



Opioid Treatment Program

Accrediting Body Policies and Procedures

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Policy Area: Behavioral Health Agency Accreditation	Subject: OTP Accreditation Requirements
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Title of Policy: Accrediting Body Responsibilities	Number: 42 CFR 8.3(b)(10), 42 CFR 8.4(c)(2)(i)(ii)(d)(2)(3)(4)(5)(6)(g)
Effective Date: 09/01/2019	Page Number(s): 1-3
Approved Date: 09/01/2019 Revision Date: 09/01/2019	Approved by: Ramiro Cantu, Director, Office of Health Systems Oversight

Policy:

Washington State Department of Health (DOH) attests that it will comply with and carry out all of the duties and responsibilities as an opioid treatment accreditation body, as required by the Substance Abuse and Mental Health Services Administration (SAMHSA).

Procedure:

Step 1: DOH will maintain records of its accreditation activities for at least 5 years from the creation of the record. Such records will contain sufficient detail to support each accreditation decision made by DOH.

Step 2: DOH shall require each employee to sign a confidentiality statement to protect confidential information collected or received in their role as accreditation bodies. DOH will ensure compliance with all Federal and State laws, including 42 CFR part 2 related to patient confidential information.

Step 3: DOH will ensure information collected or received for the purpose of carrying out accreditation body responsibilities will not be used for any other purpose or disclosed, other than to SAMHSA or its duly designated representatives, unless otherwise required by law or with the consent of the Opioid Treatment Programs (OTP).

Step 4: DOH will ensure nonpublic information that SAMHSA shares with the accreditation body concerning an OTP will not be further disclosed except with the written permission of SAMHSA.

Step 5: DOH will provide to SAMHSA any documents and information requested by SAMHSA within 5 business days of receipt of the request.

Step 6: DOH will make a summary of the results of each accreditation survey available to SAMHSA upon request. Such summaries shall contain sufficient detail to justify the accreditation action taken.

Step 7: DOH will provide SAMHSA, upon request a list of each OTP surveyed and the identity of all individuals involved in the conduct and reporting of survey results.

Step 8: DOH will submit to SAMHSA semiannually, on January 15 and July 15 of each calendar year, a report consisting of a summary of the results of each accreditation survey conducted in the past year. The summary shall contain sufficient detail to justify each accreditation action taken.

Step 9: DOH will comply with all reporting requirements listed in this section by sending all reports to SAMHSA.

Attachment: Confidentiality Statement

GENERAL RULE

As a general rule, all records in the Department of Health (DOH) are disclosable to the public. In very specific and narrow circumstances, identified in law, the department may withhold some or all of a record from the public.

RESPONSIBILITIES REGARDING CONFIDENTIAL INFORMATION

As an employee, volunteer, or federal assignee of the Washington State Department of Health (DOH), I understand that I may handle or have access to confidential information. I understand that I am responsible for maintaining the confidentiality of certain information collected, maintained, stored, or analyzed within DOH.

I recognize and respect the confidential nature of certain information I may have access to during the course of my employment with DOH. I will not at any time, or in any manner, either directly or indirectly, disclose confidential information to anyone outside the scope of my position, unless authorized by law. If I am authorized to disclose confidential information I will follow applicable rules/regulations and policies.

I have received and read the DOH confidentiality policy (17.005) and acknowledge that I understand the policy and the responsibilities delegated to me in it. My supervisor and I have identified the following types of confidential information I will likely access during my work this year:

I understand that I will receive guidance from my supervisor on the practices for handling this and other confidential information.

PENALTIES FOR DISCLOSING CONFIDENTIAL INFORMATION

I understand that if I disclose confidential information to any one in violation of federal and state law, administrative rule and this policy, through any means, it is grounds for disciplinary action against me, which may include termination of employment with DOH.

I understand that my unauthorized use or disclosure of confidential information may be considered an ethics violation and subject to civil damages or other penalties.

I understand that specific sources of confidential information which include but are not limited to HIV/STD conditions, mental health, and drug and alcohol treatment, are subject to specific state and federal law and administrative rules/regulations. I understand that if I disclose such confidential information in violation of those laws and administrative rules/regulations, I may be subject to civil damages and criminal penalties, including fines and/or imprisonment.

Employee signature:

Date:

Please print name:

I understand that I must provide information to my employee on the specific information that is confidential in within the scope of my employee's job responsibilities, and my program, and the practices for handling this information.

Supervisor signature:

Date:

Please print name:

Date received by Human Resources Office _____

Policy Area: Behavioral Health Agency Accreditation	Subject: OTP Accreditation Requirements
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Title of Policy: Conflict of Interest	Number: 42 CFR 8.3(b)(5), 42 CFR 8.4(h)(2)
Effective Date: 09/01/2019	Page Number(s): 1
Approved Date: 09/01/2019 Revision Date: 09/01/2019	Approved by: Ramiro Cantu, Director, Office of Health Systems Oversight

Policy Statement:

Washington State Department of Health (DOH) will as an accreditation body monitor for and avoid conflicts of interest, or the appearance of conflicts of interest, by professional personnel, consultants, administrative personnel, and other representatives.

Procedures:

Step 1: DOH will ensure that all professional personnel, consultants, administrative personnel and other representatives that have an actual or perceived conflict of interest will not participate in survey or investigative activities.

Step 2: Survey team members will recuse themselves at any time from any survey or investigation in which either they, DOH or the OTP believes there is an actual or perceived conflict of interest.

Policy Area: Behavioral Health Agency Accreditation	Subject: OTP Accreditation Requirements
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Title of Policy: Education, Training and Experience of Accreditation Staff Members	Number: 42 CFR 8.3(b)(6)(7), 42 CFR 8.4(h)(i)(ii)(iii)(iv)
Effective Date: 09/01/2019	Page Number(s): 1
Approved Date: 09/01/2019 Revision Date: 09/01/2019	Approved by: Ramiro Cantu, Director, Office of Health Systems Oversight

Policy Statement:

Department of Health (DOH) survey team members conducting opioid treatment program (OTP) accreditation surveys will consist of healthcare professionals with expertise in drug abuse treatment and, in particular, opioid treatment. The combined expertise of survey team members conducting an OTP survey or investigation will include: The dispensing and administration of drugs subject to control under the Controlled Substances Act (21 U.S.C. 801 et seq.); medical issues relating to the dosing and administration of opioid agonist treatment medications for the treatment of opioid use disorder; psychosocial counseling of individuals undergoing opioid treatment; and organizational and administrative issues associated with opioid treatment programs. All survey team members will be Health Services Consultant 4's, Nurse Consultants and/or physicians.

Procedures:

Step 1: Survey team members will complete and pass the SAMHSA Prescription Medication: Misuse, Abuse, and Dependence Course within 6 months of hire.

Step 2: Survey team members will complete and pass the SAMHSA Prescription Medication: Addressing Addiction Course within 6 months of hire.

Step 3: Survey team members will take the ASAM Provider Education Course: The ASAM Fundamentals of Addiction Medicine within one year of hire.

Step 4: Survey team members will attend the annual American Association for the Treatment of Opioid Dependence, to include the pre-conference trainings.

Step 5: Survey team members will take advantage of opioid specific trainings offered by Washington State Nursing Commission, Pharmacy Commission, and the Medical Commission or any other qualified organizations as they come available throughout the year.

Policy Area: Behavioral Health Agency Accreditation	Subject: OTP Accreditation Requirements
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Title of Policy: Survey, Accreditation and Decision Making Process	Number: 42 CFR 8.3(a)(4)(i)(iv)(v), 42 CFR 8.4(a)(2)(3)(b)(i)(ii)(iii)(2)
Effective Date: 09/01/2019	Page Number(s): 1-2
Approved Date: 09/01/2019 Revision Date: 09/01/2019	Approved by: Ramiro Cantu, Director, Office of Health Systems Oversight

Policy:

Washington State Department of Health’s accrediting standards will ensure that each Opioid Treatment Program (OTP) surveyed is qualified to meet and subsequently meets each of the federal opioid treatment standards set forth in 42 CFR Part 8 and the Federal Guidelines for Opioid Treatment Programs aka ‘CSAT Guidelines’ (January, 2015).

Procedures:

OTP Accreditation

Step 1: The OTP will apply to the Washington State Department of Health (DOH) for a behavioral health agency license, to include paying a behavioral health agency licensing fee. The OTP will indicate on the application that they are applying for DOH accreditation.

Step 2: The OTP will provide all required forms, to include policy and procedures that cover 42 CFR part 8 and the CSAT to the DOH for review.

Step 3: DOH will review draft policy and procedures and provide the OTP with identified deficient areas for revision prior to approval.

Step 4: The Washington State Pharmacy Quality Assurance Commission will coordinate with the Drug Enforcement Agency (DEA) for an on-site compliance review for state licensure and SAMHSA provisional certification.

Step 5: DOH will schedule an OTP on-site survey on or about six months after state licensure and provisional SAMHSA certification, to determine accreditation status. If accreditation is granted DOH will thereafter conduct routine on-site surveys no later than 60 days prior to the accreditation expiration date.

Step 6: For all on-site surveys to include complaint investigations, DOH determines if the OTP is in compliance with 42 CFR part 8 and CSAT standards.

Step 7: DOH will meet with the OTP at the conclusion of the on-site survey to provide them preliminary verbal overview of the results of the on-site survey.

Step 8: DOH may provide the OTP a statement of deficiency report with the results of the survey and may require the OTP to submit a written plan of correction within ten business days after receiving the report, or may issue a notice of intent to deny accreditation.

Step 9: DOH will review the plan of correction submitted by the OTP to ensure it adequately addresses the OTP’s non-compliance with applicable standards. If the plan of correction is found to be incomplete or

inadequate, DOH may request that the OTP timely submit a revised plan of correction. Once a plan of correction is approved by DOH, it will accept the OTP's plan of correction as an attestation of implementation, or depending on the scope and severity of the deficiencies, DOH may monitor for implementation of the plan to include an on-site revisit.

Step 10: Depending on the scope and severity of the deficiencies or the OTP's failure or inability to plan and implement corrections to cited deficiencies, DOH may make an accreditation decision from the following options: non-accreditation to included denial, provisional accreditation, one-year accreditation, or three year accreditation. After the on-site survey the agency will be notified in writing of the Department of Health's accreditation decision to include appeal rights.

Step 11: DOH will notify SAMHSA within forty eight hours of any adverse accreditation decision to an agency.

Accreditation Decisions

All accreditation decisions will be conducted in accordance with the Department of Health's Office of Health Systems Oversight Case Management Team protocols. Each OTP must demonstrate that it meets all established standards in accordance with 42 CFR Part 8 and CSAT. While an OTP may not be in compliance with all applicable standards, the Department of Health's accreditation decision will be based on the scope and severity of the deficiencies identified by the accrediting body survey team.

Three-Year Accreditation

The OTP meets and demonstrates substantial compliance with all established standards.

One-Year Accreditation

The OTP meets and demonstrates substantial compliance with most of the established standards. Although there are significant areas of improvement the OTP needs to make, the OTP has shown the capability and commitment to make the necessary changes to meet compliance standards.

Provisional Accreditation

Provisional Accreditation may be issued to an OTP that demonstrates partial compliance with some of the established standards. A Provisional Accreditation is issued for a period of time not to exceed one year. The provisional accreditation may include specific and directed programmatic and performance changes to be implemented by a date certain. OTP's under provisional accreditation will be subject to re-inspection and may be de-accredited for failure to timely effect changes outlined by DOH or improve overall compliance with standards.

Non-accreditation

The OTP has significant areas of deficient practice in most areas of the established standards. The scope and severity of the areas of deficient practice raises serious questions as to the health, safety and wellbeing of the patients being served by this OTP. DOH may permit an OTP that receives a non-accreditation decision to re-apply to be re-accredited by the DOH, but only after a specified amount of time determined by DOH.

Policy Area: Behavioral Health Agency Accreditation	Subject: OTP Accreditation Requirements
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Title of Policy: OTP Complaint Investigation	Number: 42 CFR 8.3(b)(9), 42 CFR 8.4(e)
Effective Date: 09/01/2019	Page Number(s): 1
Approved Date: 09/01/2019 Revision Date: 09/01/2019	Approved by: Ramiro Cantu, Director, Office of Health Systems Oversight

Policy Statement:

Washington State Department of Health (DOH) as an accrediting body will assess reports from SAMHSA, patients, facility staff, and others, within a reasonable period of time but not more than 5 business days from the receipt of the complaint. All complaints will be reviewed by the Department of Health’s Case Management Team. The Department of Health’s Case Management Team is comprised of members from the Department of Health’s Office of Investigative and Legal Services, Office of Community Health Services, and the Office of Health Systems Oversight.

Procedures:

Step 1: DOH will receive all reported allegations through the Office of Investigative and Legal Services, Complaint Intake Unit.

Step 2: All reported allegations will be forwarded to the Department of Health’s Case Management Team meeting for review.

Step 3: The Case Management Team will review all reported allegations and make a team based decision on whether to authorize for investigation or to close without investigation.

Step 4: The Case Manager will notify SAMHSA immediately after an investigation has been authorized by the Department to confirm SAMHSA approval.

Step 5: DOH will keep SAMHSA informed of the results of all OTP investigations.

Policy Area: Behavioral Health Agency Accreditation	Subject: OTP Accreditation Requirements
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Title of Policy: Appeal of Adverse Accreditation Decision	Number: 42 CFR Part 8.3(b)(4)(vii)
Effective Date: 09/01/2019	Page Number(s): 1
Approved Date: 09/01/2019 Revision Date: 09/01/2019	Approved by: Ramiro Cantu, Director, Office of Health Systems Oversight

Policy Statement:

An Opioid Treatment Program (OTP) that receives a one year accreditation, provisional accreditation, or non-accreditation decision from the Department of Health (DOH) based on an on-site survey or investigation from DOH may appeal that accreditation decision.

Procedures:

Step 1: DOH must receive written notice of the appeal, including any written response and/or supporting materials the OTP would like DOH to consider during the appeal process, from the OTP within ten business days from the date on the notice communicating the Department of Health’s accreditation decision. DOH may not consider information not provided within 10 business days. The documents submitted by the OTP must detail how the OTP believes the Department of Health’s accreditation decision was not warranted based on the established standards in accordance with 42 CFR Part 8 and CSAT.

Step 2: All appeals will be reviewed by the Department of Health’s Case Management Team. The Department of Health’s review will be ‘paper only’ and will not include in-person testimony by witnesses or oral argument, etc.

Step 3: DOH will affirm the initial accreditation decision, or issue another accreditation decision, based on consideration of all the relevant information timely provided by the OTP to the Case Management Team.

Step 4: If DOH does not receive a timely written notice of appeal and corresponding documentation, the Department of Health’s accreditation decision stands as final and is not subject to further review or appeal. All decisions and determinations related to and interpretations of this appeal process shall be determined at the Department of Health’s sole and binding discretion.

Policy Area: Behavioral Health Agency Licensing	Subject: OTP Licensing and Certification
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Title of Policy: Opioid Treatment Program (OTP) Licensing and Certification	Number: 42 CFR 8.3(b)(4)(vi)
Effective Date: 09/01/2019	Page Number(s): 1-3
Approved Date: 09/01/2019 Revision Date: 01/25/2024	Approved by: Julie Tomaro, Facilities Program Director, Office of Community Health Systems

Policy statement for licensure as a state behavioral health agency:

The Department of Health (DOH) will license and certify Opioid Treatment Programs (OTP) in accordance with RCW 71.24 and Chapter 246-341 WAC.

Procedures:

Note regarding Tribal Attestation: Tribal BHAs, which include OTPs, applying for licensure and certification may attest that its agency meets the state minimum standards. DOH does not assert regulatory jurisdiction over a BHA license under a tribal attestation.

Tribally attested OTPs are not required to submit a Community Relations Plan (CRP) to DOH with their attestation and license application. In addition, required consultation with local legislative or tribal authorities is confirmed through the approved attestation. DOH does not conduct additional consultation with local legislative authorities regarding tribally attested OTPs.

Step 1: Proposed OTP will conduct an assessment of the need for an OTP in the community in which the OTP would be located. The assessment must include the consideration of other OTPs near the service area, population density, the transportation systems that would provide service to the program, and whether the transportation systems will provide reasonable opportunities to access the program for persons in need of treatment.

Step 2: Proposed OTP will communicate with the county legislative authority, and if applicable, the city legislative authority or tribal authority, in order to secure a location for the new OTP that meets county, tribal or city land use ordinances

Step 3: Proposed OTP will obtain siting determination from the county, city and tribe, as applicable, that the OTP will be located on property that is sited in accordance with the appropriate county, city, and tribal land use ordinances.

Step 4: Proposed OTP will submit a copy of siting determination to the DOH facilities program manager.

Step 5: Proposed OTP will develop a community relations plan (CRP) in consultation with the county, city, or tribal authority or their designee using the DOH form and complete "[Part One](#)"

Step 6: Proposed OTP will submit a [behavioral health agency \(BHA\) application](#) (including request for outpatient assessment, intervention and treatment certification), CRP, policies and procedures, and fee to DOH., New applicants who operate OTPs in another state must submit copies of all review reports written by their national accreditation body and state certification, if applicable, within the past six years (change of location applicants are not considered "new.") Additionally, the OTP must submit an [application for drug other controlled substance registration](#) to the WA State Pharmacy Commission, obtain accreditation from a federally recognized accrediting organization, and obtain approval from the Drug Enforcement Administration (DEA), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

Step 7: After the determination is made by the DOH Credentialing Unit that the BHA application, and fee is complete, the Credentialing Unit will send a work order to the DOH facilities program manager that includes a copy of the application and community relations plan within 1 business day that the completed applications and fee have been received.

Step 8: The DOH facilities program manager will review the community relations plan for deficiencies within one week of receiving a copy from the Credentialing Unit. The facilities program manager will notify the proposed OTP if any further information is needed.

Step 9: The DOH facilities program manager will notify the Office of Health Systems Oversight OTP Accreditation staff and the HCA/State Opioid Treatment Authority that a completed application has been received.

Step 10: After the facilities program manager reviews the community relations plan, DOH will consult with the county and city legislative authorities where the applicant proposes to locate the program to confirm that the applicant has consulted with legislative authorities on the development of the community relations plan and on securing a location of the proposed program to ensure that it meets county, tribal or city land use ordinances. The information and feedback will be requested by sending an email, with delivery and read notifications. Included in the information and feedback request will be a copy of the CRP and a Proposed OTP Consultation Form for the legislative authority representative to use to submit their response. Responses to the information and feedback requests will be due two weeks from the date it was sent, with an option to request additional time. If a response is not received within that time, the DOH facilities program manager will attempt to contact the legislative authority and document all attempts.

Step 11: After receiving the work order notification from the Credentialing Unit and reviewing the CRP, the DOH facilities program manager will consult with the DOH communications staff to identify the appropriate media outlets in order to provide public notice in the community in which the OTP is proposed to be located that states the applicant is proposing a facility in that community. The legal ad will run for one day and a broader notification will be sent via GovDelivery to all appropriate media outlets. A copy of the ad will be posted to the Proposed OTP webpage along with the community relations plan. For OTPs licensed under tribal attestation, DOH will work with the tribal OTP representative to determine the timing of the public notice.

Step 12: If there has been no previous response to the local legislative authority outreach for consultation, the DOH facilities program manager will, prior to licensure, follow up with county and city legislative authority and/or tribal representative or designee, as applicable for a response to the process outlined in step 10 regarding the proposed OTP and location. If no response is received after one week, the licensure process will proceed.

Step 13: The DOH facilities program manager will send the city/county legislative authority consultation response, or documentation of attempts to contact the legislative authority, date that the public notice was published, and copies of the siting determination to the DOH Credentialing Unit to keep on file with the application.

Step 14: Office of Health Systems Oversight (OHSO) staff will review the submitted policies and procedures to identify and inform the proposed OTP of any revision to the policies and procedures needed for approval. Once OHSO approves the policies and procedures, notification will be sent to the credentialing program.

Step 15: The Credentialing Unit will verify the applicant has an active Drug Other Controlled Substance registration and then obtain approval from the facilities program manager prior to issuing the behavioral health agency license or OTP certification.

Step 16: The credentialing program will issue the behavioral health agency license and OTP certification. The credentialing program will notify the OTP and the DOH facilities program manager that the license and certification are active within one business day.

Step 17: The DOH facilities program manager will notify HCA/Opioid Treatment Authority that the OTP is licensed.