

Opioid Treatment Program (OTP) Rulemaking: Workshop #4 Notes

Fixed-Site Medication Units

Proposed WAC Revisions	Comments to Consider	Notes
<p>WAC 246-341-0342</p> <p>Agency licensure and certification—Off-site locations.</p> <p>(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.</p> <p>(2) For the purposes of this section:</p> <p>(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.</p> <p>(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.</p> <p>(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).</p> <p>(3) A behavioral health agency that provides off-site services at an established off-site location(s) shall:</p> <p>(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:</p> <p>(i) The name and address of the location the services are provided;</p> <p>(ii) The primary purpose of the off-site location;</p> <p>(iii) The service(s) provided; and</p> <p>(iv) The date off-site services began at that location;</p> <p>(b) Maintain an individual's confidentiality at the off-site location;</p> <p>and</p> <p>(c) Securely transport confidential information and individual records between the licensed agency and the off-site location, if applicable.</p>	<ol style="list-style-type: none"> 1. Federal definition of fixed-site medication unit. 2. Why are we developing rules for fixed-site medication units? 3. What other regulations apply? 4. Define medication unit to capture both fixed-site and mobile. 5. DOH – Move OTP medication unit subsection to WAC 246-341-0300 – Agency licensing and certification section. 	<ol style="list-style-type: none"> 1. The definition of a fixed-site medication unit is the same as the definition of "medication unit" referenced in 42 C.F.R. Part 8.2 and means: <ul style="list-style-type: none"> • <i>Under the current CFR - Medication unit</i> means a facility established as part of, but geographically separate from, an opioid treatment program from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication or collect samples for drug testing or analysis. • The proposed CFR will update the medication unit definition to clarify that medication units include fixed-site unit (or brick and mortar) as well as mobile units. It also clarifies that a medication unit may provide a full range of OTP services based on the space and privacy available in the unit. • <i>Under proposed CFR - Medication unit</i> means an entity that is established as part of, but geographically separate from, an OTP from which appropriately licensed OTP practitioners, contractors working on behalf of the OTP, or community pharmacists may dispense or administer MOUD, collect samples for drug testing or analysis, or provide other OTP services. Medication units can be a brick-and-mortar location or mobile unit. 2. SB 5536 requires the department to adopt rules for fixed-site medication units that may be established as part of a licensed OTP. Share link to the bill. 3. Pharmacy Quality Assurance Commission – requires a drug other controlled substance registration. <p>Drug Enforcement Administration (DEA) – requires a separate controlled substance registration. This is different than the mobile medication unit, where the registration of the brick and mortar is extended to the mobile unit. This includes regulations in 21 CFR Part 1300, 1301, 1304, and 1306.</p> <p>The Substance Abuse and Mental Health Services Administration (or SAMHSA) regulations in 42 CFR Part 8 also apply. They require, like mobile medication units, for the OTP to submit a SMA-162 before establishing a medication unit.</p>

(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 ~~may operate~~ing a medication unit as defined in 42 C.F.R. part 8.2, that is a brick-and-mortar location, or a mobile narcotic treatment program as defined in 21 C.F.R. Part 1300. An opioid treatment program must:

(a) Notify the department in a manner outlined by the department;

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

(c) Comply with 21 C.F.R. Parts 1300, 1301, ~~and~~1304, 1306, 42 C.F.R. Part 8, and any applicable rules of the pharmacy quality assurance commission.

4. Develop a rule to outline the state approval requirements, while also including the relevant federal definitions.

- a. SAMHSA defines medication units, which are inclusive of both mobile and fixed.
- b. DEA defines mobile narcotic treatment programs.

a. Under subsection 6, updated the language by referring to these units as medication units to capture both, while also clarifying who defines them. Approval requirements for both are similar – notification to the department, copy of DEA approval, and comply with federal regulations and state pharmacy regulations.

5. Move the OTP medication unit requirements to WAC 246-341-0300 to be included with all other BHA licensing and certification requirements.

No public comments. Questions:

- If we are applying for a new Opioid Treatment license, do we use the old WAC language for policy?

- **Department Response:** Continue to use the current WAC references until the revised WAC becomes effective. Once effective, you will need to update your policies and procedures. Agencies will be able to add fixed-site medication units to their existing brick and mortar license once the new rule becomes effective.