



RULE-MAKING ORDER EMERGENCY RULE ONLY

CR-103E (December 2017) (Implements RCW 34.05.350 and 34.05.360)

CODE REVISER USE ONLY

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STATE OF WASHINGTON
FILED

DATE: December 15, 2021

TIME: 11:10 AM

WSR 22-01-147

Agency: Department of Health

Effective date of rule:

Emergency Rules

- Immediately upon filing.
- Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

- Yes
 - No
- If Yes, explain:

Purpose: WAC 246-341-0342, Agency licensure and certification-Off-site locations. The Department of Health (department) is adopting an emergency rule to amend WAC 246-341-0342 to define a mobile unit for Behavioral Health Agencies in Washington and allow Opioid Treatment Programs (OTPs) to add a mobile unit as an extension of their existing license. This will align existing rule with the federal changes published in Title 21 of the Code of Federal Regulations, Parts 1300, 1301, and 1304 (21 C.F.R.). On July 28, 2021, these federal rules were revised to allow OTPs to operate mobile units under their existing federal Drug Enforcement Administration (DEA) license. Although current Behavioral Health Agency (BHA) licensing and certification rules reference 21 C.F.R., these rules went into effect on July 1, 2021, prior to the federal change, and need to be updated to ensure that OTPs in Washington are complying with the current version of the federal rule. The amendments to WAC 246-341-0342 define what a mobile unit is, require OTPs to notify the department in writing prior to operating a mobile unit, and outline requirements for OTPs that operate a mobile narcotic treatment program. These requirements include submitting a copy of the DEA approval for the unit and complying with 21 CFR Parts 1300, 1301, and 1304.

Citation of rules affected by this order:

New: None
 Repealed: None
 Amended: WAC 246-341-0342
 Suspended: None

Statutory authority for adoption: RCW 71.24.037, RCW 71.24.585, RCW 71.24.595

Other authority: Title 21 C.F.R. Parts 1300, 1301, and 1304

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

- That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.
- That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: This emergency rule updates department rules to align with the recently updated federal rules in 21 C.F.R., which allow OTPs to add and operate a mobile unit under their existing DEA license. Without this change, the rules would direct OTPs to comply with an outdated version of federal regulations that did not include the ability to operate a mobile OTP component. Furthermore, this has become an emergent issue as a result of the ongoing opioid crisis in Washington state, which has been exacerbated by the Coronavirus disease 2019 (COVID-19) pandemic. This amendment will allow the department to approve mobile units without delay, increasing access to treatment for individuals who suffer from opioid use disorder, while maintaining regulatory oversight to ensure client and public safety. The department is considering adopting these changes as part of a permanent rulemaking process, under WSR 21-14-010.

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

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|----------------------------------|-----|----------|---------|----------|----------|----------|
| Federal statute: | New | <u>0</u> | Amended | <u>0</u> | Repealed | <u>0</u> |
| Federal rules or standards: | New | <u>0</u> | Amended | <u>1</u> | Repealed | <u>0</u> |
| Recently enacted state statutes: | New | <u>0</u> | Amended | <u>0</u> | Repealed | <u>0</u> |

The number of sections adopted at the request of a nongovernmental entity:

| | | | | | |
|-----|----------|---------|----------|----------|----------|
| New | <u>0</u> | Amended | <u>0</u> | Repealed | <u>0</u> |
|-----|----------|---------|----------|----------|----------|

The number of sections adopted on the agency's own initiative:

| | | | | | |
|-----|----------|---------|----------|----------|----------|
| New | <u>0</u> | Amended | <u>0</u> | Repealed | <u>0</u> |
|-----|----------|---------|----------|----------|----------|

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

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|-----|----------|---------|----------|----------|----------|
| New | <u>0</u> | Amended | <u>0</u> | Repealed | <u>0</u> |
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The number of sections adopted using:

| | | | | | | |
|--------------------------------|-----|----------|---------|----------|----------|----------|
| Negotiated rule making: | New | <u>0</u> | Amended | <u>0</u> | Repealed | <u>0</u> |
| Pilot rule making: | New | <u>0</u> | Amended | <u>0</u> | Repealed | <u>0</u> |
| Other alternative rule making: | New | <u>0</u> | Amended | <u>1</u> | Repealed | <u>0</u> |

Date Adopted: 12/15/2021

Name: Kristin Peterson, JD for Umair A. Shah, MD, MPH

Title: Deputy Secretary for Policy and Planning for Secretary of Health

Signature:



WAC 246-341-0342 Agency licensure and certification—Off-site locations and mobile units. (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 ((outpatient)) 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.

~~((2))~~ (4) In addition to meeting the requirements in subsection ((1)) (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.

~~((3) 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.)~~ (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.