

# Significant Legislative Rule Analysis

WAC 246-341-0200, 246-341-0300, 246-341-0342, and 246-341-1000 through 246-341-1100

Rules Concerning Opioid Treatment Program Licensing and Regulations.

OCTOBER 2024

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## SECTION 1

**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.**

The Department of Health (department) is proposing to revise the Behavioral Health Agency (BHA) Opioid Treatment Program (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 Code of Federal Regulations (CFR) Part 8, Subpart C (2024), and implement changes enacted by the legislature under Second Engrossed Second Substitute Senate Bill (2E2SSB) 5536 (chapter 1, Laws of 2023, 1st Special Session).

In 2018, the authority for BHA licensing and certification was transferred to the department. Since then, the department has updated many areas of the BHA rules, but OTP regulations have largely stayed the same. This was partially due to limited feedback from interested parties in the initial phases of rulemaking. The department attempted to incorporate a limited number of recommended revisions during a previous phase of rulemaking. However, it became clear during those discussions that more information, discussions, and input would be needed before making any revisions to OTP regulations.

Over the last two years, the department has received input from interested parties and partners that allowed for meaningful engagement to examine, discuss, and consider revisions to OTP licensing and certification requirements. In addition, federal regulations were revised, which impacts references and requirements in the WAC. Therefore, it is important to ensure that references to federal regulations are accurate. Federal regulations were adopted April 2024.

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 rulemaking is needed to develop a process and standards for licensing and approving fixed-site medication units. These units will allow licensed OTPs to expand access to the treatment of opioid use disorder (OUD), especially in rural areas of the 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.

The department is proposing to amend WACs 246-341-0200, 246-341-0342, and 246-341-1000. The department is also proposing to repeal WACs 246-341-1005, 246-341-1010, 246-341-1015, 246-341-1020, and 246-341-1025 and incorporate portions of these WACs into the rules that are being amended. The proposed amendments are intended to address the various

needs identified above. The department is also proposing to correct two internal citations from a previous rules project in WACs 246-341-0300 and 246-341-1100.

## SECTION 2

### Significant Analysis Requirement

As defined in RCW 34.05.328, portions of the rule require significant analysis because this rule makes significant changes to a regulatory program. With these rules, the department will amend the licensing and regulation requirements for opioid treatment programs.

The following SA Table 1 identifies rule sections or portions of rule sections that have been determined exempt from significant analysis based on the exemptions provided in RCW 34.05.328(5) (b) and (c).

**SA Table 1. Summary of Sections not requiring Significant Analysis**

WAC Section and Title	Description of Proposed Changes	Rationale for Exemption Determination
<p><b>WAC 246-341-0200</b>  <b>Behavioral health – Definitions.</b>  <b>(amended)</b></p>	<p>Adds a definition of “community relations plan”</p> <p>Adds a definition of “medication unit”</p> <p>Adds a definition of “opioid treatment program”</p>	<p>This section of rule is exempt from analysis under RCW 34.05.328(5)(b)(iv). Definitions clarify language of the rule without changing its effect.</p>
<p><b>WAC 246-341-0300</b>  <b>Agency licensure and certification—General information.</b>  <b>(amended)</b></p>	<p>For streamlining and readability, the department is proposing to incorporate subsections (1), (2)(b), (3), and (4) from WAC 246-341-1005 which is being repealed.</p> <p>The proposed rule requires mobile or fixed-site medication units to notify the department prior to providing services</p>	<p>This section of rule is exempt from analysis under RCWs 34.05.328(5)(b)(iv) and 34.05.328(5)(c)(i)(B). The proposed changes clarify language of the rule without changing its effects and establish a process requirement for making application to the department.</p>

<p><b>WAC 246-341-0342, Agency licensure and certification—Off-site locations</b></p>	<p>Provides clarification that other requirements must be met before operating a mobile unit.</p> <p>Moves language from section (5) regarding OTP mobile unit information to WAC 246-341-0300.</p> <p>Moves language from section (5) regarding compliance references to WAC 246-341-1000.</p> <p>Repeals language that requires OTPs to submit proof to the department of DEA approval. DEA approval is still required but the department will not ask for this information as part of its licensing/approval process.</p>	<p>The proposed rule amendment is exempt under RCW 34.05.328(5)(b)(iv) by providing clarification with out changing the effect of the rule, and RCW 34.05.328(5)(b)(iii) by incorporating by reference without change another Washington state rule.</p>
<p><b>WAC 246-341-1005, Opioid treatment programs (OTP) – Agency certification requirements. (repealed)</b></p>	<p>For streamlining and readability, the department is proposing to repeal this section of WAC and move the following subsections:</p> <ul style="list-style-type: none"> <li>• subsections (1), (2)(b), and (3) into WAC 246-341-0300;</li> <li>• subsections (2)(a)(i) and (ii) into WAC 246-341-0200; and</li> <li>• subsections (2)(a)(iii) and (4) into WAC 246-341-1000.</li> </ul>	<p>This section of rule is exempt from analysis under RCW 34.05.328(5)(b)(iv). The proposed changes clarify language of the rule without changing its effect.</p>
<p><b>WAC 246-341-1010, Opioid treatment programs (OTP)—Agency staff requirements. (repealed)</b></p>	<p>The department is proposing to repeal this section of WAC and incorporate subsection (4) into WAC 246-341-1000.</p>	<p>This section of rule is exempt from analysis under RCW 34.05.328(5)(b)(iv). The proposed changes clarify language of the rule without changing its effect.</p>

<p><b>WAC 246-341-1015, Opioid treatment programs (OTP) – Individual service record content and documentation requirements. (repealed)</b></p>	<p>The department is proposing to repeal this section of WAC. All of the requirements in this section are duplicative of what is already covered in 42 CFR Part 8, Subpart C.</p>	<p>This section of rule is exempt from analysis under RCW 34.05.328(5)(b)(iv). The proposed changes clarify language of the rule without changing its effect.</p>
<p><b>WAC 246-341-1020, Opioid treatment programs (OTP) – Medical director responsibility. (repealed)</b></p>	<p>The department is proposing to repeal this section of WAC. All of the requirements in this section, with the exception of subsections (3), (9) and (10), are duplicative of what is already covered in 42 CFR Part 8 and RCW 71.24.560. Subsections (3), (9) and (10) will be moved to WAC 246-341-1000.</p>	<p>This section of rule is exempt from analysis under RCW 34.05.328(5)(b)(iv). The proposed changes clarify language of the rule without changing its effect.</p>
<p><b>WAC 246-341-1025, Opioid treatment programs (OTP) – Medication management. (repealed)</b></p>	<p>The department is proposing to repeal this section of WAC. All of the requirements in this section, with the exception of subsections (3)(b), (6), and (7) are duplicative of what is already covered in 42 CFR Part 8. Subsections (3)(b), (6), and (7) will be moved to WAC 246-341-1000.</p>	<p>This section of rule is exempt from analysis under RCW 34.05.328(5)(b)(iv). The proposed changes clarify language of the rule without changing its effect.</p>
<p><b>WAC 246-341-1100, Withdrawal Management – Certification Standards. (amended)</b></p>	<p>The proposed rule corrects a citation in subsection (4). The current rule references WAC 246-341-1104 which has been repealed.</p>	<p>This section of rule is exempt from analysis under RCW 34.05.328(5)(b)(iv), as the proposed change corrects a typographical error, without changing its effect.</p>

## SECTION 3

### **Goals and objectives of the statute that the rule implements.**

The Behavioral Health Agency Licensing and Certification Requirements in chapter 246-341 WAC, as it relates to opioid treatment programs (OTP), implements RCW 71.24.590, which governs program licensing or certification by the department and was amended by 2E2SSB 5536 (chapter 1, Laws of 2023, 1st Special Session).

The overarching intent of the statute is to establish OTP licensing and certification so that individuals can access timely and appropriate treatment services. The intent as it relates specifically to the department is to establish licensure requirements and standards for behavioral health agencies and services to assure access, safety, and quality of care through regulation and policy.

In 2023, there was legislative focus on behavioral health which included OTPs in Washington state. The legislation resulted in an amendment to RCW 71.24.590 to include mobile and fixed-site medication units as part of an OTP. The intent of medication units is to increase access to vulnerable individuals and rural communities. Rules are already in place for mobile units and this proposed rule will include standards for licensing and approving fixed-site medication units.

The department worked with partners and interested parties to examine the rules and identify where changes could be made to support the intent of the statutes inclusive of the amendments made by the legislature. The proposed rule meets the intent of these statutes by:

- Developing a process and standards for approving fixed-site medication units to increase access to care by supporting the use of OTP medication units.
- Reducing duplicative, inefficient, burdensome, and unnecessary regulations for OTPs.
- Aligning state regulations with federal certification and treatment standards for OTPs in 42 CFR Part 8, Subpart C (2024).



## SECTION 4

**Explanation of why the rule is needed to achieve the goals and objectives of the statute, including alternatives to rulemaking and consequences of not adopting the proposed rule.**

RCW 71.24.590 requires OTPs to be licensed to provide treatment and directs the department to establish rules for the certified services. As a result, the only way to achieve the goals of this project is through rulemaking. Without adopting new rules, licensure and certification standards would not be fully aligned with the department's mission and agencies would be limited in their ability and face unnecessary burdens to deliver OTP services. Rules are needed to establish enforceable standards.

The department held weekly rules workshop webinars in October and November of 2023. The workshops were open to the public and interested parties. There was significant participation by interested parties and partners for all workshops. These proposed amendments represent the department's collective best efforts to improve these regulations and take the next step forward in improving the delivery of OTP services in Washington state.

## SECTION 5

**Analysis of the probable costs and benefits (both qualitative and quantitative) of the proposed rule being implemented, including the determination that the probable benefits are greater than the probable costs.**

### Background

To help better understand the costs of the proposed rule, the department conducted a survey of behavioral health agencies (BHA) 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. The survey guided respondents through a series of questions as to whether their agency is already in compliance with each section of the proposed rule. If they answered “yes” they were guided to the next 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, including any additional 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 ten will be included as part of the 19 analyzed responses.

- Six (6/19) respondents identified as a small business<sup>1</sup>.

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<sup>1</sup> [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 or fewer employees.”

- 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.

## **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) incorporate subsections of multiple WACs that are being repealed without changing the language, incorporate 42 CFR Part 8 Subpart C (2024) by reference, and adds the definition of “central registry”. These subsections of rule are exempt from analysis under RCW 34.05.328(5)(b)(iii) and 34.05.328(5)(b)(iv). The proposed changes incorporate federal statutes without material change and clarify language of the rule without changing its effect.

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 CFR 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)<sup>2</sup> or Compliance Officers (\$38.55/hour)<sup>3</sup> 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.”*

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<sup>2</sup> 2023 mean wage - \$64.64/hour for Medical and Health Services Managers, National Estimate ([bls.gov](https://www.bls.gov)) | Accessed on August 9, 2024

<sup>3</sup> 2023 mean wage - \$38.55/hour for Compliance Officers, National Estimate ([bls.gov](https://www.bls.gov)) | Accessed on August 9, 2024

- 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 SA Table 2.

**SA Table 2. One-time cost estimates to update policies and procedures to comply with the proposed rule.**

	Duration of hours to complete	Estimated hourly wage	Estimated cost range
Update policies <sup>4</sup>	10 – 40	\$64.64	\$646.40 - \$2,585.60
		\$38.55	\$385.50 - \$1,542
Additional training costs	Negligible – Unknown	Unknown	Negligible - Unknown
<b>One-time cost estimate</b>			\$385.50 - \$2,585.60 + negligible to unknown training costs

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

**Benefit(s):** Use of the registry allows one location for OTPs to check for dual enrollment, communicate with individuals receiving OTP services and verify dose information during an emergency.

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<sup>4</sup> 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.)

**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 and benefits 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%, 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<sup>5</sup> 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.

- The person responsible for administering the vaccine would be either a registered nurse (RN)<sup>6</sup> or medical assistant (MA)<sup>7</sup>
- 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 5 minutes.<sup>8</sup>
  - The department estimates negligible time (<1 minute) to review patient immunization history and educate the patient.<sup>9</sup>

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<sup>5</sup> [CDC Vaccine price list](#) | Accessed August 9, 2024

<sup>6</sup> 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

<sup>7</sup> 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

<sup>8</sup> 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/>

<sup>9</sup> 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/>

- Price per Hepatitis A vaccine is listed per dose between \$39.55 to \$81.32.<sup>10</sup> 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.<sup>11</sup>
  - The department estimates a possible one-time cost of a Pyxis System at \$19,000 plus a monthly subscription fee of \$110.<sup>12</sup>

### Summary:

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

The cost for 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%, 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 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.

- The person responsible for administering the vaccine would be either a registered nurse (RN)<sup>13</sup> or medical assistant (MA)<sup>14</sup>
- Respondents were asked how long it would take to administer the vaccine; however, no responses were received.

<sup>10</sup> [Current CDC Vaccine Price List | VFC Program | CDC](#). Accessed on October 8, 2024.

<sup>11</sup> Previously approved, compact, affordable refrigerators average cost is \$490 | [Home Depot](#) | [Lowes](#) | Information provided by department vaccine coordinator on April 11, 2024

<sup>12</sup> 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

<sup>13</sup> 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

<sup>14</sup> 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

- The department estimates the time to give a one patient one vaccine at 5 minutes.<sup>15</sup>
- The department estimates negligible time (<1 minute) to review patient immunization history and educate the patient.<sup>16</sup>
- Price per Hepatitis B vaccine is listed per dose between \$32.67 to \$147.63.<sup>17</sup> 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.<sup>18</sup>
  - The department estimates a possible one-time cost of a Pyxis System at \$19,000 plus a monthly subscription fee of \$110.<sup>19</sup>

### Summary:

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

The cost for 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.

### TB Screening:

More than half of the respondents (58%, 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.

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<sup>15</sup> 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/>

<sup>16</sup> 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/>

<sup>17</sup> [Current CDC Vaccine Price List | VFC Program | CDC](#). Accessed on October 8, 2024.

<sup>18</sup> Previously approved, compact, affordable refrigerators average cost is \$490 | [Home Depot](#) | [Lowes](#) | Information provided by department vaccine coordinator on April 11, 2024

<sup>19</sup> 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



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)<sup>20</sup> or medical assistant (MA)<sup>21</sup>
- 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%, 11/19) responded that they are already in compliance with the proposed rule, therefore no additional costs.

The cost for 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**

More than half of the respondents (53%, 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.<sup>22</sup>.. 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%, 10/19) responded that they are already in compliance with the proposed rule, therefore no additional costs.

The cost for for OTPs to provide referral is negligible.

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<sup>20</sup> Washington State Mean Hourly Wage of Registered Nurses, \$53.38. [Washington - May 2023 OEWS State Occupational Employment and Wage Estimates \(bls.gov\)](https://www.bls.gov/news.release/ohwage/ohwage08222024.pdf) | Accessed on August 22, 2024

<sup>21</sup> Washington State Mean Hourly Wage of Medical Assistants, \$25.86. [Washington - May 2023 OEWS State Occupational Employment and Wage Estimates \(bls.gov\)](https://www.bls.gov/news.release/ohwage/ohwage08222024.pdf) | Accessed on August 22, 2024

<sup>22</sup> [TB Blood Test | Quest® \(questhealth.com\)](https://www.questhealth.com/quest/tb-blood-test) | Accessed on September 9, 2024



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 that the Department of Health 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 cost 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 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.

**Benefit(s):** The potential benefits for the proposed rules include increased access to care, decreased barriers to treatment, and reduced administrative burdens with streamlining the state requirements with the federal regulations.

**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.

**Benefit(s):** Ensures that the department is aware of the number of deaths that are occurring in OTPs versus the number of deaths of individuals enrolled in services that do not occur on the OTP campus.

**SA Table 4. Summary of Section 5 probable cost(s) and benefit(s)**

WAC Section and Title	Probable Cost(s)	Probable Benefit(s)
<p>WAC 246-341-1000 Opioid treatment programs (OTP)—General.</p>	<p>Subsections (2) and (3)</p> <p>Estimate ranges between \$385.50 - 2,585.60 to update policies and procedures plus negligible to unknown cost of staff training on the updated policies and procedures.</p>	<p>The proposed amendments clarify the specific policies and procedures that an OTP must comply with.</p>
<p>WAC 246-341-1000 Opioid treatment programs (OTP)—General.</p>	<p>Subsection (4)</p> <p><b>Hepatitis A Vaccination:</b>                      Nearly half of the OTP survey respondents are already in compliance with the proposed rule, therefore no additional costs.</p> <p>The cost for for OTPs to provide referral is negligible.</p> <p>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.</p> <p><b>Hepatitis B Vaccination:</b>                      More than half of the OTP survey respondents are already in compliance with the proposed rule, therefore no additional costs.</p> <p>The cost for for OTPs to provide referral is negligible.</p> <p>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.</p>	<p>Individuals will have additional access to vaccinations, testing, and treatment services.</p>

	<p><b>Tuberculosis Screening:</b>  More than half of the OTP survey respondents are already in compliance with the proposed rule, therefore no additional costs.</p> <p>The cost for for OTPs to provide referral is negligible.</p> <p>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.</p> <p><b>Tuberculosis Testing:</b>  More than half of the survey respondents are already in compliance with the proposed rule, therefore no additional costs.</p> <p>The cost for for OTPs to provide referral is negligible.</p> <p>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.</p> <p>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.</p>	
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<p>WAC 246-341-1000 Opioid treatment programs (OTP)—General.</p>	<p>Subsection (13) The department does not anticipate any additional costs. The BHA already has to include critical incidents in their report to the department.</p>	<p>Ensures that the department is aware of the number of deaths that are occurring in OTPs versus the number of deaths of individuals enrolled in services that do not occur on the OTP campus.</p>
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**Determination**

**Probable Benefits greater than Probable Costs**

It was determined that the probable benefits of increased access to care and a streamlined process establishing a fixed-site medication unit are greater than the probable costs, ranging from no additional cost impact, up to indeterminate additional probable costs for those that choose to offer a fixed site medication unit. It is important to note that this is an optional service, for OTPs 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.

## SECTION 6

**List of alternative versions of the rule that were considered including the reason why the proposed rule is the least burdensome alternative for those that are required to comply and that will achieve the goals and objectives of the proposed rule.**

Over the course of multiple rule workshops, the department continually assessed interested party and partner feedback and sought the advice of internal and external partners on aligning OTP licensing and certification requirements with federal OTP regulations in 42 CFR Part 8 (2024) and developing rules for fixed-site medication units.

Existing rules reference the previous version of 42 CFR Part 8 (2024) and included duplicate requirements that were, in some cases, paraphrased sections of federal regulations.

The department considered not incorporating the CFR by reference but rejected that alternative. It was decided that incorporating by reference was the more efficient way to revise the rule. This route will reduce administrative burdens for the OTPs.

## SECTION 7

**Determination that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.**

The rule does not require those to whom it applies to take action that violates the requirements of federal or state law.

## SECTION 8

**Determination that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.**

The rule does not impose more stringent performance requirements on private entities than on public entities.

## SECTION 9

**Determination if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.**

The proposed rules do not differ from any applicable federal regulation or statute applicable to the same activity or subject matter.



## SECTION 10

**Demonstration that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.**

The department is proposing to align the state medication unit requirements with federal regulations. The proposed rules were written taking the applicable federal, state, and local laws into account.