

5122-40-05

Personnel.

(A) Each licensed opioid treatment program shall have a program sponsor, who is the person that assumes responsibility for the operation of and the employees of the opioid treatment component of a community addiction services provider. The program sponsor shall agree on behalf of the opioid treatment program to adhere to all requirements set forth in federal or state laws, rules, or regulations regarding the use of medications in the treatment of opioid use disorder.

- (1) The program sponsor is responsible for the general establishment, certification, licensure, and operation of the opioid treatment program.
- (2) The program sponsor need not be a licensed physician. If the program sponsor is not a licensed physician, the opioid treatment program shall employ a licensed physician for the position of medical director.

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

- (1) The medical director shall be a physician licensed to practice medicine or osteopathy in the state of Ohio and shall have either:

- (a) Certification from the American board of addiction medicine;
- (b) Certification from a member board of medical subspecialties with an addiction subspecialty;
- (c) Certification from the American academy of health care providers in the addictive disorders as a certified addiction specialist; ~~or~~;
- (d) Certification from the American Osteopathic Academy with an addiction medicine subspecialty; or,

~~(d)~~(e) A written plan to attain competence in opioid treatment resulting in one of the designated certifications within a probationary time period.

- (i) The medical director may submit a written plan to attain competence in opioid treatment to the department for approval at least two weeks prior to employment at an opioid treatment program.
- (ii) The time for completion of the plan may not exceed twenty-four months from the date of the appointment as medical director. The physician may work as a medical director during this probationary time period, subject to the supervision and reporting requirements of this rule. Waivers may be granted by the department if there are problems scheduling certification examinations.

- (iii) During the probationary time period, the medical director shall be directly supervised at least once a week by a physician who holds an appropriate medical certification in the field of opioid treatment pursuant to paragraph (B)(1) of this rule.
 - (iv) Consultation with and supervision of a medical director during the probationary time period may be provided by telephone or video conferencing and shall be documented, signed, and dated by both the supervising physician and the supervised physician.
 - (v) The department may request periodic documentation of progress towards completion of the training plan.
 - (vi) The program administrator of the opioid treatment program is responsible for maintaining documentation regarding the medical director's training and experience in a file which is current and readily available at all times. The program administrator is also responsible for ensuring that the plan of development is completed within the approved time lines.
- (2) The medical director shall maintain authority over the medical aspects of treatment offered by the opioid treatment program. The medical director is responsible for:
- (a) All medication treatment decisions;
 - (b) Operation of all medical aspects of the treatment program;
 - (c) Administration and supervision of all medical services;
 - (d) Medication storage and review of safe handling of medications;
 - (e) Ensuring that the opioid treatment program is in compliance with all applicable federal, state and local laws, rules and regulations;
 - (f) 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;
 - (g) 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;

- (h) 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;
 - (i) Ensuring all medical orders are signed as required by federal, state, or local laws and regulations;
 - (j) Developing or approving policy and procedures for take-home doses of medication used for medication assisted treatment;
 - (k) Ensuring that justification for take-home doses is recorded in the patient's clinical record;
 - (l) Ensuring individuals are appropriately admitted to the opioid treatment program;
 - (m) Ensuring all medical services are appropriately performed by the opioid treatment program;
 - (n) Obtaining and maintaining their own continuing medical education in the field of addiction on a documented and ongoing basis;
 - (o) Determining the ability of the program physicians or physician extenders to work independently within the applicable scope of practice; and,
- (3) Each opioid treatment program shall have at least one medical director per program location. Medical directors will provide one hour of onsite service per week for every forty patients, with a minimum of six hours of service per week. If the onsite time is greater than twenty-four hours, then other program physicians or certified nurse practitioners with a SAMHSA exemption may contribute to the patient to medical director ratio to fulfill the standard. ~~These site-level medical directors shall be present at the opioid treatment program at least forty per cent of the time that the program administers or dispenses medication. Site-level medical directors may serve in their same capacity at additional sites as long as they are present at the ancillary opioid treatment programs at least forty per cent of the time that the program administers or dispenses medication and can satisfactorily discharge all of their duties for each program.~~
- (a) Opioid treatment programs may appoint one additional person who meets the qualifications in paragraph (B)(1) of this rule to be a co-medical director. The co-medical director may contribute to the patient to medical director ratio in paragraph (B)(3) of this rule. ~~Co-medical director's may both contribute to the organization's requirements to be on staff for at~~

~~least forty per cent of the time that the program administers or dispenses medication.~~

- (b) Opioid treatment programs that employ co-medical directors shall inform the department of such an arrangement in writing.
- (4) ~~Opioid treatment programs in the first sixty days of operation may reduce the time requirement medical directors must be present on site to at least twenty per cent of the time that the program administers or dispenses medication. On the sixty-first day of operation the program shall be subject to the requirements of paragraph (B)(3) of this rule.~~
- (5) The medical director must have a current U.S. drug enforcement administration (DEA) registration for prescribing, administering, or dispensing controlled substances, and the medical director must have a DEA waiver if they or any other healthcare professional they supervise prescribes, administers, or dispenses partial opioid agonists.
- (6) If a program utilizes regional medical directors, they are expected to supervise site-level medical directors. ~~The regional medical director must be present at each methadone program each week, but is exempted from the time requirements in paragraph (B)(3) of this rule.~~ The regional medical director may contribute to the patient to medical director ratio in paragraph (B)(3) of this rule. The regional medical director must meet the requirements in paragraph (B)(1)(a) or (B)(1)(b) of this rule. A regional medical director may take on some of the roles of the site level medical director if an organization has multiple programs in different locations. The program must inform the department of such an arrangement in writing, including:
- (a) The schedule, including total hours per week the regional medical director will spend at each methadone program location.
- (b) The division of responsibilities between the regional and site-level medical director.
- (c) If the regional medical director serves in this or a similar capacity for any opioid treatment programs located outside the state of Ohio
- (C) Each licensed opioid treatment program shall have a program administrator, who shall have at minimum either a master's degree in any field or a bachelor's degree and two years work experience in a related healthcare field.
- (1) The program administrator 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, including, but not limited to assuring:

- (a) Development and enforcement of policies and procedures for operation of the facility;
 - (b) Maintenance and security of the facility;
 - (c) Employment, credentialing, evaluation, scheduling, training and management of staff;
 - (d) Protection of patient rights;
 - (e) Conformity of the program with federal confidentiality regulations, namely, 42 CFR Part 2; and,
 - (f) Management of the facility budget.
- (2) A regional program administrator may take on some of the roles of the site-level program administrator if an organization has multiple programs in different locations. The program must inform the department of such an arrangement in writing, including:
- (a) The portion of the program administrator time spent with each program, and include mention of any competing priorities that might take away time allocated to the treatment programs.
 - (b) The division of responsibilities between the regional and site-level program administrator.
 - (c) If the regional program administrator serves in this or a similar capacity for any opioid treatment programs located outside the state of Ohio.
- (D) The opioid treatment program may employ and use program physicians, physician extenders and other health care professionals working within their scope of practice who have received sufficient education, training and experience, or any combination thereof, to enable that person to perform the assigned functions. All physicians, nurses and other licensed professional care providers must comply with the credentialing requirements of their respective professions. The opioid treatment program may only employ certified nurse practitioners or clinical nurse specialists, physician 's assistants, certified addiction registered nurses, or board certified addiction specialist registered nurses as physician extenders. A pharmacist may be a physician extender if authorized to manage drug therapy pursuant section 4729.39 of the Revised Code

and specifically authorized by a consult agreement and to the extent specified in the agreement.

- (1) All physicians and physician extenders employed by the opioid treatment program shall be actively licensed in Ohio and shall have:
 - (a) A minimum of one year's experience in an addiction treatment settings; or
 - (b) Completion within six months of a plan of education for obtaining competence in addiction treatment methods. The plan of education must be developed in consultation with and approved by the medical director. The medical director shall certify the individual's completion of the plan of education when, in the discretion of the medical director, it is satisfactorily accomplished. If the medical director is completing a plan of competency described in paragraph (B)(1)(c) of this rule, the medical director may assist the physician or physician extender develop a plan and the plan shall be approved by the medical director's supervising physician.
- (2) During all hours of operation, every opioid treatment program shall have a licensed 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 shall have present and on duty at the facility at least one of the following:
 - (a) Physician assistant;
 - (b) Registered nurse acting in accordance with division (B) of section 4723.01 of the Revised Code;
 - (c) Licensed practical nurse acting in accordance with division (F) of section 4723.01 of the Revised Code ~~who has proof of completion of a course in medication administration approved by the Ohio board of nursing; or,~~
 - (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) Certified nurse practitioner with a SAMHSA exemption request; or,
 - (f) Physician.

- (4) Each opioid treatment program will have adequate medical staff, and they will ensure proper implementation of the medical plan of care. A prescriber will be available for consultation either in person or by telephone during all hours of operation. A medical director will be present onsite at least two days a week. Alternatively, a program physician or certified nurse practitioner with a SAMHSA exemption may account for one day of the two-day standard.
- (5) In the event of medical director absence for a limited- time period (six weeks or less) alternative coverage arrangements may be acceptable with departmental notice. Such alternative coverage arrangements may satisfy the medical director hours and on-site requirements set forth in paragraphs (B)(3) and (D)(4) of this rule.
- (6) An employee will not be appointed medical director or co-medical director of more than a total of three opioid treatment programs or two opioid treatment programs if the combined patient census is greater than one thousand patients.
- ~~(4)~~(7) The medical director or a program physician at the opioid treatment program shall meet with each patient in person within seventy-two hours of the ~~assessment~~ admission. The medical director or program physician shall see patients ~~and~~ at least once every six months thereafter during treatment. Telehealth meetings will only be conducted for stable patients. Each meeting shall be documented in the patient's record. After the first year of treatment, then the medical director or program physician may only meet with the patient once per year if the program employs a certified nurse practitioner who has prescriptive authority for the patient.
- ~~(5)~~(8) Certified nurse practitioners with a SAMHSA exemption who personally furnish medication assisted treatment at opioid ~~Opioid~~ treatment programs ~~that utilize certified nurse practitioners to personally furnish medication assisted treatment shall have certified nurse practitioners~~ will meet with their patients at least once every three months during treatment, however the meeting with a medical director or program physician in paragraph (D)(5) of this rule may be used to fulfill this standard for one of the quarterly meetings. Telehealth meetings will only be conducted for stable patients. Each meeting shall be documented in the patient's record.
- (a) Certified nurse practitioners, with a SAMHSA exemption, personally furnishing medication assisted treatment shall have a standard care arrangement with the opioid treatment programs medical director pursuant section 4723.431 of the Revised Code. If the medical director has five existing certified nurse practitioners with a standard of care arrangement, then the standard of care arrangement shall be between a

certified nurse practitioner and a program physician employed by the opioid treatment program.

- (b) Use of a certified nurse practitioner, with a SAMHSA exemption, to personally furnish medication assisted treatment does not remove the obligation of a medical director or program physician to meet with patients.
- (E) Counselors with less than one year of full time equivalent experience in the field of addiction treatment shall 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 must specify the frequency of face-to-face clinical supervision meetings between the counselor and supervisor, and the time-frame for achieving competency which shall be no more than one year.
- (F) Each program shall conduct a criminal records check of each staff who shall have access to any form of medication. All criminal records checks conducted in accordance with this rule shall 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 shall 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 shall 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.

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