WSR 24-22-054
PROPOSED RULES
DEPARTMENT OF HEALTH
[Filed October 28, 2024, 1:39 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 23-17-078.

Title of Rule and Other Identifying Information: Behavioral health agency (BHA) licensing and certification requirements as they relate to opioid treatment programs (OTP). The department of health (department) is proposing updates to WAC 246-341-0200, 246-341-0300, 246-341-0342, 246-341-1000, and 246-341-1100; and repealing WAC 246-341-1005 through 246-341-1025. The proposed amendments and repeals are to address general cleanup, streamline the licensing and certification requirements, remove duplicate requirements, align OTP regulations with C.F.R., and implement 2E2SSB 5536 (chapter 1, Laws of 2023, 1st sp. sess.).

Hearing Location(s): On December 18, 2024, at 1:30 p.m., at the Department of Health, Town Center 2, Room 166/167, 111 Israel Road S.E., Tumwater, WA 98501; or virtual. Register in advance for this webinar https://us02web.zoom.us/webinar/register/WN_OmrQeTulTxaqbNiaqd9jtA. After registering, you will receive a confirmation email containing information about joining the webinar.

Date of Intended Adoption: December 27, 2024.

Submit Written Comments to: Michelle Weatherly, P.O. Box 47843, Olympia, WA 98504-7843, email https://fortress.wa.gov/doh/policyreview/, beginning the date and time of this filing, by December 18, 2024, 11:59 p.m.

Assistance for Persons with Disabilities: Contact Michelle Weatherly, phone 360-236-2992, TTY 711, email michelle.weatherly@doh.wa.gov, by December 6, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The department is proposing updates to chapter 246-341 WAC, Behavioral health agency licensing and certification requirements, as related to OTP. The purpose of the proposed rules is to provide greater access to care by streamlining the approval and certification process to operate an opioid treatment program, aligning the state OTP regulations with the recently revised C.F.R., and implementing 2E2SSB 5536. The department is also taking this opportunity to correct two internal citations from a previous rules project in WAC 246-341-0300 and 246-341-1100.

Reasons Supporting Proposal: In 2023, there was legislative focus on behavioral health which included OTPs in Washington state. 2E2SSB 5536 passed, which resulted in a change to licensing and certification of OTPs by allowing OTPs to operate a fixed-site medication unit as an extension of their existing licensed OTP. The proposed rules will provide greater access to opioid use disorder treatment by streamlining the certification process to operate an OTP and aligning state regulations with the C.F.R. The proposed amendments represent the department's efforts to improve the regulations and the delivery of OTP services in Washington state. Fixed-site medication units are already allowed under federal regulations. The proposed rules align with federal regulations by reference and do not include additional requirements other than notification to the department.

Statutory Authority for Adoption: RCW 71.24.037 and 2E2SSB 5536 (chapter 1, Laws of 2023, 1st sp. sess.), codified as RCW 71.24.590.

Statute Being Implemented: RCW 71.24.590.

Rule is necessary because of federal law, 42 C.F.R. Part 8, Subpart C (2024).

Name of Proponent: Department of health, governmental.

Name of Agency Personnel Responsible for Drafting, Implementation, and Enforcement: Michelle Weatherly, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-2992.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Michelle Weatherly, P.O. Box 47843, Olympia, WA 98504-7843, phone 360-236-2992, fax 360-236-2321, TTY 711, email michelle.weatherly@doh.wa.gov.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(3) as the rules are adopting or incorporating by reference without material change federal statutes or regulations, Washington state statutes, rules of other Washington state agencies, shoreline master programs other than those programs governing shorelines of statewide significance, or, as referenced by Washington state law, national consensus codes that generally establish industry standards, if the material adopted or incorporated regulates the same subject matter and conduct as the adopting or incorporating rule; rules only correct typographical errors, make address or name changes, or clarify language of a rule without changing its effect; and rules adopt, amend, or repeal a procedure, practice, or requirement relating to agency hearings; or a filing or related process requirement for applying to an agency for a license or permit.

Explanation of exemptions:

WAC Section and Title	Rationale for Exemption
WAC 246-341-0200 Behavioral health —Definitions. (amended)	This section of rule is exempt from analysis under RCW 34.05.310 (4)(d). Definitions clarify the language of the rule without changing its effect.
WAC 246-341-0300 Agency licensure and certification—General information. (amended)	This section of rule is exempt from analysis under RCW 34.05.310 (4)(d) and 34.05.310 (4)(g). The proposed changes clarify language of the rule without changing its effects and establish a process requirement for making application to the department.
WAC 246-341-0342 Agency licensure and certification—Off-site locations.	The proposed rule amendment is exempt under RCW 34.05.310 (4)(d) by providing clarification without changing the effect of the rule, and RCW 34.05.310 (4)(c) by incorporating by reference without changing another Washington state rule.
WAC 246-341-1000 Opioid treatment programs (OTP)—General.	These subsections of rule are exempt from analysis under RCW 34.05.310 (4)(c). The proposed changes incorporate federal statutes without material change. These subsections of rule are exempt from analysis under RCW 34.05.310 (4)(d). The proposed changes clarify the language of the rule without changing its effect.
WAC 246-341-1005 Opioid treatment programs (OTP)—Agency certification requirements. (repealed)	This section of rule is exempt from analysis under RCW 34.05.310 (4)(d). The proposed changes clarify language of the rule without changing its effect.
WAC 246-341-1010 Opioid treatment programs (OTP)—Agency staff requirements. (repealed)	This section of rule is exempt from analysis under RCW 34.05.310 (4)(d). The proposed changes clarify the language of the rule without changing its effect.
WAC 246-341-1015 Opioid treatment programs (OTP)—Individual service record content and documentation requirements. (repealed)	This section of rule is exempt from analysis under RCW 34.05.310 (4)(d). The proposed changes clarify the language of the rule without changing its effect.

WAC Section and Title	Rationale for Exemption
WAC 246-341-1020 Opioid treatment programs (OTP)—Medical director responsibility. (repealed)	This section of rule is exempt from analysis under RCW 34.05.310 (4)(d). The proposed changes clarify language of the rule without changing its effect.
WAC 246-341-1025 Opioid treatment programs (OTP)—Medication management. (repealed)	This section of rule is exempt from analysis under RCW 34.05.310 (4)(d). The proposed changes clarify the language of the rule without changing its effect.
WAC 246-341-1100 Withdrawal management—Certification standards. (amended)	This section of rule is exempt from analysis under RCW 34.05.310 (4)(d), as the proposed change corrects a typographical error without changing its effect.

Scope of exemption for rule proposal:
Is partially exempt:
Explanation of partial exemptions: See explanation above.

The proposed rule does impose more-than-minor costs on businesses.

Small Business Economic Impact Statement

A brief description of the proposed rule including the current situation/rule, followed by the history of the issue and why the proposed rule is needed. A description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule: The department is proposing to revise BHA OTP licensing and certification regulations in chapter 246-341 WAC to address general cleanup, streamline the licensing and certification requirements, remove duplicate requirements, align with federal certification and treatment standards for OTPs in 42 C.F.R. Part 8, Subpart C (2024), and implement changes enacted by the legislature under 2E2SSB 5536 (chapter 1, Laws of 2023, 1st special session).

Over the last two years, the department has received input from interested parties and partners that has allowed for meaningful engagement to examine, discuss, and consider revisions to OTP licensing and certification requirements.

In the 2023 legislative session, 2E2SSB 5536 was passed and included a clarification that mobile units or fixed-site medication units may be established as part of a licensed OTP. Rules are already in place for mobile units. However, additional rule making is needed to develop a process and standards for licensing and approving fixed-site medication units. Fixed-site medication units will allow licensed OTPs to expand access to the treatment of opioid use disorder, especially in rural areas of the state.

By establishing these standards, the department is in effect adding compliance requirements in rule for businesses that want to operate a fixed-site medication unit, including small businesses. However, a portion of the rule making is to align state requirements with federal certification and treatment standards for OTPs which will dictate the certification and treatment standards that all OTPs must adhere to. Throughout the rule-making process, the department has worked to balance the need for patient safety with the flexibility to determine a successful business model that will work in the best interest for both the business and greater access to care.

Identification and summary of which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS):

Table 1. Summary of Businesses Required to

Comply with the Proposed Rule

NAICS Code (4, 5 or 6 Digit)	NAICS Business Description	Number of Businesses in Washington State	Minor Cost Threshold
621420	Outpatient Mental Health and Substance Abuse Centers	393	$4,376.75

Analysis of probable costs of businesses in the industry to comply with the proposed rule and includes the cost of equipment, supplies, labor, professional services, and administrative costs. The analysis considers if compliance with the proposed rule will cause businesses in the industry to lose sales or revenue:

Background: To help better understand the costs of the proposed rule, the department conducted a survey of BHAs that operate an opioid treatment program (OTP).

Survey questions were grouped based on those who are already in compliance with the proposed rules, and those that would need to take action to come into compliance with the proposed rules. Survey respondents were asked through a series of questions whether their agency is already in compliance with each section of the proposed rule. If they answered "yes" they were guided to the next applicable question. If they answered "no" they were directed to answer additional questions about how and what they would need to do to come into compliance, and any potential costs.

Throughout each of the WAC sections in this analysis, the department has provided the number of respondents that the answer was applicable to, as well as the number of respondents that answered the question.

The respondents were provided with the following prompt prior to beginning the survey:

The department is primarily interested in additional costs for you to comply with the rule, therefore anything that you already do or already exists (e.g., standards, training, existing equipment, etc.) will be excluded from this analysis and you do not need to provide a response for (the survey questions will guide you).

Respondents: The department received 28 responses. The following response rate is worth noting:

- Eight responses were from one organization, all providing the same answers.
- Two responses were from one organization, both providing the same answers.
- Two responses were submitted by the same person. The answers provided were the same.

For the purposes of analysis, the department will analyze the 19 responses that are not duplicates. Providing contact information as part of the survey was optional. Ten respondents chose not to include any contact information, so it is unknown if any of those responses are also duplicates. All 10 will be included as part of the 19 analyzed responses.

- Six (6/19) respondents identified as a small business[1].
- Eleven (11/19) respondents indicated their agency employs 51 or more people, and therefore do not meet the definition of a small business.
- Two (2/19) respondents indicated they do not know the number of people employed at their agency.

The department considered the costs for several of the requirements of the proposed amendments, which are described below.

WAC 246-341-1000 Opioid treatment programs (OTP)—General.

Description: This section of rule establishes the certification standards for opioid treatment programs.

Subsections (1), (5)-(12), (14), and (15) are exempt from analysis under RCW 34.05.310 (4)(c) and (d).

The remaining subsections of the rule are analyzed as follows:

Subsection (2): The proposed amendments provide a list of policies and procedures that an OTP must develop, maintain, and implement in compliance with:

- Specific requirements in 42 C.F.R. Part 8, Subpart C (2024);
- The OTP's accreditation body standards; and
- After-hours contact service.

Subsection (3): The proposed amendment requires use of the state's "central registry" which is defined under subsection (15) of this rule.

Cost(s): The proposed amendments require OTPs to update their policies and procedures. The department used the following information to produce cost estimates:

Based on guidance from the results from the survey, the department assumes that medical and health services managers ($64.64/hour)[2] or compliance officers ($38.55/hour)[3] would update the policies and procedures as needed.

The department asked OTPs if they would need to hold additional assumed trainings to update staff on the revised policies and procedures and received the following responses.

- Six (6/9) responded yes, they would need to hold an additional training to update staff on the policies and procedures. One respondent commented "As a company we review and revise our P&Ps annually. Or as needed when new rules or regulations are required."
- Three (3/9) responded no, they would not need to hold an additional training to update staff on the policies and procedures. One respondent commented that "Updates would be reported to employees during regularly scheduled meetings for the appropriate groups."

Therefore, the department estimates that in some cases training costs would be negligible as it may be completed in regularly scheduled meetings and that in some cases additional training would be needed. The department did not ask for a cost estimate of the additional training; therefore, the costs of additional training is unknown. It is also of note that the majority of the proposed rule revisions align with federal regulations that are already in place and OTPs are required by their accreditation organization to have policies and procedures for federal requirements. This leads the department to believe that costs will likely be negligible.

The one-time cost estimates for OTPs to update their policies and procedures is outlined in the table below.

	Duration of Hours to Complete	Estimated Hourly Wage	Estimated Cost Range
Update policies[4]	10 - 40	$64.64	$646.40 - $2,585.60
		$38.55	$385.50 - $1,542

	Duration of Hours to Complete	Estimated Hourly Wage	Estimated Cost Range
Additional training costs	Negligible - Unknown	Unknown	Negligible - Unknown
		One-time cost estimate	$385.50 - $2,585.60 + negligible to unknown training costs

The proposed amendments also require OTP to use the central registry which is defined in subsection (15) below. There is no cost to OTP for use of the central registry outside of person time. Registry costs for new and existing OTPs are paid for by the Washington state health care authority (HCA). To the department's knowledge, all OTPs currently use the registry as it is required by HCA.

Description: Proposed amendments to subsection (4): The existing language only requires OTPs to provide education on substance use disorder, relapse prevention, infectious diseases, sexually transmitted infections, and tuberculosis (TB). The proposed amendments require OTPs to offer to each individual admitted, either on-site or by referral, vaccination for hepatitis A and B, and screening, testing and treatment for infectious diseases including HIV, hepatitis B and C, syphilis, and TB.

Screening, testing and treatment for HIV, hepatitis B and C, and syphilis are included in federal regulations and therefore exempt from analysis under RCW 34.05.328 (5)(b)(iii) by incorporating federal statutes without material change. Therefore, the department analyzed the costs of OTPs offering each individual admitted, either on-site or by referral, vaccination for hepatitis A and B, and screening and testing for TB

Cost(s): Hepatitis A vaccination: Nearly half of the respondents (47 percent, 9/19) responded that they are already in compliance with the proposed rule. Of the four (4/19) respondents that answered they do not currently offer hepatitis A vaccination to everyone admitted, two (2/4) indicated they would comply with the proposed rule by offering the vaccine by referral; one (1/4) indicated they would comply by offering the vaccine both on-site and by referral; and one (1/4) respondent indicated they did not know if they would comply with the rule by offering it on-site or by referral.

Should an OTP decide to offer hepatitis A vaccination[5] on site additional costs include staff time to administer the vaccine and supplies and equipment necessary to administer and store the vaccine. The department used data provided by the respondent who indicated that they would comply with the rule by offering the vaccination on-site as well as research from literature and conversations with experts indicated that:

- The person responsible for administering the vaccine would be either a registered nurse (RN)[6] or medical assistant (MA).[7]
- Respondents were asked how long it would take to administer the vaccine; however, no responses were received.
  - The department estimates the time to give a one patient one vaccine at five minutes.[8]
  - The department estimates negligible time (<1 minute) to review patient immunization history and educate the patient.[9]
- Price per Hepatitis A vaccine is listed per dose between $39.55 to $81.32.[10] However this cost is not included in the total estimate as this cost is likely reimbursable to the OTP.

- Equipment they would need to purchase to offer the vaccine on-site would be "*Medication Refrigerator or Pyxis System to store vaccines.*"
  - The department estimates a possible cost of a medication refrigerator at a one-time cost of $490.00.[11]
  - The department estimates a possible one-time cost of a Pyxis System at $19,000 plus a monthly subscription fee of $110.00.[12]

Summary: Nearly half of the respondents (47 percent, 9/19) responded that they are already in compliance with the proposed rule, therefore there are no additional costs.

The cost for OTPs to provide referral is negligible.

The cost for OTPs to provide one vaccine per one patient (in person time) at $2.16 to $4.45. The department is unable to estimate a total annual cost as vaccine volume is unknown. Additional costs would be realized for equipment or supply purchase if needed, however the entire cost of equipment was not added to the estimate because it would likely be a shared costs with other vaccinations and services, which the department was unable to estimate.

Hepatitis B vaccination: More than half of the respondents (58 percent, 11/19) responded that they are already in compliance with the proposed rule. Of the two (2/19) respondents that answered they do not currently offer hepatitis B vaccination to everyone admitted, both indicated they would comply with the proposed rule by offering the vaccine both on-site and by referral.

Should an OTP decide to offer hepatitis B vaccination on site including staff time to administer the vaccine and supplies and equipment necessary to administer and store the vaccine. The department used data provided by the respondent who indicated that they would comply with the rule by offering the vaccination on-site as well as research from literature and conversations with experts.

- The person responsible for administering the vaccine would be either a registered nurse (RN)[13] or medical assistant (MA).[14]
- Respondents were asked how long it would take to administer the vaccine; however, no responses were received.
  - The department estimates the time to give a one patient one vaccine at five minutes.[15]
  - The department estimates negligible time (<1 minute) to review patient immunization history and educate the patient.[16]
- Price per Hepatitis B vaccine is listed per dose between $32.67 to $147.63.[17] However this cost is not included in the total estimate as this cost is likely reimbursable to the OTP.
- Equipment they would need to purchase to offer the vaccine on-site would be "*Medication Refrigerator or Pyxis System to store vaccines.*"
  - The department estimates a possible cost of a medication refrigerator at a one-time cost of $490.00.[18]
  - The department estimates a possible one-time cost of a Pyxis System at $19,000 plus a monthly subscription fee of $110.00.[19]

Summary: More than half of the respondents (58 percent, 11/19) responded that they are already in compliance with the proposed rule, therefore there are no additional costs.

The cost for OTPs to provide referrals is negligible.

The cost for OTPs to provide one vaccine per one patient (in person time) at $2.16 to $4.45. The department is unable to estimate a total annual cost as vaccine volume is unknown. Additional costs would be realized for equipment or supply purchase if needed; however, the entire cost of equipment was not added to the estimate because it would likely be a shared costs with other vaccinations and services, which the department was unable to estimate.

TB Screening: More than half of the respondents (58 percent, 11/19) responded that they are already in compliance with the proposed rule. Of the two (2/19) respondents that answered they do not currently offer TB screening to everyone admitted, one (1/2) respondent indicated they would comply with the proposed rule by offering the screening on-site, and one (1/2) respondent indicated they would comply with the proposed rule by offering the screening both on-site and by referral.

One (1/2) respondent indicated that they would need to purchase supplies, and one (1/2) indicated they would not need to purchase any supplies. One (1/2) respondent indicated that they would not need to purchase any equipment to offer on-site TB screening, and one (1/2) did not provide a response.

Should an OTP decide to add TB screening on-site there will be additional costs.

- The person responsible for administering the vaccine would be either a registered nurse (RN)[20] or medical assistant (MA).[21]
- Respondents were asked how long it would take to screen a patient; however, no estimates were given, however one respondent highlighted the difference in screening for latent or active TB. Because no estimates were given the department estimates this to be negligible.
- No respondents included information about what equipment or supplies would need to be purchased to conduct TB screening.

It is of note that one respondent said this service is currently "*available through the Health District*."

Summary: More than half of the respondents (58 percent, 11/19) responded that they are already in compliance with the proposed rule, therefore there are no additional costs.

The cost for OTPs to provide referral is negligible.

The cost for OTPs to provide one screening per one patient (in person time) is estimated at negligible. The department is unable to estimate a total annual cost as screening volume is unknown. Additional costs would be realized for equipment or supply purchase if needed.

TB Testing[22]: More than half of the respondents (53 percent, 10/19) responded that they are already in compliance with the proposed rule. Of the one (1/19) respondent that answered they do not currently offer TB testing to everyone admitted, they did not know if they would comply with the rule by offering it on-site or by referral.

Should an OTP decide to add TB testing on site there will be additional costs but the department was unable to estimate additional costs because no survey respondents provided details about additional costs. A potential cost estimate for an overall cost for providing one test to one patient is $149.00.[23] Additional costs to provide services could include person time, syringes, alcohol wipes, etc.

It is of note that one respondent said this service is currently "*available at the Health District.*"

Summary: More than half of the respondents (53 percent, 10/19) responded that they are already in compliance with the proposed rule, therefore no additional costs.

The cost for OTPs to provide referral is negligible.

The cost for OTPs to provide one test per one patient (in person time) is unknown. The department is unable to estimate a total annual cost as testing volume is unknown. Additional costs would be realized for equipment or supply purchase if needed.

The survey asked respondents if there were any other costs to you that the department missed to comply with the proposed rule and to not include anything already included in the cost survey.

Four (4/19) provided the following comments:

- Not that I'm aware of additional costs. Process of P&P updates and training are a part of our responsibilities.
- Are these additional services expected to be offered as part of the bundled rate? Or is there funding for the additional requirements? Staff time to update policy, develop training, quality control around supply ordering, management of refrigerated medication, staff time to report vaccine administration to state database and appropriate support as well as auditing records to ensure compliance. There could also be additional costs to configure our EHR software to accommodate additional services.
- Administrative time, increased time to train, document, and monitor for compliance.
- Unknown.

The department did not produce any estimates based on these additional comments although it acknowledges these as potential additional costs to comply.

It is of note that the department believes many of OTPs are already in compliance with the proposed rule (as confirmed by the survey). Additionally, for those that are not in compliance, they have an option to come into compliance with the proposed rule by referring out for services and across the board, the department estimates referral for services is negligible. Should an OTP elect to provide services on-site, costs will be incurred.

Description: Proposed amendment to subsection (13).

The proposed amendment establishes that the "critical incidents" reported to the department by the BHA must include the number of deaths that occur on the OTP's campus.

Cost(s): The department does not anticipate any additional costs. All licensed BHAs already report critical incidents to the department.

Summary of all Cost(s):

Table 2. Summary of Section 3 Probable Cost(s)

WAC Section and Title	Probable Cost(s)
WAC 246-341-1000 Opioid treatment programs (OTP)—General.	Subsections (2) and (3) Estimate ranges between $385.50 to $2,585.60 to update policies and procedures plus negligible to unknown cost of staff training on the updated policies and procedures.
WAC 246-341-1000 Opioid treatment programs (OTP)—General.	Subsection (4) **Hepatitis A Vaccination:** Nearly half of the OTP survey respondents are already in compliance with the proposed rule, therefore there are no additional costs.

WAC Section and Title	Probable Cost(s)
	The cost for OTPs to provide referrals is negligible. The cost for OTPs to provide one vaccine per one patient at $2.16 to $4.45. The department is unable to estimate a total cost as vaccine volume is unknown. Additional costs would be realized for equipment or supply purchase if needed. **Hepatitis B Vaccination:** More than half of the OTPsurvey respondents are already in compliance with the proposed rule, therefore there are no additional costs. The cost for OTPs to provide referral is negligible. The cost for OTPs to provide one vaccine per one patient at $2.16 to $4.45. The department is unable to estimate a total cost as vaccine volume is unknown. Additional costs would be realized for equipment or supply purchase if needed. **Tuberculosis Screening:** More than half of the OTP survey respondents are already in compliance with the proposed rule, therefore there are no additional costs. The cost for OTPs to provide referral is negligible. The cost for OTPs to provide one screening per one patient is estimated at negligible. The department is unable to estimate a total cost as screening volume is unknown. Additional costs would be realized for supply or equipment or supply purchase if needed. **Tuberculosis Testing:** More than half of the survey respondents are already compliant with the proposed rule, therefore there are no additional costs. The cost for OTPs to provide referrals is negligible. The cost for OTPs to provide one test per one patient (in person time) is unknown. The department is unable to estimate a total annual cost as testing volume is unknown. Additional costs would be realized for equipment or supply purchase if needed. Many OTPs are already in compliance with the proposed rule (as confirmed by the survey). Additionally, for those that are not in compliance, they have an option to come into compliance with the proposed rule by referring out for services, and referral for services is estimated as negligible. Should an OTP elect to provide services on-site costs will be incurred.
WAC 246-341-1000 Opioid treatment programs (OTP)—General.	Subsection (13) The department does not anticipate any additional costs. The BHA already has to include critical incidents in their report to the department.

Analysis on if the proposed rule may impose more than minor costs for businesses in the industry: Because some costs of the proposed rule changes are unknown the department assumes that the costs may exceed the minor cost threshold.

Summary of how the costs were calculated: The minor cost threshold for outpatient mental health and substance abuse centers as of 2022 is $4,376.75, based on 0.3 percent of average annual gross business income as calculated by data collected by the United States Bureau of Labor Statistics (Table 1).

For updating policies and procedures, survey data indicated a one-time cost range to the OTP of $385.50 - $2,585.60 plus negligible to unknown training costs. It is of note that this estimate alone (not including training costs) does fall under the minor cost threshold. The proposed amendment requires OTPs to offer vaccinations for hepatitis A and B and screening and testing for TB either on-site or by referral. Should an OTP elect to provide services on-site, additional costs will be incurred; however, patient volume for such services is unknown and therefore a total cost is unable to be calculated. The department believes many OTPs are already in compliance with the proposed rule (as confirmed by the survey) and for those that are not in compliance, they have an option to come into compliance with the proposed rule by referring out for services. Across the board, the department estimates referral for services is negligible.

However, based on the inability to estimate due to patient volume, the department has selected that costs may exceed the minor cost threshold of $4,376.75.

Determination on if the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule: The department assumes the proposed rules do not have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

Explanation of the determination: The proposed requirements align OTP regulations with 42 C.F.R. Part 8, Subpart C (2024) which the OTPs must already comply with. OTPs are not required to establish a fixed-site medication unit. For those who do, the only additional requirement is notifying the department prior to offering services. There is no fee associated with the required notification.

All OTPs will have to update their policies and procedures and may need to train staff on the updated policies and procedures to comply with the new requirements. Information yielded by the survey indicates a one-time cost range to the OTP of $385.50 - $2,585.60 plus negligible to unknown training costs. The only place in the proposed rule that the department believes could potentially provide a disproportionate impact to small businesses would be updating policies and procedures, but as this estimate falls under the minor cost threshold, the department does not believe this is enough to determinate a disproportionate impact on small business. For training, as the number of staff is proportional to the size of a business the department does not expect training, as a cost component, to have a disproportionate impact on small businesses.

The department believes many OTPs are already in compliance with the proposed rule (as confirmed by the survey) regarding the provision of services (vaccination, screening, testing) and for those that are not in compliance they have an option to come into compliance with the proposed rule by referring out for services and across the board the department estimates referral for services is negligible. For those that decide to offer on-site services, there will be additional costs. However, because of the option to provide referrals to services, the department does not believe there to be a disproportionate impact on small businesses.

Additionally, the department has taken steps to mitigate the burden of costs to small businesses while recognizing the benefit of these services to opioid use disorder patients, particularly in rural areas. Therefore, while the overall cost is unknown, it is the department's assumption that there will not be a disproportionate impact on small businesses when considering cost by category.

1 RCW 19.85.020: Definitions "(3) "Small business" means any business entity, including a sole proprietorship, corporation, partnership, or other legal entity, that is owned and operated independently from all other businesses, and that has fifty of fewer employees."

2 2023 mean wage - $64.64/hour for Medical and Health Services Managers, National Estimate (bls.gov) | Accessed on August 9, 2024

3 2023 mean wage - $38.55/hour for Compliance Officers, National Estimate (bls.gov) | Accessed on August 9, 2024

4 One outlier response, more than 2.4 standard deviations from the mean, was removed (Reference: Aquinis et.al, Best-Practice Recommendations for Defining, Identifying and Handling Outliers; Organizational Research Methods, pg. 270-301, 2013.)

5 CDC Vaccine price list | Accessed August 9, 2024

6 Washington State Mean Hourly Wage of Registered Nurses, $53.38. Washington - May 2023 OEWS State Occupational Employment and Wage Estimates (bls.gov) | Accessed on August 22, 2024

7 Washington State Mean Hourly Wage of Medical Assistants, $25.86. Washington - May 2023 OEWS State Occupational Employment and Wage Estimates (bls.gov) | Accessed on August 22, 2024

8 Shen A, Khavjou O, King G, Bates L, Zhou F, Leidner AJ, Yarnoff B. Provider time and costs to vaccinate adult patients: Impact of time counseling without vaccination. Vaccine. 2019 Feb 4;37(6):792-797. doi: 10.1016/j.vaccine.2018.12.045. Epub 2019 Jan 11. PMID: 30639460; PMCID: PMC6848970. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6848970/

9 Shen A, Khavjou O, King G, Bates L, Zhou F, Leidner AJ, Yarnoff B. Provider time and costs to vaccinate adult patients: Impact of time counseling without vaccination. Vaccine. 2019 Feb 4;37(6):792-797. doi: 10.1016/j.vaccine.2018.12.045. Epub 2019 Jan 11. PMID: 30639460; PMCID: PMC6848970. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6848970/
10 Current CDC Vaccine Price List | VFC Program | CDC. Accessed on October 8, 2024.
11 Previously approved, compact, affordable refrigerators average cost is $490 | Home Depot | Lowes | Information provided by department vaccine coordinator on April 11, 2024
12 Cost data pulled from a cost survey previously conducted by the department in 2024 on WAC 246-341-0110, 246-341-0200, 246-341-0365, 246-341-0515, 246-341-0901, 246-341-0912, 246-341-1140 and new WAC 246-341-0903, a Rule Concerning 23-Hour Crisis Relief Centers in Washington State
13 Washington State Mean Hourly Wage of Registered Nurses, $53.38. Washington - May 2023 OEWS State Occupational Employment and Wage Estimates (bls.gov) | Accessed on August 22, 2024
14 Washington State Mean Hourly Wage of Medical Assistants, $25.86. Washington - May 2023 OEWS State Occupational Employment and Wage Estimates (bls.gov) | Accessed on August 22, 2024
15 Shen A, Khavjou O, King G, Bates L, Zhou F, Leidner AJ, Yarnoff B. Provider time and costs to vaccinate adult patients: Impact of time counseling without vaccination. Vaccine. 2019 Feb 4;37(6):792-797. doi: 10.1016/j.vaccine.2018.12.045. Epub 2019 Jan 11. PMID: 30639460; PMCID: PMC6848970. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6848970/
16 Shen A, Khavjou O, King G, Bates L, Zhou F, Leidner AJ, Yarnoff B. Provider time and costs to vaccinate adult patients: Impact of time counseling without vaccination. Vaccine. 2019 Feb 4;37(6):792-797. doi: 10.1016/j.vaccine.2018.12.045. Epub 2019 Jan 11. PMID: 30639460; PMCID: PMC6848970. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6848970/
17 Current CDC Vaccine Price List | VFC Program | CDC. Accessed on October 8, 2024.
18 Previously approved, compact, affordable refrigerators average cost is $490 | Home Depot | Lowes | Information provided by department vaccine coordinator on April 11, 2024
19 Cost data pulled from a cost survey previously conducted by the department in 2024 on WAC 246-341-0110, 246-341-0200, 246-341-0365, 246-341-0515, 246-341-0901, 246-341-0912, 246-341-1140 and new WAC 246-341-0903, a Rule Concerning 23-Hour Crisis Relief Centers in Washington State
20 Washington State Mean Hourly Wage of Registered Nurses, $53.38. Washington - May 2023 OEWS State Occupational Employment and Wage Estimates (bls.gov) | Accessed on August 22, 2024
21 Washington State Mean Hourly Wage of Medical Assistants, $25.86. Washington - May 2023 OEWS State Occupational Employment and Wage Estimates (bls.gov) | Accessed on August 22, 2024
22 TB Blood Test | Quest® (questhealth.com) | Accessed on September 9, 2024
23 TB Blood Test | Quest® (questhealth.com) | Accessed on September 9, 2024

A copy of the statement may be obtained by contacting Michelle Weatherly, P.O. Box 47843, Olympia, WA 98504-7843, phone 360-236-2992, TTY 711, email michelle.weatherly@doh.wa.gov.

October 28, 2024
Kristin Peterson, JD
Chief of Policy
for Umair A. Shah, MD, MPH
Secretary of Health

OTS-5853.2

AMENDATORY SECTION (Amending WSR 24-17-003, filed 8/8/24, effective 9/8/24)

WAC 246-341-0200 Behavioral health—Definitions. The definitions in this section and RCW 71.05.020, 71.24.025, and 71.34.020 apply throughout this chapter unless the context clearly requires otherwise.

(1) "23-hour crisis relief center" has the same meaning as under RCW 71.24.025.

(2) "Administrator" means the designated person responsible for the day-to-day operation of either the licensed behavioral health agency, or certified treatment service, or both.

(3) "Adult" means an individual 18 years of age or older. For purposes of the medicaid program, adult means an individual 21 years of age or older.

(4) "ASAM criteria" means admission, continued service, transfer, and discharge criteria for the treatment of substance use disorders as published by the American Society of Addiction Medicine (ASAM).

(5) "Assessment" means the process of obtaining all pertinent bio-psychosocial information, as identified by the individual, and family and collateral sources, for determining a diagnosis and to plan individualized services and supports.

(6) "Behavioral health" means the prevention, treatment of, and recovery from any or all of the following disorders: Substance use disorders, mental health disorders, co-occurring disorders, or problem gambling and gambling disorders.

(7) "Behavioral health agency," "licensed behavioral health agency," or "agency" means an entity licensed by the department to provide behavioral health services under chapter 71.24, 71.05, or 71.34 RCW.

(8) "Behavioral health service" means the specific service(s) that may be provided under an approved certification.

(9) "Branch site" means a physically separate licensed site, governed by the same parent organization as the main site, where qualified staff provides certified treatment services.

(10) "Campus" means an area where all of the agency's buildings are located on contiguous properties undivided by:

(a) Public streets, not including alleyways used primarily for delivery services or parking; or

(b) Other land that is not owned and maintained by the owners of the property on which the agency is located.

(11) "Care coordination" or "coordination of care" means a process-oriented activity to facilitate ongoing communication and collaboration to meet multiple needs of an individual. Care coordination includes facilitating communication between the family, natural supports, community resources, and involved providers and agencies, organizing, facilitating and participating in team meetings, and providing for continuity of care by creating linkages to and managing transitions between levels of care.

(12) "Certified" or "certification" means the status given by the department that authorizes the agency to provide specific types of behavioral health services included under the certification category.

(13) "Child," "minor," and "youth" mean:

(a) An individual under the age of 18 years; or

(b) An individual age 18 to 21 years who is eligible to receive and who elects to receive an early and periodic screening, diagnostic, and treatment (EPSDT) medicaid service. An individual age 18 to 21 years who receives EPSDT services is not considered a "child" for any other purpose.

(14) "Clinical supervision" means regular and periodic activities performed by a mental health professional, co-occurring disorder specialist, or substance use disorder professional licensed, certified, or registered under Title 18 RCW. Clinical supervision may include review of assessment, diagnostic formulation, individual service plan development, progress toward completion of care, identification of barriers to care, continuation of services, authorization of care, and the direct observation of the delivery of clinical care. In the context of this chapter, clinical supervision is separate from clinical supervision required for purposes of obtaining supervised hours toward fulfilling requirements related to professional licensure under Title 18 RCW.

(15) <u>"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 the community.</u>

(16) "Complaint" means an alleged violation of licensing or certification requirements under chapters 71.05, 71.12, 71.24, 71.34 RCW, and this chapter, which has been authorized by the department for investigation.

((~~(16)~~)) (17) "Consent" means agreement given by an individual after being provided with a description of the nature, character, anticipated results of proposed treatments and the recognized serious possible risks, complications, and anticipated benefits, including alternatives and nontreatment, that must be provided in a terminology that the individual can reasonably be expected to understand. Consent can be obtained from an individual's parent or legal representative, when applicable.

((~~(17)~~)) (18) "Consultation" means the clinical review and development of recommendations by persons with appropriate knowledge and experience regarding activities or decisions of clinical staff, contracted employees, volunteers, or students.

((~~(18)~~)) (19) "Co-occurring disorder" means the coexistence of both a mental health and a substance use disorder. Co-occurring treatment is a unified treatment approach intended to treat both disorders within the context of a primary treatment relationship or treatment setting.

((~~(19)~~)) (20) "Cultural competence" or "culturally competent" means the ability to recognize and respond to health-related beliefs and cultural values, disease incidence and prevalence, and treatment efficacy. Examples of culturally competent care include striving to overcome cultural, language, and communications barriers, providing an environment in which individuals from diverse cultural backgrounds feel comfortable discussing their cultural health beliefs and practices in the context of negotiating treatment options, encouraging individuals to express their spiritual beliefs and cultural practices, and being familiar with and respectful of various traditional healing systems and beliefs and, where appropriate, integrating these approaches into treatment plans.

((~~(20)~~)) (21) "Deemed" means a status that is given to a licensed behavioral health agency as a result of the agency receiving accreditation by a recognized behavioral health accrediting body which has a current agreement with the department.

((~~(21)~~)) (22) "Disability" means a physical or mental impairment that substantially limits one or more major life activities of the individual and the individual:

(a) Has a record of such an impairment; or

(b) Is regarded as having such impairment.

((~~(22)~~)) (23) "Face-to-face" means either in person or by way of synchronous video conferencing.

((~~(23)~~)) (24) "Individual service record" means either a paper, or electronic file, or both that is maintained by the behavioral health agency and contains pertinent behavioral health, medical, and clinical information for each individual served.

((~~(24)~~)) (25) "Licensed" or "licensure" means the status given to behavioral health agencies by the department under its authority to license and certify mental health and substance use disorder programs under chapters 71.05, 71.12, 71.34, and 71.24 RCW and its authority to certify problem gambling and gambling disorder treatment programs under RCW 43.70.080(5) and 41.05.750.

((~~(25)~~)) (26) "Medical practitioner" means a physician licensed under chapter 18.57 or 18.71 RCW, advance registered nurse practition-

er (ARNP) licensed under chapter 18.79 RCW, or physician assistant licensed under chapter 18.71A RCW.

((~~(26)~~)) (27) "Medication unit" means either:

(a) A fixed-site brick and mortar entity that is established as part of, but geographically separate from, an opioid treatment program from which appropriately licensed opioid treatment program practitioners, contractors working on behalf of the opioid treatment program, or community pharmacists may dispense or administer medication for opioid use disorder, collect samples for drug testing or analysis, or provide other opioid treatment program services; or

(b) A mobile medication unit which is a component of an opioid treatment program that the United States Drug Administration has approved to operate as a mobile narcotic treatment program pursuant to 21 C.F.R. § 1301.13(e)(4).

(28) "Mental health disorder" means any organic, mental, or emotional impairment that has substantial adverse effects on a person's cognitive or volitional functions.

((~~(27)~~)) (29) "Mental health professional" or "MHP" means a person who meets the definition in RCW 71.05.020.

((~~(28)~~)) (30) "Opioid treatment program" means the same as defined in RCW 71.24.590.

(31) "Peer" means a peer counselor as defined in WAC 182-538D-0200 or a certified peer specialist certified under chapter 18.420 RCW.

((~~(29)~~)) (32) "Peer support" means services provided by peer counselors to individuals under the supervision of a mental health professional or individual appropriately credentialed to provide substance use disorder treatment. Peer support provides scheduled activities that promote recovery, self-advocacy, development of natural supports, and maintenance of community living skills.

((~~(30)~~)) (33) "Problem gambling and gambling disorder" means one or more of the following disorders:

(a) "Gambling disorder" means a mental disorder characterized by loss of control over gambling, progression in preoccupation with gambling and in obtaining money to gamble, and continuation of gambling despite adverse consequences;

(b) "Problem gambling" is an earlier stage of gambling disorder that compromises, disrupts, or damages family or personal relationships or vocational pursuits.

((~~(31)~~)) (34) "Progress notes" means permanent written or electronic record of services and supports provided to an individual documenting the individual's participation in, and response to, treatment or support services, progress in recovery, and progress toward intended outcomes.

((~~(32)~~)) (35) "Secretary" means the secretary of the department of health.

((~~(33)~~)) (36) "State minimum standards" means minimum requirements established by rules adopted by the secretary and necessary to implement chapters 71.05, 71.24, and 71.34 RCW for delivery of behavioral health services.

((~~(34)~~)) (37) "Substance use disorder professional" or "SUDP" means a person credentialed by the department as a substance use disorder professional (SUDP) under chapter 18.205 RCW.

((~~(35)~~)) (38) "Substance use disorder professional trainee" or "SUDPT" means a person credentialed by the department as a substance use disorder professional trainee (SUDPT) under chapter 18.205 RCW.

((~~(36)~~)) (39) "Summary suspension" means the immediate suspension of either a facility's license or program-specific certification or both by the department pending administrative proceedings for suspension, revocation, or other actions deemed necessary by the department.

((~~(37)~~)) (40) "Supervision" means the regular monitoring of the administrative, clinical, or clerical work performance of a staff member, trainee, student, volunteer, or employee on contract by a person with the authority to give direction and require change.

((~~(38)~~)) (41) "Suspend" means termination of a behavioral health agency's license or program specific certification to provide behavioral health treatment program service for a specified period or until specific conditions have been met and the department notifies the agency of the program's reinstatement of license or certification.

AMENDATORY SECTION (Amending WSR 22-24-091, filed 12/6/22, effective 5/1/23)

WAC 246-341-0300 Agency licensure and certification—General information. The department licenses behavioral health agencies and certifies them to provide behavioral health services. To obtain and maintain licensure and certification, an applicant shall meet the requirements of this chapter, applicable local and state rules, and applicable state and federal statutes and regulations. Licensure and certification under this chapter does not exempt a behavioral health agency from obtaining any other applicable state or federal licenses or registrations that are necessary to operate and provide services.

(1) The ((~~following~~)) behavioral health agency licensure process described in this section does not apply to a tribe that is licensed or seeking licensure via attestation as described in WAC 246-341-0367.

(2) Initial licensure of a behavioral health agency - Main site. The applicant shall submit a licensing application for a main site to the department that is signed by the agency's designated official. The application must include the following:

(a) The physical address of the agency;

(b) The type of certification(s) the agency is requesting, including the behavioral health services the agency will provide under the type of certification(s);

(c) A statement assuring the location where the services will be provided meets the Americans with Disabilities Act (ADA) standards and that any agency-operated facility where behavioral health services will be provided is:

(i) Suitable for the purposes intended, including having adequate space for private personal consultation with an individual and individual service record storage that adheres to confidentiality requirements;

(ii) Not a personal residence; and

(iii) Approved as meeting all local and state building and safety requirements, as applicable.

(d) Payment of associated fees according to WAC 246-341-0365;

(e) A copy of the applicant's master business license that authorizes the organization to do business in Washington state;

(f) A copy of the disclosure statement and report of findings from a background check of the administrator completed within the previous three months of the application date; and

(g) A copy of the policies and procedures specific to the agency and the certifications and behavioral health services for which the applicant is seeking approval that address all of the applicable requirements of this chapter.

(3) The department may issue a single agency license when the applicant identifies behavioral health treatment services will be provided in multiple buildings and either:

(a) The applicant operates the multiple buildings on the same campus as a single integrated system with governance by a single authority or body over all staff and buildings; or

(b) All behavioral health treatment services will be provided in buildings covered under a single hospital license.

(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:

(a) A written declaration that a current copy of agency policies and procedures that address all of the applicable requirements of this chapter are accessible to the branch site;

(b) A copy of policies and procedures for any behavioral health certifications and services that are unique to the branch site location, if applicable; and

(c) A copy of the disclosure statement and report of findings from a background check of the administrator completed within the previous three months of the application date, if the administrator of the branch site is different than the administrator of the main site location.

(5) In addition to the information required by subsections (2) through (4) of this section, an applicant seeking certification as an opioid treatment program must submit the following information with their application:

(a) Documentation that the applicant has communicated with the county legislative authority and, if applicable, the city legislative authority or tribal legislative authority, in order to secure a location that meets county, tribal, or city land use ordinances when proposing to open a new, or move an existing, opioid treatment program;

(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), Substance Abuse and Mental Health Services 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).

(7) A mobile or fixed-site medication unit may be established as part of an opioid treatment program. Opioid treatment programs may establish a mobile or fixed-site medication unit and must notify the department on forms provided by the department. Department approval must

be given before services can be provided from a mobile or fixed-site medication unit.

(8) License renewal. To renew a main site or branch site license and certification, an agency shall submit to the department a renewal request signed by the agency's designated official. The renewal request must:

(a) Be received by the department before the expiration date of the agency's current license; and

(b) Include full payment of the specific renewal fee according to WAC 246-341-0365.

((~~(6)~~)) (9) Amending a license. A license amendment is required when there is a change in the administrator, when adding or removing a certification or behavioral health service, or when closing a location. To amend a license the agency shall submit to the department a licensing application requesting the amendment that is signed by the agency's designated official. The application shall include the following requirements as applicable to the amendment being requested:

(a) Change of the administrator. The application must include a copy of the disclosure statement and report of findings from a background check of the new administrator completed within the previous three months of the application date and within 30 calendar days of the change;

(b) Adding a certification. The agency must submit an application for certification before providing the behavioral health services listed under the certification. The application must include:

(i) The physical address or addresses of the agency-operated facility or facilities where the new type of certified service(s) will be provided;

(ii) A copy of the agency's policies and procedures relating to the new certification and behavioral health service(s) that will be provided; and

(iii) Payment of fees according to WAC 246-341-0365.

(c) Adding a behavioral health service. The agency may add a behavioral health service that is included under its existing certification by submitting the notification of the added service to the department within 30 calendar days of beginning the service. The notification must include:

(i) The physical address or addresses of the agency-operated facility or facilities where the new behavioral health service(s) will be provided; and

(ii) A copy of the agency's policies and procedures relating to the new behavioral health service(s) that will be provided.

(d) Canceling a behavioral health service or certification.

(i) The agency must provide notice to individuals who receive the service(s) to be canceled. The notice shall be provided at least 30 calendar days before the service(s) are canceled and the agency must assist individuals in accessing services at another location.

(ii) The application must include the physical address or addresses of the agency-operated facility or facilities where the service(s) will no longer be provided.

(e) Closing a location.

(i) The application must include the name of the licensed agency or entity storing and managing the records, including:

(A) The method of contact, such as a telephone number, electronic address, or both; and

(B) The mailing and street address where the records will be stored.

(ii) When a closing agency that has provided substance use disorder services arranges for the continued storage and management of individual service records by a qualified service organization (QSO), the closing agency must enter into a written agreement with the QSO that meets the requirements of 42 C.F.R. Part 2.

(iii) In the event of an agency closure the agency must provide each individual currently being served:

(A) Notice of the agency closure at least 30 calendar days before the date of closure;

(B) Assistance with accessing services at another location; and

(C) Information on how to access records to which the individual is entitled.

((~~(7)~~)) (10) Change of ownership.

(a) Change of ownership means one of the following:

(i) The ownership of a licensed behavioral health agency changes from one distinct legal owner to another distinct legal owner;

(ii) The type of business changes from one type to another, such as, from a sole proprietorship to a corporation; or

(iii) The current ownership takes on a new owner of five percent or more of the organizational assets.

(b) When a licensed behavioral health agency changes ownership, the agency shall submit to the department:

(i) An initial license application from the new owner in accordance with subsection (2) of this section. The new agency must receive a new license under the new ownership before providing any behavioral health service; and

(ii) A statement from the current owner regarding the disposition and management of individual service records in accordance with applicable state and federal statutes and regulations.

((~~(8)~~)) (11) Change in location. A licensed behavioral health agency must receive a new license under the new location's address before providing any behavioral health service at that address. The agency shall submit to the department a licensing application requesting a change in location that is signed by the agency's designated official. The application must include:

(a) The new address;

(b) A statement assuring the location meets the Americans with Disabilities Act (ADA) standards and that any agency-operated facility where behavioral health services will be provided is:

(i) Suitable for the purposes intended, including having adequate space for private personal consultation with an individual and individual service record storage that adheres to confidentiality requirements;

(ii) Not a personal residence; and

(iii) Approved as meeting all local and state building and safety requirements, as applicable.

(c) Payment of initial licensure fees according to WAC 246-341-0365.

((~~(9)~~)) (12) Granting a license. A new or amended license or certification will not be granted to an agency until:

(a) All of the applicable notification and application requirements of this section are met; and

(b) The department has reviewed and approved the policies and procedures for initial licensure or addition of new certifications that demonstrate that the agency will operate in compliance with the licensure and certification standards.

((~~(10)~~)) (13) Effective date. An agency's license and any behavioral health services certification is effective for up to 12 months from the date of issuance, subject to the agency maintaining compliance with the minimum license and certification standards in this chapter.

((~~(11)~~)) (14) After receiving the license. The agency shall post the department-issued license and certification(s) in a conspicuous place on the agency's premises, and, if applicable, on the agency's branch site premises.

AMENDATORY SECTION (Amending WSR 22-24-091, filed 12/6/22, effective 12/10/22)

WAC 246-341-0342 Agency licensure and certification—Off-site locations. (1) A behavioral health agency may provide certified services at an off-site location or from a mobile unit under the existing behavioral health agency license.

(2) For the purposes of this section:

(a) "Off-site" means the provision of services by a licensed behavioral health agency at a location where the assessment or treatment is not the primary purpose of the site, such as in schools, hospitals, long-term care facilities, correctional facilities, an individual's residence, the community, or housing provided by or under an agreement with the agency.

(b) "Established off-site location" means a location that is regularly used and set up to provide services rather than a location used on an individual, case-by-case basis.

(c) "Mobile unit" means a vehicle, lawfully used on public streets, roads, or highways with more than three wheels in contact with the ground, from which behavioral health services are provided at a nonpermanent location(s).

(3) A behavioral health agency that provides off-site services at an established off-site location(s) shall:

(a) Maintain a list of each established off-site location where services are provided on a regularly scheduled ongoing basis and include, for each established off-site location:

(i) The name and address of the location the services are provided;

(ii) The primary purpose of the off-site location;

(iii) The service(s) provided; and

(iv) The date off-site services began at that location;

(b) Maintain an individual's confidentiality at the off-site location; and

(c) Securely transport confidential information and individual records between the licensed agency and the off-site location, if applicable.

(4) In addition to meeting the requirements in subsection (3) of this section, an agency providing services to an individual in their place of residence or services in a public setting that is not an established off-site location where services are provided on a regularly scheduled ongoing basis must:

(a) Implement and maintain a written protocol of how services will be offered in a manner that promotes individual, staff member, and community safety; and

(b) For the purpose of emergency communication and as required by RCW 71.05.710, provide access to a wireless telephone or comparable device to any employee, contractor, student, or volunteer when making home visits to individuals.

(5) Before operating a mobile unit, agencies providing behavioral health services from a mobile unit must notify the department in writing in a manner outlined by the department. The notification must include that a mobile unit is being added under the agency license and indicate what services will be provided from the mobile unit((~~, including whether it is operating as a mobile narcotic treatment program as defined in 21 C.F.R. Part 1300.01.~~

~~(6) An opioid treatment program operating a mobile narcotic treatment program must:~~

~~(a) Submit a copy of the Drug Enforcement Administration (DEA) approval for the mobile narcotic treatment program; and~~

~~(b) Comply with 21 C.F.R. Parts 1300, 1301, and 1304 and any applicable rules of the pharmacy quality assurance commission~~)). Opioid treatment programs must also comply with WAC 246-341-0300(7) before operating a mobile unit.

AMENDATORY SECTION (Amending WSR 21-12-042, filed 5/25/21, effective 7/1/21)

WAC 246-341-1000 Opioid treatment programs (OTP)—((~~General~~)) Certification standards. ((~~(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.~~

~~(2) 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.~~

~~(3) An agency must:~~

~~(a) Use evidence-based therapy in addition to medication in the treatment program;~~

~~(b) Identify individual mental health needs during assessment process and refer them to appropriate treatment if not available on-site;~~

~~(c) Provide education to each individual admitted, totaling no more than fifty percent of treatment services, on:~~

~~(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;~~

~~(iv) Sexually transmitted infections; and~~

~~(v) Tuberculosis (TB);~~

~~(d) Provide information to each individual on:~~

~~(i) Emotional, physical, and sexual abuse;~~

~~(ii) Nicotine use disorder;~~

~~(iii) The impact of substance 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; and~~

~~(iv) Family planning.~~

~~(c) 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.~~

~~(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.~~

~~(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.~~

~~(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.~~

~~(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;~~

~~(b) Treatment is provided to an individual in compliance with 42 C.F.R. Part 8;~~

~~(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 is reported to the department within forty-eight hours.~~)) An

agency providing opioid treatment program services must comply with the following:

(1) All applicable requirements, including those specific to medication units, of 21 C.F.R. §§ 1300, 1301, 1304, and 1306, and 42 C.F.R. Part 8, in effect as of April 2024. Copies of the incorporated version of 21 C.F.R. Part 1301 and 42 C.F.R. Part 8 are available at www.doh.wa.gov/otp or by contacting the department at 360-236-4700 and are available for public inspection at the department's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501.

(2) 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

(ix) 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) The response to medical and psychiatric emergencies; and

(f) 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.

(3) Use the state's central registry, as defined in subsection (15) of this rule, for, but not limited to, emergencies and dual enrollment, including submitting and maintaining all required data and tasks within the central registry;

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

(a) Hepatitis A and Hepatitis B vaccine;

(b) Screening, testing, and treatment for infectious diseases including:

(i) Human immunodeficiency virus (HIV);

(ii) Hepatitis B and C;

(iii) Syphilis; and

(iv) Tuberculosis (TB).

(5) Provide the following information to each individual admitted:

(a) Information and education, as appropriate, on:

(i) Emotional, physical, and sexual abuse;

(ii) The impact of opioid use and opioid use disorder medications during pregnancy as required by RCW 71.24.560 to all pregnant individuals before they are prescribed medications as part of their treatment, and to all individuals who become pregnant while receiving services; and

(iii) Reproductive health.

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

(6) 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.

(7) 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.

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

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

(8) 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).

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

(10) Notify the federal 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.

(11) 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.

(12) Report to the department deaths of individuals enrolled in an opioid treatment program, that do not occur on campus, within 48 hours upon learning of the death.

(13) 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).

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

(15) 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.

AMENDATORY SECTION (Amending WSR 22-24-091, filed 12/6/22, effective 5/1/23)

WAC 246-341-1100 Withdrawal management—Certification standards.

(1) Substance use disorder withdrawal management services are provided to assist in the process of withdrawal from psychoactive substances in a safe and effective manner that includes medical management or medical monitoring. Substance use disorder withdrawal management services under this certification include:

(a) Adult withdrawal management; and

(b) Youth withdrawal management.

(2) An agency certified for withdrawal management services must:

(a) Ensure the individual receives a substance use disorder screening before admission;

(b) Provide counseling to each individual that addresses the individual's:

(i) Substance use disorder and motivation; and

(ii) Continuing care needs and need for referral to other services.

(c) Maintain a list of resources and referral options that can be used by staff members to refer an individual to appropriate services; and

(d) Post any rules and responsibilities for individuals receiving treatment, including information on potential use of increased motivation interventions or sanctions, in a public place in the facility.

(3) Ensure that each staff member providing withdrawal management services to an individual, with the exception of substance use disorder professionals, substance use disorder professional trainees, physicians, physician assistants, advanced registered nurse practitioners, or person with a co-occurring disorder specialist enhancement, completes a minimum of 40 hours of documented training before being assigned individual care duties. This personnel training must include the following topics:

(a) Substance use disorders;

(b) Infectious diseases, to include hepatitis and tuberculosis (TB); and

(c) Withdrawal screening, admission, and signs of trauma.

(4) An agency certified for withdrawal management services must meet the certification standards for residential and inpatient behavioral health services in WAC ((~~246-341-1104~~)) 246-341-1105 and the individual service requirements for inpatient and residential substance use disorder services in WAC 246-341-1108.

REPEALER

The following sections of the Washington Administrative Code are repealed:

WAC 246-341-1005	Opioid treatment programs (OTP)—Agency certification requirements.
WAC 246-341-1010	Opioid treatment programs (OTP)—Agency staff requirements.
WAC 246-341-1015	Opioid treatment programs (OTP)—Individual service record content and documentation requirements.
WAC 246-341-1020	Opioid treatment programs (OTP)—Medical director responsibility.
WAC 246-341-1025	Opioid treatment programs (OTP)—Medication management.