



## Ohio Administrative Code

### Rule 5122-40-05 Personnel.

Effective: January 31, 2025

---

(A) Each opioid treatment program will have a program sponsor . .

(1) The program sponsor is responsible for the general establishment, certification, licensure, and operation of, as well as the employees of, the opioid treatment program.

(2) The program sponsor is to agree, on behalf of the opioid treatment program, to adhere to all requirements set forth in federal or state statutes, rules, or regulations regarding the use of medications used in medication-assisted treatment.

(3) The program sponsor need not be a licensed physician. If the program sponsor is not a licensed physician, the opioid treatment program will employ a physician for the position of medical director as specified in paragraph (B) of this rule.

(B) Each opioid treatment program will have a designated medical director.

(1) The medical director is to be available for consultation by program prescribers during all hours of the opioid treatment program's operation.

(2) The medical director is responsible for ensuring that the opioid treatment program is in compliance with all applicable federal, state, and local statutes, rules, and regulations.

(3) The medical director is responsible for maintaining authority over the medical aspects of treatment offered by the opioid treatment program, which includes all of the following:

(a) All medication treatment decisions;

(b) Administration and supervision of all medical services;



- (c) Medication storage and review of safe handling of medications;
  - (d) Ensuring that evidence of current physiologic dependence on an opioid, length of opioid dependence, and exceptions to admission criteria are documented in the patient's clinical record before the patient receives the initial dose of medication used in medication-assisted treatment;
  - (e) Ensuring that a medical history and a physical examination have been done before a patient receives the initial dose of medication used in medication-assisted treatment;
  - (f) Ensuring that appropriate laboratory studies have been performed and reviewed. The initial dose of medication may be administered before the results of the laboratory tests are reviewed;
  - (g) Ensuring all medical orders are signed as mandated by federal, state, or local statutes, rules, and regulations;
  - (h) Developing or approving policy and procedures for take-home doses of medications used in medication-assisted treatment;
  - (i) Ensuring that justification for take-home doses is recorded in the patient's clinical record;
  - (j) Ensuring individuals are appropriately admitted to the opioid treatment program;
  - (k) Ensuring all medical services are appropriately performed by the opioid treatment program;
  - (l) Obtaining and maintaining their own continuing medical education in the field of addiction on a documented and ongoing basis;
  - (m) Determining the ability of program prescribers, other than physicians, to work independently within the applicable scope of practice.
- (4) The medical director is to be a physician .
- (5) The medical director will have a current U.S. drug enforcement administration (DEA)



registration for prescribing, administering, or dispensing controlled substances.

(C) Each opioid treatment program will have a program director.

(1) The program director is responsible for the day-to-day operation of the opioid treatment program in a manner consistent with the laws and regulations of the United States department of health and human services, United States drug enforcement administration, and the laws and rules of the state of Ohio.

(2) The program director is to be available for consultation by program staff during all hours of the OTP's operation.

(3) The program director is to ensure documentation of a root cause analysis or intensive review of systems is completed for all of the following reportable incidents:

(a) A medication error resulting in hospitalization of an active patient or permanent harm to an active patient.

(b) A death of an active patient occurring as a result of an overdose or a death of a former patient occurring within five days of that patient's discharge or termination of services.

(c) An overdose of an active patient, or the allegation of such an overdose, that was reported to the OTP.

(d) A call made by OTP staff for emergency medical services to be dispatched to the OTP site, including a parking lot used by the OTP's patients.

(4) The program director is to ensure documentation of individual case reviews is completed for both of the following:

(a) An individual who voluntarily discontinues OTP medical services; and

(b) An individual who declines or refuses non-medication services.



(5) The program director is to ensure a review of information in the drug database established and maintained by the state of Ohio board of pharmacy under section 4729.75 of the Revised Code, as described in paragraph (A) of rule 5122-40-08 of the Administrative Code, is completed, if this task is delegated to the program director by a physician.

(6) The program director is to ensure the opioid treatment program has a policy assigning all of the following responsibilities to specific staff of the opioid treatment program:

- (a) Development and enforcement of policies and procedures for operation of the opioid treatment program;
- (b) Maintenance and security of the opioid treatment program;
- (c) Employment, credentialing, evaluation, scheduling, training, and management of opioid treatment program staff;
- (d) Protection of patient rights;
- (e) Conformity of the opioid treatment program with federal confidentiality regulations, namely 42 C.F.R. part 2; and
- (f) Management of the opioid treatment program's budget.

(D) An opioid treatment program may employ and use health care professionals who are working within their scope of practice and appropriately licensed by an Ohio professional licensing board to perform their assigned functions within the OTP.

(1) All program prescribers will be actively licensed in Ohio and will have:

- (a) A minimum of one year's experience in an addiction treatment settings; or
- (b) Completion within six months of initial hire date a plan of education for obtaining competence in



addiction treatment methods. The plan of education will be developed in consultation with and approved by the medical director. The medical director will certify the individual's completion of the plan of education when, in the discretion of the medical director, it is satisfactorily accomplished.

(2) During all hours of operation, every opioid treatment program will have a physician on call and available for consultation with other staff members at any time.

(3) During all hours of operation when medication is being administered, every opioid treatment program will have present and on duty at the facility at least one of the following:

(a) A physician assistant;

(b) A registered nurse acting in accordance with division (B) of section 4723.01 of the Revised Code;

(c) A licensed practical nurse acting in accordance with division (F) of section 4723.01 of the Revised Code;

(d) A pharmacist who is authorized to manage drug therapy pursuant section 4729.39 of the Revised Code but only if specifically authorized by a consult agreement and to the extent specified in the agreement;

(e) A certified nurse practitioner ; or

(f) A physician.

(4) Each opioid treatment program will have adequate medical staff, and they will ensure proper implementation of the medical plan of care. A program prescriber will be available for consultation either in person or by telephone during all hours of operation.

(5) In the event of medical director absence for a limited-time period ( more than six weeks) alternative coverage arrangements may be acceptable with departmental notice.



(6) The medical director or a program prescriber at the opioid treatment program will meet with each patient within two weeks of the admission. The medical director or a program prescriber will see patients at least once every six months thereafter during treatment. Each meeting will be documented in the patient's record. .

(E) If an opioid treatment program employs a program prescriber pursuant to paragraph (D) of this rule who is not a physician, the following requirements are to be met: :

(1) There is to be a written plan for ongoing supervision and case discussion of the program prescriber who is not a physician, to include such program prescriber's participation in:

(a) Regularly scheduled supervisory sessions with the medical director or prescribing physician. Sessions will be at least one hour of supervision every two weeks;

(b) Team meetings where cases are reviewed with the medical director or prescribing physician present.

In addition, if the program prescriber is a certified nurse practitioner, that certified nurse practitioner is to have a standard care arrangement with the opioid treatment program's medical director pursuant to section 4723.431 of the Revised Code unless the medical director has five existing certified nurse practitioners with a standard of care arrangement. In that latter circumstance, the certified nurse practitioner is to have a standard care arrangement with a program physician.

(2) The opioid treatment program is to maintain a ratio of no more than five program prescribers who are not physicians per medical director or prescribing physician

(3) A program prescriber who is not a physician must complete all federal training requirements.

(4) At initial hire, a program prescriber who is not a physician must submit a training and supervision plan to the SOTA .

(5) A supervision and training log must be maintained for each program prescriber who is not a physician documenting compliance with paragraphs (E)(1) and (E)(3) of this rule.



(F) Counselors with less than one year of full time equivalent experience in the field of addiction treatment will develop with their supervisor a plan to achieve competency prior to providing counseling services without their supervisor present during or constantly observing counseling sessions. The plan will specify the frequency of face-to-face clinical supervision meetings between the counselor and supervisor, and the time-frame for achieving competency which will be no more than one year.

(G) Each program will conduct a criminal records check of each staff who will have access to any form of medication. All criminal records checks conducted in accordance with this rule will consist of both a bureau of criminal identification and investigation to conduct (BCI&I) criminal records check and a federal bureau of investigations records check.

(1) The criminal records check will be based on electronic fingerprint impressions that are submitted directly to BCI&I from a "webcheck" provider agency located in Ohio. The employer may accept the results of a criminal records check based on ink impressions from a "webcheck" provider agency only in the event that readable electronic fingerprint impressions cannot be obtained.

(2) A program will not employ in a position which allows access to any form of medication to any person who has been convicted of a felony relating to controlled substances.