



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

**NOTICE OF ADOPTION
POLICY STATEMENT**

Title of Policy Statement: Enforcement of Opioid Treatment Program Rules in Chapter 246-341 WAC | Policy Number: CHS-04-08-24.

Issuing Entity: Department of Health

Subject Matter: Department of Health enforcement discretion of certain requirements in chapter 246-341 WAC applicable to Opioid Treatment Program licensing and certification.

Effective Date: April 2, 2024

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Policy Statement

Title: Enforcement of Opioid Treatment Program Rules in Chapter 246-341 WAC **Number:** CHS-04-08-24

References: [Chapter 246-341 WAC](#); [WAC 246-341-1000](#); [WAC 246-341-1020](#); [WAC 246-341-1025](#); [42 CFR Part 8](#); [42 CFR Part 8.12](#); [SAMHSA Methadone Take-Home Flexibilities Extension Guidance](#).

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Approved By: Christie Spice, Policy Director

It is the Department of Health’s (department) position that the following requirements under [chapter 246-341 WAC](#) related to Opioid Treatment Program (OTP) licensing and certification will not be enforced due to changes in the federal regulations related to OTP certification and standards for the treatment of Opioid Use Disorder (OUD) under [42 CFR Part 8](#):

- **WAC 246-341-1000(6)(a)** – requires programs providing treatment to youth to ensure that before admission the youth has had two documented attempts at short-term withdrawal management or drug—free treatment within a twelve-month period, with a waiting period of no less than seven days between the first and second short-term withdrawal management treatment.
 - The revised 42 CFR Part 8 removes these requirements.
- **WAC 246-341-1000(4)** - requires an agency providing OTP services to ensure that an individual is not admitted to opioid treatment withdrawal management services more than two times in a twelve-month period following admission to services.
 - The revised 42 CFR Part 8 removes this requirement but for withdrawal management requires an OTP to maintain current procedures that are designed to ensure that those patients who choose to taper from Medications for Opioid Use Disorder (MOUD) are provided the opportunity to do so with informed consent and at a mutually agreed-upon rate that minimizes taper-related risks. OTPs may follow the updated federal requirements outlined in [42 CFR Part 8.12\(e\)\(3\)](#).

- **WAC 246-341-1020(1)** – WAC 246-341-1020(1)(a) requires the program physician or medical practitioner under supervision of the medical director to verify an individual is currently addicted to an opioid drug and that the individual became addicted at least 12 months before admission to treatment. WAC 246-341-1020(1)(b) allows the program physician or medical practitioner to waive the 12-month requirement in WAC 246-341-1020(1)(a) upon receiving documentation that the individual was released from a penal institution if the release was within the previous six months; is pregnant; or was previously treated within the previous 24 months.
 - The revised 42 CFR Part 8 removes these requirements.
- **WAC 246-341-1020(7)(b)** – requires a documented assessment for the appropriateness of Sunday and holiday take-home medications as required in 42 CFR Part 8.12(i).
 - The revised 42 CFR Part 8 does not require a documented assessment.
- **WAC 246-341-1025(2)(b)** - requires an agency providing OTP services to ensure that the initial dose of methadone must not exceed thirty milligrams and the total dose for the first day must not exceed forty milligrams unless the program physician documents in the individual’s record that forty milligrams did not suppress opioid abstinence symptoms.
 - 42 CFR Part 8 was amended to increase the initial dosage limit from 40 milligrams up to 50 milligrams unless the OTP medical practitioner finds sufficient medical rationale and documents in the patient record that a higher dose is clinically indicated. OTPs may follow the amended requirement for the initial dosage limit of methadone outlined in 42 CFR Part 8.12(h)(3)(ii).
- **WAC 246-341-1025(4)(a)** and **WAC 246-341-1025(4)(d)** – WAC 246-341-1025(4)(a) requires programs to ensure that all take-home medications are authorized only to stable individuals who have received MOUD for a minimum of ninety days and have not had any positive drug screens in the last sixty days. WAC 246-341-1025(4)(d) requires programs to ensure that all take-home medications are not allowed in short-term withdrawal management or interim maintenance treatment.
 - Take-home requirements in 42 CFR Part 8 were updated to adopt the [SAMHSA methadone flexibilities](#) that were allowed during COVID-19 pandemic, which allow for the medical practitioner to determine take-home eligibility for each patient admitted to treatment. OTPs may follow the updated federal requirement for take-homes outlined in 42 CFR Part 8.12(i).

On April 2, 2024, the Substance Abuse and Mental Health Administration (SAMHSA) adopted updated regulations in 42 CFR Part 8 related to OTP accreditation, certification, and standards for the treatment of OUD with MOUD.

All OTPs are required to follow the federal regulations in 42 CFR Part 8 in addition to state regulations outlined in chapter 246-341 WAC. SAMHSA is allowing agencies until October 2, 2024 to comply with the revised federal regulations. However, agencies may want to begin following the

revised federal rule sooner because it removed unnecessary barriers to expand access to OUD treatment. The federal rule changes were created in an evidence-based manner to support engagement in treatment, and other activities that are associated with recovery ([42 CFR Part 8 Final Rule - Frequently Asked Questions | SAMHSA](#)). The rise in fentanyl use or exposure and overdose deaths necessitated changes to increase access to care. Removing enforcement for certain state regulations outlined in this policy statement will further support access to care in Washington state.

The department has initiated a rulemaking project under [WSR 23-17-078](#) to align chapter 246-341 WAC with requirements in 42 CFR Part 8. This policy statement will be withdrawn after the rule changes to chapter 246-341 WAC go into effect.