

WAC 246-341-1000 Opioid treatment programs (OTP)—Certification standards. 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 enrollment, 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.

[Statutory Authority: RCW 71.24.037 and 2023 1st sp. s. c 1. WSR 25-03-021, s 246-341-1000, filed 1/7/25, effective 1/31/25. 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.]