DRAFT

246-341-1000

Opioid treatment programs (OTP)—Certification standards.

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 following requirements are met:

(1) 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.

(2) Use 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.

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

(a) Hepatitis A and Hepatitis B vaccine;

(b) Screening, testing, and treatment for:

(i) Syphilis; and

(ii)Tuberculosis (TB).

(4) Provide each individual admitted:

(a) Information and education, as appropriate on:

(i) Emotional, physical, and sexual abuse;

(ii) The impact of opioid and opioid use disorder medications during pregnancy according to RCW 71.24.560; and

(iii) Reproductive health.

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

(5) 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.

(6) 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.

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

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

(7) 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).

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

(9) Notify the federal Substance Abuse and Mental Health Services Administration (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.

(10) 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.

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

(12) 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).

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

(14) 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.

Commented [MW10]: 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 [MW11]: This was originally in -1005 and then moved to -0300 agency licensing and certification requirements. We then moved it here to the main OTP section because it is not as part of the licensure process but is a required activity.