Opioid Treatment Program (OTP) Rulemaking Workbook: Workshop #5

WAC 246-341-0200 – Definitions
WAC 246-341-0300 – Agency Licensure and Certification
WAC 246-341-1000 – OTP Certification Standards

Proposed WAC Revisions	Notes
WAC 246-341-0200 - Definitions	
"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 community members near the proposed location of the opioid treatment program.	Added a definition of community relations plan because: • Community Relations Plan is mentioned in multiple sections of the WAC, specifically in -0300 regarding agency licensure requirements and -1000 which is the now the main OTP section. This is consistent with standard WAC formatting for definitions; • This language was originally included in the OTP licensing and certification section of the WAC, which we moved to -0300 where all of the BHA licensure information is located. When we did that we realized that although a community relations plan is required as part of the licensure process, we didn't need to include the definition in that particular section of the WAC. **Notes:** No questions or concerns from workshop.
WAC 246-341-0300 – Agency Licensure and Certification – General Requirements	
(5) An opioid treatment program must submit additional information with their application to include: (a) 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 when proposing to open a new, or move an existing opioid treatment program that meets county, tribal or city land use ordinances; (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),	Subsection (5) regarding OTP licensing • Moved the OTP agency certification requirements from WAC 246-341-1005 to WAC 246-341-0300 which includes all of the licensing and certification requirements for all Behavioral Health Agencies. Subsection (6) regarding fixed-site medication units • Moved the OTP mobile medication unit and fixed-site medication unit information from WAC 246-341-0342 to WAC 246-341-0300 so that it is included with all of the other licensure requirements in one location of the WAC. • The process for both mobile and fixed-site medication units will mostly be the same. The biggest difference right now is that the mobile uses it's existing DEA registration, but the fixed-site medication unit will require a separate DEA registration. Because of this, I will be checking with our DEA partners to determine what DEA approval will look like for the fixed-site medication unit. More to come on that. **Notes:** • **This is not my expertise- may I assume that DEA designation be per Provider and not facility/mobile?** ○ **Department:** This information will need to come from the DEA. We will be meeting with them in the near future to discuss the requirements. • **I agree with Michelle, I would assume any feedback to come from the DEA, will need to come from the DEA and is TBD.**

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). (6) An opioid treatment program may operate a medication unit as defined in 42 C.F.R. Part 8.2, that is a brick-and-mortar location, or a mobile narcotic treatment program as defined in 21 C.F.R. Part 1300. An opioid treatment program operating a medication unit must: (a) Notify the department in a manner outlined by the department; (b) Submit a copy of the Drug Enforcement Administration (DEA) approval for the medication unit.	
WAC 246-341-1000 – 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.	We condensed the WAC requirements to one section and changed the title to *OTP Certification Standards* and aligned it with CFR, removed duplication, and included references to RCW 71.24.560 regarding pregnant women and RCW 71.24.594 opioid overdose reversal medication requirements. • Added the highlighted language from WAC section 1005. It fits more appropriately here and clarifies that OTPs must comply with both SAMHSA and DEA regulations. • Previously workshopped, we are aligning with CFR regarding policies and procedures for each of their requirements. • Regarding subsection (1)(e), laboratory testing, I believe this is covered under required services in CFR, which is referenced under the P&Ps. Thinking we can remove this. Are there any concerns or thoughts we should consider? **Notes:** No questions or concerns from workshop.
(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:	Subsection (2) and (3) were previously workshopped: • Central Registry - New requirement. HCA currently pays for the use of this registry for OTPs. • Hep A and Hep B vaccine – New requirement. • Referral means that the program just does a referral for a service – for example a list of resources or places where they can get that service.

(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.	• (3)(b) this is screening, testing, and treatment of Syphilis and TB – this is in addition to what is required by SAMHSA. Subsection (4) also previously workshopped but would like to point out that we are referring to RCWs regarding pregnant women and access to opioid overdose reversal medication. **Notes:** No questions or concerns from workshop.
(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.	Subsection (6) regarding the medical director – these are in addition to the requirements already in CFR that we align with above. This allows the medical director to do these or delegate to a medical practitioner under their supervision. **Notes:** No questions or concerns from workshop.

(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.
	Subsection (10) this was moved from the medication unit section that is now located in -0300 regarding licensure and certification. It's included here because compliance with these regulations are required, however this is not required as part of the DOH licensure process.
	
	Subsection (12) – mentioned in the slides but this was to clarify the difference between reporting a death that occurs on campus of the OTP v. off campus. A death that occurs on campus is considered a critical incident so would be reported differently.
	
	Subsection (13) regarding the community relations plan. This was moved out of the licensure section in -0300 because an ongoing community relations plan, although a required activity, it is not required for licensure.
	
	Notes:
	• **Did I understand correctly, that when a death occurs after the client has left services with an agency, the death needs to be reported?**
	  ○ **Department:** You need to report the death of each enrolled patient, even if the patient has left the site or campus. Deaths that occur on campus are reported as a critical incident through the online DOH Intake Form. OTP patient deaths that occur off-site, are reported through the online OTP Death Reporting Form.
	• **Wasn't there a 72 hour rule somewhere (at some time) that sentinel events should be reported if known? It was pre-2018.**
	  ○ **Department:** This is not part of the current BHA/OTP rules.

(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.	