

**DRAFT**

**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.

(1) The following behavioral health agency licensure process in this section does not apply to a tribe that is licensed or seeking licensure via attestation as described in WAC 246-341-0367. Any federal or other state licensure requirements are not exempted by this chapter.

(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.

**Commented [MW1]:** This relates to the OTP licensure process. Attestation for PQAC controlled substance registration is not available at this time. Rulemaking related to that registration is outside of the scope of this project. All other federal requirements, such as DEA and SAMHSA approval still apply.

(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 (4)(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) An opioid treatment program must submit additional information with their application to include:

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

(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:

**Commented [WML(2):** Technical fix of an error that occurred in the last round of rule-making. Doesn't change any requirements.

The numbering changed but was not fixed here.

(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 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).

(6) An opioid treatment program may operate 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 medication unit.

(57) 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.

(68) 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:

**Commented [MW3]:** [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(4):** 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

(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.

(79) 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~~10) 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~~11) 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.

(12~~9~~) 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.

(134) 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.