DRAFT

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 comply with the applicable requirements in 42 C.F.R. Part 8 and 21 C.F.R. Part 1301 and ensure that the ~~agency's individual record system complies with all federal and state reporting requirements relevant to opioid drugs approved for use in treatment of opioid use disorder, alcohol use disorder, tobacco use disorder, and reversal of opioid overdose~~ following requirements are met:~~.~~

Commented [MW1]: Moved here from WAC 246-341-1005

~~(3) An agency must:~~

(~~a~~1) ~~Use evidence-based therapy in addition to medication in the treatment program~~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

(viiii) 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) Laboratory testing;

(f) The response to medical and psychiatric emergencies; and

(g) 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.

(2b) Use ~~Identify individual mental health needs during assessment process and refer them to appropriate treatment if not available on-site~~the state's central registry for, but not limited to, emergencies and dual enrollment, including submitting and maintaining all required data and tasks within the central registry;

(3c) ~~Provide~~ Offer on-site, or by referral, to ~~education~~ to each individual admitted~~, totaling no more than fifty percent of treatment services, on~~:

(a~~i~~) ~~Alcohol, other drugs, and substance use disorder~~Hepatitis A and Hepatitis B vaccine;

(b~~ii~~) ~~Relapse prevention~~Screening, testing, and treatment for~~:~~:

(i) Syphilis; and

~~(A)~~ (ii)Tuberculosis (TB).

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

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

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

(4d) Provide information and education to each individual, as appropriate on:

(i) Emotional, physical, and sexual abuse;

~~(ii) Nicotine use disorder;~~

(~~i~~ii) The impact of ~~substance~~ opioid and opioid use disorder medications 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~~ according to RCW 71.24.560; and

(i~~i~~v) ~~Family planning~~Reproductive health.

(5) 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.

~~(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:~~

Commented [MW2]: Link to: RCW 71.24.560: Opioid treatment programs—Pregnant individuals—Information and education. (wa.gov)

Commented [MW3]: Moved to main OTP section -1000 from the mobile unit notification process that is now located in -0300 regarding licensure and certification. Compliance with these regulations is required, however it is not required as part of the DOH licensure process.

~~(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 or medical director 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~~6) Report to ~~T~~the department deaths of ~~an~~ individuals enrolled in an opioid treatment program, that do not occur on campus, ~~is reported to the department~~ within forty-eight hours upon learning of the death.

(7) 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).

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

(9) 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.

~~[Statutory Authority:~~
~~RCW **71.24.037**, **71.05.560**, **71.34.380**, **18.205.160**, **71.24.037** and chapters **71.05**, 71.24, and **71.34** RCW. WSR 21-12-042, § 246-341-1000, filed 5/25/21, effective 7/1/21. Statutory Authority: 2018 c 201 and 2018 c 291. WSR 19-09-062, § 246-341-1000, filed 4/16/19, effective 5/17/19.]~~

~~PDF **246-341-1005**~~

~~Opioid treatment programs (OTP)—Agency certification requirements.~~

~~An agency applying to provide o~~Opioid treatment program~~s services~~ must submit additional information with their application to include:

(1) ~~Submit to the department d~~Documentation that the agency has communicated with the county legislative authority and if applicable, the city legislative authority or tribal authority, in order to secure a location ~~for the new~~when proposing to open a new, or move an existing opioid treatment program that meets county, tribal or city land use ordinances.

(2) ~~Ensure that a~~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~~, in order to minimize the impact of the opioid treatment programs upon the business and residential neighborhoods in which the program is located~~. A community relations plan is a plan to ~~minimize~~ inform and educate the community about the ~~impact of an~~ opioid treatment program~~. as defined by the Center for Substance Abuse Guidelines for the Accreditation of Opioid Treatment Programs, section 2.C.(4).~~ The plan must include:

(a) Documentation of the strategies used to:

(i) Obtain ~~stakeholder~~ community input regarding the proposed location;

(ii) Address any concerns identified by ~~stakeholders~~community members near the proposed location of the opioid treatment program; and

Commented [MW4]: Link to: WAC 246-341-0420:

Commented [MW5]: This language was added after the workshops to clarify the difference between reporting a death of a patient that occurs on campus v. off campus. They are reported differently.

Commented [MW6]: Moved from -1005 to main OTP section. This is required as an ongoing activity, but not as part of the licensure process.

Commented [MW7]: Repeal and move updated version to WAC 246-341-0300

Commented [MW8]: Move to the definition section in WAC 246-341-0200

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

(b) 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.

(3) Prior to an opioid treatment program license being issued, the applicant must obtain approval from:~~Have concurrent approval to provide an opioid treatment program by~~:

(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 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).

(4) An agency must ~~ensure that the opioid treatment program is provided to an individual in compliance~~comply with the applicable requirements in 42 C.F.R. Part 8 and 21 C.F.R. Part 1301.

~~(5) The department may deny an application for certification when the applicant has not demonstrated in the past, the capability to provide the appropriate services to assist individuals using the program to meet goals established by the legislature.~~

~~[Statutory Authority:~~

~~RCW **71.24.037**, **71.05.560**, **71.34.380**, **18.205.160**, **71.24.037** and chapters **71.05**, 71.24, and **71.34** RCW. WSR 21-12-042, § 246-341-1005, filed 5/25/21, effective 7/1/21. Statutory Authority: 2018 c 201 and 2018 c 291. WSR 19-09-062, § 246-341-1005, filed 4/16/19, effective 5/17/19.]~~

PDF ~~**246-341-1010**~~

~~Opioid treatment programs (OTP)—Agency staff requirements.~~

~~An agency providing substance use disorder opioid treatment program services must:~~

~~(1) Appoint a program sponsor, as defined in 42 C.F.R. Part 8, who is responsible for notifying the United States Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA), the United States Drug Enforcement Administration (DEA), the department, and the~~

Commented [MW9]: Moved from -1005 to main OTP section. This is required as an ongoing activity, but not as part of the licensure process.

Commented [MW10]: Move to main OTP section WAC 246-341-1000. This is not required as part of the licensing process.

Commented [MW11]: Repeal and incorporate into main OTP section -1000.

Commented [MW12]: Removed since Medical Director and Program Sponsor are covered in the administrative and organizational structure in CFR which is included above . Staffing requirements also covered in BHA WAC 246-341-0515.

~~Washington pharmacy quality assurance commission of any theft or significant loss of a controlled substance that resulted in filing a DEA Form 106.~~

~~(2) Ensure there is an appointed medical director, as defined in 42 C.F.R. Part 8, who:~~

~~(a) Is licensed by the department under chapter **18.57** RCW or the Washington medical commission under chapter **18.71** RCW to practice medicine and practices within their scope of practice;~~

~~(b) Is responsible for all medical services performed;~~

~~(c) Ensures all medical services provided are in compliance with applicable federal, state, and local rules and laws.~~

~~(3) Ensure at least one staff member has documented training in:~~

~~(a) Family planning;~~

~~(b) Prenatal health care; and~~

~~(c) Parenting skills.~~

(41) Ensure that at least one staff member is on duty at all times who has documented training in:

(a) Cardiopulmonary resuscitation (CPR); and

(b) Management of opioid overdose.

~~[Statutory Authority:~~
~~RCW **71.24.037**, **71.05.560**, **71.34.380**, **18.205.160**, **71.24.037** and chapters **71.05**, 71.24, and **71.34** RCW. WSR 21-12-042, § 246-341-1010, filed 5/25/21, effective 7/1/21. Statutory Authority: 2018 c 201 and 2018 c 291. WSR 19-09-062, § 246-341-1010, filed 4/16/19, effective 5/17/19.]~~

PDF ~~**246-341-1015**~~

~~Opioid treatment programs (OTP)—Individual service record content and documentation requirements.~~

~~An agency providing opioid treatment program services must maintain an individual's individual service record. The individual service record must contain:~~

~~(1) Documentation that the agency made a good faith effort to review if the individual is enrolled in any other opioid treatment program and take appropriate action;~~

Commented [MW13]: Same as above re: Program Sponsor

Commented [MW14]: Repeal. This information is covered in CFR under Recordkeeping.

(2) Documentation that the individual received a copy of the rules and responsibilities for treatment participants, including the potential use of interventions or sanction;

(3) Documentation that the individual service plan was reviewed quarterly and semi-annually after two years of continuous treatment;

(4) Documentation when an individual refuses to provide a drug testing specimen sample. The refusal is considered a positive drug screen specimen;

(5) Documentation in progress notes of timely interventions used to therapeutically address the disclosure of illicit drug use, a positive drug test, or possible diversion of opioid medication, as evidenced by the absence of opioids or related metabolites in drug toxicology test results;

(6) Documentation of all medical services including:

(a) Results of physical examination;

(b) Medical and family history;

(c) Nursing notes;

(d) Laboratory reports including results of regular toxicology screens, a problem list, and list of medications updated as clinically indicated; and

(e) Progress notes including documentation of all medications and dosages, if available.

[Statutory Authority:
RCW **71.24.037**, **71.05.560**, **71.34.380**, **18.205.160**, **43.70.080**(5), **41.05.750**, **43.70.250**, and **74.09.520** and chapters **71.05**, 71.12, 71.24 and **71.34** RCW. WSR 22-24-091, § 246-341-1015, filed 12/6/22, effective 5/1/23. Statutory Authority:
RCW **71.24.037**, **71.05.560**, **71.34.380**, **18.205.160**, **71.24.037** and chapters **71.05**, 71.24, and **71.34** RCW. WSR 21-12-042, § 246-341-1015, filed 5/25/21, effective 7/1/21. Statutory Authority: 2018 c 201 and 2018 c 291. WSR 19-09-062, § 246-341-1015, filed 4/16/19, effective 5/17/19.]

PDF **246-341-1020**

Opioid treatment programs (OTP)—Medical director responsibility.

Commented [MW15]: Repeal and incorporate into main OTP section -1000

An agency providing substance use disorder opioid treatment program services must ensure the program physicianThe medical director, or the medical practitioner under supervision of tThe medical director ensures that, performs and meets the following:

(1) The program physician or medical practitioner under supervision of the medical director:

~~(a) Is responsible to verify an individual is currently addicted to an opioid drug and that the individual became addicted at least 12 months before admission to treatment; or~~

~~(b) May waive the 12-month requirement in (a) of this subsection upon receiving documentation that the individual:~~

~~(i) Was released from a penal institution, if the release was within the previous six months;~~

~~(ii) Is pregnant; or~~

~~(iii) Was previously treated within the previous 24 months.~~

~~(2) A documented physical evaluation must be completed on the individual before admission and before starting medications approved to treat opioid use disorder that includes the determination of opioid use disorder consistent with the current and applicable Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria;~~

(~~1~~3) There is a ~~A~~ documented review of the department prescription drug monitoring program data on the individual:

(a) At admission;

(b) Annually after the date of admission; and

(c) Subsequent to any incidents of concern.

~~(4) All relevant facts concerning the use of the opioid drug must be clearly and adequately explained to each individual;~~

~~(5) Current written and verbal information must be provided to pregnant individuals, before the initial prescribed dosage regarding:~~

~~(a) The concerns of possible substance use disorder, health risks, and benefits the opioid treatment medication may have on the individual and the developing fetus;~~

~~(b) The risk of not initiating opioid treatment medication on the individual and the developing fetus;~~

~~(c) The potential need for the newborn baby to be treated in a hospital setting or in a specialized support environment designed to address and manage neonatal opioid or other drug withdrawal syndromes; and~~

~~(d) Referral options to address and manage neonatal opioid or other drug withdrawal syndromes.~~

~~(6) Each individual voluntarily choosing to receive maintenance treatment must sign an informed consent to treatment;~~

~~(7) Within 14 days of admission, a medical examination must be completed that includes:~~

~~(a) Documentation of the results of serology and other tests, as determined by the medical practitioner; and~~

Commented [MW16]: This is covered in -1000 with a reference to what is required for pregnant women under 71.24.560.

(b) A documented assessment for the appropriateness of Sunday and holiday take-home medications as required by 42 C.F.R. Part 8.12(i).

(8) When exceptional circumstances exist for an individual to be enrolled with more than one opioid treatment program agency, justification granting permission must be documented in the individual's individual service record at each agency;

(92) For Eeach individual admitted to withdrawal management services must have an approved withdrawal management schedule that is medically appropriate is developed; and

(10) For Eeach individual administratively discharged from services must have an approved withdrawal management schedule that is medically appropriate is developed;

(11) An assessment for other forms of treatment must be completed for each individual who has two or more unsuccessful withdrawal management episodes within 12 consecutive months; and

(12) An annual medical examination must be completed on each individual, either in person or via telehealth technologies, that includes the individual's overall physical condition and response to medication. The medical practitioner may use their professional and clinical judgment when determining the appropriateness of telehealth technologies for the annual medical exam and must document, in the patient's record, their decision to use telehealth technologies. The initial medical exam must be completed in person as required by 42 C.F.R. Part 8.12(f)(2).

[Statutory Authority:
RCW **71.24.037**, **71.05.560**, **71.34.380**, **18.205.160**, **43.70.080**(5), **41.05.750**, **43.70.250**, and **74.09.520** and chapters **71.05**, 71.12, 71.24 and **71.34** RCW. WSR 22-24-091, § 246-341-1020, filed 12/6/22, effective 5/1/23. Statutory Authority:
RCW **71.24.037**, **71.05.560**, **71.34.380**, **18.205.160**, **71.24.037** and chapters **71.05**, 71.24, and **71.34** RCW. WSR 21-12-042, § 246-341-1020, filed 5/25/21, effective 7/1/21. Statutory Authority: 2018 c 201 and 2018 c 291. WSR 19-09-062, § 246-341-1020, filed 4/16/19, effective 5/17/19.]

PDF **246-341-1025**

Opioid treatment programs (OTP)—Medication management.

Commented [MW17]: Repeal and incorporate into main OTP section -1000.

An agency providing opioid treatment program services must ensure the medication management requirements in this section are met.

(1) An agency must use only those opioid treatment medications that are approved by the United States Food and Drug Administration under section 505 of

~~the United States Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid use disorder.~~

~~(2) An agency providing opioid treatment program services must ensure that initial dosing requirements are met as follows:~~

~~(a) Methadone must be administered or dispensed only in oral form and is formulated in such a way as to reduce its potential for parenteral abuse;~~

~~(b) The initial dose of methadone must not exceed thirty milligrams and the total dose for the first day must not exceed forty milligrams, unless the program physician documents in the individual's record that forty milligrams did not suppress opioid abstinence symptoms; and~~

~~(c) The establishment of the initial dose must consider:~~

~~(i) Signs and symptoms of withdrawal;~~

~~(ii) Individual comfort; and~~

~~(iii) Side effects from over-medication.~~

(3) ~~An agency providing an opioid treatment program services must e~~Ensure that:

~~(a) Each opioid treatment medication used by the program is administered and dispensed in accordance with its approved product labeling;~~

(b) Each individual admitted to an opioid treatment program ~~shall~~ receive~~s overdose prevention education and~~ information about, and ~~on how to~~ access to opioid overdose reversal medication in accordance with RCW 71.24.594;

~~(c) All dosing and administration decisions are made by a:~~

~~(i) Program physician; or~~

~~(ii) Medical practitioner under supervision of a program physician familiar with the most up-to-date product labeling.~~

~~(d) Any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the individual's record.~~

~~(4) An agency providing opioid treatment program services must ensure that all take-home medications are:~~

~~(a) Consistent with 42 C.F.R. Part 8.12 (i)(1) through (5) and are authorized only to stable individuals who:~~

~~(i) Have received opioid treatment medication for a minimum of ninety days; and~~

~~(ii) Have not had any positive drug screens in the last sixty days.~~

~~(b) Assessed and authorized, as appropriate, for a Sunday or legal holiday as identified in RCW **1.16.050**;~~

Commented [MW18]: Covered under CFR requirements listed in -1000.

~~(c) Assessed and authorized, as appropriate, when travel to the facility presents a safety risk for an individual or staff member due to inclement weather; and~~

~~(d) Not allowed in short-term withdrawal management or interim maintenance treatment.~~

~~(5) Registered nurses and licensed practical nurses may dispense up to a thirty-one day supply of medications approved by the United States Food and Drug Administration for the treatment of opioid use disorder under an order or prescription.~~

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

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

[Statutory Authority:
RCW **71.24.037**, **71.05.560**, **71.34.380**, **18.205.160**, **71.24.037** and chapters **71.05**, 71.24, and **71.34** RCW. WSR 21-12-042, § 246-341-1025, filed 5/25/21, effective 7/1/21. Statutory Authority: 2018 c 201 and 2018 c 291. WSR 19-09-062, § 246-341-1025, filed 4/16/19, effective 5/17/19.]