Opioid Treatment Program (OTP) Rulemaking: Workshop #3 Notes

WAC 246-341-1015 – OTP General
WAC 246-341-1005 – OTP – Agency Certification Requirements
WAC 246-341-1010 – Agency Staff Requirements

Proposed WAC Revisions	Comments to Consider	Notes
WAC 246-341-1015 – Individual Service Record Content and Documentation Requirements		
An agency providing opioid treatment program services must maintain an individual's individual service record in accordance with 42 CFR Part 8.12 and the opioid treatment program's current accreditation body standards. ~~The individual service record must contain:~~ ~~(1) Documentation that the agency made a good faith effort to review if the individual is enrolled in any other opioid treatment program and take appropriate action;~~ ~~(2) Documentation that the individual received a copy of the rules and responsibilities for treatment participants, including the potential use of interventions or sanction;~~ ~~(3) Documentation that the individual service plan was reviewed quarterly and semi-annually after two years of continuous treatment;~~ ~~(4) Documentation when an individual refuses to provide a drug testing specimen sample. The refusal is considered a positive drug screen specimen;~~ ~~(5) Documentation in progress notes of timely interventions used to therapeutically address the disclosure of illicit drug use, a positive drug test, or possible diversion of opioid medication, as evidenced by the absence of opioids or related metabolites in drug toxicology test results;~~ ~~(6) Documentation of all medical services including:~~ ~~(a) Results of physical examination;~~ ~~(b) Medical and family history;~~ ~~(c) Nursing notes;~~ ~~(d) Laboratory reports including results of regular toxicology screens, a problem list, and list of medications updated as clinically indicated; and~~ ~~(e) Progress notes including documentation of all medications and dosages, if available.~~	1. DOH – adding in reference to CFR. (1-5) is duplicative 2. Survey comment - Expand documentation requirements. 3. Survey comment - Timeframes for documentation? So much redundancy and repetitiveness that there should be a way to streamline and improve the efficiency of the work to allow clinicians to not treat the paper, but the individual instead. 4. Survey comment – (3) Recommend that treatment plans be updated quarterly for 1st year, then semi-annually thereafter. Updates also occur at critical junctures. 5. Survey comment - Remove 2nd clause ("The refusal is considered a positive drug screen specimen"), feels punitive and like a legacy issue. Refusal should be assessed by clinicians. 6. Survey comment - Define timely. It's not absence of opioids, it absence of dispensed medication. Remove "as evidenced by the absence of opioids or related metabolites in drug toxicology test results". 7. Survey comment - "(e) Progress notes including documentation of all medications and dosages, if available." It can be quite onerous for a clinic to collect the individual dosages of a list of medications prescribed at an outside clinic, especially as those doses are changed by other providers. As a physician, I would find more clinical utility in having our team note significant changes to medications, rather than embarking on the tedious task of	• **Department Question:** Are there any questions prior to new topics questions? ○ No public response. **Department No. 2 Survey Comment:** • **Department Response:** In addition to what the CFR already requires, would anyone like to speak to this comment and let us know how they would like to see this expanded? ○ No public response. **Department No. 3 Survey Comment:** • **Department Response:** Timeframes for documentation are included in CFR, which we reference. The CFR and guidelines provide timelines. For example, CFR requires that within 14 days of admission, programs must complete the medical exam to include the results of serology and other tests; the bio-psychosocial narrative must be prepared within 30 days of admission. Referencing the CFR addresses the comment but please let us know if there is a need to put more information in WAC regarding documentation timeframes? ○ No public response. **Department No. 4 Survey Comment:** • **Department Response:** Refer to CFR. It is addressed in CFR under initial and periodic assessment services. Please let us know if you prefer something different. ○ No public response. **Department No. 5 Survey Comment:** • **Department Response:** This has been struck. It is not in CFR or guidelines and therefore not necessary. The department is proposing to remove. **Department No. 6 Survey Comment:** • **Department Response:** This came up in 2020 rule making and providers decided on timely. The guidelines use "rapidly". The "as evidenced" language is from guidelines. The department proposes to remove it.

	keeping mostly irrelevant outside medication dosages up to date.	**<u>Department No. 7 Survey Comment:</u>** • **Department Response:** These are outlined in guidelines. The department proposes to remove and refer to CFR. Any issues? ○ No public response.
WAC 246-341-1020 – Medical Director Responsibility		
An agency providing substance use disorder opioid treatment program services must ensure the program physician, or the medical practitioner under supervision of the medical director, performs and meets the ~~following~~ <u>requirements in 42 CFR Part 8; and must perform and meet the following</u>: ~~(1) The program physician or medical practitioner under supervision of the medical director:~~ ~~(a) Is responsible to verify an individual is currently addicted to an opioid drug and that the individual became addicted at least 12 months before admission to treatment; or~~ ~~(b) May waive the 12-month requirement in (a) of this subsection upon receiving documentation that the individual:~~ ~~(i) Was released from a penal institution, if the release was within the previous six months;~~ ~~(ii) Is pregnant; or~~ ~~(iii) Was previously treated within the previous 24 months.~~ ~~(2) A documented physical evaluation must be completed on the individual before admission and before starting medications approved to treat opioid use disorder that includes the determination of opioid use disorder consistent with the current and applicable Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria;~~	1. DOH – refer to CFR for Medical Director requirements. 2. Survey comment - The twelve months of addiction is irrelevant in the current Fentanyl crises. Addiction is much quicker and the law should allow for physician judgment to determine addiction. Federal rules are proposing removal of 12 months. Remove 12-month requirement and all exceptions as well. 3. DOH – subsection 2 is duplicative.	**<u>Department No. 2 Survey Comment:</u>** • **Department Response:** The department proposes to be removing and referring to the CFR.
3) A documented review of the department prescription drug monitoring program data on the individual: (a) At admission; (b) Annually after the date of admission; and (c) Subsequent to any incidents of concern. ~~(4) All relevant facts concerning the use of the opioid drug must be clearly and adequately explained to each individual;~~ (5) Current written and verbal information must be provided to pregnant individuals, before the initial prescribed dosage regarding: (a) The concerns of possible substance use disorder, health risks, and benefits the opioid treatment medication may have on the individual and the developing fetus; (b) The risk of not initiating opioid treatment medication on the individual and the developing fetus;	4. DOH – subsection (4) is duplicative.	No public comments or questions.

(c) The potential need for the newborn baby to be treated in a hospital setting or in a specialized support environment designed to address and manage neonatal opioid or other drug withdrawal syndromes; and (d) Referral options to address and manage neonatal opioid or other drug withdrawal syndromes.		
~~(6) Each individual voluntarily choosing to receive maintenance treatment must sign an informed consent to treatment;~~ ~~(7) Within 14 days of admission, a medical examination must be completed that includes:~~ ~~(a) Documentation of the results of serology and other tests, as determined by the medical practitioner; and~~ ~~(b) A documented assessment for the appropriateness of Sunday and holiday take-home medications as required by 42 C.F.R. Part 8.12(i).~~ ~~(8) When exceptional circumstances exist for an individual to be enrolled with more than one opioid treatment program agency, justification granting permission must be documented in the individual's individual service record at each agency;~~	5. DOH (6-8) – duplicative a. Change to 30 days to make consistent with other requirements. b. There are no tests that are indicated in every patient with OUD. Putting time limit on it is unreasonable. Any indicated serology should be done at a time that's appropriate. c. Removing the requirement for labs and extending the assessment to be completed within 30 days compared to 14 days would greatly improve compliance with regulations and patient care. Providers can use their discretion to order labs, complete annual reviews on patients when it is medically necessary, patient who cannot/refuse to complete labs when a provider orders it can have the justification documented in their chart.	No public comments or questions.
(9) Each individual admitted to withdrawal management services must have an approved withdrawal management schedule that is medically appropriate; (10) Each individual administratively discharged from services must have an approved withdrawal management schedule that is medically appropriate; ~~(11) An assessment for other forms of treatment must be completed for each individual who has two or more unsuccessful withdrawal management episodes within 12 consecutive months; and~~ ~~(12) An annual medical examination must be completed on each individual, either in person or via telehealth technologies, that includes the individual's overall physical condition and response to medication. The medical practitioner may use their professional and clinical judgment when determining the appropriateness of telehealth technologies for the annual medical exam and must document, in the patient's record, their decision to use telehealth technologies. The initial medical exam must be completed in person as required by 42 C.F.R. Part 8.12(f)(2).~~	6. DOH (11) - duplicative 7. Survey comment – (12) Remove the requirement for annual review. 8. Survey comment – (12) "Overall physical condition" should be changed to "overall health". 9. Survey comment - Would appreciate if there was criteria outlining a patient's right to meet or have an appointment with MD.	**<u>Department No. 7 and 8 Survey Comment:</u>** • **Department Response:** This is not in the current CFR, however, it will be in the future CFR. This language is in federal regulations and would need to be addressed at a federal level. **<u>Department No. 9 Survey Comment:</u>** • **Department Response:** This is covered in future CFR under initial and periodic physical and behavioral health assessment services, which states, "The periodic physical examination should occur not less than one time each year and be conducted by an OTP practitioner." ○ **Public Comment:** The federal regulations say "any serology." They do not specify that any particular tests are indicated or required. So it may be appropriate to perform no serology for a particular patient. It was just a response to the comment, "it's a federal regulation." • **Department Response:** This is addressed in the CFR. If you have suggestions for doing things differently, let the department know.
WAC 246-341-1025 – Medication Management		

An agency providing opioid treatment program services must ~~ensure~~ meet the medication ~~management~~ administration, dispensing, and use requirements in ~~this section are met~~ 42 CFR Part 8.12, and the following requirements:~~.~~ ~~(1) An agency must use only those opioid treatment medications that are approved by the United States Food and Drug Administration under section 505 of the United States Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid use disorder.~~ ~~(2) An agency providing opioid treatment program services must ensure that initial dosing requirements are met as follows:~~ ~~(a) Methadone must be administered or dispensed only in oral form and is formulated in such a way as to reduce its potential for parenteral abuse;~~ ~~(b) The initial dose of methadone must not exceed thirty milligrams and the total dose for the first day must not exceed forty milligrams, unless the program physician documents in the individual's record that forty milligrams did not suppress opioid abstinence symptoms; and~~ ~~(c) The establishment of the initial dose must consider:~~ ~~(i) Signs and symptoms of withdrawal;~~ ~~(ii) Individual comfort; and~~ ~~(iii) Side effects from over medication.~~	1. DOH – (1) duplicative a. Survey comment - The law as written expressly states, in WAC …1025, that we can "only" "use" certain medications, which prevents OTPs from gaining clarity or confidence in whether they're able to provide these medications to patients in the dispensary along with "approved" OAT/MOUD. As fentanyl deaths rise and patients have more difficulty every year getting through the first two weeks of treatment, it's time to relieve OTPs of the restrictions few other medical care settings seem to be burdened with. 2. DOH – (2) Duplicative; (2)(c) prescriber decision. a. Eliminate (2) because product labeling (as indicated in (3)) indicates how the medication should be used. b. Concerning (2)(b) and (c). These parameters for first day dosing do allow for a first day dosage greater than 40 mg in those instances wherein documentation by the program physician provides evidence that forty milligrams did not suppress opioid abstinence symptoms and did not produce side effects of over medication. Individuals who are habituated to moderate to large daily amounts of Fentanyl are highly likely to require more than 40 milligrams of methadone to suppress opioid abstinence symptoms. This is no longer an unusual occurrence. Consideration should be given to expanding these dosage parameters specifically in consideration of Fentanyl.	**Department No. 1 Survey Comments:** • **Department Response:** This language is from CFR, however, the WAC leaves out other options from CFR for deviating from those medications, which states "significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record." **Department No. 2 Survey Comment:** • **Department Response:** There was a survey question regarding Subsection (2). These are duplicative of what is in CFR. We propose removing all of subsection (2). Any concerns?
(3) ~~An agency providing an opioid treatment program services must~~ ensure that: ~~(a) Each opioid treatment medication used by the program is administered and dispensed in accordance with its approved product labeling;~~ (b) Each individual admitted to an opioid treatment program ~~shall~~ receives information about, and ~~overdose prevention education and information on~~	3. DOH – (3) Reference RCW 71.24.594; other information is duplicative.	No public comments or questions.

~~how to~~ access to opioid overdose reversal medication in accordance with RCW 71.24.594; ~~(c) All dosing and administration decisions are made by a:~~ ~~(i) Program physician; or~~ ~~(ii) Medical practitioner under supervision of a program physician familiar with the most up-to-date product labeling.~~ ~~(d) Any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the individual's record.~~		
(4) ~~An agency providing opioid treatment program services must e~~Ensure that all take-home medications are~~:~~ ~~(a) Consistent~~authorized and dispensed in accordance with 42 C.F.R. Part 8.12; and ~~(i)(1) through (5) and are authorized only to stable individuals who:~~ ~~(i) Have received opioid treatment medication for a minimum of ninety days; and~~ ~~(ii) Have not had any positive drug screens in the last sixty days.~~ ~~(b) Assessed and authorized, as appropriate, for a Sunday or legal holiday as identified in RCW 1.16.050;~~ ~~(c) Assessed and authorized, as appropriate, when travel to the facility presents a safety risk for an individual or staff member due to inclement weather; and~~ ~~(d) Not allowed in short-term withdrawal management or interim maintenance treatment.~~ ~~(5) Registered nurses and licensed practical nurses may dispense up to a thirty-one day supply of medications approved by the United States Food and Drug Administration for the treatment of opioid use disorder under an order or prescription.~~ (6) All exceptions to take-home requirements must be submitted and approved by the state opioid treatment authority and Substance Abuse and Mental Health Services Administration (SAMHSA). (7) An agency providing opioid treatment program services may accept, possess, and administer patient-owned medications.	4. Survey comment - WAC 246-341-1025 (4) - Section needs to be completely rewritten to be in agreement with new federal rules. Rules should be exactly the same as federal rules with no additional interpretations (e.g. 4(a)(ii)). 5. Survey comments re: take-homes: a. There is not a lot of clarity within this WAC regarding the Schedule of Maximal Take-Home Medications per 42 CFR 8.12. Are all take-home medications considered 'special' under this WAC? b. Waived during COVID, and as I understand it we are not going back to pre-COVID rules regarding take home medication phases and when a patient can "earn" them. c. Take home medications should be directed by clinical judgement and not just time on the program and clean urine. This can be punitive and restricts how individuals are treated. d. This section talks about 90 days of treatment for take homes and 60 days of clean DSA. However, new SAMHSA guidelines are different. Is this outside of that exception? 6. Survey comment – (7) I would appreciate if this were more clear on the federal level. SAMHSA's FGOTP document from 2015 states this may happen, but state PQACs concurrently say that "white-bagging" is not allowed (in which an OTP accepts a labeled medication for a patient), and the DEA has	**Department No. 4 Survey Comment:** • **Department Response:** This is being updated to reference CFR because it is duplicative. Requests need to go to SAMHSA if you want to deviate from CFR. **Department No. 5 Survey Comment:** • **Department Response:** Survey comment regarding take-home requirements. CFR outlines take-home requirements. The department proposes referencing CFR. If a program needs an exception to the requirements in CFR then they would need to request that from SAMHSA. The department proposes removing. **Department No. 6 Survey Comment:** • **Department Response:** This language is in RCW. The department is checking with the pharmacy commission. We can invite the pharmacy commission to speak to this issue at future at future meetings if needed.

	said that an OTP cannot accept and dispense a controlled medication that the patient got from the pharmacy, which would often be very helpful for an OTP to do from a misuse and diversion standpoint.	