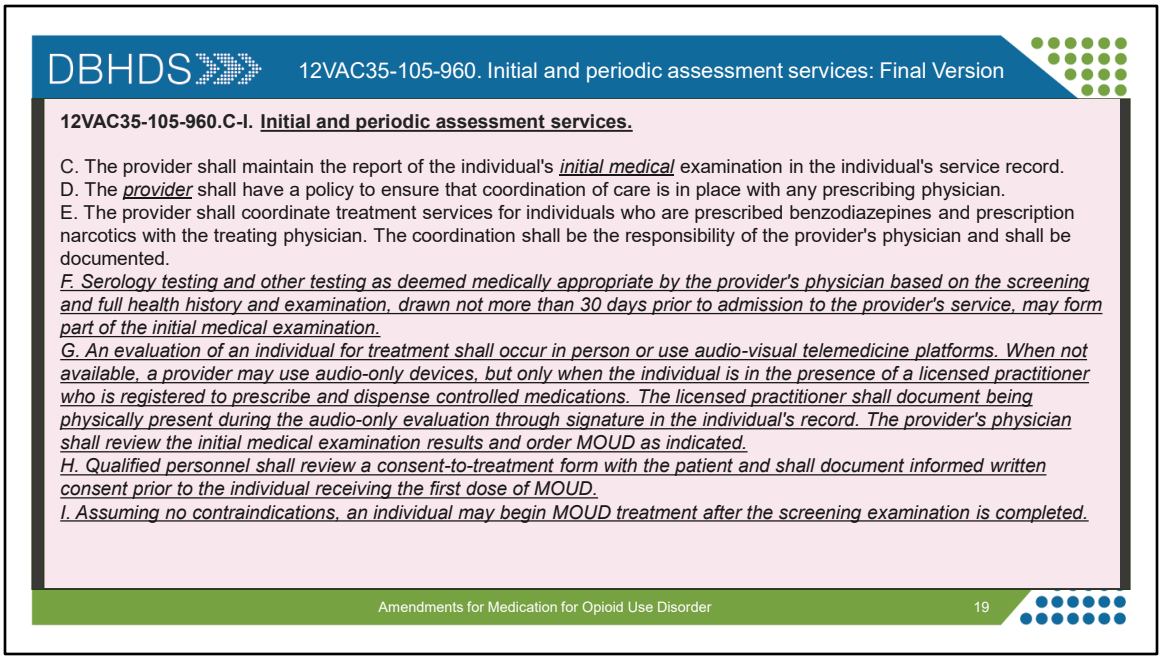


12VAC35-105-945 Criteria for patient discharge.

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

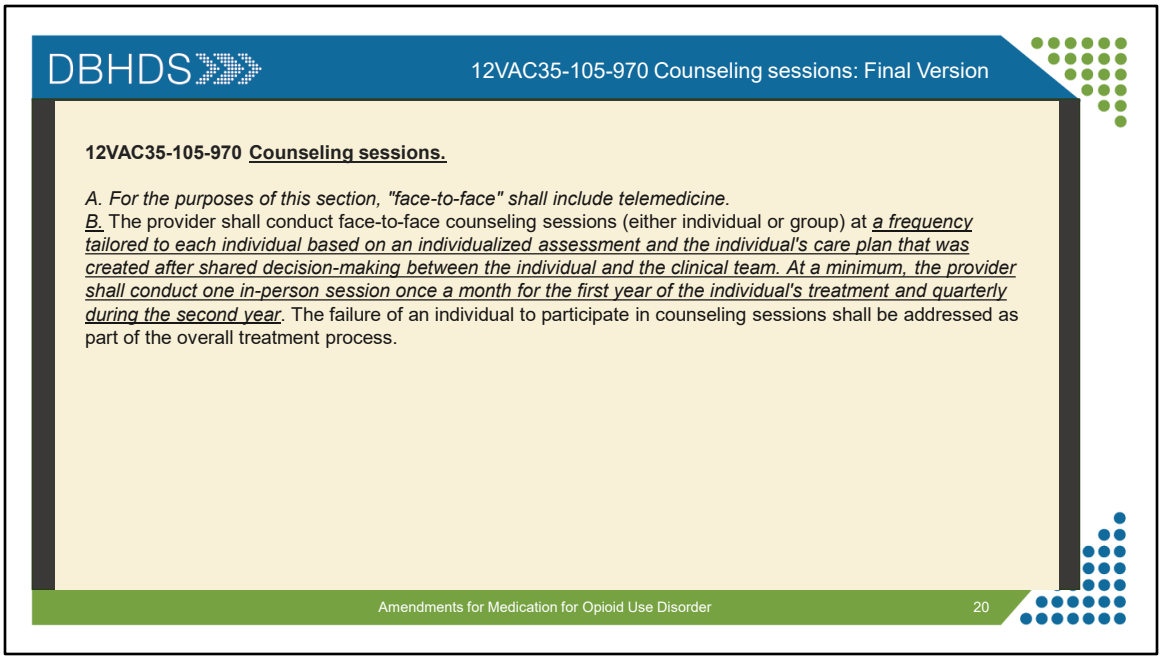


12VAC35-105-960.Initial and periodic assessment services.
Regarding A & B, the requirements for initial medical examinations have been updated. The amendments allow screening examinations to be performed by practitioners external to the Opioid Treatment Program under certain conditions.



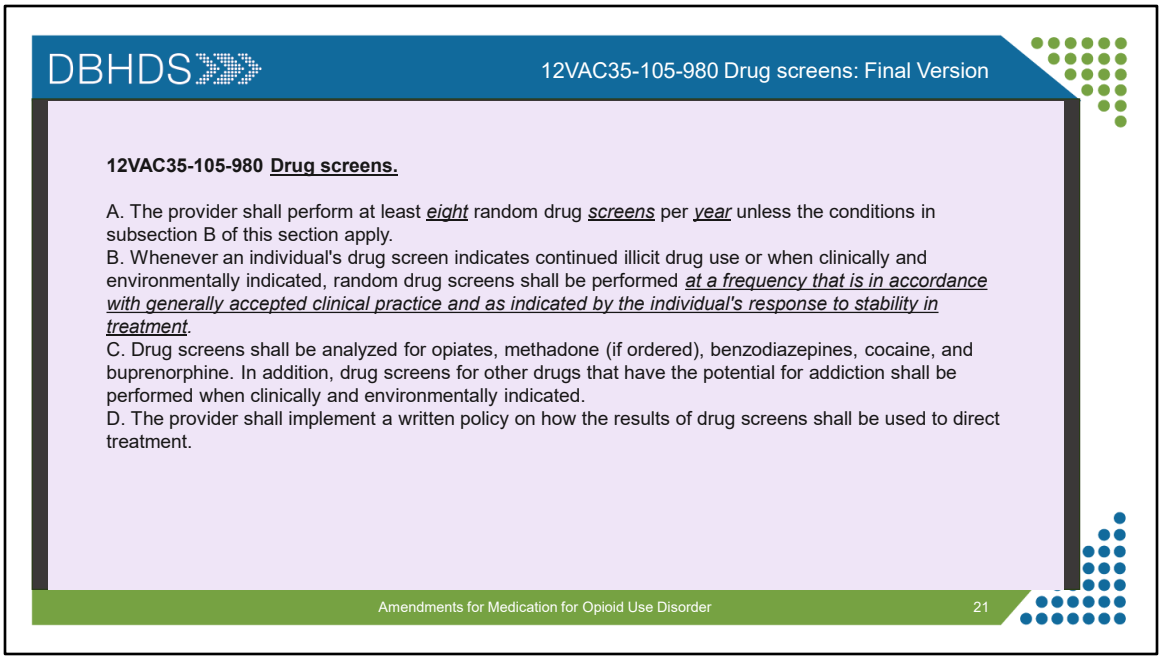
960.C-I: These amendments allow the screening of individuals for admission via audio-only or audio-visual telehealth technology if certain requirements are met.

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



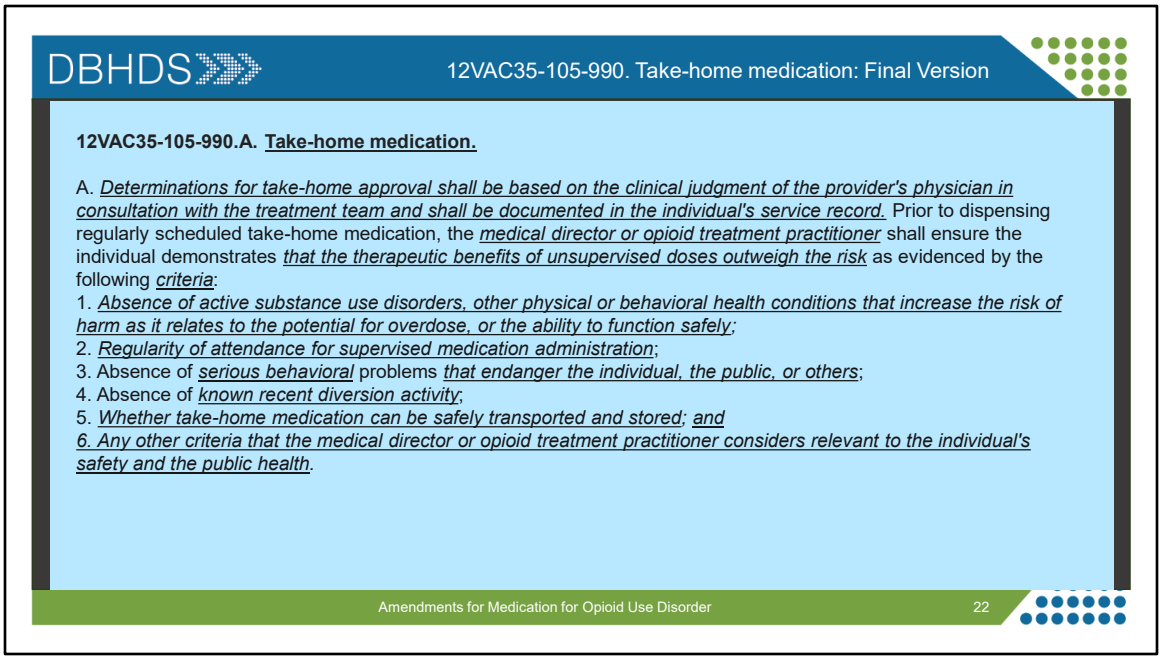
12VAC35-105-970 Counseling sessions.

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.

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.

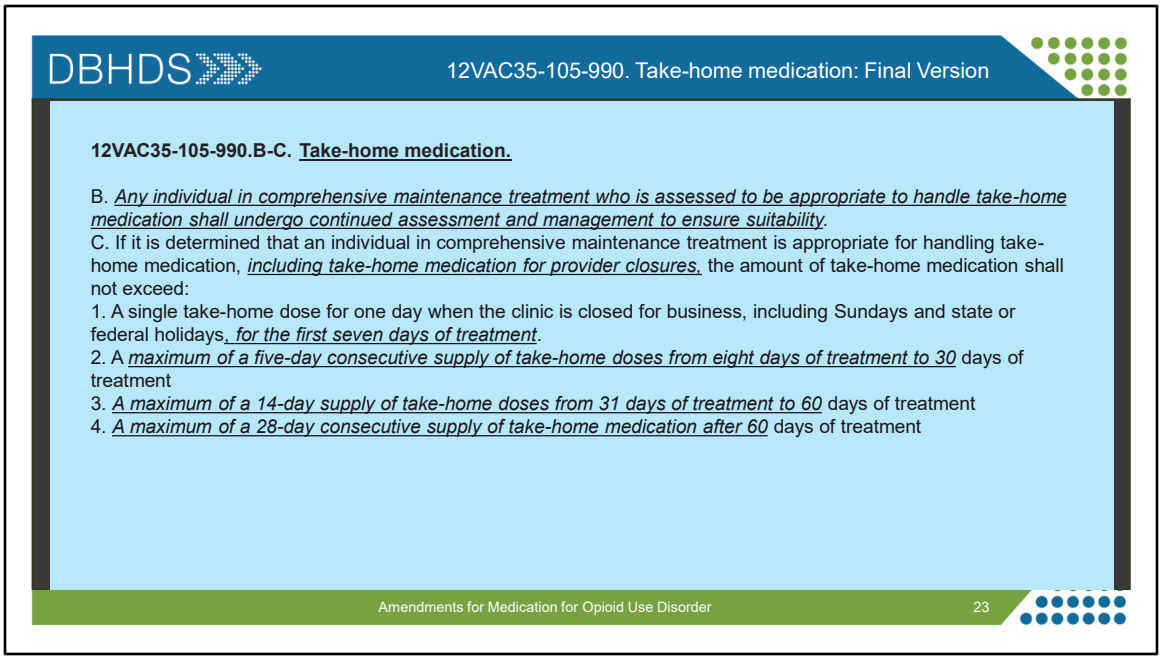


The next few slides are related to 12VAC35-105-990. Take-home medication.

Let's start with 990.A

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

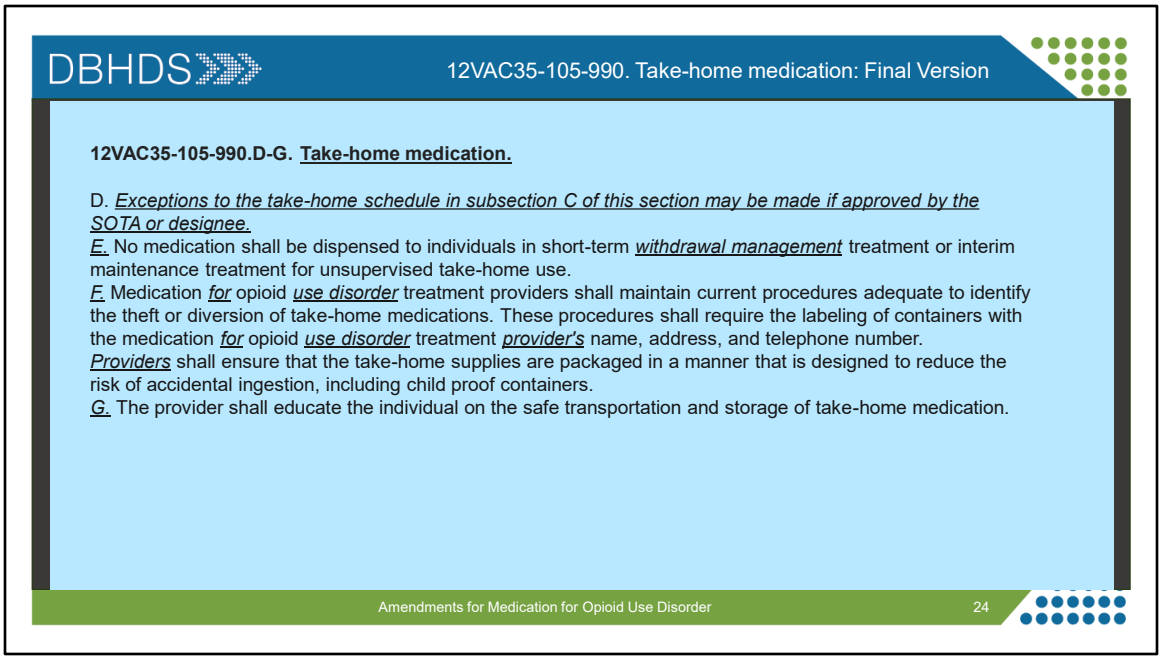
The amended regulations make the Covid 19 flexibilities permanent. These flexibilities demonstrated that wider access to methadone improves outcomes without increasing rates of diversion when paired with individualized treatment, clinical judgement, safeguards and education.



990.B-C:

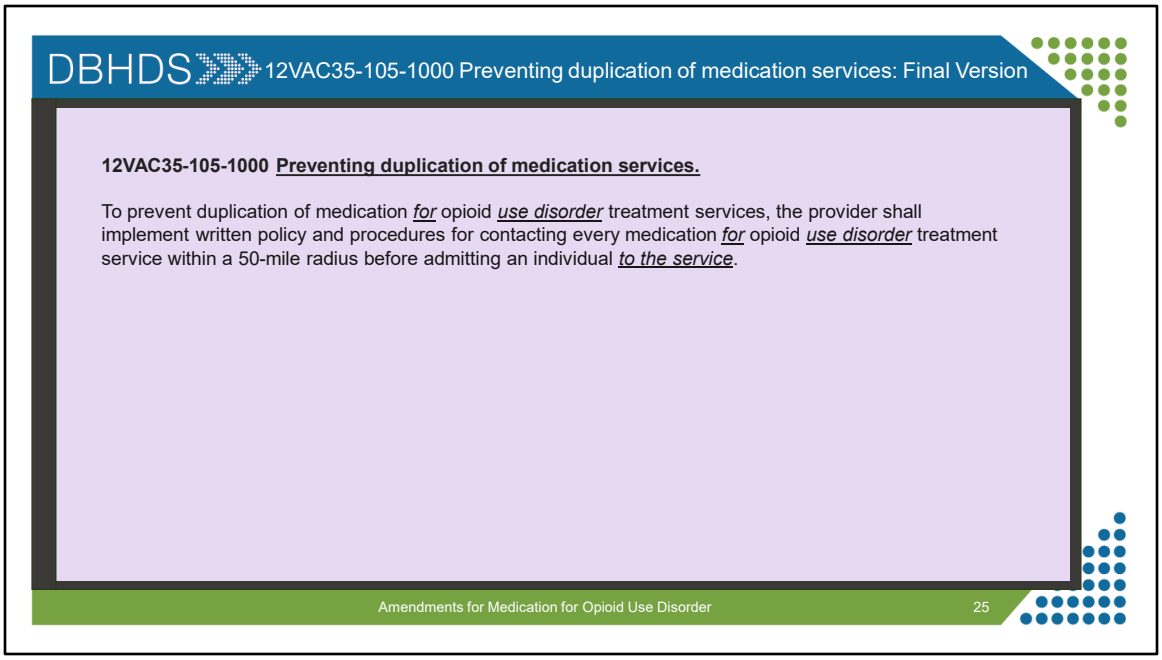
Amendments to these regulation align the criteria for assessment for suitability for take-home medication with federal regulations.
These changes update criteria for consideration of take-home doses of methadone and allow individuals to receive a single take-home dose from the first week of treatment, 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.

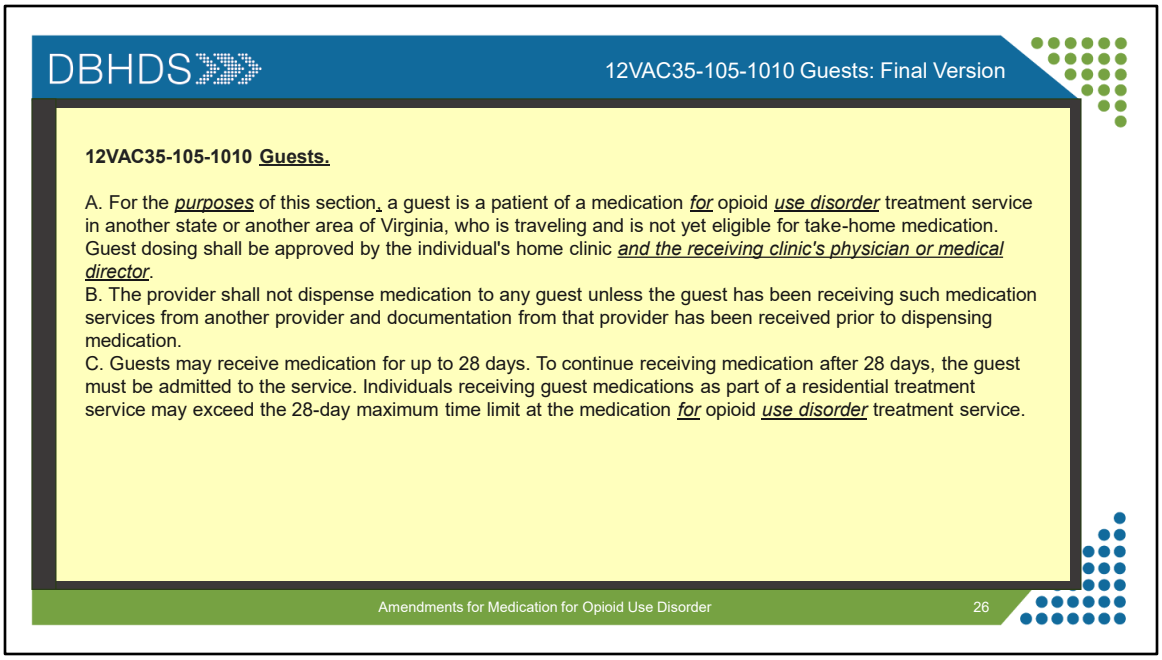


990.D-G. Take-home medication.

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

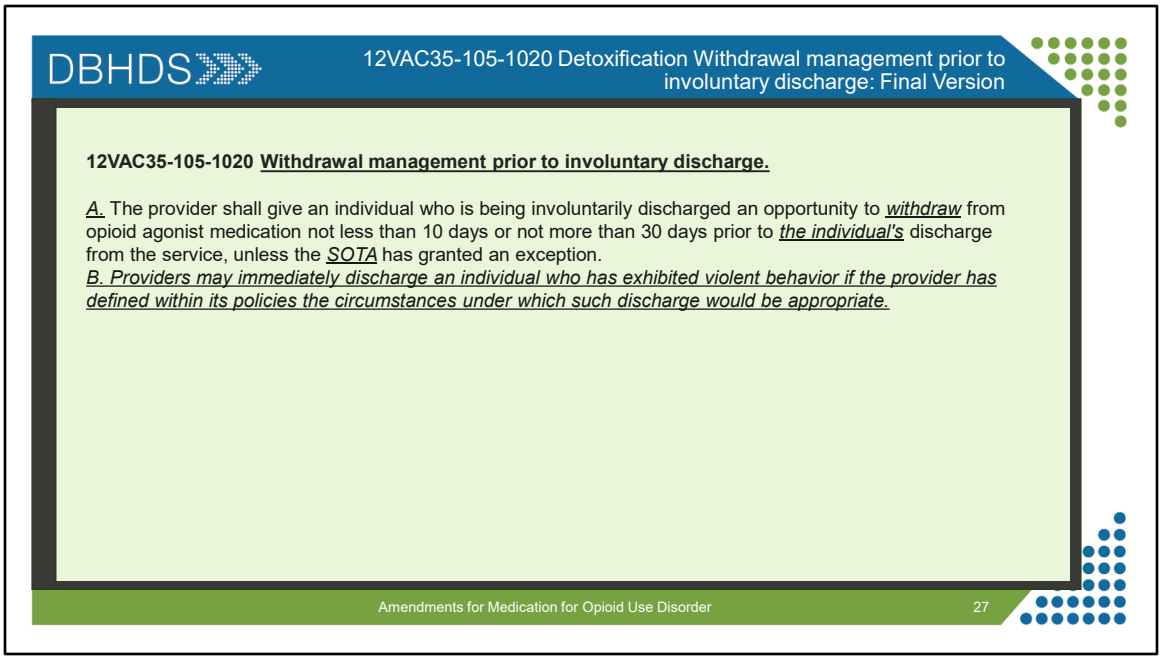


12VAC35-105-1000 Preventing duplication of medication services
These changes align with federal changes and current terminology.



12VAC35-105-1010 Guests

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

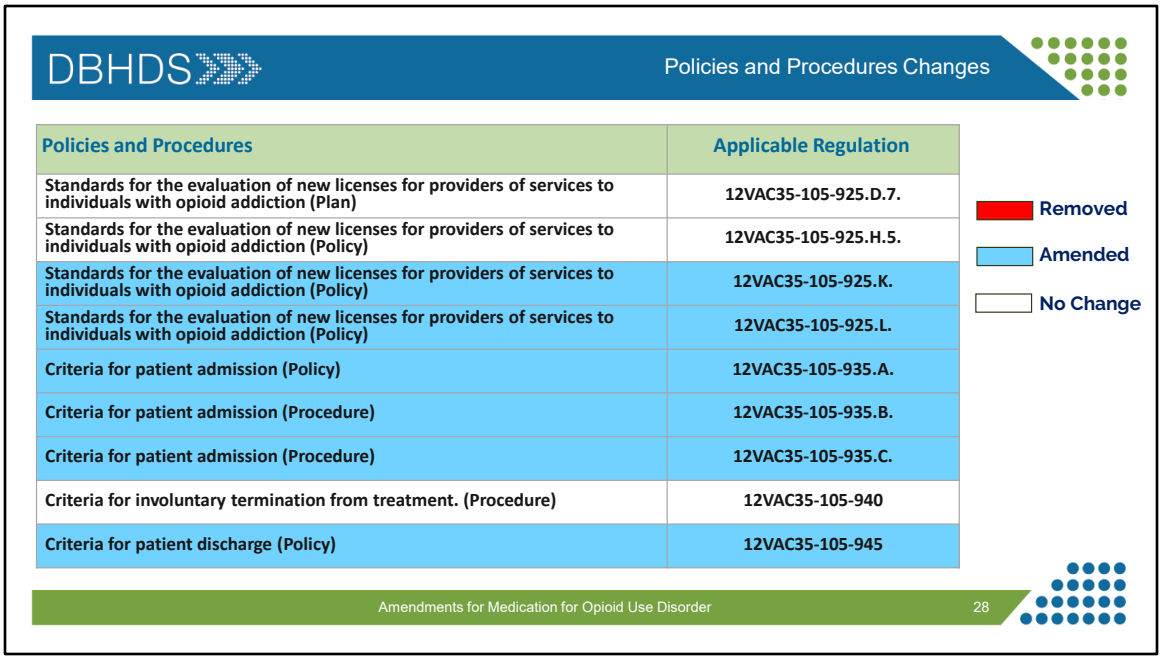


12VAC35-105-1020 Detoxification Withdrawal management prior to involuntary discharge

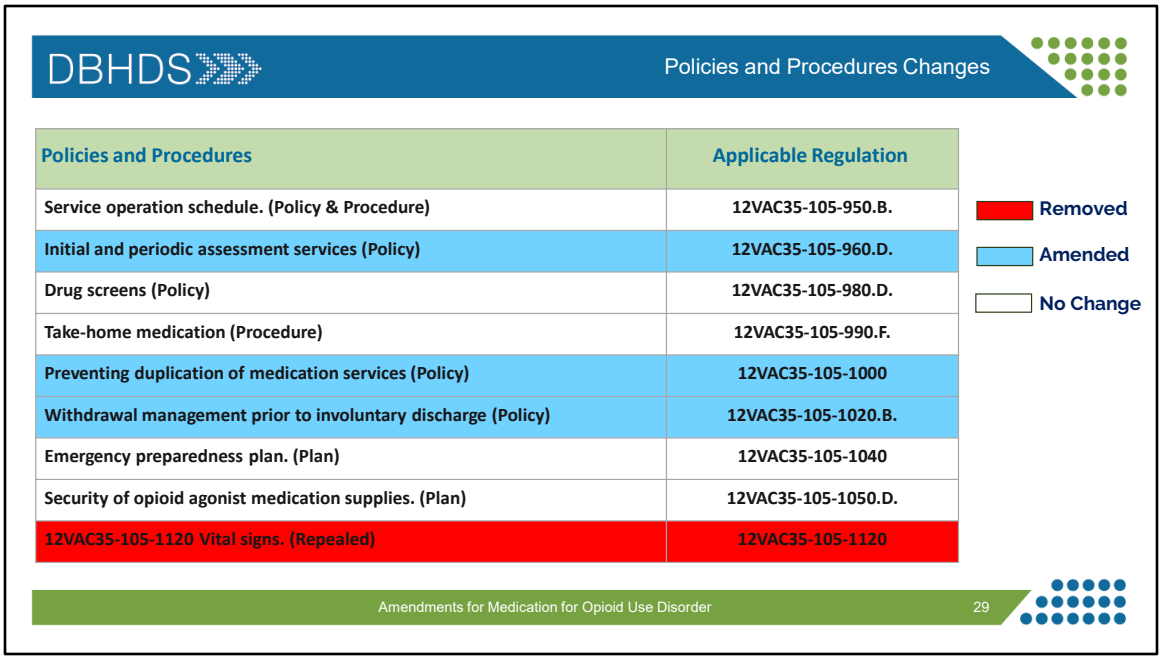
Regulation title changed to replace the term "Detoxification" with "Withdrawal management". Subsections A and B have been added. Updated "state methadone authority" to "State Opioid Treatment Authority", or "SOTA".

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.



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.



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**

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