

DRAFT Language – Fixed-site Medication Units
OTP Rulemaking Workshop #4
October 31, 2023

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 ~~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 ~~operating a medication unit~~ 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
- (b) 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.

Commented [MW1]: [42 CFR 8.2 - Definitions.](#) (govregs.com) Medication unit 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.

Proposed CFR definition - Medication unit 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.

Commented [WML(2): DOH will update the notification form to include the fixed-sites.

The overall proposed process for operating a medication unit, which builds on the current process for mobile units:

- Notification form to DOH
- PQAC drug other controlled substance registration
- DEA registration (mobile NTP - this would be a letter; fixed-site medication unit - this would be a copy of their approved controlled substance registration. DOH to check with DEA to confirm.
- Submit SMA-162 to SAMHSA
- SOTA approval

Commented [MW3]: Move OTP medication unit subsection to WAC 246-341-0300 - Agency licensing and certification section