BHA/Opioid Treatment Program (OTP) Rulemaking Workbook: Workshop #1
WAC 246-341-0300 – General Information
WAC 246-341-1100 – Withdrawal Management
WAC 246-341-0200 - Definitions
WAC 246-341-1000 – OTP General

Proposed WAC Revisions	Comments to Consider	Notes
WAC 246-341-0300(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:	DOH - Technical fix to correct an inaccurate citation that are currently referenced in WAC 246-341-0300. Doesn't change any requirements. The numbering changed from subsection (1) to (2), but the reference was not corrected in subsection (4).	No public comments or questions.
WAC 246-341-1100(3)(c) 3)(c) An agency certified for withdrawal management services must meet the certification standards for residential and inpatient behavioral health services in ~~WAC 246-341-1104~~ WAC **246-341-1105** and the individual service requirements for inpatient and residential substance use disorder services in WAC **246-341-1108**.	DOH - Technical fix to correct WAC reference. WAC 246-341-1104 was repealed for the sake of numbering but was not corrected here. WAC 246-341-1105 - residential and inpatient behavioral health services, is the correct reference.	No public comments or questions.

WAC 246-341-0200 – Definitions
"Opioid treatment program" means the same as defined in RCW 71.24.590
	DOH - Add OTP definition to the BHA definition section.	• What is the current definition?
		  ○ **Department Answer:** Not included and department wants to include.
		• What does comprehensive mean?
		  ○ **Department Answer:** Not defined. CFR may mention it and the department needs to consider whether this needs to be defined.
		• Makes sense. No concerns.
		• Appreciate that the definition is fairly flexible, and it could cover a wide array of services that an OTP setting could offer.

WAC 246-341-1000
OTP ~~General~~ Certification Standards
	DOH - Title change	• When does HCA plan to put in place for these WAC changes if you are not waiting on the 42 CFR Part 8 final rule?
		  ○ **Department Answer:** Department wants to align timing with HCA and SAMHSA.
		  ○ **HCA:** That is correct.

~~(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.~~	1. Survey comment - Evidence-based practice language is restrictive. Other types of care are not limited in this way. 2. Survey comment - Language describing FDA-approved MOUD in combination with terms "withdrawal management" is problematic. Other types of care not limited in this way.	• The language in ...1000 is restrictive with regard to using "medications approved by the FDA for the treatment of OUD, AUD, TUD, and opioid overdose" compared to CFR (as is WAC ...1025 though that won't be addressed today). 42 CFR 8.12(h)(2) does reference FDA approval but does so in the context of opioid agonist medication, not for all medication used for OUD and the other SUDs listed here. There are many non-agonist OUD medications that are useful and used off-label (up to 20% of medications in the US are prescribed off-label, Ach Intern Med 2006) and will never gain FDA approval due to the cost and length of that process. The problem with this language is the risk of restricting treatment, and it should more closely reflect the CFR language with regard to agonist treatment only. ○ **Department Answer:** Language is in the statute and would have to be a legislative fix. Department can note but it is addressed in WAC -1025.

		• Along with the land acknowledgement, it might be worthwhile to acknowledge that OTPs were developed during a federal "war on drugs", aimed largely at urban people of African descent, and in other ways fundamentally discriminatory toward those who struggle with drug use. I cannot think of another common/serious health problem so heavily regulated, and it remains unclear to what extent (if any) such regulation benefits patients, providers, and society. ○ **Department Answer:** Thank you for sharing this information. It is important to remember where these came from. The department will find a way to acknowledge that in future workshops. • Why wouldn't we want EBP for OTP's? • I think having a "goal" of EBP and/or Best Practices is operationally necessary; however, does that need to be called out in WAC? ○ **Department Answer:** You want to be using EBP. With SAMHSA guidance it is an expectation already. Department doesn't feel that it needs to be addressed in a WAC. Please speak up if you disagree. • Do other BHA setting types have EBP in their WAC sections? If not, maybe removing would be helpful for streamlining purposes. ○ **Department Answer:** Already a general requirement WAC 246.341.0410. Quality management plans should already improve quality of plan and allow for flexibility. • EBP can be restrictive should not be in WAC. • I think it's not really necessary to be there. ○ **Department Answer:** The department pulled it out of OTP section because it's duplicative. It is already stated in another section. The department can revisit at a later time.
(12) 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 approved for use in treatment of opioid use disorder, alcohol use disorder, tobacco use disorder, and reversal of opioid overdose~~the following requirements are met~~.~~:	1. Survey comment - Align with CFR and remove duplication.	No public comments or questions.
~~3) An agency must:~~ (a) ~~Use evidence-based therapy in addition to medication in the treatment program~~Develop, maintain, and implement policies and procedures for: (i) Requirements in 42 C.F.R. Part 8.12 to include: (A) Administrative and organizational structure; (B) Continuous quality improvement; (C) Staff credentials; (D) Patient admission criteria; (E) Required services (F) Recordkeeping and patient confidentiality; (G) Medication administration, dispensing, and use; (H) Unsupervised or take-home use; and (I) Interim maintenance treatment. (ii) Requirements of the opioid treatment program's accreditation body.	1. Survey comment - Align with CFR and remove duplication. 2. HCA - Require after-hours service. 3. HCA - Require the use of the state's central registry for emergency situations and to verify dual enrollment?	**Department Questions:** Any concerns with afterhours language and dose amounts? Any concerns about central registry funded via HCA? • Sorry, couldn't type this response in time before the conversation on the section ended. Thanks Michelle for commenting on the statute including the FDA approval language. If we cannot change the WAC to make this less restrictive, can the state at least clarify whether the language in …1000 and ...1025 implies that OTPs can ONLY use (order, dispense, etc) the medications listed here, or that they can use those FDA approved medications, and that that sentence shouldn't also imply that they CANNOT use any others? For instance, the SMAHSA 2015 document Federal Guidelines for OTPs states: "OTPs may determine that directly observed therapy may enhance patients' compliance with their regimen for psychotropic medications, which may be subject to abuse, and medications for illness and chronic health conditions. These medications may be dispensed with the daily opioid dose." • This implies that SAMHSA is supportive of OTPs ordering and dispensing other medications (beyond those which are "FDA approved for" SUDs) that is within their

(iii) After-hours contact service to confirm patient dose amounts, seven days a week, 24 hours a day. (b) Use the state's central registry for, but not limited to, emergencies and dual enrollment.		practitioners scope of practice. The problem we've run into is that DEA and PQAC have interpreted this WAC when I inquire about using other medications, for withdrawal management for instance, in our dispensary as not allowed if they are not expressly FDA-approved for that purpose. This creates barriers for patients and doesn't make sense re: practitioner licensing and training. In the absence of being able to change the statute, maybe the state could just clarify whether the WAC should be read as saying we can use FDA approved medications for the above SUDs, or can only use FDA approved medications for the above SUDs. ○ **Department Answer:** The department needs to have another conversation with the Pharmacy Commission. We don't want to be restrictive on how it is used in the real world. Also want to discuss with DEA so that we have a consensus. We will need to talk to our partners to have a common consensus. The department will follow up. We can have those conversations. There may be other things we can do around policy for interpretation. Policy statement is one tool – but the end goal is to get a rule with a policy statement. Rules are used to clarify what isn't clear in statute. We want to approach as to how we include without limiting and provide direction. The department will move this forward. ○ **HCA:** Correct, they do want other medications if possible.
~~(b) Identify individual mental health needs during assessment process and refer them to appropriate treatment if not available on-site;~~ (c) ~~Provide~~ Offer on-site or by referral to ~~education to~~ each individual admitted~~,~~ ~~totaling no more than fifty percent of treatment services, on~~: (i) Hepatitis A and B vaccine; (ii) Screening, testing, and treatment for: ~~(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;~~ (iii~~iv~~) ~~Sexually transmitted infections~~Syphilis; and (iv) Tuberculosis (TB); (d) 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 ~~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~~ in accordance with RCW 71.24.560; and (iii~~iv~~) ~~Family planning~~Reproductive health.	1. Survey comment - Outpatient MH services should be referred to master level therapist for counseling. 2. Survey comment - Define referral; does it require a follow up? 3. HCA/DOH Disease Control Health Statistics - OTPs must document that they offered all patients Hep A and B vaccines onsite or by referral. 4. HCA/DOH Disease Control Health Statistics - OTPs must offer infectious disease screening, testing, and treatment for HIV, viral hepatitis, TB, Syphilis, or that they offered documented referral offsite. a. Survey comment – these are not available at current OTPs, nor is funding or resources for this to be implemented. 5. DOH - Remove potential duplication of education requirements.	• Counseling is not always the indicated treatment for MH conditions. Even if indicated, Master's level therapists are in short supply. If this is retained (though I hope not) then it should be clear that we can refer but can't guarantee such a connection will occur. ○ **HCA:** WE are looking for a referral and then follow up, we know connections cannot always be made • Certified counselors could be the follow up MH ○ **HCA:** The WA SOTA office strongly supports these two items related to infectious disease vaccinations onsite or off site; and also, infectious disease screening, testing and treatment onsite or off-site. We believe it aligns with the state's public health goals and our state's goal to eliminate Hep C by 2030. • Infectious Diseases - particularly hepatitis C, has been outlined in the state's hepatitis C elimination plan and is a part of the Governor's directive to eliminate hepatitis C by 2030. OTP sites have been specifically outlined within the state's plan. ○ **Department Answer:** Regarding infectious disease, the department will follow-up on language concerning "conditions/vaccines". They specifically made it a narrow approach and identifying the population that is affected. • Specifying specific conditions/vaccines means subsequent rule changes. Should the language be more general so that we can later include more? ○ **Department Answer:** Correct. We are focusing on hepatitis because we are trying to eliminate it. This population may benefit from vaccinations. • Unfunded mandates hurt small business. ○ **Department Answer:** The department will look into the small business impact. • I think it's beneficial for individuals to be educated on all infectious diseases. ○ **Department Answer:** Agree. How specific do should the department get focusing on education around infectious diseases?

~~(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.	1. DOH - (e) move remaining items in this section under (1)(a) above – policies and procedures. 2. DOH - Diversion control – already required in CFR. 3. Survey comment - Recommend random monthly UAs as part of the recommended treatment plan. Eight UAs seems porous. 4. Survey comment - (E) Observed UAs are how we minimize falsification. Making them optional makes no sense. As written this is giving medical directors leeway to do away with observed UAs altogether. 5. Survey comment - Is there going to be guidance on what substance we must test for?	**<u>Department Comment:</u>** Please provide your feedback regarding Section E. • remove. • My literature search found no evidence that observed UA is beneficial. **<u>Ending Comments:</u>** • Thank you for all your work. Please create tribal BHA/OTP roundtable sessions prior to finalizing the proposed changes, in order to fulfill the government-to-government trust responsibility. We should not be included with other stakeholders prior to tribal consultation. Lucy from HCA and Candice at DOH can assist in this process. **Meeting ended at section F and how specific department should be regarding wording on infectious diseases. Next meeting will start at section 4.**
~~(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.~~	1. Survey comment - There is some confusion around the detox/withdrawal management and maintenance therapy. In the CSAT [guidelines] the language states "Patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the OTP physician for other forms of treatment. A program shall not admit a patient for more than two detoxification treatment episodes in one year." This is implying that we only need to check this if they are going into a detox program. However, the WAC implies that we need to check individuals in maintenance therapy to determine if they have been admitted to opioid withdrawal management.	
~~(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.~~	1. Change pregnant women to pregnant persons for those who do not identify as women but still have a uterus and are able to bear children.	
~~(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.~~	1. WAC 246-341-1000 (6)(a) - Do away with this requirement because there is no evidence that rule should be different than for adults and there's no evidence that short-term w/d management is effective. It increases the risk of overdose.	

(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 as defined in 42 C.F.R. Part 8; (b) Treatment is provided to an individual in compliance with 42 C.F.R. Part 8; and ~~(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, that does not occur on campus, is reported to the department within forty-eight hours upon learning of the death.	1. (7)(d) What does "department" mean? 2. Individual record system 3. 48 hours may not be enough time to report. 48 business hours or 48 hours from when we find out?	
WAC 246-341-1005 Agency Certification Requirements	DOH - Move section to 246-341-0300 with other BHA licensing requirements.	
An agency applying to provide opioid treatment program services must: (1) Submit to the department 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.	Survey comment - Clarify that documentation is also required when moving an existing agency.	
(2) Ensure that 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 (iii) Develop an ongoing community relations plan to address new concerns expressed by ~~stakeholders~~the community.	1. DOH - Clarify that this requirement applies when opening a new or moving an existing program. 2. Survey comment - -2a is highly stigmatizing and I doubt that chiropractors are bound by law to address concerns of community stakeholders and spend the time and money to develop an ongoing community relations plan to address new concerns expressed by stakeholders before setting up shop. 3. Survey comment - Requirements shouldn't differ from those for any outpatient health clinic. Continue to stigmatize and create barriers for people to access treatment. Double standard.	
(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) 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	Survey comment - Define "capability"	

(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 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.		
SMALL BUSINESS IMPACT FEEDBACK		