

5122-40-03

Issuance of licenses.

- (A) The department may issue a license for the program only if it has been determined to the department's satisfaction that the program is adequately staffed and equipped to maintain an opioid treatment program by demonstrating compliance with the licensure requirements set forth in section 5119.37 of the Revised Code and Chapter 5122-40 of the Administrative Code.

The department shall not issue a license if program cannot affirmatively demonstrate that it will maintain strict compliance with all laws relating to drug abuse or this chapter.

- (B) The state authority shall coordinate the licensure process among the licensing authorities including the department, SAMHSA, the United States drug enforcement administration, and the state board of pharmacy.

- (C) A license to operate an opioid treatment program is for a ~~one~~two-year time period, unless the department stipulates the opioid treatment program license period will be one year as described in paragraph (D) of this rule.

- (D) The department may stipulate an annual renewal of an opioid treatment program license for a program that the department has concerns regarding either compliance with Chapter 5122-40 of the Administrative Code or active investigations by other state or federal regulating entities. Any decision the department makes pursuant to this division is final and not subject to appeal, or further review under Chapter 119. of the Revised Code

- (1) Each program with which the department has concerns will be given a three-month period in which to make corrections based on the department's written findings of non-compliance. The three-month period will begin on the date which the department sends the findings to the opioid treatment program.

- (2) If the department determines that corrections have not been made at the end of the three-month period, the department may change the opioid treatment program license to a one-year license period beginning on a date determined by the department.

- (3) The opioid treatment program will return to a two-year license period upon the completion of two annual licensure periods with no significant findings.

- ~~(D)~~(E) A license is not transferable to any other site or property.

- ~~(E)~~(F) A license is valid only for the licensed provider named in the application, and is not transferable to or assumable by any other person, corporation, or entity, including

any person or entity which purchases the licensed program or the licensed program's corporate or managing entity, or enters into any similar purchase agreement.

~~(F)~~(G) The license must be posted in an area visible to residents and visitors at the program facility at all times and made available for inspection to any person who requests it.

~~(G)~~(H) The department may conduct surveys or inspections of licensed programs, as it deems necessary and appropriate, to determine initial or continued compliance with requirements or to determine whether deficiencies have been corrected, or upon complaint or allegation of licensure violations. Inspections or surveys may be unscheduled and unannounced. The department shall conduct inspections of all licensed opioid treatment programs at least once every ~~twelve~~twenty-four months.

~~(H)~~(I) The department shall have access to all records, accounts, and other documents relating to the operation of the program, as well as access to all areas in the program facility and to the staff, and all patients, as the department deems necessary and appropriate.

~~(I)~~(J) The program shall be responsible for notifying the department of any changes or proposed changes concerning the information submitted and attested to in the application, or in the operation of the program, or the continued compliance of the facility with the requirements for licensure.

~~(J)~~(K) The department may permit the opioid treatment program to develop a plan of correction to address any noted violations or deficiencies.

~~(K)~~(L) The department may grant a waiver or variance to the provisions of this chapter. However, requests for waivers and variances that would adversely affect the quality of services or the health and safety of patients will not be granted.

(1) A provider shall submit a written request to the department for a waiver or variance. The written request shall state clearly the rationale and need for the requested waiver or variance.

(2) The waiver shall be for a period of time determined by the department, not to exceed the expiration date of the current license.

~~(L)~~(M) The department may deny or revoke a license of an opioid treatment program for one or more of the following reasons:

(1) The program does not meet the requirements of division (C) of section 5119.37 of the Revised Code and rule 5122-40-04 of the Administrative Code;

- (2) The program fails to achieve or retain certification in accordance with Chapter 5122-25 of the Administrative Code;
- (3) The program is not in compliance with the requirements for licensure as set forth by the rules in this chapter;
- (4) The program has been cited for a pattern of serious noncompliance or repeated violations of statutes or rules during the period of current or previous licenses;
- (5) The program presents or submits false or misleading information as part of a license application, renewal, or investigation;
- (6) The program permits an employee to falsify information on patient records;
- (7) The program is aware of an employee who has abused or neglected a patient and has failed to take appropriate disciplinary action to correct the situation;
- (8) The program fails to provide timely access to its records as requested by the department;
- (9) The program is in violation of any provision of any state or federal law or rule relating to drug abuse;
- (10) The program, provider, owner, sponsor, medical director, administrator, or principal of the provider is not in good standing in any other jurisdiction in which the opioid treatment program currently provides services, or was not in good standing at all times within the past three years in any other jurisdiction in which the program previously provided substance use treatment services, that are comparable to the opioid treatment program services authorized under section 5119.37 of the Revised Code; or,
- (11) The applicant, operator, owner, sponsor, medical director, administrator, or principal is or has been a principal with a opioid treatment program that has had a previous license to operate in Ohio revoked or denied renewal for any reason other than nonpayment of the license fee unless:
 - (a) A minimum period of three years has passed from the date of the director's order denying the issuance of an initial license or a minimum period of three years has passed from the date of the director's order revoking a license or denying the renewal of a license; and,
 - (b) The licensure revocation or non-renewal was not due to any act or omission that is a violation of any provision of any state or federal law or rule relating to drug abuse.

(12) The program fails to timely notify the department of any adverse action or proposed adverse action as required by rule 5122-40-04 of the Administrative Code.

(13) The program loses licensure or certification as an opioid treatment program from SAMHSA, the United States drug enforcement administration, or the state board of pharmacy.

~~(M)~~(N) The denial or revocation of a license shall be subject to proceedings governed by Chapter 119. of the Revised Code.

~~(N)~~(O) The revocation of a license pursuant to paragraph ~~(E)~~(M) of this rule shall be subject to proceedings governed by division (L) of section 5119.37 of the Revised Code.

~~(O)~~(P) Termination of licenses

(1) A license shall be considered terminated and invalid in the following circumstances:

(a) The program has voluntarily discontinued operations; or,

(b) An application for renewal has not been received by the department ninety days prior to the expiration of the license.

(2) The termination of a license, as specified in paragraph ~~(O)~~(P)(1) of this rule, shall not be considered a denial or revocation of a license and shall not be subject to proceedings governed by Chapter 119. of the Revised Code. If the department determines that circumstances exist as specified in paragraph ~~(O)~~(P)(1) of this rule, it shall issue a letter to the operator specifying the date of termination of the license.

~~(P)~~(Q) An opioid treatment program directly operated by the department of veterans affairs, the Indian health service or any other department or agency of the United States is not required to obtain a state license.

~~(Q)~~(R) Regardless of whether the department takes action to deny, withdraw, revoke a license for the reasons listed in paragraph ~~(E)~~(M) of this rule, it may refer matters to local, state or federal officials as appropriate.

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