WASHINGTON STATE DEPARTMENT OF HEALTH

Opioid Treatment Program Accreditation Body Standards

Approved by SAMHSA October 9, 2024

Washington State Department of HEALTH

DOH 346-150 October 2024

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Washington State DOH Accrediting Body Standards
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§ 8.2 Definitions.

Accreditation Body or "the Body" means an organization that has been approved by the Secretary under § 8.3(d) in this part to accredit Opioid Treatment Programs (OTPs) dispensing medications for opioid use disorder (MOUD).

Accreditation elements means the elements or standards that are developed and adopted by the Washington State Department of Health Accreditation Body and approved by the Secretary.

Accreditation survey means an on site or virtual review and evaluation of an OTP by the Washington State Department of Health Accreditation Body to determine compliance with the federal opioid use disorder treatment standards described in § 8.12.

Accredited OTP means an opioid treatment program that is the subject of a current, valid accreditation from the Washington State Department of Health Accreditation Body approved by the Secretary under § 8.3(d).

ASAM (American Society of Addiction Medicine) The purpose of The ASAM Criteria is to promote individualized and holistic treatment planning and guide clinicians and care managers in making objective decisions about patient admission, continuing care, and movement along the continuum of care. The criteria provide a consistent way to: 1. Assess patients' biopsychosocial circumstances to identify the appropriate level of care based on their individual needs. 2. Develop comprehensive, individualized, and patient-centered treatment plans. 3. Define the services that should be available at each level of care in the care continuum.

Behavioral health services means any intervention carried out in a therapeutic context at an individual, family, or group level. Interventions may include structured, professionally

administered clinical interventions (e.g., cognitive behavior therapy or insight-oriented psychotherapy) delivered in-person, or remotely via telehealth or telemedicine, which has been shown to facilitate treatment outcomes or non-clinical interventions.

Care plan means an individualized treatment and/or recovery plan that outlines attainable treatment goals that have been identified and agreed upon between the patient and the OTP clinical team, and which specifies the services to be provided, as well as the proposed frequency and schedule for their provision.

Certification means the process by which the Secretary determines that an OTP is qualified to provide opioid use disorder (OUD) treatment under the federal opioid use disorder treatment standards.

Certified opioid treatment program means an OTP that is the subject of a current, valid certification under § 8.11.

Comprehensive treatment is treatment that includes the continued use of MOUD provided in conjunction with an individualized range of appropriate harm reduction, medical, behavioral health, and recovery support services.

Conditional certification is a type of temporary certification granted to an OTP that has requested renewal of its certification and that has received temporary accreditation for one year by an approved Accreditation Body. The one-year accreditation period is to allow the OTP to address areas of significant non-conformance with accreditation standards that do not involve immediate, high-risk health and/or safety concerns.

Continuous medication treatment means the uninterrupted treatment for OUD involving the dispensing and administration of MOUD at stable dosage levels for a period in excess of 21

days.

Dispense means to deliver a controlled medication to an ultimate user by, or pursuant to, the lawful order of, a practitioner, including the prescribing and administering of a controlled medication.

Diversion control plan means a set of documented procedures that reduce the possibility that controlled medications will be transferred or otherwise shared with others to whom the medication was not prescribed or dispensed.

Documentation means the recording of information in a manner that accurately reflects the care and services provided. Documentation should be individualized to the patient, legible, and completed within expected timelines by qualified personnel. All documentation should allow the reader to identify care, interventions, ongoing needs, significant events, unexpected outcomes, and any other information pertinent to the patient's care and needs throughout the admission. Documentation should allow personnel required to utilize the information contained in a record to identify the path the patient followed from admission through discharge and identify any areas where their specific discipline may be affected.

Federal opioid use disorder treatment standards means the standards established by the Secretary in § 8.12 that are used to determine whether an OTP is qualified to engage in OUD treatment. The federal opioid use disorder treatment standards established in § 8.12 also include the standards established by the Secretary regarding the quantities of MOUD which may be provided for unsupervised, take-home use.

For-cause inspection means an inspection, by the Secretary, an Accreditation Body, or a State authority, of an OTP that may be operating in violation of federal opioid use disorder

treatment standards, may be providing substandard treatment, may be serving as a possible source of diverted medications, or where patient well-being is at risk.

Harm reduction refers to practical and legal evidence-based strategies, including: overdose education; testing and intervention for infectious diseases, including counseling and risk mitigation activities forming part of a comprehensive, integrated approach to address human immunodeficiency virus (HIV), viral hepatitis, sexually transmitted infections, and bacterial and fungal infections; distribution of opioid overdose reversal medications; linkage to other public health services; and connecting those who have expressed interest in additional support to peer services.

Individualized *dose* means the dose of a medication for opioid use disorder, ordered by an OTP practitioner and dispensed to a patient, that sufficiently suppresses opioid withdrawal symptoms. Individualized doses may also include split doses of a medication for opioid use disorder, where such dosing regimens are indicated.

Interim treatment means that temporarily, a patient may receive some services from an OTP while awaiting access to more comprehensive treatment services. The duration of interim treatment is limited to 180 days.

Long-term care facilities mean those facilities that provide rehabilitative, restorative, and/or ongoing services to those in need of assistance with activities of daily living. Long-term care facilities include extended acute care facilities; rehabilitation centers; skilled nursing facilities; permanent supportive housing; assisted living facilities; and chronic care hospitals.

Medical director means a physician, licensed to practice medicine in the jurisdiction in which the OTP is located, who assumes responsibility for all medical and behavioral health

services provided by the program, including their administration. A medical director may delegate specific responsibilities to authorized program physicians, appropriately licensed non- physician practitioners with prescriptive authority functioning under the medical director's supervision, or appropriately licensed and/or credentialed non-physician healthcare professionals providing services in the OTP, in compliance with applicable federal and state laws. Such delegations will not eliminate the medical director's responsibility for all medical and behavioral health services provided by the OTP.

Medication for Opioid Use Disorder or MOUD means medications, including opioid agonist medications, approved by the Food and Drug Administration under section 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), for use in the treatment of OUD. As used in this part, "continuous medication treatment" is intended to be synonymous with the term "maintenance" treatment as used in 21 U.S.C. 823(h)(1), and the term "withdrawal management" is intended to be synonymous with the term "detoxification" as used in 21 U.S.C. 823(h)(1).

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.

Nationally recognized evidence-based guidelines mean a document produced by a national or international medical professional association, public health agency, such as the World Health Organization, or governmental body with the aim of assuring the appropriate

use of evidence to guide individual diagnostic and therapeutic clinical decisions for the management of OUD and other health conditions that are widely recognized within the United States.

Non-compliant condition means that an OTP is not meeting applicable accreditation or certification standards, or if a survey of the OTP by the Accreditation Body demonstrates that such standards are not being met. Non-compliant conditions are further defined as follows*:*

(1) Minor: a non-compliant condition is a condition that meets one or more of the following:

No actual harm with potential for minimal harm: A deficiency that has the potential for causing no more than a minor negative impact on patients or employees.

No actual harm with potential for more than minimal harm that is not immediate jeopardy: Noncompliance that results in the potential for no more than minimal physical, mental, and/or psychosocial harm to the patient or employee and/or that result in minimal discomfort to patients or employees of the facility but has the potential to result in more than minimal harm that is not immediate jeopardy.

Actual harm that is not immediate: Noncompliance that results in actual harm to patients or employees that is not immediate jeopardy.

Scope is isolated when one or a limited number of patients or employees is/are affected and/or a very limited area or number of locations within the facility are affected.

Scope is a pattern when more than a very limited number of patients or employees are affected, and/or the situation has occurred in more than a limited number of locations, but the locations are not dispersed throughout the facility.

(2) Significant: a non-compliant condition is a condition that meets one or more of the following:

No actual harm with potential for more than minimal harm that is not immediate jeopardy: Noncompliance that results in the potential for no more than minimal physical, mental, and/or psychosocial harm to patients or employees and/or that result in minimal discomfort to patients or employees of the facility but has the potential to result in more than minimal harm that is not immediate jeopardy.

Actual harm that is not immediate: Noncompliance that results in actual harm to patients or employees that is not immediate jeopardy.

Immediate jeopardy to health or safety: Noncompliance that results in immediate jeopardy to patient or employee health or safety in which immediate corrective action is necessary because the provider's noncompliance is likely to cause serious injury, harm, impairment or death to a patient receiving care or an employee of the facility.

Scope is isolated when one or a limited number of patients or employees is/are affected and/or a very limited area or number of locations within the facility are affected.

Scope is a pattern when more than a very limited number of patients or employees are affected, and/or the situation has occurred in more than a limited number of locations, but the locations are not dispersed throughout the facility.

Scope is widespread when the problems causing the deficiency are pervasive (affect many locations) throughout the facility and/or represent a systemic failure that affected, or has the potential to affect, a large portion or all of the patients or employees.

Opioid Treatment Program or OTP means a program engaged in OUD treatment of individuals with MOUD registered under 21 U.S.C. 823(h)(1).

Opioid Treatment Program certification means the process by which the Secretary determines that an OTP applicant is qualified to provide Opioid Use Disorder treatment under the federal opioid use disorder treatment standards described in § 8.12.Opioid Use Disorder or OUD means a cluster of cognitive, behavioral, and physiological symptoms associated with a problematic pattern of opioid use that continues despite clinically significant impairment or distress within a 12-month period.

Opioid Use Disorder treatment means the dispensing of MOUD, along with the provision of a range of medical and behavioral health services, as clinically necessary and based on an individualized assessment and a mutually agreed-upon care plan, to an individual to alleviate the combination of adverse medical, psychological, or physical effects associated with an OUD.

Patient, for purposes of this part, means any individual who receives continuous treatment or withdrawal management in an OTP.

Physical and behavioral health services include services such as medical and psychiatric screening, assessments, evaluations, examinations, and interventions, counseling, health education, peer support services, and social services (e.g., vocational and educational guidance, employment training), that are intended to help patients receiving care in OTPs achieve and sustain remission and recovery.

Practitioner, for purposes of this part, means a health care professional who is appropriately licensed by a state to prescribe and/or dispense medications for opioid use disorders and, as a result, is authorized to practice within an OTP.

Program sponsor means the person named in the application for certification described in § 8.11(b) as responsible for the operation of the OTP and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, behavioral health, or social services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall ensure that an actively licensed physician occupies the position of medical director within an OTP.

Recovery support services means:

(1) Recovery is the process of change through which people improve their health and wellness, live self-directed lives, and strive to reach their full potential.

(2) Recovery support *services* can include, but are not limited to, community-based recovery housing, peer recovery support services, social support, linkage to and coordination among allied service providers and a full range of human services that facilitate recovery and wellness contributing to an improved quality of life. The services extend the continuum of

care by strengthening and complementing substance use disorder (SUD) treatment interventions in different settings and stages.

Split dosing means dispensing of a single dose of MOUD as separate portions to be taken within a 24-hour period. Split dosing is indicated among, but not limited to, those patients who: possess a genetic variant which increases methadone metabolism; concurrently take other medications or drink alcohol that also induce hepatic enzymes leading to more rapid metabolism of methadone; who are pregnant; or for whom methadone or buprenorphine are being used to treat a concurrent pain indication in addition to the diagnosis of OUD. This leads to more stable, steady-state medication levels.

State Opioid Treatment Authority (SOTA) is the agency designated by the Governor of a state, or other appropriate official designated by the Governor, to exercise the responsibility and authority within the state or Territory for governing the treatment of OUD with MOUD in OTPs.

Telehealth or telemedicine, for purposes of this part, is the delivery and facilitation of health and health-related services including medical care, counseling, practitioner, provider and patient education, health information services, and self-care via telecommunications and digital communication technologies. This includes Health Insurance Portability and Accountability Act (HIPAA)-compliant video and audio-only communication platforms.

Withdrawal management means the dispensing of a MOUD in decreasing doses to an individual to alleviate adverse physical effects incident to withdrawal from the continuous or sustained use of an opioid and as a method of bringing the individual to an opioid-free state within such period. Long-term withdrawal management refers to the process of medication

tapering that exceeds 30 days.

Accreditation Body Standards	Subject: OTP Accreditation Body Responsibilities

Title: Accreditation Body Responsibilities	Number: 42 CFR 8.4
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Vision Statement:

Our Accrediting Body (AB) is committed to supporting the vision of the Washington State Department of Health (DOH) in promoting equity and optimal health for all. Our AB contributes to this vision by providing state and federal inspection and investigation activities for state licensed and federally certified opioid treatment programs throughout the state of Washington to ensure they meet applicable standards. DOH recognizes and respects Tribal sovereignty and will work with Tribal Leaders when conducting reviews of OTPs operated by Indian Tribes.

Accreditation Statement:

Our AB strives to promote culturally competent, patient-centered care that incorporates evidence-based practices. When approving OTP applications and conducting onsite inspections and investigations, the Washington State Department of Health will ensure that all agencies provide services based on the standards set forth in the Federal Guidelines for Opioid Treatment Programs, effective April 2, 2024, as well as Washington State Behavioral Health Agency rules, as a condition of accreditation. All OTP programs must comply with all standards in accordance with 42 CFR Part 8 and all applicable rules under WAC 246-341.

42 CFR 8.4

(a) Accreditation surveys and for cause inspections. (1) Accreditation Bodies shall conduct routine accreditation surveys for initial accreditation, and then at least every three years to allow for renewal of certification.

(2) Accreditation Bodies must agree to conduct for-cause inspections upon the request of the Secretary.

(3) Accreditation decisions shall be fully consistent with the policies and procedures submitted as part of the approved Accreditation Body application.

(b) Response to noncompliant programs. (1) If an Accreditation Body receives or discovers information that suggests that an OTP is not meeting applicable accreditation or certification standards established or authorized under this part, or if a survey of the OTP by the Accreditation

Body demonstrates that such standards are not being met, the Accreditation Body shall, within 60 days following discovery of the non-compliant condition(s) or applicable survey date:

(i) Provide written notice to the OTP that identifies each area of non-compliance, categorizes each non-compliant condition as either “minor” or “significant” as determined by the Accrediting Body, and requires the OTP to take corrective action to address the area(s) of non-compliance within a schedule, not to exceed 180 days, that the Accrediting Body deems appropriate based on the severity of the non-compliant conditions; and

(ii) Provide the Secretary with a copy of the written notice required under paragraph (b)(1)(i) of this section.

(2) Once an Accreditation Body provides an OTP with the notice described in paragraph (b)(1)(i) of this section, it shall verify the implementation of the corrective measures by the OTP within the specified schedule. Within 30 days following the last day of the specified schedule, the Accreditation Body shall provide written notice to the Secretary regarding whether the OTP has implemented the corrective measures.

(3) OTPs that meet the requirements of § 8.12 but are only required to correct minor non-compliant conditions shall be granted a three-year accreditation, beginning from the end date of the current and expiring accreditation period. Minor non-compliant conditions, found at the time of the survey that are not resolved, as determined by the Accreditation Body, within the OTP's three-year accreditation period and that remain areas of non-compliance during the OTP's subsequent three-year accreditation renewal survey, shall automatically be categorized as “significant” non-compliant conditions for purposes of the renewal survey and must be corrected in accordance with paragraph (b)(1)(i) of this section.

(4) OTPs that are required to correct significant non-compliant conditions shall be granted a one-year accreditation, beginning from the end date of the current and expiring accreditation period. An OTP's accreditation must be revoked if it fails to correct significant non-compliant conditions within the schedule provided under paragraph (b)(1)(i) of this section. If an Accrediting Body verifies that an OTP has corrected the significant non-compliant conditions identified within the specified schedule, it shall extend the OTP's accreditation period by an additional two years.

(5) In cases of severe non-compliance with the requirements of § 8.12 that pose immediate risks to patient health and safety, the Accreditation Body shall inform the OTP and Secretary within 48 hours and provide a detailed written report of the non-compliance within 5 business days. The Accreditation Body shall give the OTP 30 days from the date of the non-compliance report to correct the non-compliance issue(s). A follow-up survey shall be conducted by the Accreditation Body within 30 days of the expected correction date to ensure successful remediation. Should the OTP not rectify the non-compliance within the 30-day period, the Accreditation Body shall revoke the OTP's accreditation. The Secretary will then make a decision regarding the OTP's certification in accordance with the procedures under § 8.13.

(c) Recordkeeping. (1) Accreditation Bodies shall maintain, and make available as requested by the Secretary, records of their accreditation activities for at least 5 years from the creation of the record. Such records must contain sufficient detail to support each accreditation decision made by the Accreditation Body.

(2) Accreditation Bodies shall establish procedures to protect confidential information collected or received in their role as Accreditation Bodies that are consistent with, and that are designed to ensure compliance with, all federal and state laws, including 42 CFR part 2.

(i) Information collected or received for the purpose of carrying out Accreditation Body responsibilities shall not be used for any other purpose or disclosed, other than to the Secretary or its duly designated representatives, unless otherwise required by law or with the consent of the OTP. The DOH interacts with other state agencies and may communicate pertinent information related to OTPs to one of these agencies without express permission from SAMHSA or the OTP. 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. The AB will require each employee to comply with DOH's confidential information policy (17.005) to protect confidential information collected or received in their role as an accreditation body. DOH will ensure compliance with all applicable federal and state laws related to patient confidential information.

(ii) Nonpublic information that the Secretary shares with the Accreditation Body concerning an OTP shall not be further disclosed except with the written permission of the Secretary or as needed to ensure notification of and communication of any issues with the State Opioid Treatment Authority (SOTA), the Drug Enforcement Administration (DEA), or other offices within the DOH.

(d) Reporting. (1) Accreditation Bodies shall provide the Secretary any documents and information requested by the Secretary within 5 business days of receipt of the request unless there is a different timeline agreed to by both SAMHSA and the AB.

(2) Accreditation Bodies shall submit a summary of the results of each accreditation survey to the Secretary and the SOTA within 90 days following the survey visit. Such summaries shall contain sufficient detail to justify the accreditation action taken. The summary will be a copy of the statement of deficiencies report prepared for an agency and will be submitted to the SAMHSA regional compliance officer and/or the SAMHSA general inbox.

(3) Accreditation Bodies shall provide the Secretary a list of each OTP surveyed, and the identity of all individuals involved in the conducting and reporting of survey results.

(4) Accreditation Bodies shall submit to the Secretary the name of each OTP for which the Accreditation Body accredits conditionally, denies, suspends, or revokes accreditation, and the basis for the action, within 48 hours of the action.

(5) Notwithstanding any reports made to the Secretary under paragraphs (d)(1) through (4) of this section, each Accreditation Body shall submit to the Secretary 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.

(6) All reporting requirements listed in this section shall be provided to the Secretary at the address specified in § 8.3(b).

(e) Complaint response. Accreditation Bodies shall have policies and procedures in place to respond to complaints received from the Secretary, patients, facility staff, and others within 5 business days from the receipt of the complaint. Accreditation Bodies shall also agree to notify the Secretary within 5 business days of receipt of a complaint from a patient, facility, staff or others, and to inform the Secretary of their response to the complaint.

(f) Modifications of accreditation elements. Accreditation Bodies shall obtain the Secretary's written authorization prior to making any substantive (i.e., noneditorial) change in accreditation elements.

(g) Conflicts of interest. The Accreditation Body shall maintain and apply policies and procedures that the Secretary has approved in accordance with § 8.3 to reduce the possibility of actual conflict of interest, or the appearance of a conflict of interest, on the part of individuals who act on behalf of the Accreditation Body. Individuals who participate in accreditation surveys or otherwise participate in the accreditation decision or an appeal of the accreditation decision, as well as their spouses and minor children, shall not have a financial interest in the OTP that is the subject of the accreditation survey or decision. Each employee will comply with DOH’s ethics policy (07.015) as it pertains to conflicts of interest.

(h) Accreditation teams. (1) Department of Health (DOH) team members conducting opioid treatment program (OTP) accreditation surveys and complaint investigations will consist of healthcare professionals with training in opioid use disorder treatment. Training will include attendance at the regularly scheduled American Association for the Treatment of Opioid Dependence (AATOD) conference as well as other trainings and conferences pertinent to OTP work. The team will include certified addictions registered nurses (CARN). The team will also have access to a licensed physician or physicians who will be available for consultation on any medical issues. The team may also utilize non-clinician members to conduct inspections and investigations of OTPS with oversight by a healthcare professional. An inspection team will include at least two healthcare professionals whose combined expertise includes: (i) The dispensing and administration of medications subject to control under the Controlled Substances Act (21 U.S.C. 801 et seq.); (ii) Medical issues relating to the dosing and administration of MOUD for the treatment of OUD; (iii) Psychosocial counseling of individuals receiving OUD treatment; and (iv) Organizational and administrative issues associated with OTPs. The accreditation body will consider the size of the OTP, the OTP's accreditation history, and other factors that may impact the size and makeup of the inspection team.

(2) Members of the accreditation team must be able to recuse themselves at any time from any survey in which either they or the OTP believes there is an actual conflict of interest or the appearance of a conflict of interest. Conflict or perceived conflict of interest must be documented by the Accreditation Body and made available to the Secretary.

(i) Accreditation fees. There is no fee for an OTP agency to have Washington State as their accreditation body.

Accreditation Body Standards	Subject: OTP Accreditation Requirements

Title: Opioid Treatment Program Certification	Number: 42 CFR 8.11
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

CFR 8.11

(a) General. (1) An OTP must be the subject of a current, valid certification from the Secretary to be considered qualified by the Secretary under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(h)(1)) to dispense MOUD in the treatment of OUD. An OTP must be determined to be qualified under section 303(g)(1) of the Controlled Substances Act and must be determined to be qualified by the Attorney General under section 303(g)(1), to be registered by the Attorney General to dispense MOUD to individuals for treatment of OUD.

(2) To obtain certification from the Secretary, an OTP must meet the federal opioid use disorder treatment standards in § 8.12, must be the subject of a current, valid accreditation by an Accreditation Body or other entity designated by the Secretary and must comply with any other conditions for certification established by the Secretary.

(3) OTPs are expected to maintain certification with the Secretary and to comply with any other conditions for certification established by the Secretary. Certification shall be granted for a term not to exceed 3 years, except that certification may be renewed during the final certification year if the OTP applies for certification renewal in accordance with the steps outlined in paragraph (a)(4) of this section.

(4) OTPs which satisfy the criteria for certification under this section may apply for renewal of their certification. OTPs are expected to apply for certification renewal during the final year of the OTP's certification period. OTPs should take steps to ensure that administrative tasks associated with renewal are completed before the OTP's certification expires. OTPs may apply for certification renewal in accordance with the procedures as outlined in paragraph (b) of this section. If an OTP

anticipates any delays in routine certification renewal, an extension may be requested by submitting to the Secretary a statement justifying the extension in accordance with paragraph (e) of this section.

(5) OTPs that are certified and are seeking certification renewal, and who have been granted accreditation for one year by an Accreditation Body as provided under § 8.4(b)(1)(iii), may receive a conditional certification for one year unless the Secretary determines that such conditional certification would adversely affect patient health. An OTP must obtain a standard 3-year certification, as described in paragraph (a)(3) of this section, within the 1-year conditional certification period. If standard accreditation is not obtained by the OTP within the 1-year conditional certification period, the OTP's conditional certification will lapse, and the Attorney General will be notified that the OTP's registration should be revoked.

(6) OTPs whose certification has expired, and who seek re-certification, will be considered “new” programs and will be required to apply for provisional certification in accordance with paragraph (d) of this section.

(b) Application for initial or renewal certifications and re-certification. Applications for certification must be submitted by the OTP using form SMA–162. The application for initial or renewal of certification shall include, as determined by the Secretary:

(1) A description of the current accreditation status of the OTP;

(2) A description of the organizational structure of the OTP;

(3) The names of the persons responsible for the OTP;

(4) The addresses of the OTP and of each medication unit or other facility under the of the OTP;

(5) The sources of funding for the OTP and the name and address of each governmental entity that provides such funding;

(6) A statement that the OTP will comply with the conditions of certification set forth in paragraph (g) of this section; and

(7) The application shall be signed by the program sponsor who shall certify that the information submitted in the application is truthful and accurate.

(8) Applications for re-certification shall include an explanation of why the OTP's most recent certification expired and information regarding the schedule for an accreditation survey.

(c) Action on application. (1) Following the Secretary's receipt of an application for certification of an OTP, and after consultation with the appropriate state authority regarding the qualifications of the applicant, the Secretary may grant the application for certification, or renew an existing certification, if the Secretary determines that the OTP has satisfied the requirements for certification or renewal of certification in this section.

(2) The Secretary may deny the application if the Secretary determines that:

(i) The application for certification is deficient in any respect;

(ii) The OTP will not be operated in accordance with the federal opioid use disorder treatment standards established under § 8.12;

(iii) The OTP will not permit an inspection or a survey to proceed, or will not permit in a timely manner access to relevant records or information; or

(iv) The OTP has made misrepresentations in obtaining accreditation or in applying for certification.

(3) Within 5 days after it reaches a final determination that an OTP meets the requirements for certification in this section, the Secretary will notify the Drug Enforcement Administration (DEA) that the OTP has been determined to be qualified to provide OUD treatment under section 303(g)(1) of the Controlled Substances Act.

(d) Provisional certification. New OTPs that have not received the Secretary's certification previously, except as provided in paragraph (a)(6) of this section, who are applying for certification from the Secretary, and who have applied for accreditation with an Accreditation Body, are eligible to receive provisional certification for up to 1 year. To receive provisional certification, an OTP shall submit the information required by paragraph (b) of this section to the Secretary along with a statement identifying the Accreditation Body to which the OTP has applied for accreditation, the date on which the OTP applied for accreditation, the dates of any accreditation surveys that have taken place or are expected to take place, and the expected schedule for completing the accreditation process. Provisional certification for up to 1 year will be granted, following receipt of the information described in this paragraph (d), unless the Secretary determines that patient health would be adversely affected by the granting of provisional certification.

(e) Requirements for certification. (1) OTPs shall comply with all pertinent federal and state laws and regulations. Nothing in this part is intended to limit the authority of state and, as appropriate, local governmental entities to regulate the use of MOUD in the treatment of OUD. The provisions of this section requiring compliance with requirements imposed by state law, or the submission of applications or reports required by the state authority, do not apply to OTPs operated directly by the Department of Veterans Affairs, the Indian Health Service, or any other department or agency of the United States.

(2) OTPs shall allow, in accordance with federal controlled substances laws and federal confidentiality laws, inspections and surveys by duly authorized employees of the Department of Health and Human Services (HHS) or Substance Abuse and Mental Health Services Administration (SAMHSA), by Accreditation Bodies, by the Drug Enforcement Administration (DEA), and by authorized employees of any other federal governmental entity with legal authority to conduct inspections or surveys on an OTP's premises.

(3) Disclosure of patient records maintained by an OTP is governed by the provisions of 42 CFR part 2 and 45 CFR parts 160 and 164, and every program must comply with these regulations, as applicable. Records on the receipt, storage, and distribution of MOUD are also subject to inspection under Federal controlled substances laws and under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.). Federally sponsored treatment programs are subject to applicable federal confidentiality statutes.

(4) An OTP or medication unit or any part thereof, including any facility or any individual, shall permit a duly authorized employee of the Department of Health and Human Services or SAMHSA to have access to and to copy all records on the use of MOUD in accordance with the provisions of 42 CFR part 2 and 45 CFR parts 160 and 164.

(5) OTPs shall notify the Secretary in writing within 3 weeks of any replacement or other change in the status of the program sponsor or medical director.

(6) OTPs shall comply with all regulations enforced by the DEA under 21 CFR chapter II and must be registered by the DEA before administering or dispensing MOUD.

(7) OTPs must operate in accordance with federal opioid use disorder treatment standards and approved accreditation elements.

(f) Conditions for interim treatment program approval. (1) Before an OTP may provide interim treatment, the OTP must receive the approval of both the Secretary and the SOTA of the state in which the OTP operates.

(2) Before the Secretary may grant such approval, the OTP must provide the Secretary with documentation from the SOTA of the state in which the OTP operates demonstrating that:

(i) Such officer does not object to the providing of interim treatment in the state;

(ii) The OTP seeking to provide such treatment is unable to provide access for patients in a comprehensive treatment program within a reasonable geographic area within 14 days of the time patients seek treatment for OUD;

(iii) The authorization of the OTP to provide interim treatment will not otherwise reduce the capacity of comprehensive treatment programs in the state to admit individuals (relative to the date on which such officer so certifies); and

(iv) OTPs providing interim treatment will arrange for each individual's transfer to a comprehensive treatment program no later than 180 days from the date on which each individual first requested treatment. Individuals enrolled in interim treatment shall not be discharged without the approval of an OTP practitioner, who shall consider on-going and patient-centered treatment needs, which are to be documented in the patient record, while awaiting transfer to a comprehensive treatment program.

(3) The Secretary will provide notice to the OTP denying or approving the request to provide interim treatment. The OTP shall not provide such treatment until it has received such notice from the Secretary.

(g) Exemptions. An OTP may, at the time of application for certification or any time thereafter, request from the Secretary exemption from the regulatory requirements set forth under this section and § 8.12. An example of a case in which an exemption might be granted would be for a private practitioner who wishes to treat a limited number of patients in a non-metropolitan area with few physicians and no OUD treatment services geographically accessible, and requests exemption from some of the staffing and service standards. The OTP shall support the rationale for the exemption with thorough documentation, to be supplied in an appendix to the initial application for certification or in a separate submission. The Secretary will approve or deny such exemptions at the time of application, or any time thereafter, if appropriate. The Secretary shall consult with the appropriate state authority prior to taking action on an exemption request.

(h) Medication units, long-term care facilities and hospitals. (1) Certified OTPs may establish medication units that are authorized to dispense MOUD. Before establishing a medication unit, a certified OTP must notify the Secretary by submitting form SMA–162. The OTP must also comply with the provisions of 21 CFR part 1300 before establishing a medication unit. Medication units shall comply with all pertinent state laws and regulations. Medication units include both mobile and brick and mortar facilities.

(2) Specifically, any services that are provided in an OTP may be provided in the medication unit, assuming compliance with all applicable federal, state, and local law, and the use of units that provide appropriate privacy and have adequate space.

(3) Certification as an OTP under this part is not required for the initiation or continuity of medication treatment or withdrawal management of a patient who is admitted to a hospital, long-term care facility, or correctional facility, that is registered with the Drug Enforcement Administration as a hospital/clinic, for the treatment of medical conditions other than OUD, and who requires treatment of OUD with methadone during their stay, when such treatment is permitted under applicable federal law.

(i) The term “long-term care facility” is defined in § 8.2. Nothing in this section is intended to relieve hospitals, or long-term care facilities and correctional facilities that are registered with the Drug Enforcement Administration as a hospital/clinic, from their obligations to obtain appropriate registration from the Attorney General, under section 303(g) of the Controlled Substances Act. Treatment provided under this section should always comply with applicable federal laws.

Additional Accreditation Body Standards

Mobile Medication Units (MMU)

In addition to complying with the CFR and all pertinent state laws and regulations, OTPS must ensure:

There are policies and procedures developed, implemented, reviewed, and updated as needed specific to the mobile unit that address this service location type including, but not limited to, types of services offered, safety and security of the unit, safety and security of medication during transport in the MMU as well as between the MMU and storage at the OTP, safety and security of patients and personnel in the MMU and at the location of service, maintenance of the MMU, ADA accessibility of the unit and the unit location(s), and training requirements for staff that will be working in the MMU setting.

Fixed Site Medication Units

In addition to complying with the CFR and all pertinent state laws and regulations, OTPS must ensure:

There are policies and procedures developed, implemented, reviewed, and updated as needed specific to the fixed site medication unit that address this service location type including, but not limited to, types of services offered, safety and security of the unit, safety and security of medication, safety and security of patients and personnel at the site, maintenance of the site, ADA accessibility of the location, and training requirements for staff that will be working in the fixed site medication unit setting.

Accreditation Body Standards	Subject: OTP Accreditation Requirements

Title: Administrative Organizational Structure	Number: 42 CFR 8.12 (a) (b)
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (a)

OTPs must provide treatment in accordance with the standards in this section and must comply with these standards as a condition of certification.

42 CFR 8.12 (b)

Administrative and organizational structure.

(1) An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent federal, state, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements outlined in this part.

(2) The medical director shall assume responsibility for all medical and behavioral health services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP complies with all applicable federal, state, and local laws and regulations.

Additional Accreditation Body Standards

Medical Director Requirements – Qualifications

The medical director must be a physician licensed to practice medicine in Washington State. If there is a change of medical director, the program is responsible for formal notification to the Washington State AB within 3 weeks of the change.

Program Sponsor Requirements

The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director. If there is a change of program sponsor, the program is responsible for formal notification to SAMHSA and Washington State AB within 3 weeks of the change.

Emergency Preparedness

The OTP must ensure that policies and procedures are developed, implemented, reviewed, and updated as needed to manage medical and nonmedical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public at all locations associated with the OTP, including the main OTP, any MMUs, fixed site medication units, or other related locations. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, and natural disasters likely to occur in the facility's geographic area. The facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following at a minimum: (i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of where to go when the facility or geographic area of the facility must be evacuated and whom to contact if an emergency occurs while the patient is not in the facility. (ii) Ensuring that, at a minimum, nursing staff maintain current CPR certification; (3) Emergency plans. The facility must— (i) Have a plan to obtain emergency medical system assistance when needed; and (ii) Evaluate at least annually the effectiveness of emergency and disaster plans and update them as necessary.

Facility offices, waiting areas, and facility entrance doors should display the names and telephone number of individuals (e.g., physicians, hospitals, emergency medical technicians) who should be contacted in case of emergency or utilize 911 or similar local emergency resources. A mechanism to address patient medical or psychiatric emergencies occurring outside of program hours of operation must be provided. Typically, this includes the establishment of an emergency contact system to obtain dosage levels and other pertinent patient information on a 24-hour, 7-days-a-week basis, as appropriate under confidentiality regulations.

In the event of an emergency leading to the temporary closure of a program, an up-to-date plan for emergency administration of medications should be maintained. An alternative dosing location should be secured in advance because DEA registration of the new location may be required if it is not already an OTP. Use of the Central Registry as part of the emergency response is expected. Facilities should have the capability to respond to emergencies on a 24-hour basis. Designated staff persons should have access to a record of active patients, their medication dose, schedule, and last dose administered to provide accurate dosing at an alternative location. In addition, the plan should include a mechanism for informing patients of emergency arrangements, alternative dosing locations; and a procedure for notifying SAMHSA, DEA, and state authorities of the situation.

Voluntary and Involuntary Program Closure

OTPs must establish procedures that ensure continuity of care for patients in the event of either a voluntary or involuntary closure of programs. The plan should include steps for the notification and orderly transfer of patients, records, and assets to other programs or practitioners and the procedure for securing and maintaining patient records for a specified period under Washington State and federal regulations.

Accreditation Body Standards	Subject: OTP Accreditation Requirements

Title: Continuous Quality Improvement	Number: 42 CFR 8.12 (c) (1)
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (c)

(1) An OTP must maintain current quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes.

Additional Accreditation Body Standards

An OTP must maintain a current robust quality assurance and performance improvement (QAPI) plan.

Elements of a robust QAPI plan should include the following:

Identification of patient treatment outcomes.

Measurement and monitoring of patient treatment outcomes and processes should occur regularly, at least quarterly, to inform quality improvement.

A description of steps to be implemented to achieve patient outcome goals.

Provisions for regular and continuous staff education.

Up-to-date, individualized staff development plans.

Review and recertification of program policies and procedures at least annually.

Evaluation and modification, if needed, of the program diversion control plan.

Patient input into program policies and procedures regarding patient and community concerns.

Development, implementation, and corrective response to patient satisfaction surveys.

Adherence to universal or standard infection control precautions as promulgated by the Centers for Disease Control and Prevention (CDC).

A list of staff involved in quality assurance and quality control meetings or workgroups. The plan should include multiple staff involvement in quality plan decision making.

The OTP is responsible for identifying the outcome goals of treatment. Measurement and monitoring of patient treatment outcomes and processes should occur regularly at least quarterly to inform quality improvement.

The continuous monitoring of an OTP's policies, procedures, practices, and patient outcomes serves to improve operations, customer service, patient satisfaction, and, ultimately, treatment outcomes. An OTP shall have a continuous quality improvement plan. The plan may include topics such as: a statement of the program's patient outcome goals; a description of steps to be implemented to achieve patient outcome goals, provisions for staff education, individualized staff development plans; review and recertification of agency policies and procedures at least annually, evaluation and modification, if needed of the diversion control plan; development, implementation, and corrective response to patient satisfaction surveys; and adherence to universal standard infection control precautions as promulgated by the Centers for Disease Control and Prevention (CDC).

An OTP shall conduct measurement and monitoring of patient treatment outcomes and processes regularly, for example, quarterly to inform quality improvement. Treatment outcomes may include measuring and monitoring patient use of illicit opioids, illegal drugs, marijuana, and the problematic use of alcohol and prescription medicines; criminal activities and involvement with the criminal justice system; quality of life such as physical and mental health and functional status; retention in treatment; employment status, and engagement in recovery support services.

Significant incidents or adverse events that may require preparation, reporting, investigation, or corrective action will vary by program. These events may include accidental injury or violence on the premises; medication errors; harm to family members or others from ingesting a patient's medication; selling drugs on the premises; medication diversion; harassment or abuse of patients by staff; unexpected or suspicious deaths; deaths related to overdose or medication interactions; or any other injury or death that raises individual, family, community, or public concern.

In case a critical incident occurs, an OTP's established procedures must include protocols for documentation and investigation of the incident, implementation of any corrective actions, and ongoing monitoring of the effectiveness of corrective actions to include full documentation of the incident, investigation, review of the situation surrounding the incident, and ongoing monitoring of any corrective actions until their effectiveness is established.

Accreditation Body Standards	Subject: OTP Accreditation Requirements

Title: Diversion Control Plan	Number: 42 CFR Part 8.12 (c) (2)
Approved Date: **October 9, 2024**	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR Part 8.12

(2) An OTP must maintain a current "Diversion Control Plan" or "DCP" as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of dispensed MOUD, and that assigns specific responsibility to the OTP providers and administrative staff for carrying out the diversion control measures and functions described in the DCP.

Additional Accreditation Body Standards

The OTP must ensure that a diversion control plan (DCP) is developed, implemented, reviewed, and updated. The goal of a DCP is to reduce the scope and significance of diversion and its impact on communities. Each OTP's DCP will make every effort to balance diversion control against the therapeutic needs of the individual patient. DCPs will address at least four general areas of concern including program environment, dosing, and take-home medication, prevention of multiple program enrollment, and prescription medication misuse.

OTPs will have a DCP that addresses the steps that the OTP will take to minimize diversion throughout the program environment. This may include steps such as video surveillance or a system of rounds, with or without security personnel or other staff walking around the interior and exterior of the clinic regularly. The DCP will include consultation with community law enforcement to identify and respond to possible diversion issues.

At a minimum, OTPs will use patient surveys to advise on program policies and procedures and how they are implemented. Patients can make important contributions to problem-solving and help balance diversion control strategies with the needs of patients.

OTPs will incorporate the prevention of multiple program enrollment in their DCP. Reasonable measures will be taken to prevent patients from enrolling in treatment provided by more than one clinic or individual practitioner. An OTP, after obtaining patient consent, will contact other OTPs within a reasonable geographic distance (100 miles) and utilize the Central Registry to verify that a patient is not enrolled in another OTP. Consulting the PDMP at admission and periodically (for example, every three months) thereafter should be one of the tools used in the ongoing assessment of the patient. Evidence of these verifications should be in the patient record.

Accreditation Body Standards	Subject: OTP Licensing and Certification

Title: Staff Credentials	Number: 42 CFR 8.12 (d)
Approved Date: **October 9, 2024**	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (d)

Each person engaged in the treatment of OUD must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. All practitioners and other licensed/certified health care providers, including counselors, must comply with the credentialing and maintenance of licensure and/or certification requirements of their respective professions.

Additional Accreditation Body Standards

Personnel Credentials and Development

Each staff position in an OTP should have a specific and detailed position description that outlines the duties assigned to the position, the qualifications required to enter into the position, and the training and performance standards required to remain in the position. Before providing care to patients, staff members should receive initial education that is specific to the medication-assisted treatment(s) used in the OTP and tailored to the patient populations served. In addition, continuing education in opioid addiction treatment and related subjects, along with resources for problem-solving and troubleshooting, should be accessible. The position descriptions and assigned duties for both licensed clinical and medical professionals should respect the scope of practice assigned to each licensed

profession by the respective staff licensing authority. All licensed individuals employed in OTPs must comply at all times with the licensing and credentialing requirements of their respective professions.

Personnel File

A personnel file should be maintained for each staff person. The file should contain employment application data, date of employment, updated licensing and credentialing information, detailed job descriptions, performance evaluations, a background check, and other employment and credentialing data deemed appropriate. All staff training will be documented in each personnel file. Each employee will have a personalized annual training plan. Documentation of completed training can include a record of attendance and certificates of completion.

Accreditation Body Standards	Subject: OTP Accreditation

Title: Comprehensive Treatment	Number: 42 CFR 8.12 (e) (1)
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (e) (1)

1. An OTP shall maintain current procedures designed to ensure that patients are admitted to treatment by qualified personnel who have determined, using accepted medical criteria, that: The person meets diagnostic criteria for a moderate to severe OUD; the individual has an active moderate to severe OUD, or OUD in remission, or is at high risk for recurrence or overdose. Such decisions must be appropriately documented in the patient's clinical record. In addition, a health care practitioner shall ensure that each patient voluntarily chooses treatment with MOUD and that all relevant facts concerning the use of MOUD are clearly and adequately explained to the patient, and that each patient provides informed consent to treatment.

Additional Accreditation Body Standards

Informed Consent (Voluntary Choice for MOUD Treatment)

Informed consent must be completed by a medical provider. Appropriate counseling and informed decision-making between provider and patient must take place and be documented. Informed consent includes informing each patient about all treatment procedures, services, and other policies and regulations throughout the course of treatment. Consent for MOUD must also ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient. The OTP must ensure that before medicating the patient the physician receives voluntary, written, program-specific informed consent to treatment with the specific pharmacotherapy ordered by the physician. The provider will document in the record the medication selected, the rationale for prescribing it, and the expected impact of pharmacotherapy. They will identify the education provided to the patient about their

health conditions and any potential interactions or complications that may occur with the planned medication-assisted treatment.

Accreditation Body Standards	Subject: OTP Accreditation

Title: Comprehensive treatment for persons under the age of 18	Number: 42 CFR 8.12 (e) (2)
Approved Date: October 9, 2024	Approved by: SAMHSA

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (e) (2)

Except in States where state law grants persons under 18 years of age the ability to consent to OTP treatment without the consent of another, no person under 18 years of age may be admitted to OTP treatment unless a parent, legal guardian, or responsible adult designated by the relevant state authority consents in writing to such treatment.

Additional Accreditation Body Standards

Treatments of Adolescents

Per RCW 71.34.530, any adolescent may request and receive outpatient treatment without the consent of the adolescent's parent. Parental authorization, or authorization from a person who may consent on behalf of the minor pursuant to RCW 7.70.064, is required for outpatient treatment of a minor under the age of thirteen.

Accreditation Body Standards	Subject: OTP Accreditation

Title: Withdrawal management	Number: 42 CFR 8.12 (e) (3)
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (e) (3)

An OTP shall maintain current procedures that are designed to ensure that those patients who choose to taper from MOUD are provided the opportunity to do so with informed consent and at a mutually agreed-upon rate that minimizes taper-related risks. Such consent must be documented in the clinical record by the treating practitioner.

Additional Accreditation Body Standards

Informed Consent (Withdrawal Management)

Regardless of whether medically supervised withdrawal is conducted with or against medical advice, a very careful review of the risks and benefits of withdrawal from maintenance therapy must be provided, and thorough informed consent obtained from patients choosing medically supervised withdrawal. Informed consent must be completed by a medical provider.

Medically Supervised Withdrawal

Regardless of the reason for withdrawal, the goal is to follow a withdrawal schedule that is based on sound clinical judgment and close patient monitoring. A schedule for medically supervised withdrawal must be documented by the physician, to include the clinical decision-making process. The patient's condition during this medically supervised withdrawal and all steps to address it should be documented in the patient's record. Withdrawal services must include aftercare plans that offer a variety of supportive options as part of the transition from opioid agonist therapy. The care and aftercare plans should always include a strategy to transition back to medication-assisted treatment with antagonist or agonist therapy if needed.

Accreditation Body Standards	Subject: OTP Accreditation

Title: Required Services	Number: 42 CFR 8.12 (f) (1)
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (f) (1)

OTPs shall provide adequate medical, counseling, vocational, educational, and other screening, assessment, and treatment services to meet patient needs, with the combination and frequency of services tailored to each individual patient based on an individualized assessment and the patient's care plan that was created after shared decision making between the patient and the clinical team. These services must be available at the primary facility, except where the program sponsor has entered into a documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

Accreditation Body Standards	Subject: OTP Accreditation

Title: Initial Medical Examination	Number: 42 CFR 8.12 (f) (2)
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (f) (2)

(i) OTPs shall require each patient to undergo an initial medical examination. The initial medical examination is comprised of two parts:

A screening examination to ensure that the patient meets criteria for admission and that there are no contraindications to treatment with MOUD; and

(B) A full history and examination, to determine the patient's broader health status, with lab testing as determined to be required by an appropriately licensed practitioner. A patient's refusal to undergo lab testing for co-occurring physical health conditions should not preclude them from access to treatment, provided such refusal does not have potential to negatively impact treatment with medications.

(ii) Assuming no contraindications, a patient may commence treatment with MOUD after the screening examination has been completed. Both the screening examination and full examination must be completed by an appropriately licensed practitioner. If the licensed practitioner is not an OTP practitioner, the screening examination must be completed no more than seven days prior to OTP admission. Where the examination is performed outside of the OTP, the written results and narrative of the examination, as well as available lab testing results, must be transmitted, consistent with applicable privacy laws, to the OTP, and verified by an OTP practitioner.

(iii) A full in-person physical examination, including the results of serology and other tests that are considered to be clinically appropriate, must be completed within 14 calendar days following a patient's admission to the OTP. The full exam can be completed by a non-OTP practitioner, if the

exam is verified by a licensed OTP practitioner as being true and accurate and transmitted in accordance with applicable privacy laws.

(iv) Serology testing and other testing as deemed medically appropriate by the licensed OTP practitioner based on the screening or full history and examination, drawn not more than 30 days prior to admission to the OTP, may form part of the full history and examination.

(v) The screening and full examination may be completed via telehealth for those patients being admitted for treatment at the OTP with either buprenorphine or methadone, if a practitioner or primary care provider, determines that an adequate evaluation of the patient can be accomplished via telehealth. When using telehealth, the following caveats apply:

In evaluating patients for treatment with schedule II medications (such as Methadone), audio-visual telehealth platforms must be used, except when not available to the patient. When not available, it is acceptable to use audio-only devices, but only when the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications. The OTP practitioner shall review the examination results and order treatment medications as indicated.

(B) In evaluating patients for treatment with schedule III medications (such as Buprenorphine) or medications not classified as a controlled medication (such as Naltrexone), audio-visual or audio-only platforms may be used. The OTP practitioner shall review the examination results and order treatment medications as indicated.

Additional Accreditation Body Standards

Screenings and Preventative Care

Screening must be conducted for common co-occurring conditions even if the patient has no personal history of them. Screening must be offered onsite or by referral. Screening, testing, and treatment for infectious disease must include human immunodeficiency virus (HIV), Hepatitis B and C, Syphilis, and Tuberculosis (TB). Screening must identify the risk of undiagnosed conditions, including, but not limited to, sexually transmitted infections (STIs), cardio-pulmonary disease, and sleep apnea to determine what further diagnostic testing such as laboratory studies, a cardiogram, and others are needed. Positive screening results or identification of disease risks must have a management plan that is seen through to completion regardless of whether this is accomplished via services provided directly on-site or by referral and care coordination.

History and Examination

If the history and examination identifies any current health concerns, comorbidities, or other health-related risks, staff must provide referrals for care unless the identified service needs are provided onsite. If the services are provided on site, the OTP must ensure that policies and procedures related

to the provided services are developed, implemented, reviewed, and updated. If a patient reports a current pregnancy, confirmation of the pregnancy must be obtained.

Physical Signs of Addiction

A patient's physical examination must document the presence of clinical signs of addiction, such as old and fresh needle marks and an eroded or perforated nasal septum and/or a state or symptoms of intoxication, such as constricted or (pinpoint) pupils, slowed heart or respiratory rate, drowsiness, or signs of withdrawal, such as yawning, rhinorrhea, lacrimation, chills, restlessness, irritability, perspiration, piloerection, nausea, and diarrhea. There should be a high degree of concordance between the documented physical examination findings and the symptoms reported in the review of systems.

Substance Use Diagnosis and Severity

The OTP will ensure that the medical and counseling portions of the agency will perform independent assessments of each patient. The assessments will include a complete and comprehensive diagnosis, using the DSM 5 criteria, for all substances the patient currently endorses using. Staff will document in the patient record at the time of assessment which criteria the patient meets with examples from the patient's life.

Accreditation Body Standards	Subject: OTP Accreditation

Title of Policy: Special Services for Pregnant Patients	Number: 42 CFR 8.12 (f) (3)
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR (f) (3)

OTPs must maintain current policies and procedures that reflect the special needs and priority for treatment admission of patients with OUD who are pregnant. Pregnancy should be confirmed. Evidence-based treatment protocols for the pregnant patient, such as split dosing regimens, may be instituted after assessment by an OTP practitioner and documentation that confirms the clinical appropriateness of such an evidence-based treatment protocol. Prenatal care and other sex-specific services, including reproductive health services, for pregnant and postpartum patients, must be provided and documented either by the OTP or by referral to appropriate healthcare practitioners. Specific services, including reproductive health services, for pregnant and postpartum patients must be provided and documented either by the OTP or by referral to appropriate healthcare practitioners.

Additional Accreditation Body Standards

Pregnant Patient Discharge

If a pregnant patient requests a discharge from the OTP or if the OTP determines an administrative discharge is required for a pregnant patient, the OTP must educate the patient regarding the potential risks to both the patient and the fetus. The OTP must document in the patient record the attempts to transfer the patient to another OTP for care. If a patient is not discharged to the care of another OTP, the agency must identify the specific physician or authorized healthcare professional, as appropriate, to whom the patient is being discharged.

Informed Consent (Pregnant Patient)

Informed consent must be completed by a medical provider. Appropriate counseling and informed decision-making between provider and patient must take place and be documented. Informed consent includes informing the pregnant patient about all treatment procedures, services, and other policies and regulations throughout the course of treatment. Consent must also ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drug during pregnancy are clearly and adequately explained to the patient. The OTP will ensure that before medicating the patient the physician receives voluntary, written, program-specific informed consent to treatment with the specific pharmacotherapy ordered by the physician. The provider will document in the record the medication selected, the rationale for prescribing it, and the expected impact of pharmacotherapy. They will identify the education provided to the patient about their health conditions and any potential interactions or complications that may occur with the planned medication-assisted treatment.

Neonatal Abstinence Syndrome

Patients will be educated about neonatal abstinence syndrome, its symptoms, its potential effect on their infants, and need for treatment should it occur. To ensure appropriate follow-up and primary care for the new mother and well-baby care for the infant, programs will inform pregnant patients that newborns of OTP patients should receive prompt medical evaluation if signs or symptoms of neonatal abstinence syndrome appear after discharge from the hospital.

Accreditation Body Standards	Subject: OTP Accreditation

Title: Initial and periodic physical and behavioral health assessment services	Number: 42 CFR 8.12 (f) (4)
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (f) (4)

(i) Each patient admitted to an OTP shall be given a physical and behavioral health assessment, which includes but is not limited to screening for imminent risk of harm to self or others, within 14 calendar days following admission, and periodically by appropriately licensed/credentialed personnel. These assessments must address the need for and/or response to treatment, adjust treatment interventions, including MOUD, as necessary, and provide a patient-centered plan of care. The full, initial psychosocial assessment must be completed within 14 calendar days of admission and include preparation of a care plan that includes the patient's goals and mutually agreed-upon actions for the patient to meet those goals, including harm reduction interventions; the patient's needs and goals in the areas of education, vocational training, and employment; and the medical and psychiatric, psychosocial, economic, legal, housing, and other recovery support services that a patient needs and wishes to pursue. The care plan also must identify the recommended frequency with which services are to be provided. The plan must be reviewed and updated to reflect responses to treatment and recovery support services, and adjustments made that reflect changes in the context of the person's life, their current needs for and interests in medical, psychiatric, social, and psychological services, and current needs for and interests in education, vocational training, and employment services.

(ii) The periodic physical examination should occur not less than once each year and be conducted by an OTP practitioner. The periodic physical examination should include review of MOUD dosing, treatment response, other substance use disorder treatment needs, responses and patient-identified goals, and other relevant physical and psychiatric treatment needs and goals. The periodic physical examination should be documented in the patient's clinical record.

Additional Accreditation Body Standards

Implementation of the ASAM Criteria

The OTP must ensure:

A patient entering addiction treatment receives a multidimensional Level of Care Assessment.

The Dimensional Admission Criteria are used to interpret the patient's Level of Care Assessment and make a level of care recommendation.

The clinician works with the patient in a shared decision-making process that considers the patient's preferences and barriers to care to determine the level of care that the patient is willing and able to engage in.

Once placed in the appropriate level of care, the patient receives a comprehensive Care Planning Assessment.

The clinician works with the patient to develop a care plan that reflects the Dimensional Drivers of Admission to the current level of care and the patient's priorities.

The patient is reassessed at regular intervals to review their progress and determine when they should be transitioned to a more or less intensive level of care depending on their symptoms and circumstances.

The treatment itself should extend beyond simple resolution of observable physical, social, or mental health distress to the achievement of overall healthier functioning and wellness, where the patient demonstrates a response to treatment through new insights, attitudes, and behaviors.

Staff are well-trained in the ASAM Criteria standards and decision rules to support effective decision-making regarding level of care and continued service determinations and care transitions.

Complete Inventory of Strengths and Needs

A complete inventory of the individual's strengths and needs will be documented in the patient record. Based on the assessment and building upon the stage of treatment, an individualized care plan will then be designed.

Care Plan Goals

The development of a care plan includes the patient, provider, and therapist identifying and agreeing upon a specific set of goals and developing a care plan to achieve them. The goals should be specific, measurable, realistically attainable, and patient-centered in approach.

Effectiveness of the Care Plan

When staff meet with the patient, the evaluation of the effectiveness of the care plan must be based on the patient's progress toward the identified goal and the continued feasibility and appropriateness of the goals and their ongoing importance to the individual patient and their recovery.

Trauma

The OTP must be prepared to offer appropriate treatment or refer patients for appropriate clinical intervention for those identified as having experienced trauma.

Psychiatric Medications

If a patient is admitted to the OTP and reports current treatment with psychiatric medications, the OTP will coordinate care with the providers in the community who are prescribing the psychiatric medications.

Chronic Pain

Patients with co-occurring pain should receive treatment for both pain management and OUD utilizing a multidisciplinary approach. When possible and appropriate, programs should refer patients with chronic pain for consultation with an appropriate provider/specialist.

Aftercare Planning

Aftercare planning should begin upon admission. Taking a recovery-oriented approach to care facilitates this process. Aftercare planning should include the need for ongoing management of medical and psychiatric problems. Untreated, these problems are associated with relapse to drug use.

Accreditation Body Standards	Subject: OTP Accreditation

Title of Policy: Counseling and Psychoeducational Services	Number: 42 CFR 8.12 (f) (5)
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (f) (5)

(i) OTPs must provide adequate substance use disorder counseling and psychoeducation to each patient as clinically necessary and mutually agreed-upon, including harm reduction education and recovery-oriented counseling. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, and engage with patients, to contribute to the appropriate care plan for the patient and to monitor and update patient progress. Patient refusal of counseling shall not preclude them from receiving MOUD.

(ii) OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV), viral hepatitis, and sexually transmitted infections (STIs) and either directly provide services and treatments or actively link to treatment each patient admitted or readmitted to treatment who has received positive test results for these conditions from initial and/or periodic medical examinations.

(iii) OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational training, education, and employment services for patients who request such services or for whom these needs have been identified and mutually agreed upon as beneficial by the patient and program staff.

Additional Accreditation Body Standards

Continuing Care

The OTP will document a patient's need for continuing care at the agency. Documentation must include how the patient continues to meet criteria for substance use disorder treatment at the current level of care. Documentation must also include ongoing assessment and justification for transfer to a higher or lower level of care or discharge from treatment.

Orientation to Treatment

Orientation to treatment comprises continuous education via multiple modalities (e.g., verbal, written, video) in individual and/or group settings. Topics must include, but are not limited to:

Signs and symptoms of overdose, use of the naloxone antidote, and when to seek emergency assistance.

The nature of various addictive disorders.

The benefits of treatment and the nature of the recovery process, including stages of treatment.

An OTP's guidelines, rules, regulations, fees, and billing procedures.

Noncompliance and discharge procedures, including administrative withdrawal from medication.

Patient rights.

Confidentiality and how release of information is permitted by 42 CFR § 2.

Toxicology testing procedures.

Dispensation and the appropriate storage of medications when receiving take-homes.

Accreditation Body Standards	Subject: OTP Accreditation

Title: Drug testing services	Number: 42 CFR 8.12 (f) (6)
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (f) (6)

When conducting random drug testing, OTPs must use drug tests that have received the Food and Drug Administration's (FDA) marketing authorization for commonly used and misused substances that may impact patient safety, recovery, or otherwise complicate substance use disorder treatment, at a frequency that is in accordance with generally accepted clinical practice and as indicated by a patient's response to and stability in treatment, but no fewer than eight random drug tests per year per patient, allowing for extenuating circumstances at the individual patient level. This requirement does not preclude distribution of legal harm reduction supplies that allow an individual to test their personal drug supply for adulteration with substances that increase the risk of overdose.

Accreditation Body Standards	Subject: OTP Accreditation

Title: Confidentiality of Patient Records	Number: 42 CFR 8.12 (g) (1)
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (g) (1)

OTPs shall establish and maintain a record keeping system that is adequate to document and monitor patient care. This system is required to comply with all federal and state reporting requirements relevant to MOUD approved for use in the treatment of OUD. All records are required to be kept confidential in accordance with all applicable federal and state requirements.

Additional Accreditation Body Standards

Confidentiality

Patient records must be kept confidential. As required by 42 CFR Part 2 (b) and HIPAA, patients have a right to access their medical records and other health information. Programs must adhere to all requirements of the federal confidentiality regulations (42 CFR § 2) and HIPAA privacy, security, and breach notification regulations (45 CFR § 160 and § 164), as applicable.

Accreditation Body Standards	Subject: OTP Accreditation

Title: Patient Record Documentation	Number: 42 CFR 8.12 (g) (2)
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (g)(2)

OTPs shall include, as an essential part of the recordkeeping system, documentation in each patient's record that the OTP made a good faith effort to determine whether the patient is enrolled in any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in circumstances involving an inability to access care at the patient's OTP of record. Such circumstances include, but are not limited to, travel for work or family events, temporary relocation, or an OTP's temporary closure. If the medical director or program practitioner of the OTP in which the patient is enrolled determines that such circumstances exist, the patient may seek treatment at another OTP, provided the justification for the particular circumstances are noted in the patient's record both at the OTP in which the patient is enrolled and at the OTP that will provide the MOUD.

Accreditation Body Standards	Subject: OTP Accreditation

Title: Medication administration, dispensing, and use	Number: 42 CFR 8.12 (h) (1)
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (h) (1)

OTPs must ensure that MOUD are administered or dispensed only by a practitioner licensed under the appropriate state law and registered under the appropriate state and federal laws to administer or dispense MOUD, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner and if consistent with federal and state law.

Accreditation Body Standards	Subject: OTP Accreditation

Title: Medications for Use In OTPs	Number: 42 CFR 8.12 (h) (2) (i) (ii) (iii)
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (h) (2) (i) (ii) (iii)

OTPs shall use only those MOUD that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of OUD. In addition, OTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act for investigational use in the treatment of OUD. Currently the following MOUD will be considered to be approved by the Food and Drug Administration for use in the treatment of OUD:

(i) Methadone;

(ii) Buprenorphine and buprenorphine combination products that have been approved for use in the treatment of OUD; and

(iii) Naltrexone.

Accrediting Body Standards	Subject: OTP Accreditation

Title: Procedures for Dosing	Number: 42 CFR 8.12 (h) (3) (i) (ii)
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (h) (3) (i) (ii)

OTPs shall maintain current procedures that are adequate to ensure that the following dosage form and initial dosing requirements are met:

(i) Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral misuse.

(ii) For each new patient enrolled in an OTP, the initial dose of methadone shall be individually determined and shall include consideration of the type(s) of opioid(s) involved in the patient's opioid use disorder, other medications or substances being taken, medical history, and severity of opioid withdrawal. The total dose for the first day should not exceed 50 milligrams unless the OTP practitioner, licensed under the appropriate state law and registered under the appropriate state and federal laws to administer or dispense MOUD, finds sufficient medical rationale, including but not limited to if the patient is transferring from another OTP on a higher dose that has been verified, and documents in the patient's record that a higher dose was clinically indicated.

Additional Accreditation Body Standards

Authorized Dispensing Staff

Appropriate OTP staff are identified as nurses, providers, or pharmacists authorized to dispense or administer methadone and buprenorphine to patients admitted for treatment. The federal opioid treatment standards apply equally to both methadone and buprenorphine with the sole difference spelled out in 42 CFR § 8.12(i)(3).

Program Provider Only

The program provider is the only practitioner authorized to order and/or change a patient's dosage of methadone or buprenorphine. The provider must make an individualized decision informed by up-to-date product labeling and clinical judgment.

Dispensary

The OTP must ensure:

Policies and procedures specific to the dispensary are developed, implemented, reviewed, and updated as needed.

Infection control and prevention standards are followed.

Medication-dispensing instruments are calibrated and maintained according to the manufacturer's recommendations.

There is a mechanism in place for staff to view the entire dispensing area. Staff should be able to view the entire patient area at the dispensing window.

There is a process to create a perpetual and accurate inventory of all in-stock medications, including any pre-poured medications; and that every dose administered or dispensed is captured electronically or recorded on an administration sheet at the time the medication is administered or dispensed and recorded on the patient's individual medication dose history. The qualified person administering or dispensing the medication must sign each entry.

Accreditation Body Standards	Subject: OTP Accreditation

Title: Procedures to Ensure MOUD is Administered and Dispensed Correctly	Number: 42 CFR 8.12 (h) (4) (i) (1)
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (h) (4) (i) (1)

(4) OTPs shall maintain current procedures adequate to ensure that each MOUD used by the program is administered and dispensed in accordance with its FDA approved product labeling. The program must ensure that any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record. (i) Unsupervised or “take-home” medication doses. Unsupervised or “take-home” medication doses may be provided under the following circumstances:

(1) Any patient in comprehensive treatment may receive their individualized take-home doses as ordered for days that the clinic is closed for business, including one weekend day (e.g., Sunday) and state and federal holidays.

Additional Accreditation Body Standards

Standing Orders

Standing orders regarding the dose, schedule, or re-administration of methadone are not appropriate because of the unique pharmacologic properties, the well-established potential for fatalities in the induction period, and the risk of relapse during medically supervised withdrawal. In an OTP, an unacceptable standing order is any formulaic policy generically applied to all patients meeting specific criteria or in specific situations without evaluation by a physician or other qualified healthcare provider.

Cascading Order

The physician may choose to write a very short cascading order incorporating a COWS score or other objective measure to titrate the dose of a specific individual if appropriately trained and qualified staff (as determined by licensing criteria or credentialing) are available to evaluate the ongoing appropriateness of the physician's treatment plan and recognize the need for the patient to be re-evaluated before completion of the full course of the order. The physician must document the evidence and assessment supporting the planned use of a cascading order whenever one is used.

Accreditation Body Standards	Subject: OTP Accreditation

Title: Unsupervised Use of MOUD	Number: 42 CFR 8.12 (h) (4) (i) (2) (i) (ii) (iii) (iv) (v) (vi)
Approved Date: October 9, 2024	Approved by: SAMHSA

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (h) (4) (i) (2) (i) (ii) (iii) (iv) (v) (vi)

OTP decisions on dispensing MOUD to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section shall be determined by an appropriately licensed OTP medical practitioner or the medical director. In determining which patients may receive unsupervised medication doses, the medical director or program medical practitioner shall consider, among other pertinent factors that indicate that the therapeutic benefits of unsupervised doses outweigh the risks, the following criteria:

(i) Absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose, or the ability to function safely.

(ii) Regularity of attendance for supervised medication administration.

(iii) Absence of serious behavioral problems that endanger the patient, the public or others.

(iv) Absence of known recent diversion activity.

(v) Whether take-home medication can be safely transported and stored; and

(vi) Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health.

(3) Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined

that a patient is safely able to manage unsupervised doses of MOUD, the dispensing restrictions set forth in paragraphs (i)(3)(i) through (iii) of this section apply. The dispensing restrictions set forth in paragraphs (i)(3)(i) through (iii) of this section do not apply to buprenorphine and buprenorphine products listed under paragraph (h)(2)(ii) of this section.

During the first 14 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to 7 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 7 days, but decisions must be based on the criteria listed in paragraph (i)(2) of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record, consistent with paragraph (g)(2) of this section.

(ii) From 15 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to 14 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 14 days, but this determination must be based on the criteria listed in paragraph (i)(2) of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record, consistent with paragraph (g)(2) of this section.

(iii) From 31 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) provided to a patient is not to exceed 28 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 28 days, but this determination must be based on the criteria listed in paragraph (i)(2) of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record, consistent with paragraph (g)(2) of this section.

Accreditation Body Standards	Subject: OTP Accreditation

Title: Transporting Take-Home Medication	Number: 42 CFR 8.12 (h) (4)
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR (h) (4)

OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that each individual take-home dose is packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Pub. L. 91–601 (15 U.S.C. 1471 *et seq.*)). Programs must provide education to each patient on: Safely transporting medication from the OTP to their place of residence; and the safe storage of take-home doses at the individual's place of residence, including child and household safety precautions. The provision of this education should be documented in the patient's clinical record.

Accreditation Body Standards	Subject: OTP Accreditation

Title: Interim Requirements	Number: 42 CFR 8.12 (j) (1) (2) (3)
Approved Date: October 9, 2024	**Approved by: SAMHSA**

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

42 CFR 8.12 (j) (1) (2) (3)

The program sponsor of an OTP may admit an individual, who is eligible for admission to comprehensive treatment, into interim treatment if comprehensive services are not readily available within a reasonable geographic area and 14 days of the individual's seeking treatment. At least two drug tests shall be obtained from patients during the maximum of 180 days permitted for interim treatment. A program shall establish and follow reasonable criteria for establishing priorities for moving patients from interim to comprehensive treatment. These transition criteria shall be in writing and shall include, at a minimum, prioritization of pregnant patients in admitting patients to interim treatment and from interim to comprehensive treatment. Interim treatment shall be provided in a manner consistent with all applicable federal and state laws, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x–23, 300x–27(a), and 300y–11).

(2) The program shall notify the SOTA when a patient begins interim treatment, when a patient leaves interim treatment, and before the date of transfer to comprehensive services, and shall document such notifications.

(3) The Secretary may revoke the interim authorization for programs that fail to comply with the provisions of this paragraph (j). Likewise, the Secretary will consider revoking the interim authorization of a program if the state in which the program operates is not in compliance with the provisions of § 8.11(h).

(4) All requirements for comprehensive treatment apply to interim treatment with the following exceptions:

A primary counselor is not required to be assigned to the patient, but crisis services, including shelter support, should be available.

(ii) Interim treatment cannot be provided for longer than 180 days in any 12-month period.

(iii) By day 120, a plan for continuing treatment beyond 180 days must be created, and documented in the patient's clinical record; and

(iv) Formal counseling, vocational training, employment, economic, legal, educational, and other recovery support services described in paragraphs (f)(4) and (f)(5)(i) and (iii) of this section are not required to be offered to the patient. However, information pertaining to locally available, community-based resources for ancillary services should be made available to individual patients in interim treatment.

Accreditation Body Standards	Subject: OTP Accreditation

Title: Program Responsibilities	Number: NA
Approved Date: October 9, 2024	Approved by: SAMHSA

Accreditation Statement:

When approving OTP applications and when conducting surveys or investigations, the Washington State Department of Health will ensure that all agencies provide services based on these standards and 42 CFR 8.12.

PROGRAM RESPONSIBILITIES

1. OTPs will develop and implement policies and procedures to promote autonomy and patient responsibility and protect patients' rights as well as their health and well-being. OTPs must respond adequately to patient needs and promote dignity and humane treatment of patients, families, and visitors. Both the OTP's responsibilities and patient rights should be posted at the treatment site and reviewed with the patient following admission, at the end of the stabilization period, and when changes occur. For patients unable to read, program staff should verbally explain the patient's rights and the program's rules and regulations and document this interaction. In addition, programs should have accommodations in place for patients who do not speak English as a condition of accreditation.

Program responsibilities include:

Provide treatment that is fair and impartial, regardless of race, sex, age, and source of payment, and convey a sense of dignity and trust to the patient.

Provide treatment according to accepted clinical practice and community standards of care.

Ensure patients receive full disclosure of information about treatment and medication.

Inform patients about potential interactions with and adverse reactions to other substances, including alcohol, other prescribed or OTC pharmacological agents, food, and medical procedures.

Inform patients about the financial aspects of treatment, including the consequences of nonpayment of required fees. An OTP should establish payment expectations and work with the patient on following agreed-upon procedures to ensure payment for services rendered is received. Also,

processes that help patients resolve financial difficulties that might occur over the course of treatment should be explained.

Advise patients of their right to give informed consent before becoming involved in research projects and to retain a copy of the informed consent form.

Provide an adequate number of competent, qualified, and experienced professional clinical staff to implement and supervise the treatment plan, consistent with patient needs.

Inform patients about alternative medications, treatment alternatives, alternative modalities, and scientific advances affecting treatment.

Protect patients, staff, and the public from another patient who acts in a manner that disrupts the safety of the clinic environment. Programs, however, also have a responsibility to attempt to determine the cause of the patient's behavior so an appropriate referral may be made to an alternative method of care.

Do not deny treatment and services to patients who refuse to participate in research activities.

Develop and display patient grievance policies and procedures that specify the minimum elements of due process applicable to the program setting and resources used to prevent, investigate, and resolve patient complaints. Program administration will obtain and be responsive to patients' feedback concerning their care.

Establish procedures to provide medication to traveling patients and consider providing take-home medication. At times, when patients must transfer to a different level of care or location, it may be appropriate for the program to provide enough medication for the patient until arrival at the new location. Under these circumstances, a record of the chain of custody for transporting methadone to the new program may be required.

Accommodate the patient's desire to remain in opioid therapy at an alternative program before the patient is discharged.

Obtain patient consent before changing the patient's dose of opioids or other medications unless the patient signs a document waiving such consent.

CONSUMER BILL OF RIGHTS

2. OTPs must develop and display a Consumer Bill of Rights and Responsibilities to include applicable policies and procedures to the requirements in 42 CFR 8.12 to maintain accreditation. The consumer Bill of Rights and Responsibilities must include:

The right to receive adequate and humane services as a patient at the OTP.

The right to receive services in an environment that is as least restrictive and as accommodating as possible.

Patients have the right to understand and exercise their rights:

The right to a grievance and appeals process.

The right to initiate a grievance.

The right to participate in treatment decisions.

The right to file a complaint and appeal results.

The right to complain, verbally or in writing.

The right to report any instances of suspected patient abuse or neglect, without fear of retribution.

The right to be informed of grievance procedures in a manner that can be understood by the patient.

The right to receive a decision and reason for a decision in writing.

The right to appeal the decision to a final, unbiased source.

3. OTPs are encouraged to participate in research if it does not compromise the integrity of the treatment process:

Research conducted in an OTP does not compromise the treatment process integrity.

The OTP director has the authority to ensure that the program environment is suitable and receptive to research studies.

Treatment and other services are not jeopardized for any patient who refuses to participate in research activities.