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New SAMHSA Rule Expands Access to Medications for the Treatment of Opioid Use Disorder

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Introduction/Background:

On February 2nd, the U.S. Department of Health and Human Services (HHS) released a <u>final rule</u> expanding patient access to medications for the treatment of opioid use disorder ("OUD"). This new final rule implements changes that facilitate the use of telehealth generally and in connection with the delivery of care in mobile units, thereby expanding the geographic reach and patient access to opioid treatment programs ("OTPs").

This announcement closely coincides with the two-year milestone since the launch of the Biden administration's <u>Overdose Prevention Strategy</u>, which featured a substantial \$8 billion investment to combat OUD. The prevalence of OUD has developed into a national crisis, and since 1999, overdose deaths from synthetic opioids, including fentanyl, have increased over 100-fold. The Federal government cites abundant evidence showing that methadone, buprenorphine, and naltrexone all reduce opioid use and OUD-related symptoms, and they reduce the risk of infectious disease transmission as well as criminal behavior associated with drug use. Using these medications in controlled environments to address OUD reduces narcotic cravings, effectively blocking the euphoric effects that unrestricted use of street drugs and other synthetic opioids have. The demand for buprenorphine treatment is evident, with approximately 40,000 new patients seeking assistance each month, culminating in a monthly total of around 860,000 patients.

Relative to access to opioid-assisted treatment of OUDs, in June 2021, the U.S. Drug Enforcement Administration (DEA) announced that it would allow all opioid treatment programs to add mobile units to help increase access to medications for opioid use disorder in rural and tribal areas, lifting a 13-year moratorium on new vehicles. As such, in the current environment, OTPs can dispense medication in a brick-and-mortar location or through mobile units. Because of the new rule allowing a telehealth clinician to visit for patient intake and to initiate treatment, individuals suffering from OUD may be reached in situations where they do not have reliable access to transportation and clinicians do not need to travel to reach patients.

Key Takeaways from the February 2nd Final Rule:

- **Telehealth Initiatives**: Allows the initiation of treatment through telehealth, facilitating the use of audio-visual technology for OUD treatment and audio-only technology for buprenorphine treatment.
- Provider Eligibility Expansion: Expands provider eligibility under Federal law to prescribe opioids through an OTP. Now, where state law allows, nurse practitioners and physician assistants may initiate OTP treatment for an individual suffering from OUD.
- Take-home Doses Flexibility: Provides flexibility in the provision of take-home doses of
 methadone via telehealth. Removes prior limitations on unsupervised or take-home use.
 OTPs can now dispense up to 28 days of "take-home" methadone doses for "stable" patients
 and up to 14 doses for "less stable" patients, subject to the OTP's assessment of the patient's
 ability to handle take-home medication safely.
- **Reduced Eligibility Requirement**: Removes the previous requirement for patients to have a one-year history of addiction before becoming eligible for treatment.
- **Mobile Unit Regulations**: Eases regulations regarding mobile units and enables states to utilize block grant funds for the purchase and use of these units.

These OUD treatment expansions are designed to stem disruptions to patients' employment, education, family-care and other responsibilities and allow for a more continuous and reliable treatment plan. Creating more flexibility in accessing treatment is particularly beneficial for individuals facing challenges with reliable transportation.

While this rule broadens telehealth access and provider eligibility, adherence to state requirements is crucial, as they may vary and limit the impact of these expansions. For example, some states may mandate physician supervision for certain healthcare professionals to order methadone. Federal OTP regulations do not override separate state requirements. Additionally, the final rule does not apply to providers prescribing medication for OUDs outside of OTPs.

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