

Opioid Treatment Program (OTP) Rulemaking: Workshop #2 Notes
WAC 246-341-1000 – OTP General
WAC 246-341-1005 – OTP – Agency Certification Requirements
WAC 246-341-1010 – Agency Staff Requirements

Proposed WAC Revisions	Comments to Consider	Notes
<p>WAC 246-341-0200 – Definitions</p> <p>“Opioid treatment program” means the same as defined in RCW 71.24.590.</p> <p>A program that engages in the treatment of opioid use disorder with medications approved by the United States food and drug administration for the treatment of opioid use disorder and reversal of opioid overdose and provides a comprehensive range of medical and rehabilitative services.</p>	<p>Define OTP</p> <p>Question from workshop: What does “comprehensive” mean?</p>	<ul style="list-style-type: none"> ○ It all depends on how it's interpreted during accreditation – in relation to the definition. ○ Would it be better to change the definition to not include or change "medications approved" as that may limit treatment to only being "FDA approved" and exclude medications for symptom treatment or off-label treatment? ● Department: The definition is in the statute, so it cannot be changed outside of legislation. However, the department will be working on exploring options to clarify the use of medications in a later section of WAC (-1025).
<p>WAC 246-341-1000 – continued from last meeting:</p> <p>(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 overdoses the following requirements are met:</p> <p>3) An agency must:</p> <p>(a) Use evidence based therapy in addition to medication in the treatment program Develop, maintain, and implement policies and procedures for:</p> <p>(ii) Urinalysis and drug testing, to include:</p> <p>(E) Observed samples, when clinically appropriate; and</p>	<p>1. Revisit observed UAs.</p> <p>a. 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.</p> <p>b. Workshop #1 comments – remove/no evidence that observed UA is beneficial.</p>	<ul style="list-style-type: none"> ○ Observed UAs are intrusive and lack respect for patient dignity. They should only be used when there is a clinical indication, e.g., there is suspicion that an individual patient may be falsifying their specimen. ● Department: The rule language states, “when clinically appropriate”, with the intent of being broad enough for clinics to make a decision on when it is needed. Does that help? <ul style="list-style-type: none"> ○ It does but it's an unnecessary detail. ● HCA: It is important that these UA are only used when clinically appropriate – is questioner willing to come off mute to provide examples? <ul style="list-style-type: none"> ○ This is not about observed samples, the concern is about falsifying samples. Perhaps language can state that programs will take steps to minimize falsification – an observed test is only one option, an oral test is another option. When you go into detail you risk only one solution. ○ in favor of "when clinically indicated" ○ I like the definition for UAs. It gives autonomy when communicating with the courts. I would rather tell the courts that I do not need to observe UAs unless clinically appropriate. Instead of it being mandatory. ● Department: The department will take all these comments into consideration.
<p>(b) 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.</p>	<p>1. HCA - Require the use of the state's central registry for emergency situations and to verify dual enrollment.</p> <p>a. Include required data and tasks within the registry</p> <p>b. Include definition of “central registry”</p>	<ul style="list-style-type: none"> ○ So all clients that are enrolled in a BH program would need to be entered into a system? And all of these clients would be viewable to other BH agencies? ● Department: No, they would not be viewable to other agencies. <ul style="list-style-type: none"> ○ why picture? ● Department: This is part of the HCA requirements for identification purposes.

<p>Draft for DOH rule: For the purposes of this section, “central registry” means the software system used to determine whether the patient is enrolled in any other OTP and to provide a continuum of care in times of disaster or emergency.</p>		<ul style="list-style-type: none"> ○ are stored photos required for those prescribed controlled drugs at pharmacies? photo id at time of receipt is different than photo stored in a database associated with diagnosis.
<p>(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.</p>	<p>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.</p>	<p>No public comments or questions.</p>
<p>(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.</p>	<p>1. Survey comment - 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.</p>	<p>No public comments or questions.</p>
<p>(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.</p>	<p>1. Survey comment - 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.</p>	<p>No public comments or questions.</p>
<p>(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,</p>	<p>1. Survey comment - (7)(d) What does “department” mean? 2. DOH - Individual record system</p>	<ul style="list-style-type: none"> • Department Question: Do we want to collect that amount of information: <ul style="list-style-type: none"> a. Date of birth b. Gender c. Zip code of residence

<p>program sponsor as defined in 42 C.F.R. Part 8, or medical director <u>as defined in 42 C.F.R. Part 8</u>;</p> <p>(b) Treatment is provided to an individual in compliance with 42 C.F.R. Part 8; <u>and</u></p> <p>(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</p> <p>(d) The death of an individual enrolled in an opioid treatment program, <u>that does not occur on campus</u>, is reported to the department within forty-eight hours <u>upon learning of the death</u>.</p>	<p>3. Survey comment - 48 hours may not be enough time to report. 48 business hours or 48 hours from when we find out?</p>	<p>d. Date of last dispensed opioid dose</p> <p>e. Date of admission</p> <p>f. Number of take-homes at last visit</p> <p>g. Treatment objective</p> <p>h. Date of most recent drug test and results</p> <p>i. List of known OTC and Rx meds at the time of last visit</p> <p>j. Date of most recent PMP</p> <p>k. Results of autopsy and toxicology report (when available)</p> <ul style="list-style-type: none"> • Department: The information would be used if we needed to investigate. And we have had comments that folks would like to collect this information. <ul style="list-style-type: none"> ○ Only if you have a purpose for the data. Collecting it just to do so is a burden. If you need the info for investigation, you will get that from the patient record. • Department: Noted and brought up due to public comments. <ul style="list-style-type: none"> ○ are non-OTP patients receiving opioids or other dangerous drugs subject to similar investigations? • Department: There is a reporting responsibility – the answer is yes for those facilities for reporting that the death occurred and can provide as much info as they want – the more information we have upfront the less we have to use resources to investigate. And that is helpful for collecting information. • Department: If a patient is in treatment, yes. Correct, the more info the less likely there will be an investigation. • Department: We don't want them to delay, and they wouldn't be penalized for not providing all information- can we put the list in as an example of what can be included. If they choose not to include it than we would be required to do more of an investigation • Department: We can look at reworking the language at the next workshop. Please add your comments to the chat. <p>○ I would rather provide further information if needed in the case of an investigation than to provide all of the above information, in addition to the info already provided in the prose section of the current version, for every death, which I don't think would be warranted if the state doesn't often need the information from the OTPs.</p>
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WAC 246-341-1005 – OTP – Agency Certification Requirements

<p>WAC 246-341-1005 Agency Certification Requirements</p>	<p>DOH - Move section to 246-341-0300 with other BHA licensing requirements.</p>	<p>No public comments or questions.</p>
<p>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</p>	<p>DOH - Clarify that documentation is also required when moving an existing agency.</p>	<p>No public comments or questions.</p>

<p>newwhen proposing to open a new, or move an existing opioid treatment program that meets county, tribal or city land use ordinances.</p>		
<p>(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 <u>inform and educate the community about</u> 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:</p> <p>(a) Documentation of the strategies used to:</p> <p>(i) Obtain <u>stakeholder community</u> input regarding the proposed location;</p> <p>(ii) Address any concerns identified by stakeholders <u>community members near the proposed location of the opioid treatment program</u>; and</p> <p>(iii) Develop an ongoing community relations plan to address new concerns expressed by stakeholder <u>the community</u>.</p>	<ol style="list-style-type: none"> DOH - Clarify that this requirement applies when opening a new or moving an existing program. 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. 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. 	<ul style="list-style-type: none"> ○ My comment relates to stigma, discrimination, and fairness. are OTP and BH agency patients targeted for reasons related to diagnosis more than general public health concerns? ● Department: The department appreciates this sentiment. This is a very politicized topic and will be brought up with leadership. We hope to take steps that remove some of the problematic language so that people can get the treatment that they need.
<p>(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.</p> <p>(3) Have concurrent approval to provide an opioid treatment program by:</p> <p>(a) The Washington state department of health pharmacy quality assurance commission;</p> <p>(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</p> <p>(c) The United States Drug Enforcement Administration (DEA).</p> <p>(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.</p> <p>(5) The department may deny an application for certification when the applicant has not demonstrated in the past, the <u>capability</u> to provide the appropriate services to assist individuals using the program to meet goals established by the legislature.</p>	<p>Survey comment - Define "capability"</p>	<ul style="list-style-type: none"> ● Department: Thoughts on defining "capability" – This language comes directly from the statute. We can either keep it or remove it because it will already apply. We will need to loop in the AAG and circle back. ● Department: I vote remove it. I already look for it in doing a survey for the AB side.
<p>WAC 246-341-1010 – Agency Staff Requirements</p>		
<p>An agency providing substance use disorder opioid treatment program services must:</p>	<ol style="list-style-type: none"> DOH – Refer to CFR Survey comment – this is fine for medical staff. What about the clinical and leadership staff? 	<ul style="list-style-type: none"> ● Department No. 2 and 3 Survey Questions: The department doesn't set ratios. However, some states have set staff to patient ratios. Does the group have additional thoughts on patient to staff ratios? Due to the challenges in workforce

<p>(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 Washington pharmacy quality assurance commission of any theft or significant loss of a controlled substance that resulted in filing a DEA Form 106.</p>	<p>a. Expand on staffing requirements.</p> <p>3. Survey comment - Strongly encourage inclusion of maximum staff to patient ratio regarding caseloads. Many states have max of 1:40 or 1:50. Without this criteria, programs have no limits which jeopardizes patient care, retention and course of treatment. Caseloads in WA OTPs currently exceed 100 much of the time. Counselor burnout is high as is the rate of turnover for these jobs. They need our support!</p> <p>a. Survey comment - Please prioritize including staff to patient ratio regarding caseloads. Thank you for giving us a voice!</p> <p>b. Survey comment - Establishing a counselor to patient ratio standard in all OTP. Different ratios for SUDP and for SUDPT.</p> <p>4. Higher pay must be considered at some point in order to maintain optimal staff. Rules regarding salary and compensation or tuition reimbursement for SUDP's and their ongoing yearly license fees.</p> <p>5. Should the agency administrator have experience in behavioral health?</p> <p>6. Do we need to have security personnel?</p>	<p>and community needs it is difficult to come up with specific ratios. There was one ratio related to supervisors – where you had to limit your caseload, but that language was removed from the WAC.</p> <ul style="list-style-type: none"> ○ What purpose for OTP specific vs BHA general staff requirements? ● Department: Covered in other sections of WAC. Unless you feel strongly about changing language, we can keep the language. ● Department No. 4 Survey Question: This is out of scope for this rulemaking workshop. ● Department No. 5 Survey Question: Should the agency administrator have experience in behavioral health? This is covered in another WAC. ● Department No. 6 Survey Question: This is addressed at the federal level, but do you want additional language?
<p>(2) Ensure there is an appointed medical director, as defined in 42 C.F.R. Part 8, who:</p> <p>(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;</p> <p>(b) Is responsible for all medical services performed;</p> <p>(c) Ensures all medical services provided are in compliance with applicable federal, state, and local rules and laws.</p> <p>(3) Ensure at least one staff member has documented training in:</p> <p>(a) Family planning/Reproductive health;</p> <p>(b) Prenatal health care; and</p> <p>(c) Parenting skills.</p> <p>(4) Ensure that at least one staff member is on duty at all times who has documented training in:</p> <p>(a) Cardiopulmonary resuscitation (CPR); and</p> <p>(b) Management of opioid overdose.</p>	<p>1. DOH – remove (b) and (c) – duplicative</p> <p>2. Expand Medical Director opportunity to ARNPs to meet current needs.</p> <p>3. Survey comment – (3) – What is documented training? Who would be trained?</p> <p>4. DOH – discuss (3).</p>	<ul style="list-style-type: none"> ● Department No. 2 Survey Comment: ARNPs are not considered a physician under RCW 18.57 or 18.71. Allowing this would requires a change at the federal level. The CFR requires MD to be a licensed physician. SAMHSA requires an exemption for an ARNP to function as a MD. For example, SAMHSA approved of such a request for a limited time on the condition that the ARNP had a physician to consult with during this time period. ● Department No. 3: Transcript or document that would be tracked in the file. It would be up to the agency to track and determine which staff are trained. ● Department No. 4 RE: Subsection (3): This is not in CFR. The guidelines mention offering these services or referring but do not specifically call out documented training for staff in these areas. <ul style="list-style-type: none"> ○ Vote to remove it. Surveyors already look for it in doing a survey for the accreditation side. <p>Next workshop: Wednesday, October 18.</p>

