




LICENSING ALERT 07-2024

Exceptions related to 42 CFR Part 8

Kelly Primus 
Deputy Secretary
Department of Drug and Alcohol Programs

September 27, 2024

Effective date: Immediately

Purpose: To grant statewide exceptions under [28 Pa. Code § 701.11](#) to Narcotic Treatment Programs (NTPs) to expand access to medication for the treatment of opioid use disorder (MOUD) if they comply with updated federal regulations for the certification of Opioid Treatment Programs (OTPs) under [42 CFR Part 8](#).

Background: In February 2024, the U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA) published a final rule amending the federal regulations for the certification of OTPs in [42 CFR Part 8](#). The changes to the federal rules were used temporarily to improve access to treatment during the COVID-19 federal public health emergency. SAMHSA has now made those changes permanent. The Department intends to implement the updated federal rules and reduce barriers to treatment. Through this Licensing Alert, the Department is granting exceptions to some state rules for OTPs if the OTPs comply with the rules in [42 CFR Part 8](#). The Department plans to include the changes to the federal rules when it updates its own state rules. Some of the changes include:

- Not making someone be physically dependent on opioids for one year prior to being admitted for treatment.
- Allowing verbal consent to treatment.
- Allowing a wider range of dosages based on physician discretion.
- Allowing eight drug screens per year instead of 12.
- Allowing more people to take their medication home instead of going to the OTP for it as often.
- Making counseling requirements unique to each person's needs.

The federal regulations continue to require OTPs and clinicians to comply with pertinent state laws and regulations. See [42 CFR 8.11\(e\)\(1\)](#). For this reason, the Department is not currently granting an exception to the provision in [28 Pa. Code § 715.9](#) that requires a face-to-face determination at intake. Regulations of the State Board of Medicine and State Board of Nursing require a physical, in-person examination before prescribing, administering, or dispensing a controlled substance like methadone. Even though the updated federal regulations allow for an

initial evaluation and screening to be completed by telehealth in some cases, clinicians must remain in compliance with their professional licensure requirements. Other state agencies share the goal to expand access to MOUD and the Department will provide more information if those rules change as well.

Procedures: The Department is granting the exceptions listed below by issuing this Licensing Alert. There is no need for OTPs to submit exception requests or to inform the Department if they are using these exceptions.

[28 Pa. Code § 715.9\(a\)\(1\)](#) – The Department will allow an exception to the rule that a person must be 18 years of age to receive MOUD provided that the OTP gets written consent from the client in accordance with [42 CFR § 8.12\(e\)\(2\)](#).

[28 Pa. Code § 715.9\(a\)\(4\)](#) – The Department will allow an exception to the rule that a person must be dependent on a narcotic drug for at least one year prior to starting MOUD provided that the OTP has a trained person to diagnose the client using medical criteria in accordance with [42 CFR § 8.12\(e\)\(1\)](#) and documents the reason for admission for MOUD treatment in the record.

[28 Pa. Code § 715.12](#) – The Department will allow an exception to the rule requiring written consent provided that the OTP gets informed consent from the client verbally in accordance with [42 CFR § 8.12\(e\)\(1\)](#) and documents it in the record.

[28 Pa. Code § 715.14\(a\)](#) – The Department will allow an exception to testing a person’s urine every month provided that the OTP randomly conducts a saliva or urine test on each person a minimum of eight times in a year in accordance with [42 CFR § 8.12\(f\)\(6\)](#).

[28 Pa. Code § 715.15](#) – The Department will allow an exception to the rule requiring a doctor to decide the dosage level for a person provided that a qualified practitioner within their licensed scope of practice to prescribe or dispense MOUD decides the dosage based on an individualized determination in accordance with [42 CFR § 8.12\(h\)\(3\)\(ii\)](#). Pennsylvania laws governing the practice of medicine permit qualified practitioners to perform and sign the initial assessment but also require that any order for methadone treatment shall be made only by a physician. See Medical Practice Act of 1965, 63 P.S. § 422.13(c.1)(7); Osteopathic Medical Practice Act, 63 P.S. § 271.10(g.2)(1)(vii); and The Professional Nursing Law, 63 P.S. § 218.2(c.1)(8).

[28 Pa. Code § 715.16. Take-home privileges](#) – The Department will allow an exception to the rule requiring time frames for take-home medications provided that the OTP approves take-home medications only if the benefits are greater than the risks in accordance with [42 CFR § 8.12\(i\)](#).

[28 Pa. Code § 715.19\(1-3\)](#) – The Department will allow an exception to the rule requiring an OTP to provide mandatory minimum amounts of psychotherapy each month based on the patient’s time in treatment. Provided the OTP delivers adequate counseling and psychoeducation to each patient as clinically necessary and mutually agreed upon. Patient refusal of counseling shall not preclude them from receiving MOUD in accordance with [42 CFR § 8.12\(f\)\(4\)\(i\)](#).

[28 Pa. Code § 715.24\(1\)](#) – The Department will allow an exception to the 180-day limit for detoxification services provided that the OTP allows a person to reduce MOUD at a mutually agreed-upon rate in accordance with [42 CFR § 8.12\(e\)\(3\)](#).

Please send an email to RA-licensuredivision@pa.gov with questions about this Licensing Alert.