

WSR 25-03-021

PERMANENT RULES

DEPARTMENT OF HEALTH

[Filed January 7, 2025, 8:12 a.m., effective January 31, 2025]

Effective Date of Rule: January 31, 2025.

Other Findings Required by Other Provisions of Law as Precondition to Adoption or Effectiveness of Rule: The opioid epidemic has resulted in imminent peril to the public health, safety, and welfare, and it is in the best interest of public health to have these rules be effective less than 31 days after filing as allowed by RCW 34.05.380 (3) (c).

Purpose: Behavioral health agency licensing and certification requirements as they relate to opioid treatment programs (OTP). The department of health (department) is adopting updates to chapter 246-341 WAC to provide greater access to care by streamlining the approval and certification process to operate an OTP and aligning state regulations with federal certification and treatment standards for OTPs in 42 C.F.R. Part 8, Subpart C (2024).

The department is also adopting updates to implement changes enacted by the legislature in 2E2SSB 5536 (chapter 1, Laws of 2023, 1st sp. sess.) that allow licensed OTPs to operate a mobile or fixed-site medication unit as part of, but geographically separate from, their existing licensed OTP. Finally, the department is adopting updates that correct two internal citations from a previous rules project.

Citation of Rules Affected by this Order: Repealing WAC 246-341-1005, 246-341-1010, 246-341-1015, 246-341-1020 and 246-341-1025; and amending WAC 246-341-0200, 246-341-0300, 246-341-0342, 246-341-1000, and 246-341-1100.

Statutory Authority for Adoption: RCW 71.24.037 and 2E2SSB 5536 (chapter 1, Laws of 2023, 1st sp. sess.), codified as RCW 71.24.590.

Adopted under notice filed as WSR 24-22-054 on October 28, 2024.

A final cost-benefit analysis is available by contacting Michelle Weatherly, P.O. Box 47843, Olympia, WA 98504-7843, phone 360-236-2992, TTY 711, email michelle.weatherly@doh.wa.gov, website www.doh.wa.gov.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 5, Repealed 5.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 5, Repealed 5.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 5, Repealed 5.

Date Adopted: January 7, 2025.

Kristin Peterson, JD
Chief of Policy
for Umair A. Shah, MD, MPH
Secretary of Health

OTS-5853.2

AMENDATORY SECTION (Amending WSR 24-17-003, filed 8/8/24, effective 9/8/24)

WAC 246-341-0200 Behavioral health—Definitions. The definitions in this section and RCW 71.05.020, 71.24.025, and 71.34.020 apply throughout this chapter unless the context clearly requires otherwise.

(1) "23-hour crisis relief center" has the same meaning as under RCW 71.24.025.

(2) "Administrator" means the designated person responsible for the day-to-day operation of either the licensed behavioral health agency, or certified treatment service, or both.

(3) "Adult" means an individual 18 years of age or older. For purposes of the medicaid program, adult means an individual 21 years of age or older.

(4) "ASAM criteria" means admission, continued service, transfer, and discharge criteria for the treatment of substance use disorders as published by the American Society of Addiction Medicine (ASAM).

(5) "Assessment" means the process of obtaining all pertinent bio-psychosocial information, as identified by the individual, and family and collateral sources, for determining a diagnosis and to plan individualized services and supports.

(6) "Behavioral health" means the prevention, treatment of, and recovery from any or all of the following disorders: Substance use disorders, mental health disorders, co-occurring disorders, or problem gambling and gambling disorders.

(7) "Behavioral health agency," "licensed behavioral health agency," or "agency" means an entity licensed by the department to provide behavioral health services under chapter 71.24, 71.05, or 71.34 RCW.

(8) "Behavioral health service" means the specific service(s) that may be provided under an approved certification.

(9) "Branch site" means a physically separate licensed site, governed by the same parent organization as the main site, where qualified staff provides certified treatment services.

(10) "Campus" means an area where all of the agency's buildings are located on contiguous properties undivided by:

(a) Public streets, not including alleyways used primarily for delivery services or parking; or

(b) Other land that is not owned and maintained by the owners of the property on which the agency is located.

(11) "Care coordination" or "coordination of care" means a process-oriented activity to facilitate ongoing communication and collaboration to meet multiple needs of an individual. Care coordination includes facilitating communication between the family, natural supports, community resources, and involved providers and agencies, organizing, facilitating and participating in team meetings, and providing for continuity of care by creating linkages to and managing transitions between levels of care.

(12) "Certified" or "certification" means the status given by the department that authorizes the agency to provide specific types of behavioral health services included under the certification category.

(13) "Child," "minor," and "youth" mean:

(a) An individual under the age of 18 years; or

(b) An individual age 18 to 21 years who is eligible to receive and who elects to receive an early and periodic screening, diagnostic, and treatment (EPSDT) medicaid service. An individual age 18 to 21 years who receives EPSDT services is not considered a "child" for any other purpose.

(14) "Clinical supervision" means regular and periodic activities performed by a mental health professional, co-occurring disorder specialist, or substance use disorder professional licensed, certified, or registered under Title 18 RCW. Clinical supervision may include review of assessment, diagnostic formulation, individual service plan development, progress toward completion of care, identification of barriers to care, continuation of services, authorization of care, and the direct observation of the delivery of clinical care. In the context of this chapter, clinical supervision is separate from clinical supervision required for purposes of obtaining supervised hours toward fulfilling requirements related to professional licensure under Title 18 RCW.

(15) "Community relations plan" means a plan to inform and educate the community about the opioid treatment program, which documents strategies used to obtain community input regarding the proposed location and address any concerns identified by the community.

(16) "Complaint" means an alleged violation of licensing or certification requirements under chapters 71.05, 71.12, 71.24, 71.34 RCW, and this chapter, which has been authorized by the department for investigation.

~~((16))~~ (17) "Consent" means agreement given by an individual after being provided with a description of the nature, character, anticipated results of proposed treatments and the recognized serious possible risks, complications, and anticipated benefits, including alternatives and nontreatment, that must be provided in a terminology that the individual can reasonably be expected to understand. Consent can be obtained from an individual's parent or legal representative, when applicable.

~~((17))~~ (18) "Consultation" means the clinical review and development of recommendations by persons with appropriate knowledge and experience regarding activities or decisions of clinical staff, contracted employees, volunteers, or students.

~~((18))~~ (19) "Co-occurring disorder" means the coexistence of both a mental health and a substance use disorder. Co-occurring treatment is a unified treatment approach intended to treat both disorders within the context of a primary treatment relationship or treatment setting.

~~((19))~~ (20) "Cultural competence" or "culturally competent" means the ability to recognize and respond to health-related beliefs and cultural values, disease incidence and prevalence, and treatment efficacy. Examples of culturally competent care include striving to overcome cultural, language, and communications barriers, providing an environment in which individuals from diverse cultural backgrounds feel comfortable discussing their cultural health beliefs and practices in the context of negotiating treatment options, encouraging individuals to express their spiritual beliefs and cultural practices, and being familiar with and respectful of various traditional healing systems and beliefs and, where appropriate, integrating these approaches into treatment plans.

~~((20))~~ (21) "Deemed" means a status that is given to a licensed behavioral health agency as a result of the agency receiving accredi-

tation by a recognized behavioral health accrediting body which has a current agreement with the department.

~~((21))~~ (22) "Disability" means a physical or mental impairment that substantially limits one or more major life activities of the individual and the individual:

(a) Has a record of such an impairment; or

(b) Is regarded as having such impairment.

~~((22))~~ (23) "Face-to-face" means either in person or by way of synchronous video conferencing.

~~((23))~~ (24) "Individual service record" means either a paper, or electronic file, or both that is maintained by the behavioral health agency and contains pertinent behavioral health, medical, and clinical information for each individual served.

~~((24))~~ (25) "Licensed" or "licensure" means the status given to behavioral health agencies by the department under its authority to license and certify mental health and substance use disorder programs under chapters 71.05, 71.12, 71.34, and 71.24 RCW and its authority to certify problem gambling and gambling disorder treatment programs under RCW 43.70.080(5) and 41.05.750.

~~((25))~~ (26) "Medical practitioner" means a physician licensed under chapter 18.57 or 18.71 RCW, advance registered nurse practitioner (ARNP) licensed under chapter 18.79 RCW, or physician assistant licensed under chapter 18.71A RCW.

~~((26))~~ (27) "Medication unit" means either:

(a) A fixed-site brick and mortar entity that is established as part of, but geographically separate from, an opioid treatment program from which appropriately licensed opioid treatment program practitioners, contractors working on behalf of the opioid treatment program, or community pharmacists may dispense or administer medication for opioid use disorder, collect samples for drug testing or analysis, or provide other opioid treatment program services; or

(b) A mobile medication unit which is a component of an opioid treatment program that the United States Drug Administration has approved to operate as a mobile narcotic treatment program pursuant to 21 C.F.R. § 1301.13 (e) (4).

(28) "Mental health disorder" means any organic, mental, or emotional impairment that has substantial adverse effects on a person's cognitive or volitional functions.

~~((27))~~ (29) "Mental health professional" or "MHP" means a person who meets the definition in RCW 71.05.020.

~~((28))~~ (30) "Opioid treatment program" means the same as defined in RCW 71.24.590.

(31) "Peer" means a peer counselor as defined in WAC 182-538D-0200 or a certified peer specialist certified under chapter 18.420 RCW.

~~((29))~~ (32) "Peer support" means services provided by peer counselors to individuals under the supervision of a mental health professional or individual appropriately credentialed to provide substance use disorder treatment. Peer support provides scheduled activities that promote recovery, self-advocacy, development of natural supports, and maintenance of community living skills.

~~((30))~~ (33) "Problem gambling and gambling disorder" means one or more of the following disorders:

(a) "Gambling disorder" means a mental disorder characterized by loss of control over gambling, progression in preoccupation with gambling and in obtaining money to gamble, and continuation of gambling despite adverse consequences;

(b) "Problem gambling" is an earlier stage of gambling disorder that compromises, disrupts, or damages family or personal relationships or vocational pursuits.

~~((31))~~ (34) "Progress notes" means permanent written or electronic record of services and supports provided to an individual documenting the individual's participation in, and response to, treatment or support services, progress in recovery, and progress toward intended outcomes.

~~((32))~~ (35) "Secretary" means the secretary of the department of health.

~~((33))~~ (36) "State minimum standards" means minimum requirements established by rules adopted by the secretary and necessary to implement chapters 71.05, 71.24, and 71.34 RCW for delivery of behavioral health services.

~~((34))~~ (37) "Substance use disorder professional" or "SUDP" means a person credentialed by the department as a substance use disorder professional (SUDP) under chapter 18.205 RCW.

~~((35))~~ (38) "Substance use disorder professional trainee" or "SUDPT" means a person credentialed by the department as a substance use disorder professional trainee (SUDPT) under chapter 18.205 RCW.

~~((36))~~ (39) "Summary suspension" means the immediate suspension of either a facility's license or program-specific certification or both by the department pending administrative proceedings for suspension, revocation, or other actions deemed necessary by the department.

~~((37))~~ (40) "Supervision" means the regular monitoring of the administrative, clinical, or clerical work performance of a staff member, trainee, student, volunteer, or employee on contract by a person with the authority to give direction and require change.

~~((38))~~ (41) "Suspend" means termination of a behavioral health agency's license or program specific certification to provide behavioral health treatment program service for a specified period or until specific conditions have been met and the department notifies the agency of the program's reinstatement of license or certification.

AMENDATORY SECTION (Amending WSR 22-24-091, filed 12/6/22, effective 5/1/23)

WAC 246-341-0300 Agency licensure and certification—General information. The department licenses behavioral health agencies and certifies them to provide behavioral health services. To obtain and maintain licensure and certification, an applicant shall meet the requirements of this chapter, applicable local and state rules, and applicable state and federal statutes and regulations. Licensure and certification under this chapter does not exempt a behavioral health agency from obtaining any other applicable state or federal licenses or registrations that are necessary to operate and provide services.

(1) The ~~((following))~~ behavioral health agency licensure process described in this section does not apply to a tribe that is licensed or seeking licensure via attestation as described in WAC 246-341-0367.

(2) Initial licensure of a behavioral health agency - Main site. The applicant shall submit a licensing application for a main site to the department that is signed by the agency's designated official. The application must include the following:

(a) The physical address of the agency;

(b) The type of certification(s) the agency is requesting, including the behavioral health services the agency will provide under the type of certification(s);

(c) A statement assuring the location where the services will be provided meets the Americans with Disabilities Act (ADA) standards and that any agency-operated facility where behavioral health services will be provided is:

(i) Suitable for the purposes intended, including having adequate space for private personal consultation with an individual and individual service record storage that adheres to confidentiality requirements;

(ii) Not a personal residence; and

(iii) Approved as meeting all local and state building and safety requirements, as applicable.

(d) Payment of associated fees according to WAC 246-341-0365;

(e) A copy of the applicant's master business license that authorizes the organization to do business in Washington state;

(f) A copy of the disclosure statement and report of findings from a background check of the administrator completed within the previous three months of the application date; and

(g) A copy of the policies and procedures specific to the agency and the certifications and behavioral health services for which the applicant is seeking approval that address all of the applicable requirements of this chapter.

(3) The department may issue a single agency license when the applicant identifies behavioral health treatment services will be provided in multiple buildings and either:

(a) The applicant operates the multiple buildings on the same campus as a single integrated system with governance by a single authority or body over all staff and buildings; or

(b) All behavioral health treatment services will be provided in buildings covered under a single hospital license.

(4) Initial licensure of a behavioral health agency - Branch site. To add a branch site, an existing behavioral health agency shall meet the application requirements in subsection ~~((1))~~ (2)(a) through (c) of this section and submit to the department:

(a) A written declaration that a current copy of agency policies and procedures that address all of the applicable requirements of this chapter are accessible to the branch site;

(b) A copy of policies and procedures for any behavioral health certifications and services that are unique to the branch site location, if applicable; and

(c) A copy of the disclosure statement and report of findings from a background check of the administrator completed within the previous three months of the application date, if the administrator of the branch site is different than the administrator of the main site location.

(5) In addition to the information required by subsections (2) through (4) of this section, an applicant seeking certification as an opioid treatment program must submit the following information with their application:

(a) Documentation that the applicant has communicated with the county legislative authority and, if applicable, the city legislative authority or tribal legislative authority, in order to secure a location that meets county, tribal, or city land use ordinances when proposing to open a new, or move an existing, opioid treatment program;

(b) A community relations plan developed and completed in consultation with the county, city, or tribal authority or their designee when proposing to open a new, or move an existing opioid treatment program; and

(c) For new applicants who operate opioid treatment programs in another state, copies of all review reports written by their national accreditation body and state certification, if applicable, within the past six years.

(6) Prior to an opioid treatment program license being issued, the applicant must obtain approval from:

(a) The Washington state department of health pharmacy quality assurance commission;

(b) The United States Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA), as required by 42 C.F.R. Part 8 for certification as an opioid treatment program; and

(c) The United States Drug Enforcement Administration (DEA).

(7) A mobile or fixed-site medication unit may be established as part of an opioid treatment program. Opioid treatment programs may establish a mobile or fixed-site medication unit and must notify the department on forms provided by the department. Department approval must be given before services can be provided from a mobile or fixed-site medication unit.

(8) License renewal. To renew a main site or branch site license and certification, an agency shall submit to the department a renewal request signed by the agency's designated official. The renewal request must:

(a) Be received by the department before the expiration date of the agency's current license; and

(b) Include full payment of the specific renewal fee according to WAC 246-341-0365.

((+6)) (9) Amending a license. A license amendment is required when there is a change in the administrator, when adding or removing a certification or behavioral health service, or when closing a location. To amend a license the agency shall submit to the department a licensing application requesting the amendment that is signed by the agency's designated official. The application shall include the following requirements as applicable to the amendment being requested:

(a) Change of the administrator. The application must include a copy of the disclosure statement and report of findings from a background check of the new administrator completed within the previous three months of the application date and within 30 calendar days of the change;

(b) Adding a certification. The agency must submit an application for certification before providing the behavioral health services listed under the certification. The application must include:

(i) The physical address or addresses of the agency-operated facility or facilities where the new type of certified service(s) will be provided;

(ii) A copy of the agency's policies and procedures relating to the new certification and behavioral health service(s) that will be provided; and

(iii) Payment of fees according to WAC 246-341-0365.

(c) Adding a behavioral health service. The agency may add a behavioral health service that is included under its existing certification by submitting the notification of the added service to the de-

partment within 30 calendar days of beginning the service. The notification must include:

(i) The physical address or addresses of the agency-operated facility or facilities where the new behavioral health service(s) will be provided; and

(ii) A copy of the agency's policies and procedures relating to the new behavioral health service(s) that will be provided.

(d) Canceling a behavioral health service or certification.

(i) The agency must provide notice to individuals who receive the service(s) to be canceled. The notice shall be provided at least 30 calendar days before the service(s) are canceled and the agency must assist individuals in accessing services at another location.

(ii) The application must include the physical address or addresses of the agency-operated facility or facilities where the service(s) will no longer be provided.

(e) Closing a location.

(i) The application must include the name of the licensed agency or entity storing and managing the records, including:

(A) The method of contact, such as a telephone number, electronic address, or both; and

(B) The mailing and street address where the records will be stored.

(ii) When a closing agency that has provided substance use disorder services arranges for the continued storage and management of individual service records by a qualified service organization (QSO), the closing agency must enter into a written agreement with the QSO that meets the requirements of 42 C.F.R. Part 2.

(iii) In the event of an agency closure the agency must provide each individual currently being served:

(A) Notice of the agency closure at least 30 calendar days before the date of closure;

(B) Assistance with accessing services at another location; and

(C) Information on how to access records to which the individual is entitled.

~~((7))~~ (10) Change of ownership.

(a) Change of ownership means one of the following:

(i) The ownership of a licensed behavioral health agency changes from one distinct legal owner to another distinct legal owner;

(ii) The type of business changes from one type to another, such as, from a sole proprietorship to a corporation; or

(iii) The current ownership takes on a new owner of five percent or more of the organizational assets.

(b) When a licensed behavioral health agency changes ownership, the agency shall submit to the department:

(i) An initial license application from the new owner in accordance with subsection (2) of this section. The new agency must receive a new license under the new ownership before providing any behavioral health service; and

(ii) A statement from the current owner regarding the disposition and management of individual service records in accordance with applicable state and federal statutes and regulations.

~~((8))~~ (11) Change in location. A licensed behavioral health agency must receive a new license under the new location's address before providing any behavioral health service at that address. The agency shall submit to the department a licensing application requesting a change in location that is signed by the agency's designated official. The application must include:

- (a) The new address;
- (b) A statement assuring the location meets the Americans with Disabilities Act (ADA) standards and that any agency-operated facility where behavioral health services will be provided is:
 - (i) Suitable for the purposes intended, including having adequate space for private personal consultation with an individual and individual service record storage that adheres to confidentiality requirements;
 - (ii) Not a personal residence; and
 - (iii) Approved as meeting all local and state building and safety requirements, as applicable.
- (c) Payment of initial licensure fees according to WAC 246-341-0365.

~~((9))~~ (12) Granting a license. A new or amended license or certification will not be granted to an agency until:

- (a) All of the applicable notification and application requirements of this section are met; and
- (b) The department has reviewed and approved the policies and procedures for initial licensure or addition of new certifications that demonstrate that the agency will operate in compliance with the licensure and certification standards.

~~((10))~~ (13) Effective date. An agency's license and any behavioral health services certification is effective for up to 12 months from the date of issuance, subject to the agency maintaining compliance with the minimum license and certification standards in this chapter.

~~((11))~~ (14) After receiving the license. The agency shall post the department-issued license and certification(s) in a conspicuous place on the agency's premises, and, if applicable, on the agency's branch site premises.

AMENDATORY SECTION (Amending WSR 22-24-091, filed 12/6/22, effective 12/10/22)

WAC 246-341-0342 Agency licensure and certification—Off-site locations. (1) A behavioral health agency may provide certified services at an off-site location or from a mobile unit under the existing behavioral health agency license.

(2) For the purposes of this section:

(a) "Off-site" means the provision of services by a licensed behavioral health agency at a location where the assessment or treatment is not the primary purpose of the site, such as in schools, hospitals, long-term care facilities, correctional facilities, an individual's residence, the community, or housing provided by or under an agreement with the agency.

(b) "Established off-site location" means a location that is regularly used and set up to provide services rather than a location used on an individual, case-by-case basis.

(c) "Mobile unit" means a vehicle, lawfully used on public streets, roads, or highways with more than three wheels in contact with the ground, from which behavioral health services are provided at a nonpermanent location(s).

(3) A behavioral health agency that provides off-site services at an established off-site location(s) shall:

(a) Maintain a list of each established off-site location where services are provided on a regularly scheduled ongoing basis and include, for each established off-site location:

(i) The name and address of the location the services are provided;

(ii) The primary purpose of the off-site location;

(iii) The service(s) provided; and

(iv) The date off-site services began at that location;

(b) Maintain an individual's confidentiality at the off-site location; and

(c) Securely transport confidential information and individual records between the licensed agency and the off-site location, if applicable.

(4) In addition to meeting the requirements in subsection (3) of this section, an agency providing services to an individual in their place of residence or services in a public setting that is not an established off-site location where services are provided on a regularly scheduled ongoing basis must:

(a) Implement and maintain a written protocol of how services will be offered in a manner that promotes individual, staff member, and community safety; and

(b) For the purpose of emergency communication and as required by RCW 71.05.710, provide access to a wireless telephone or comparable device to any employee, contractor, student, or volunteer when making home visits to individuals.

(5) Before operating a mobile unit, agencies providing behavioral health services from a mobile unit must notify the department in writing in a manner outlined by the department. The notification must include that a mobile unit is being added under the agency license and indicate what services will be provided from the mobile unit (~~(, including whether it is operating as a mobile narcotic treatment program as defined in 21 C.F.R. Part 1300.01.~~

~~(6) An opioid treatment program operating a mobile narcotic treatment program must:~~

~~(a) Submit a copy of the Drug Enforcement Administration (DEA) approval for the mobile narcotic treatment program; and~~

~~(b) Comply with 21 C.F.R. Parts 1300, 1301, and 1304 and any applicable rules of the pharmacy quality assurance commission). Opioid treatment programs must also comply with WAC 246-341-0300(7) before operating a mobile unit.~~

AMENDATORY SECTION (Amending WSR 21-12-042, filed 5/25/21, effective 7/1/21)

WAC 246-341-1000 Opioid treatment programs (OTP)—(General)
Certification standards. (~~(1) Opioid treatment programs (OTP) may order, possess, dispense, and administer medications approved by the United States Food and Drug Administration for the treatment of opioid use disorder, alcohol use disorder, tobacco use disorder, and reversal of opioid overdose. OTP services include withdrawal management and maintenance treatment along with evidence-based therapy.~~

~~(2) An agency providing opioid treatment program services must ensure that the agency's individual record system complies with all federal and state reporting requirements relevant to opioid drugs ap-~~

~~proved for use in treatment of opioid use disorder, alcohol use disorder, tobacco use disorder, and reversal of opioid overdose.~~

~~(3) An agency must:~~

~~(a) Use evidence-based therapy in addition to medication in the treatment program;~~

~~(b) Identify individual mental health needs during assessment process and refer them to appropriate treatment if not available on-site;~~

~~(c) Provide education to each individual admitted, totaling no more than fifty percent of treatment services, on:~~

~~(i) Alcohol, other drugs, and substance use disorder;~~

~~(ii) Relapse prevention;~~

~~(iii) Infectious diseases including human immunodeficiency virus (HIV) and hepatitis A, B, and C;~~

~~(iv) Sexually transmitted infections; and~~

~~(v) Tuberculosis (TB);~~

~~(d) Provide information to each individual on:~~

~~(i) Emotional, physical, and sexual abuse;~~

~~(ii) Nicotine use disorder;~~

~~(iii) The impact of substance use during pregnancy, risks to the developing fetus before prescribing any medications to treat opioid use disorder, the risks to both the expecting parent and fetus of not treating opioid use disorder, and the importance of informing medical practitioners of substance use during pregnancy; and~~

~~(iv) Family planning.~~

~~(e) Create and implement policies and procedures for:~~

~~(i) Diversion control that contains specific measures to reduce the possibility of the diversion of controlled substances from legitimate treatment use, and assign specific responsibility to the medical and administrative staff members for carrying out the described diversion control measures and functions;~~

~~(ii) Urinalysis and drug testing, to include:~~

~~(A) Obtaining specimen samples from each individual, at least eight times within twelve consecutive months;~~

~~(B) Documentation indicating the clinical need for additional urinalysis;~~

~~(C) Random samples, without notice to the individual;~~

~~(D) Samples in a therapeutic manner that minimizes falsification;~~

~~(E) Observed samples, when clinically appropriate; and~~

~~(F) Samples handled through proper chain of custody techniques.~~

~~(iii) Laboratory testing;~~

~~(iv) The response to medical and psychiatric emergencies; and~~

~~(v) Verifying the identity of an individual receiving treatment services, including maintaining a file in the dispensary with a photograph of the individual and updating the photographs when the individual's physical appearance changes significantly.~~

~~(4) An agency must ensure that an individual is not admitted to opioid treatment withdrawal management services more than two times in a twelve-month period following admission to services.~~

~~(5) An agency providing services to a pregnant woman must have a written procedure to address specific issues regarding their pregnancy and prenatal care needs, and to provide referral information to applicable resources.~~

~~(6) An agency providing youth opioid treatment program services must:~~

~~(a) Ensure that before admission the youth has had two documented attempts at short-term withdrawal management or drug-free treatment~~

~~within a twelve-month period, with a waiting period of no less than seven days between the first and second short-term withdrawal management treatment; and~~

~~(b) Ensure that when a youth is admitted for maintenance treatment, written consent by a parent or if applicable, legal guardian or responsible adult designated by the relevant state authority, is obtained.~~

~~(7) An agency providing opioid treatment program services must ensure:~~

~~(a) That notification to the federal Substance Abuse and Mental Health Services Administration (SAMHSA) and the department is made within three weeks of any replacement or other change in the status of the program, program sponsor as defined in 42 C.F.R. Part 8, or medical director;~~

~~(b) Treatment is provided to an individual in compliance with 42 C.F.R. Part 8;~~

~~(c) The individual record system complies with all federal and state reporting requirements relevant to opioid drugs approved for use in treatment of opioid use disorder; and~~

~~(d) The death of an individual enrolled in an opioid treatment program is reported to the department within forty-eight hours.) An agency providing opioid treatment program services must comply with the following:~~

~~(1) All applicable requirements, including those specific to medication units, of 21 C.F.R. §§ 1300, 1301, 1304, and 1306, and 42 C.F.R. Part 8, in effect as of April 2024. Copies of the incorporated version of 21 C.F.R. Part 1301 and 42 C.F.R. Part 8 are available at www.doh.wa.gov/otp or by contacting the department at 360-236-4700 and are available for public inspection at the department's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501.~~

~~(2) Develop, maintain, and implement policies and procedures for:~~

~~(a) Requirements in 42 C.F.R. Part 8.12 to include:~~

~~(i) Administrative and organizational structure;~~

~~(ii) Continuous quality improvement;~~

~~(iii) Staff credentials;~~

~~(iv) Patient admission criteria;~~

~~(v) Required services;~~

~~(vi) Recordkeeping and patient confidentiality;~~

~~(vii) Medication administration, dispensing, and use;~~

~~(viii) Unsupervised or take-home use; and~~

~~(ix) Interim maintenance treatment.~~

~~(b) The opioid treatment program's accreditation body standards;~~

~~(c) After-hours contact service to confirm patient dose amounts, seven days a week, 24 hours a day;~~

~~(d) Urinalysis and drug testing, to include:~~

~~(i) Documentation indicating the clinical need for additional urinalysis;~~

~~(ii) Observed samples, when clinically indicated; and~~

~~(iii) Samples handled through proper chain of custody techniques.~~

~~(e) The response to medical and psychiatric emergencies; and~~

~~(f) Verifying the identity of an individual receiving treatment services, including maintaining a file in the dispensary with a photograph of the individual and updating the photographs when the individual's physical appearance changes significantly.~~

~~(3) Use the state's central registry, as defined in subsection (15) of this rule, for, but not limited to, emergencies and dual en-~~

rollment, including submitting and maintaining all required data and tasks within the central registry;

(4) Offer on-site, or by referral, to each individual admitted:

(a) Hepatitis A and Hepatitis B vaccine;

(b) Screening, testing, and treatment for infectious diseases including:

(i) Human immunodeficiency virus (HIV);

(ii) Hepatitis B and C;

(iii) Syphilis; and

(iv) Tuberculosis (TB).

(5) Provide the following information to each individual admitted:

(a) Information and education, as appropriate, on:

(i) Emotional, physical, and sexual abuse;

(ii) The impact of opioid use and opioid use disorder medications during pregnancy as required by RCW 71.24.560 to all pregnant individuals before they are prescribed medications as part of their treatment, and to all individuals who become pregnant while receiving services; and

(iii) Reproductive health.

(b) Information about, and access to, opioid overdose reversal medication in accordance with RCW 71.24.594.

(6) Have at least one staff member on duty at all times who has documented training in:

(a) Cardiopulmonary resuscitation (CPR); and

(b) Management of opioid overdose.

(7) The medical director ensures that:

(a) There is a documented review of the department prescription drug monitoring program data on the individual:

(i) At admission;

(ii) Annually after the date of admission; and

(iii) Subsequent to any incidents of concern.

(b) For each individual admitted to withdrawal management services an approved withdrawal management schedule that is medically appropriate is developed; and

(c) For each individual administratively discharged from services an approved withdrawal management schedule that is medically appropriate is developed.

(8) All exceptions to take-home requirements are submitted and approved by the state opioid treatment authority and Substance Abuse and Mental Health Services Administration (SAMHSA).

(9) An agency providing opioid treatment program services may accept, possess, and administer patient-owned medications.

(10) Notify the federal SAMHSA and the department within three weeks of any replacement or other change in the status of the program, program sponsor, or medical director as defined in 42 C.F.R. Part 8.

(11) An agency operating a medication unit must comply with 21 C.F.R. Parts 1300, 1301, 1304, 1306, 42 C.F.R. Part 8, and any applicable rules of the pharmacy quality assurance commission.

(12) Report to the department deaths of individuals enrolled in an opioid treatment program, that do not occur on campus, within 48 hours upon learning of the death.

(13) Report to the department deaths that occur on the campus of an opioid treatment program as a critical incident according to WAC 246-341-0420(12).

(14) Develop an ongoing community relations plan to address new concerns expressed by the community.

(15) For the purposes of this section, "central registry" means the software system used to determine whether the patient is enrolled in any other opioid treatment program and to provide a continuum of care in times of disaster.

AMENDATORY SECTION (Amending WSR 22-24-091, filed 12/6/22, effective 5/1/23)

WAC 246-341-1100 Withdrawal management—Certification standards.

(1) Substance use disorder withdrawal management services are provided to assist in the process of withdrawal from psychoactive substances in a safe and effective manner that includes medical management or medical monitoring. Substance use disorder withdrawal management services under this certification include:

(a) Adult withdrawal management; and

(b) Youth withdrawal management.

(2) An agency certified for withdrawal management services must:

(a) Ensure the individual receives a substance use disorder screening before admission;

(b) Provide counseling to each individual that addresses the individual's:

(i) Substance use disorder and motivation; and

(ii) Continuing care needs and need for referral to other services.

(c) Maintain a list of resources and referral options that can be used by staff members to refer an individual to appropriate services; and

(d) Post any rules and responsibilities for individuals receiving treatment, including information on potential use of increased motivation interventions or sanctions, in a public place in the facility.

(3) Ensure that each staff member providing withdrawal management services to an individual, with the exception of substance use disorder professionals, substance use disorder professional trainees, physicians, physician assistants, advanced registered nurse practitioners, or person with a co-occurring disorder specialist enhancement, completes a minimum of 40 hours of documented training before being assigned individual care duties. This personnel training must include the following topics:

(a) Substance use disorders;

(b) Infectious diseases, to include hepatitis and tuberculosis (TB); and

(c) Withdrawal screening, admission, and signs of trauma.

(4) An agency certified for withdrawal management services must meet the certification standards for residential and inpatient behavioral health services in WAC (~~(246-341-1104)~~) 246-341-1105 and the individual service requirements for inpatient and residential substance use disorder services in WAC 246-341-1108.

REPEALER

The following sections of the Washington Administrative Code are repealed:

- WAC 246-341-1005 Opioid treatment programs (OTP)—Agency certification requirements.
- WAC 246-341-1010 Opioid treatment programs (OTP)—Agency staff requirements.
- WAC 246-341-1015 Opioid treatment programs (OTP)—Individual service record content and documentation requirements.
- WAC 246-341-1020 Opioid treatment programs (OTP)—Medical director responsibility.
- WAC 246-341-1025 Opioid treatment programs (OTP)—Medication management.