

5122-40-04

**General licensure requirements.**

- (A) An alcohol and drug addiction program desiring to obtain an initial license or renew a license as an opioid treatment program shall:
- (1) Be certified as a provider pursuant to Chapter 5122-25 of the Administrative Code at a minimum for the following services:
    - (a) General services in accordance with rule 5122-29-03 of the Administrative Code;
    - (b) SUD case management services in accordance with rule 5122-29-13 of the Administrative Code; and,
    - (c) Crisis intervention in accordance with rule 5122-29-10 of the Administrative Code.
  - (2) Submit with the application for initial license or license renewal a licensure fee as set by paragraph (B)(2) of rule 5122-40-08 of the Administrative Code;
  - (3) Submit a renewal application at least ninety days prior to the expiration of the current license.
  - (4) When applying for renewal licensure, be accredited as an opioid treatment program by an accreditation body that has been approved by SAMHSA;
  - (5) Be certified by SAMHSA pursuant to "certification of opioid treatment programs," 42 C.F.R. Part 8.11;
  - (6) Have a category III terminal distributor of dangerous drugs license from the state board of pharmacy pursuant to Chapter 4729. of the Revised Code;
  - (7) Have a security and alarm system that is approved by the United States drug enforcement administration;
  - (8) Meet the security requirements for the distribution and storage of controlled substances as required by 21 C.F.R. 1301.72 to 21 C.F.R. 1301.76;
  - (9) Operate the program in accordance with 21 C.F.R. 291.505, conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of various classes of narcotic addicts under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (Oct. 27, 1970);

- (10) Have a program sponsor who has signed and submitted SAMHSA form SMA-162, application for certification to use opioid drugs in a treatment program under 42 CFR 8.11;
- (11) Be in good standing with the state board of pharmacy, centers for medicare and medicaid services, Ohio department of medicaid, , and the United States drug enforcement administration;
- (12) Be in good standing as defined by ~~division (C)(1) of section 5119.391 of the Revised Code until June 29, 2019 and~~ division (C)(1) of section 5119.37 of the Revised Code ~~after June 29, 2019~~;
- (13) Demonstrate the ability to meet the standards of medical care for opioid treatment services established by the American society of addiction medicine (ASAM) criteria, third edition (2013), or other nationally recognized standards organization selected by the director;

(B) Geographic restrictions:

- (1) A program applying for an initial license shall not be issued a license if the provider is requesting an initial license for a particular location that is located on a parcel of real estate that is within a radius of five hundred linear feet of the boundaries of a parcel of real estate having situated on it a public or private school, child day-care center licensed under Chapter 5104. of the Revised Code, or child-serving agency regulated by the department under Chapter 5119. of the Revised Code.
- (2) The five-hundred foot restriction may be waived if the program obtains a letter of support from each public or private school, licensed child day-care center, or other child-serving agency within the five hundred linear foot radius of the location where the opioid treatment program is to operate.
- (3) Programs will perform their due diligence to evaluate this criterion before submitting the application for licensure.
- (4) If a determination was not applied for and made by the program prior to submitting a license application pursuant to ~~section 5119.392 of the Revised Code until June 29, 2019 or~~ section 5119.371 of the Revised Code ~~after June 29, 2019~~, the department, upon receiving a license application, shall proceed to make the determination if there is such a public or private school, licensed child day-care center, or other child-serving agency regulated by the department under Chapter 5119. of the Revised Code within the five-hundred foot radius of the location listed on the application and issue a declaration of its findings in accordance

with ~~section 5119.392 of the Revised Code until June 29, 2019~~ or section 5119.371 of the Revised Code ~~after June 29, 2019~~.

- (5) For license renewals, the geographic restrictions of this paragraph shall not apply pursuant to division (K) of ~~section 5119.391 of the Revised Code until June 29, 2019~~, or section 5119.37 of the Revised Code ~~after June twenty-ninth~~, so long as the program remains continuously licensed.
- (C) An opioid treatment provider shall inform the department of any adverse action or proposed adverse action that is issued to the provider or owner, or is issued to any other program, corporation, entity or partnership with which the opiate treatment program's sponsor, medical director, administrator or a principal is associated. Adverse action is defined as a notice issued by a state, province federal or similar licensing or regulatory authority to deny, revoke, suspend, place on probation or take similar action against a provider's license, certificate or other approval to operate an opioid treatment program. Notice provided to the department shall consist of a copy of the notice of adverse action or proposed adverse action, and all of that opioid treatment program's compliance or monitoring reports issued for the prior three-year period. The opioid treatment provider shall provide this information to the department at the following times:
- (1) At the time of initial or renewal application; and,
  - (2) Within seven days of receipt of notice.
- (D) Upon receipt of an application, the department shall review the materials to determine if they are complete. If an application is incomplete, the department shall notify the applicant of corrections or additions needed, and may return the materials to the applicant. Incomplete materials shall not be considered an application for licensure, and return of the materials or failure to issue a license shall not constitute a denial of an application for licensure.

Effective: 6/11/2021

Five Year Review (FYR) Dates: 3/25/2021 and 06/11/2026

CERTIFIED ELECTRONICALLY

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Certification

06/01/2021

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Date

Promulgated Under: 119.03  
Statutory Authority: 5119.37  
Rule Amplifies: 5119.37  
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