




LICENSING ALERT 01-2025

Exceptions related to 42 CFR Part 8

****This Licensing Alert rescinds and replaces Licensing Alert 07-2024, “Exceptions related to 42 CFR Part 8,” issued September 27, 2024.****

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Deputy Secretary
Department of Drug and Alcohol Programs

March 12, 2025

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](#). The Department of Drug and Alcohol Programs (DDAP) first granted statewide exceptions based on these federal regulations by issuing Licensing Alert 07-2024 in September 2024. This alert expands the exceptions to allow expanded use of telehealth in initial screening and physical examinations consistent with medical practice regulations of the State Board of Medicine.

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 treatment using buprenorphine or methadone following an initial telehealth examination, using appropriate methods of communication based on the person’s individual needs and followed by an in-person physical examination within 14 days after admission.
- 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\(e\)\(1\)](#). Effective [December 21, 2024](#), the State Board of Medicine amended its regulation regarding prescribing, administering, and dispensing controlled substances. The updated regulation mirrors federal regulations by allowing regulated practitioners in OTPs to conduct initial physical examinations by telehealth and initiate treatment with buprenorphine or methadone in compliance with federal requirements and requires an in-person physical examination to be completed within 14 days after admission. Therefore, DDAP is also granting an exception to allow use of telehealth for initial screenings and examinations under the same conditions.

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 requires a face-to-face determination whether a person has been 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. The Department will allow telehealth for the initial screening and medical examination provided that the clinician determines that they can complete an adequate examination through that method, that the mode of telehealth is permissible for the MOUD to be used in accordance with [42 CFR 8.12\(f\)\(2\)\(v\)](#), and that OTP completes a full in-person physical examination within 14 days of admission in accordance with [42 CFR 8.12\(f\)\(2\)\(iii\)](#).

[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\(a\)](#) and (b) – The Department will allow an exception to the rule requiring a narcotic treatment physician to decide the initial dosage level for a person, provided that a qualified practitioner, acting within their licensed scope of practice to prescribe or dispense methadone, decides the initial dosage. Licensing regulations at [28 Pa. Code § 715.6\(e\)](#) already allow other licensed practitioners to perform functions of the narcotic treatment physician if those functions

are within the practitioners scope of practice and delegated and supervised in accordance with the applicable licensing board. There is no need for an OTP to request a mid-level exemption from SAMHSA to allow a physician assistant or certified registered nurse practitioner make the initial dosing decision for methadone or any other MOUD. Any initial dosing decision for methadone must be 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, 63P.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 person’s time in treatment. Provided the OTP delivers adequate counseling and psychoeducation to each person as clinically necessary and mutually agreed upon. Individual refusal of counseling shall not preclude them from receiving MOUD in accordance with [42 CFR § 8.12\(5\)](#).

[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.