

OFFICE OF THE SECRETARY OF STATE

SHEMIA FAGAN
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE



ARCHIVES DIVISION

STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 415
OREGON HEALTH AUTHORITY
HEALTH SYSTEMS DIVISION: ADDICTION SERVICES

FILED

01/20/2023 9:37 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Establishes American Society of Addiction Medicine (ASAM) Criteria Requirements and the use of ASAM standards

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 02/28/2023 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Dana Peterson
503-569-6760
dana.c.peterson@dhsosha.state.or.us

500 Summer St NE
Salem, OR 97301

Filed By:
Kalina Bathke
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 02/16/2023

TIME: 11:00 AM - 11:45 AM

OFFICER: Kalina Bathke

HEARING LOCATION

ADDRESS: Due to COVID-19 hearings are virtual, Salem, OR 97301

SPECIAL INSTRUCTIONS:

Zoom link: <https://www.zoomgov.com/j/1616941836?pwd=Tml0cHJnWHFVSkFleGwxRDl1OFg5QT09>

Meeting ID: 160 853 9251

Passcode: 256970

Call-in Number: 1-669-254-5252

The meeting location is accessible to persons with disabilities. A request for an interpreter for the hearing impaired or for other accommodations for persons with disabilities should be made at least 48 hours before the meeting to Kalina Bathke at kalina.m.bathke@dhsosha.state.or.us.

NEED FOR THE RULE(S)

The Centers for Medicare and Medicaid Services (CMS) Approved Oregon's application for a five-year Medicaid 1115 Demonstration Waiver, which will increase access to treatment services for people with substance use disorders (SUD) who are covered by the Oregon Health Plan (OHP). The waiver is effective April 8, 2021 through March 31, 2026. As part of the waiver, CMS requires the state of Oregon to utilize the nationally recognized SUD-specific program standards of the American Society of Addiction Medicine (ASAM) criteria to set provider licensure and certification qualifications and to establish a utilization management approach that ensures Medicaid beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis level of care and that the program standards are delivered consistently across the state and through the entire SUD continuum of

care.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Approved Center for Medicare & Medicaid Services (CMS) 1115 SUD Waiver demonstration project, special terms and conditions (STC) and the American Society of Addiction Medicine (ASAM) Criteria Third Edition and ASAM specific tools.

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

The changes will impact all Oregon licensed and/or certified SUD treatment programs. Provider engagement and listening sessions have identified the issue that treatment programs that are culturally, racially and/or linguistically specific may have additional barriers and financial burdens on implementing ASAM rule requirements. OHA/HSD is committed to providing additional support to these programs to ensure equitable implementation. Continued collaboration, listening, and partnership with communities and programs is essential throughout the rule making process and into implementation.

Black, Latinx, Asian and Native Americans and Alaskans are disproportionately impacted by behavioral health disorders, especially within the context of communities that have experienced historical and contemporary racism, trauma, and social, political, and economic injustices. OHA/HSD is committed to continued engagement with communities and programs across Oregon throughout the rule making process, to include Black, Indigenous, People of Color, and Tribal members to gather feedback and to be responsive and supportive to community needs and concerns.

Tribal Leaders have been informed of these proposed changes, including communications regarding possible impacts on Tribes. Tribal Leaders have been invited to RAC meetings as well. OHA/HSD has sent the "Dear Tribal Leader Letter" to the OHA tribal Affairs in accordance with OHA's Tribal consultation policy, for distribution to Oregon's nine federal recognized tribes.

OHA/HSD is aware of the fiscal impact these changes will have on the SUD providers especially to programs serving individuals that have been historically underserved and marginalized. Affordability is a concern for these programs and OHA/HSD desires to provide fiscal support for ASAM training and implementing the use of the ASAM criteria. OHA/HSD recognizes the request to have tools available in alternate languages such as but not limited to: Spanish, Russian, & Ukrainian. OHA/HSD also recognized concerns raised regarding ASAM tools not being culturally specific and may not be trauma informed for some cultures.

FISCAL AND ECONOMIC IMPACT:

The 1115 SUD waiver demonstration project will have a budget neutral impact for the agency as it relates to delivering the Medicaid benefit. However, implementing the use of ASAM to fidelity including the utilization management approach of requiring all SUD programs to use ASAM criteria will have an indeterminate fiscal impact on business, especially small and culturally specific business (less than 100 providers). The Health Systems Division of the Oregon Health Authority (OHA/HSD) desires to mitigate fiscal burden on the SUD providers by creating fiscal support opportunities. The funds will assist the SUD providers with ASAM training costs and costs associated with the implementation and use of the ASAM criteria. Due to the investments required to mitigate burden on providers, OHA/HSD will have a fiscal impact.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the

expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) OHA/HSD and Local County Community Mental Health Programs (CMHPs) and Oregon Licensed and/or Certified Treatment programs delivering SUD treatment services and supports.

(2) Indeterminate fiscal impact

(a) Less than 100

(b) indeterminate fiscal impact. Programs will be required to adjust administrative activities, reporting and recordkeeping to align with the use of ASAM criteria

(c) indeterminate fiscal impact. Program will be required to adjust and comply with new OARs related to the use of ASAM placement requirements as it relates to professional services and supports. Note: Medicaid reimbursement rates for SUD Assessments and treatment have been increased to support the waiver activities associated with the ASAM requirements.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

OHA/HSD held multiple listening sessions November 2022 and a Rules Advisory Committee (RAC) meeting platform was used to obtain input on proposed rule changes. RAC invitation included small businesses.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

415-020-0005, 415-020-0010, 415-020-0020, 415-020-0025, 415-020-0030, 415-020-0035, 415-020-0040, 415-020-0050, 415-020-0065, 415-020-0075

AMEND: 415-020-0005

RULE SUMMARY: Added new definitions for "The ASAM Criteria", "ASAM Level of Care", and "Level of Care". Added additional clarification language regarding being consistent with ASAM criteria and refined language from his/her to "their"

CHANGES TO RULE:

415-020-0005

Definitions ¶¶

(1) "Accreditation" means the process of review and acceptance by an accreditation body.¶¶

(2) "Accreditation Body" means an organization that has been approved by the Substance Abuse and Mental Health Services Administration (SAMHSA) to accredit opioid treatment programs that use opioid agonist treatment medications.¶¶

(3) "The ASAM Criteria" means the most current edition of the American Society of Addiction Medicine (ASAM) Criteria for the assessment, level of care placement and treatment of addictive, substance related, and co-occurring conditions, which is a clinical guide to develop patient-centered service plans and make objective decisions about admission, continuing care, and transfer or discharge for individuals and is incorporated by reference in these rules.¶¶

(4) "ASAM Level of Care" means one of several discrete intensities of services and supports within a substance use disorders program, that are delivered in a structured, programmatic fashion, by a certified outpatient or licensed program.¶¶

(5) "Assessment" means the process of obtaining all pertinent biopsychosocial information, through a face-to-face interview and additional information as provided by the individual, family and collateral sources as relevant, to determine a diagnosis and to plan individualized services and supports. The assessment is multidimensional and consistent with The ASAM Criteria.¶¶

(46) "Certificate" means the document or documents issued by the Division, which identifies and declares certification of a provider pursuant to OAR 309-008-0100 to 309-008-1600. A letter accompanying issuance of the certificate will detail the scope, The ASAM Criteria level of care and approved service delivery locations of the

certificate.¶¶

(57) "Community Mental Health Program (CMHP)" means the organization of various services for individuals with a mental health diagnosis or addictive disorders operated by or contractually affiliated with a local mental health authority and operated in a specific geographic area of the state under an agreement with the Division pursuant to OAR chapter 309, division 014.¶¶

(68) "Comprehensive maintenance treatment" means opioid agonist medication treatment that includes a broad range of clinically appropriate medical and rehabilitative services.¶¶

(79) "Diversion Control Plan" means a plan implemented by the opioid treatment program that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use.¶¶

(810) "Division" means the Health Systems Division of the Oregon Health Authority (OHA).¶¶

(911) "Employee" means an individual who provides a program service or who takes part in a program service and who receives wages, a salary, or is otherwise paid by the program for providing the service.¶¶

(102) "Federal Protocols" means the standards established by the United States Secretary of Health and Human Services that determines whether an opioid treatment program is qualified to engage in opioid treatment.¶¶

(143) "Interim Maintenance Treatment" means treatment provided in conjunction with appropriate medical services while a patient is awaiting transfer to a program that provides comprehensive maintenance treatment.¶¶

(124) "Level of Care" means the range of available services based off The ASAM Criteria's multidimensional assessment.¶¶

(15) "Maintenance Treatment" means the administration of an opioid agonist treatment medication at stable dosage levels for a period longer than 21 days.¶¶

(136) "Medical Director" means a physician licensed to practice medicine in the State of Oregon who is designated by the opioid treatment program to be responsible for the program's medical services.¶¶

(147) "Medically Supervised Withdrawal" means the administration of an opioid agonist treatment medication in decreasing doses to an individual to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of an opioid drug and as a method of bringing the individual to a drug free state.¶¶

(158) "Medically Supervised Withdrawal Treatment" means treatment for a period of more than 30 days but not exceeding 180 days.¶¶

(169) "Medical Professional" means a medical or osteopathic physician, physician's assistant licensed by the Board of Medical Examiners, or a registered nurse or nurse practitioner licensed by the Board of Nursing.¶¶

(1720) "Opiate Addiction" means a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opiates despite significant opiate-induced problems. Opiate addiction is characterized by repeated self-administration that usually results in tolerance, withdrawal symptoms, and compulsive drug taking.¶¶

(218) "Opioid Agonist Medication" means any drug that is approved by the Food and Drug Administration under Section 505 of Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opiate addiction.¶¶

(4922) "Opioid Treatment Program (OTP) or program" means a program that dispenses and administers opioid agonist medications in conjunction with appropriate counseling, supportive, and medical services.¶¶

(203) "Patient" means any individual who receives services in an opioid treatment program.¶¶

(244) "Patient Record" means the official legal written file for each patient, containing all the information required to demonstrate compliance with these rules. Information in program records maintained in electronic format must be able to be produced in a printed form, authenticated by signature, whether physical or digital, and date of the person who provided the service, and placed in the patient record.¶¶

(225) "Program Staff" means:¶¶

(a) An employee or person who, by contract with the program, provides a clinical service and who has the credentials required in these rules to provide the clinical service; and¶¶

(b) Any other employee of the program.¶¶

(236) "Quality Assurance" means the process of objectively and systematically monitoring and evaluating the appropriateness of patient care to identify and resolve identified problems.¶¶

(247) "Rehabilitation" means those services, such as vocational rehabilitation or academic education, which assist in overcoming the problems associated with drug abuse or drug dependence and which enable the patient to function at his or her highest potential.¶¶

(258) "State Opioid Treatment Authority" means the State Opioid Treatment Authority designated pursuant to section 409 of Public Law 92-255, the Drug Abuse Office and Treatment Act of 1972, or in lieu thereof, any other State authority designated by the Governor for purposes of exercising the authority under this section. The State Opioid Treatment Authority for Oregon is the Oregon Health Authority designee to serve in that role.¶¶

(269) "Treatment" means the specific medical and non-medical therapeutic techniques employed to assist the patient in recovering from drug abuse or drug dependence.¶¶

(2730) "Urinalysis Test" or "Urinalysis" means an analytical procedure to identify the presence or absence of

specific drugs or metabolites in a urine specimen.¶

(~~2831~~) "Volunteer" means an individual who provides a program service or who takes part in a program service and who is not an employee of the program and is not paid for services. The services must be non-clinical unless the individual has the required credentials to provide a clinical service.

Statutory/Other Authority: ORS 430.256

Statutes/Other Implemented: ORS 430.010(4)(b), 430.560 - 430.590

AMEND: 415-020-0010

RULE SUMMARY: Housekeeping to spell out the acronym "SAMHSA" and use the acronym "DEA"

CHANGES TO RULE:

415-020-0010

Program Approval ¶¶

(1) Letter of Approval: No person or governmental entity shall operate an Opioid Treatment Program (OTP) without a letter of approval from the State Opioid Treatment Authority in Oregon.¶¶

(2) Application: To receive a certificate for the provision of behavioral health treatment services an ~~Opioid Treatment Program~~ TP must meet the criteria under OAR 309-008-0100 to 309-008-1600; in addition, the ~~Opioid Treatment Program~~ TP must:¶¶

(a) Meet the standards set forth in these rules and any other administrative rules applicable to the program;¶¶

(b) Comply with the federal regulations contained in 42 CFR Part 2 and 42 CFR Part 8;¶¶

(c) Submit documentation of accreditation as an opioid treatment program by an accreditation body approved by the Federal Substance Abuse and Mental Health Services Administration (SAMHSA) under 42 CFR Part 8; and¶¶

(d) Specify in the application the identity and financial interest of any person (if the person is a corporation, the name of any stockholder holding stock representing an interest of 5 percent or more) or other legal entity who has an interest of 5 percent or more or 5 percent of a lease agreement for the facility.¶¶

(3) Renewal: The renewal of a Certificate shall be governed by OAR 309-008-0100 to 309-008-1600.¶¶

(4) Denial, Revocation, Nonrenewal, Suspension: The denial, revocation, nonrenewal, or suspension of a letter of approval or license for an opioid treatment program may be based on any of the grounds set forth in OAR 309-008-1100.¶¶

(5) Federal Protocols: The program shall be responsible for filing and maintaining all necessary protocols and documentation required by the National Institute on Drug Abuse (NIDA), the Federal Substance Abuse and Mental Health Services Administration (SAMHSA), and the Federal Drug Enforcement Administration (DEA).

Statutory/Other Authority: ORS 430.256

Statutes/Other Implemented: ORS 430.010(4)(b), 430.560 - 430.590

RULE SUMMARY: Housing keeping to remove an old medication "Levomethadyl acetate" and clarify that clients be informed of ALL drugs being dispensed at the OTP

CHANGES TO RULE:

415-020-0020

Patient Rights ¶¶

(1) Patient Record Confidentiality: An Opioid Treatment Program (OTP) shall comply with federal regulations (42 CFR part 2, 45 CFR 205.50) and state statutes (ORS 179.505 and 430.399) pertaining to confidentiality of patient records.¶¶

(2) Informed Consent: Participation in an ~~Opioid Treatment Program~~ TP shall be voluntary. Patients shall be fully informed concerning possible risks and side effects associated with the use of opioid agonist medications, including the effects of alcohol and other drugs taken in combination with these drugs. Programs ~~dispensing both methadone and Levomethadyl acetate (LAAM)~~ must inform patients of the differences between the action of ~~these all~~ drugs dispensed. The program shall ensure that all relevant facts concerning the use of opioid agonist medications are clearly and adequately explained to the patient and that the patient gives written informed consent to treatment. A copy of the information above, signed by the patient, must be placed in the patient record.¶¶

(3) Allowable Restrictions: No person shall be denied services or discriminated against on the basis of age or diagnostic or disability category unless predetermined clinical or program criteria for service restrict the service to specific age or diagnostic groups or disability category.¶¶

(4) Policies and Procedures: Each patient shall be assured the same civil and human rights as other persons. Each program shall develop and implement and inform patients of written policies and procedures which protect patients' rights, including:¶¶

(a) Protecting patient privacy and dignity;¶¶

(b) Assuring confidentiality of records consistent with federal and state laws;¶¶

(c) Prohibiting physical punishment or physical abuse;¶¶

(d) Prohibiting sexual abuse or sexual contact between patients and staff, including volunteers, interns, and students; and¶¶

(e) Providing adequate treatment or care.¶¶

(5) Services Refusal: The patient shall have the right to refuse service, including any specific procedure. If consequences may result from refusing the service, such as termination from other services or referral to a person having supervisory authority over the patient, that fact must be explained verbally and in writing to the patient.¶¶

(6) Access to Records: Access includes the right to obtain a copy of the record within five days of requesting it and making payment for the cost of duplication. The patient shall have the right of access to the patient's own records except:¶¶

(a) When the medical director of the program determines that disclosure of records would constitute immediate and grave detriment to the patient's treatment; or¶¶

(b) If confidential information has been provided to the program on the basis that the information not be redisclosed.¶¶

(7) Informed Participation in Treatment Planning: The patient and others of the patient's choice shall be afforded an opportunity to participate in an informed way in planning the treatment services, including the review of progress toward treatment goals and objectives. Patients shall be free from retaliation for exercising their rights to participate in the treatment planning process.¶¶

(8) Informed Consent to Fees for Services: The amount and schedule of any fees or co-payments to be charged must be disclosed in writing and agreed to by the patient. The fee agreement shall include but is not limited to a schedule of rates, conditions under which the rates can be changed, and the program's policy on refunds at the time of discharge or departure.¶¶

(9) Grievance Policy: The program shall develop, implement, and fully inform patients of policy and procedure regarding grievances, which provide for:¶¶

(a) Receipt of written grievances from patients or persons acting on their behalf;¶¶

(b) Investigation of the facts supporting or disproving the written grievance;¶¶

(c) Initiating action on substantiated grievances within five working days; and¶¶

(d) Documentation in the patient's record of the receipt, investigation, and any action taken regarding the written grievance.¶¶

(10) Barriers to Treatment: Where there is a barrier to services due to culture, language, illiteracy, or disability, the program shall develop a holistic treatment approach to address or overcome those barriers. This may

include:¶¶

(a) Making reasonable modifications in policies, practices, and procedures to avoid discrimination (unless the program can demonstrate that doing so would fundamentally alter the nature of the service, program, or activity) such as:¶¶

(A) Providing individuals capable of assisting the program in minimizing barriers (such as interpreters);¶¶

(B) Translation of written materials to appropriate language or method of communication;¶¶

(C) To the degree possible, providing assistive devices which minimize the impact of the barrier; and¶¶

(D) To the degree possible, acknowledging cultural and other values, which are important to the patient.¶¶

(b) Not charging patients for costs of the measures, such as the provision of interpreters, that are required to provide nondiscriminatory treatment to the patient; and¶¶

(c) Referring patients to another provider if that patient requires treatment outside of the referring program's area of specialization and if the program would make a similar referral for an individual without a disability.¶¶

(11) Patient Work Policy: Any patient labor performed as part of the patient's treatment plan or standard program expectations or in lieu of fees shall be agreed to, in writing, by the patient¶¶

(12) Voter Registration: All publicly funded programs primarily engaged in providing services to persons with disabilities must provide onsite voter registration and assistance. Program staff providing voter registration services may not seek to influence an applicant's political preference or party registration or display any such political preference or party allegiance, such as buttons, expressing support for a particular political party or candidates for partisan political office. However, such program staff may wear buttons or otherwise display their preference on nonpartisan political matters and issues.

Statutory/Other Authority: ORS 430.256

Statutes/Other Implemented: ORS 430.010(4)(b), 430.560 - 430.590.

RULE SUMMARY: Expanded admission criteria to allow individuals that have a recent history of overdose or recent discharge from hospital/acute care setting to access OTP services/support for opioids

CHANGES TO RULE:

415-020-0025

Admission Policies and Procedures ¶¶

(1) Admission Criteria: The Opioid Treatment Program (OTP) shall have written criteria for accepting or rejecting admission requests. The criteria shall be available to patients, staff, and the community, and require:¶¶

(a) Evidence of current physical dependence on narcotics or opiates as determined by the program physician, medical director, or a qualified nurse practitioner, or physicians' assistant;¶¶

(b) A one-year history, immediately prior to admission, of a continuous physical dependence on narcotics or opiates as documented by medical records, records of arrests for possession of narcotics, or records from drug treatment programs; or¶¶

(c) Documentation that medically supervised withdrawal or medically supervised withdrawal with acupuncture and counseling has proven ineffective or that a physician licensed by the Oregon State Board of Medical Examiners/ Medical Board has documentation in the patient record that there is a medical need to administer opioid agonist medications;¶¶

(d) Documentation that an initial urinalysis test has been completed and screened for opiates, methadone, benzodiazepines, barbiturates, cocaine, amphetamines, and Tetrahydrocannabinol (THC);¶¶

(e) That each patient voluntarily chooses opioid treatment and that all relevant facts concerning the use of an opioid agonist drug have been clearly and adequately explained;¶¶

(f) Documentation that the patient has provided written informed consent to treatment.¶¶

(2) Admission Criteria Exceptions: If clinically appropriate, the program physician may waive the requirement for a one-year history of opioid addiction for patients who:¶¶

(a) Have been released from a corrections facility within the previous six months;¶¶

(b) Are pregnant and whose pregnancy has been verified by the program physician; or¶¶

(c) Have previously been treated and discharged from ~~opioid treatment programs within the last two years~~ OTPs within the last two years; or¶¶

(d) Has a recent history of overdose or release from hospital or other acute care setting due complications of opioid use or opioid overdose.¶¶

(3) Refusing Admissions: A patient may be refused opioid treatment even if the patient meets admission standards if, in the professional judgment of the medical director, a particular patient would not benefit from opioid treatment. The reasons for the refusal must be documented in the patient file within seven days following the refusal decision.¶¶

(4) Minors: No person under 18 years of age may be admitted to an ~~opioid treatment program~~ OTP unless:¶¶

(a) A parent, legal guardian, or responsible adult designated by the State provides written consent for treatment; and¶¶

(b) The program can document two unsuccessful attempts at short-term medically supervised withdrawal or drug free treatment within a 12-month period.¶¶

(5) Pregnant Patients: Admission and treatment of pregnant patients regardless of age is allowed under the following conditions:¶¶

(a) The patient has had a documented narcotic dependency in the past and may be in direct jeopardy of returning to narcotic dependency. For such patients, evidence of current physiological dependence on narcotic drugs is not needed if a program physician certifies the pregnancy and, in ~~his or her~~ their reasonable clinical judgment, finds treatment to be medically justified. Evidence of all findings and the criteria used to determine the findings are required to be recorded in the patient's record by the admitting program physician, or by program personnel supervised by the admitting program physician;¶¶

(b) The patient undergoes a prenatal exam and health check to verify the pregnancy and identify any health problems;¶¶

(c) The patient is given the opportunity for prenatal care either by the program or by referral to appropriate health care providers. If a program cannot provide direct prenatal care for pregnant patients in treatment, the program shall establish a system for informing the patient of the publicly or privately funded prenatal care opportunities available. If there are no publicly funded prenatal referral opportunities and the program cannot provide such services or the patient cannot afford them or refuses them, then the treatment program shall, at a minimum, offer her basic prenatal instruction on maternal, physical, and dietary care as part of its counseling service;¶¶

(d) The patient is fully informed concerning risks to ~~themselves~~ themselves and ~~their~~ their unborn child from the use of methadone

and other drugs, including alcohol.¶¶

(6) Intake Procedures: The program shall utilize a written intake procedure. The procedure shall require:¶¶

(a) Documentation that the medical director has:¶¶

(A) Examined and approved all admissions;¶¶

(B) Recorded in the patient's record the criteria used to determine the patient's current dependence and history of addiction; and¶¶

(C) Determined that the ~~opioid treatment program~~ OTP's services are appropriate to the needs of the patient.¶¶

(b) A specific time limit within which the initial patient assessment must be completed on each patient prior to the initial dose of an opioid agonist treatment medication;¶¶

(c) Documentation that individuals not admitted to the ~~opioid treatment program~~ OTP were referred to appropriate treatment or other services.¶¶

(7) Orientation Information: The program shall give to, and document the receipt of, written program orientation information. The program shall also make the information available to others. The information given shall include:¶¶

(a) The program's philosophical approach to treatment;¶¶

(b) A description of the program's stages of treatment;¶¶

(c) Information on patients' rights and responsibilities, including confidentiality, while receiving services;¶¶

(d) Information on the rules governing patient behavior and those infractions that may result in discharge or other actions. As a minimum these rules shall state the consequence of alcohol and other drug use, absences from appointments, non-payment of fees, criminal behavior, and failure to participate in the planned treatment program including school, work, or homemaker activities;¶¶

(e) Information on the specific hours of service available, methods to accommodate patient needs before and after normal working hours, and emergency services information; and¶¶

(f) A schedule of fees and charges.¶¶

(8) Patient Record: The following information shall be recorded in each patient's record at the time of admission:¶¶

(a) Name, address, and telephone number;¶¶

(b) Whom to contact in case of an emergency;¶¶

(c) Name of individual completing intake; and¶¶

(d) If the patient refuses to provide necessary information, documentation of that fact in the patient file.¶¶

(9) Initial Medical Examination Services: ~~Opioid Treatment Program~~ OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a physician, or medical professional under the supervision of a physician before admission to the program. The laboratory tests must be completed within 14 days of admission and must include:¶¶

(a) A skin test for tuberculosis, followed by a chest x-ray if the test is positive;¶¶

(b) A screening test for syphilis; and¶¶

(c) Other laboratory tests as clinically indicated by the patient history and physical examination.

Statutory/Other Authority: ORS 430.256

Statutes/Other Implemented: ORS 430.010(4)(b), 430.560 - 430.590

AMEND: 415-020-0030

RULE SUMMARY: Updated language to indicate "consistent with the ASAM Criteria"

CHANGES TO RULE:

415-020-0030

Diagnostic Assessment ¶

(1) Written Procedure: The Opioid Treatment Program shall develop and implement a written procedure for assessing each patient's treatment needs ~~based on the American Society of Addictions Medicine Patient Placement Criteria, 2nd Edition Revised (ASAM PPC 2R)~~consistent with The ASAM Criteria.¶

(2) The diagnostic assessment shall be documented in the permanent patient record. It shall consist of the elements described in ~~¶The ASAM PPC 2RCriteria~~ and documentation of the patient's self-identified cultural background. Cultural information documented should include level of acculturation, knowledge of own culture, primary language, spiritual or religious interests, and cultural attitudes toward alcohol and other drug use.

Statutory/Other Authority: ORS 430.256

Statutes/Other Implemented: ORS 430.010(4)(b), 430.560 - 430.590

AMEND: 415-020-0035

RULE SUMMARY: Clarification regarding treatment summary within 30 days of last contact, consistent with the ASAM Criteria

CHANGES TO RULE:

415-020-0035

Treatment Planning and Documentation of Treatment Progress ¶¶

- (1) The Opioid Treatment Program (OTP) shall develop treatment plans, progress notes, and discharge plans consistent with ~~the ASAM PPC-2R Criteria.~~ ¶
- (2) Treatment Plan: The ~~PO~~TP shall develop an individualized treatment plan within 30 days of admission and shall be documented in the patient's record. The treatment plan shall:¶
- (a) Describe the primary patient-centered issues;¶
 - (b) Focus on one or more individualized treatment plan objectives that are consistent with the patient's strengths and abilities and that address the primary obstacles to recovery;¶
 - (c) Define the treatment approach, which shall include services and activities to be used to achieve the individualized objectives;¶
 - (d) Document the participation of significant others in the planning process and the treatment where appropriate; and¶
 - (e) Document the patient's participation in developing the content of the treatment plan and any subsequent modifications, with the patient's signature.¶
- (3) Documentation of Progress: The treatment staff shall document in the permanent record any current obstacles to recovery and the patient's progress toward achieving the individualized objectives in the treatment plan.¶
- (4) Treatment Plan Review: The permanent patient record shall document that the treatment plan is reviewed and modified continuously as needed and as clinically appropriate, consistent with ~~the ASAM PPC-2R Criteria.~~ ¶
- (5) Modifications: Changes in the patient's treatment needs identified by the review process must be addressed by modifications in the treatment plan. Any modifications to the treatment plan shall be made in conjunction with the patient.¶
- (6) Treatment Summary: No later than 30 days after the last service contact, the program shall document in the permanent patient record a summary describing the ~~reason for discharge, consistent with the ASAM PPC-2R, contact~~ and the patient's progress toward the treatment objectives, consistent with The ASAM Criteria and any reason for discharge. ¶
- (7) Discharge Plan: Upon successful completion or planned interruption of the treatment services, the treatment staff and patient shall jointly develop a discharge plan. The discharge plan shall include a relapse prevention plan, which has been jointly developed by the counselor and patient.

Statutory/Other Authority: ORS 430.256

Statutes/Other Implemented: ORS 430.010(4)(b), 430.560 - 430.590

415-020-0040

Treatment Services General ¶¶

(1) Treatment Services: The Opioid Treatment Program (OTP) shall provide patients the following services and activities and document the time or manner of each service or activity in the patient record:¶¶

- (a) Dispensing of approved opioid agonist medications;¶¶
- (b) Individual group, or family counseling, as clinically indicated;¶¶
- (c) Information and training in parenting skills;¶¶
- (d) HIV, AIDS, tuberculosis, sexually transmitted diseases, and other infectious disease information;¶¶
- (e) Completion of HIV, TB, STD risk assessment within 30 days of admission;¶¶
- (f) Relapse prevention training; and¶¶

(g) For pregnant patients in a treatment program who were not admitted under OAR 415-020-0025(5), a treatment program shall give them the opportunity for prenatal care. If a program cannot provide direct prenatal care for pregnant patients in treatment, it shall establish a system of referring them for prenatal care, which may be either publicly or privately funded. If there is no publicly funded prenatal care available to which a patient may be referred, and the program cannot provide such services, or the patient cannot afford or refuses prenatal care services, then the treatment program shall, at a minimum, offer them basic prenatal instruction on maternal, physical, and dietary care as a part of its counseling service.¶¶

(2) Community Resources: The program, to the extent of community resources available and as clinically indicated, shall provide patients with information and referral to the following services:¶¶

- (a) Self-help groups and other support groups;¶¶
- (b) Educational services;¶¶
- (c) Recreational programs and activities;¶¶
- (d) Prevocational, occupational, and vocational rehabilitation;¶¶
- (e) Life skills training;¶¶
- (f) Legal services;¶¶
- (g) Smoking cessation programs;¶¶
- (h) Medical services;¶¶
- (i) Housing assistance;¶¶
- (j) Financial assistance counseling programs;¶¶
- (k) Crisis intervention; and¶¶
- (l) Comprehensive drug education.¶¶

(3) Non-compliance: Patients who are non-compliant with program rules may be discharged following medically supervised withdrawal. Clinical justification for medically supervised withdrawal schedules of less than 21 days must be documented in the patient record. For discharges because of failure to pay fees, detoxification periods of less than 21 days are not permitted.¶¶

(4) Testing for Drug Use: The program shall use observed urine drug screening as an aid in monitoring and evaluating a patient's progress in treatment. The urine drug screening shall include;¶¶

- (a) A sensitive, rapid, and inexpensive immunoassay screen to eliminate "true negative" specimens; and¶¶
- (b) If the initial test is positive, a confirmatory test, which is a second analytical procedure used to identify the presence of a specific drug or metabolite in a urine specimen. The confirmatory test must be conducted by a different analytical method from that of the initial test, to ensure reliability and accuracy.¶¶

(5) Standards for Urine Tests: All urine tests shall be performed by laboratories meeting the licensing standards of OAR 333-024-0305 through 333-024-0365.¶¶

(6) All urine tests shall, at a minimum, screen for synthetic opiates, opiates, amphetamines, cocaine, and benzodiazepines, ~~and THC.~~¶¶

(7) Frequency of urine testing: ~~The Opioid Treatment Program TP~~ must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, for each patient in maintenance treatment, in accordance with generally accepted clinical practice. More frequent drug testing shall be done if clinically indicated. The program shall document in the patient record the results of any tests and interventions made by the program to address those tests which are positive for illicit substances.

Statutory/Other Authority: ORS 430.256

Statutes/Other Implemented: ORS 430.010(4)(b), 430.560 - 430.590

AMEND: 415-020-0050

RULE SUMMARY: Added language "consistent" with the ASAM Criteria

CHANGES TO RULE:

415-020-0050

Transitional Treatment ¶

(1) The Opioid Treatment Program shall provide transitional care for patients for who continued opioid agonist medication maintenance is no longer deemed appropriate.¶

(2) Transitional treatment services shall be provided with the purpose of assisting the patient to establish and maintain a stable, drug-free lifestyle. Transitional treatment will help prepare the patient to begin a reduction in opioid agonist medication dosage and shall be continued while the patient undergoes reduction in doses. The treatment shall continue following the final dose of opioid agonist medication, consistent with the clinical needs of the patient and consistent with The ASAM PPC-2R Criteria.

Statutory/Other Authority: ORS 430.256

Statutes/Other Implemented: ORS 430.010(4)(b), 430.560 - 430.590

RULE SUMMARY: Removed the maximum length of time away from an OTP while receiving a dose from another OTP

CHANGES TO RULE:

415-020-0065

Opioid Agonist Medication Administration ¶¶

(1) The Opioid Treatment Program (OTP) shall meet the following standards for opioid agonist medication for administration:¶¶

(a) Methadone shall be administered only in oral form and shall be formulated in such a way as to reduce its potential for abuse by injection and accidental ingestion;¶¶

(b) Packaged for outpatient use in special packaging as required by 16 CFR Part 1700.14.¶¶

(2) Methadone Take-Out Doses: For take-out doses, the Poison Prevention Act (P.L. 91-601, 15 USC 1471 et seq.) must be followed. Any take-out medication must be in oral form, either liquid or diskette and shall be labeled with the ~~treatment program~~OTP name, address, telephone number, and medical director. All labeling shall be in compliance with the Oregon Board of Pharmacy standards.¶¶

(3) ~~Opioid Treatment Program~~TPs shall maintain current procedures to ensure that each opioid agonist treatment medication used by the program is administered in accordance with its approved product labeling.¶¶

(4) Records: Accurate records traceable to specific patients shall be maintained showing dates, quantity, and any other Board of Pharmacy required identification for the drug administered and shall be retained for a period of seven years.¶¶

(5) Security: The program shall meet security standards for the distribution and storage of controlled substances as required by the Federal Drug Enforcement Administration, Department of Justice.¶¶

(6) Who May Administer Opioid Agonist Treatment Medications: Medications shall be administered by:¶¶

(a) A practitioner licensed or registered under appropriate State or Federal law to order narcotic drugs for patients; or¶¶

(b) A person licensed or approved by the State Board of Nursing or the State Board of Pharmacy, supervised by and pursuant to the order of the practitioner.¶¶

(7) Responsibility: The licensed practitioner is fully accountable and personally responsible for the amounts of opioid agonist treatment medications administered.¶¶

(8) Documentation: All changes in dosage schedule will be recorded and signed by the licensed practitioner.¶¶

(9) Medical Director: The medical director shall:¶¶

(a) Assume responsibility for the amounts of opioid agonist treatment medications administered; and¶¶

(b) Review each patient's dosage level at least once every 90 days.¶¶

(10) Initial Dose: The initial dose of methadone should not exceed 30 milligrams and the total dose for the first day should not exceed 40 milligrams unless the program medical director documents in the patient's record that 40 milligrams did not suppress opiate abstinence symptoms. The initial dose of opioid agonist treatment medication to a patient whose tolerance for the drug is unknown shall not exceed 40 milligrams.¶¶

(11) Maintenance Dose: The maintenance dose should be individually determined with careful attention to the information provided by the patient. The dose should be determined by a physician, nurse practitioner, or physicians' assistant experienced in addiction treatment and should be adequate to achieve the desired effects for 24 hours or more. The desired effects are;¶¶

(a) Preventing the onset of opioid abstinence syndrome;¶¶

(b) Reducing drug cravings or hunger; and¶¶

(c) Blocking the effects of any illicitly administered opioids.¶¶

(12) All changes ordered by a physician, nurse practitioner, or physicians' assistant in the opioid agonist treatment medication shall be documented in the patient record, and each change in the dosage schedule shall be recorded, dated, and signed in each patient's record.¶¶

(13) Methadone Take Out Schedule: A patient may be permitted a temporary or permanently increased take-out schedule if it is the reasonable clinical judgment of the program physician and documented in the records that:¶¶

(a) A patient is found to have a physical disability which interferes with the patient's ability to conform to the applicable take-out schedule; or¶¶

(b) A patient, because of critical circumstances such as illness, personal or family crises, or other hardship is unable to conform to the applicable takeout schedule; and¶¶

(c) The patient may not be given more than a 30-day supply of narcotic agonist medication at one time.¶¶

(14) Patient Treatment at Another Program: The patient shall report to the same ~~treatment program~~OTP unless prior written approval is obtained from the program physician allowing the patient to receive treatment at another program. If permission is granted, the programs involved shall meet the following requirements:¶¶

- (a) The program referring the patient shall notify and obtain, in writing, permission from the other program for the patient to attend;¶
- ~~(b) The maximum period of time that a patient may attend another program is 30 days;¶~~
- ~~(c) During attendance at another program the patient may not receive more opioid agonist treatment medication take-out doses than currently authorized by his or her regular program; and¶~~
- ~~(d) The program making the referral shall provide the patient with positive identification for presentation to the other program.~~

Statutory/Other Authority: ORS 430.256

Statutes/Other Implemented: ORS 430.010(4)(b), 430.560 - 430.590

RULE SUMMARY: Added the use of ASAM as a required knowledge and experience for a clinical supervisor and treatment staff. Updated language from His/Her to "Their"

CHANGES TO RULE:

415-020-0075

Specific Staff Qualifications and Competencies

(1) Medical Director Qualifications: The Medical Director must be a physician licensed by the Oregon Board of Medical Examiners and whose license enables him or her to order, dispense, and administer opioid agonist medications. In addition, the ~~program~~ Opioid Treatment Program (OTP) shall document that the Medical Director has completed a minimum of 12 hours per year of continuing education specific to the treatment of addiction disorder.¶

(2) Administrator - Qualifications: Each ~~opioid treatment program~~ OTP shall be directed by a person with the following qualifications at the time of hire and continuously throughout employment as the program administrator:¶

(a) Five years of paid full-time experience in the field of substance use treatment, including experience in an ~~opioid treatment program~~ OTP with at least one year in a paid administrative capacity; or¶

(b) A Bachelor's degree in a relevant field and four years of paid full-time experience in the field of alcohol and drug treatment, including experience in an ~~opioid treatment program~~ OTP with at least one year in a paid administrative capacity; or¶

(c) A Master's degree in a relevant field and three years of paid full-time experience in the field of alcohol and drug treatment, including experience in an ~~opioid treatment program~~ OTP with at least one year in a paid administrative capacity.¶

(3) Management Staff - Competency: The management staff shall:¶

(a) Have knowledge and experience demonstrating competence in the performance of the following essential job functions: program planning and budgeting, fiscal management, supervision of staff, personnel management, employee performance assessment, data collection, reporting, program evaluation, quality assurance, and developing and maintaining community resources;¶

(b) Demonstrate by ~~his or her~~ their conduct the competencies required by this rule and compliance with the program policies and procedures implementing these rules.¶

(4) Clinical Supervisor - Qualifications: Each ~~opioid treatment program~~ OTP shall have an identified clinical supervisor who has one of the following qualifications at the time of hire:¶

(a) Five years of paid full-time experience in the field of alcohol and other drug treatment, including experience in an ~~opioid treatment program~~ OTP, with a minimum of two years of direct alcohol and other drug treatment experience; or¶

(b) A Bachelor's degree in a relevant field and four years of paid full-time experience, with a minimum of two years of direct alcohol and other drug treatment experience including experience in an ~~opioid treatment program~~ OTP; or¶

(c) A Master's degree in a relevant field and three years of paid full-time experience, with a minimum of two years of direct alcohol and other drug treatment experience including experience in an ~~opioid treatment program~~ OTP.¶

(5) Clinical Supervisor - Competency: All supervisors shall:¶

(a) Have knowledge and experience demonstrating competence in the performance of the following essential job functions: supervision of treatment staff including staff development, use of The ASAM Criteria, treatment planning, case management, and utilization of community resources including self-help groups; preparation and supervision of patient assessment procedures; preparation and supervision of case management procedures for client treatment; conducting of individual, group, family, and other counseling; and assurance of the clinical integrity of all patient records for cases under their supervision, including timely entry or correctness of records and requiring adequate clinical rationale for decisions in admission and assessment records, treatment plans and progress notes, and discharge records;¶

(b) Demonstrate by ~~his or her~~ their conduct the competencies required by this rule and compliance with the program policies and procedures implementing these rules; and¶

(c) Except as provided in this rule, hold a current certification or license in addiction counseling or hold a current license as a health or allied provider issued by a state licensing body.¶

(6) Clinical Supervisors - Certification: For supervisors holding a certification or license in addiction counseling, qualifications for the certificate or license must have included at least:¶

(a) 4,000 hours of supervised experience in substance use counseling;¶

(b) 300 contact hours of education and training in substance use related subjects; and¶

(c) Successful completion of a written objective examination or portfolio review by the certifying or licensing

body.¶

(7) Clinical Supervisor - Licensure: For supervisors holding a health or allied provider license, such license shall have been issued by one of the following state bodies and the supervisor must possess documentation of at least 120 contact hours of academic or continuing professional education in the treatment of substance use disorders:¶

(a) Board of Medical Examiners;¶

(b) Board of Psychologist Examiners;¶

(c) Board of Clinical Social Workers;¶

(d) Board of Licensed Professional Counselors and Therapists; or¶

(e) Board of Nursing.¶

(8) Clinical Supervisors - Existing Staff: Supervisors not having a credential or license that meets the standards identified in this rule must apply to a qualified credentialing organization or state licensing board within 90 days of the effective date of this rule, and achieve certification or licensure meeting the standards of this rule, within 24 months of the application date.¶

(9) Administrator as Clinical Supervisor: If the program's administrator meets the qualifications of the clinical supervisor, the administrator may be the clinical supervisor.¶

(10) Treatment Staff - Competency: All treatment staff shall:¶

(a) Have knowledge, skills, and abilities demonstrating competence in the following essential job functions: The ASAM Criteria, treatment of substance use disorders including patient assessment and individual, group, family, and other counseling techniques; program policies and procedures for client case management and record keeping; and accountability for recording information in the patient files assigned to them consistent with those policies and procedures and these rules;¶

(b) Demonstrate by conduct the competencies required by this rule and compliance with the program policies and procedures implementing these rules;¶

(c) Except as provided in this rule, hold a current certification or license in addiction counseling or hold a current license as a health or allied provider issued by a state licensing body.¶

(11) Treatment Staff - Certification: For treatment staff holding a certification or license in addiction counseling, qualifications for the certificate or license must have included at least:¶

(a) 1,000 hours of supervised experience in substance use counseling;¶

(b) 150 contact hours of education and training in substance use related subjects; and¶

(c) Successful completion of a written objective examination or portfolio review by the certifying body.¶

(12) Treatment Staff - Licensure: For treatment staff holding a health or allied provider license, such license shall have been issued by one of the following state bodies and the staff person must possess documentation of at least 60 contact hours of academic or continuing professional education in the treatment of substance use disorders:¶

(a) Board of Medical Examiners;¶

(b) Board of Psychologist Examiners;¶

(c) Board of Clinical Social Workers;¶

(d) Board of Licensed Professional Counselors and Therapists; or¶

(e) Board of Nursing.¶

(13) Treatment Staff - Existing Staff: Existing staff who do not hold a certificate or license that meets the standards identified in section of this rule must apply to a qualified credentialing organization or state licensing board within 90 days of the effective date of this rule and achieve certification or licensure meeting the standards of section of this rule within 36 months of the application date.¶

(14) Treatment Staff - New Hires: New hires need not hold a qualified certificate or license, but those who do not must make application within six months of employment and receive the credential or license within 36 months of the application.¶

(15) ~~The opioid treatment program~~ OTP shall provide a minimum of two hours per month of clinical supervisor consultation for each staff person or volunteer who is responsible for the delivery of treatment services. One hour of the supervision must be individual, face-to-face, and address clinical skill development. The supervision or consultation is to assist staff and volunteers to increase their treatment skills, improve quality of services to patient, and ensure compliance with program policies and procedures implementing these rules.

Statutory/Other Authority: ORS 430.256

Statutes/Other Implemented: ORS 430.010(4)(b), 430.560 - 430.590