

Secretary of State
Certificate and Order for Filing
TEMPORARY ADMINISTRATIVE RULES
A Statement of Need and Justification accompanies this form.

FILED
8-10-16 3:31 PM
ARCHIVES DIVISION
SECRETARY OF STATE

I certify that the attached copies are true, full and correct copies of the TEMPORARY Rule(s) adopted on Upon filing, by the
Oregon Health Authority, Health Systems Division: Addiction Services 415

Agency and Division Administrative Rules Chapter Number
Nola Russell (503) 945-7652

Rules Coordinator Telephone
500 Summer St. NE, Salem, OR 97301

Address
To become effective 08/10/2016 through 02/05/2017.

RULE CAPTION

Temporary amendments to OAR 415-020 regarding outpatient Opiate Treatment Programs.

Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

RULEMAKING ACTION

Secure approval of new rule numbers with the Administrative Rules Unit prior to filing.

- ADOPT:**
- AMEND:**
415-020-0000, 415-020-0005, 415-020-0010, 415-020-0090
- SUSPEND:**

Statutory Authority:
ORS 413.042

Other Authority:

Statutes Implemented:
ORS 813.500 - 813.520

RULE SUMMARY

These rules prescribe standards for the development and operation of Opioid Treatment Programs approved by the Health Systems Division of the Oregon Health Authority (OHA).

Nola Russell nola.russell@state.or.us

Rules Coordinator Name Email Address

Secretary of State
STATEMENT OF NEED AND JUSTIFICATION
A Certificate and Order for Filing Temporary Administrative Rules
accompanies this form

FILED
8-10-16 3:31 PM
ARCHIVES DIVISION
SECRETARY OF STATE

Oregon Health Authority, Health Systems Division: Addiction Services
Agency and Division

415
Administrative Rules Chapter Number

Temporary amendments to OAR 415-020 regarding outpatient Opiate Treatment Programs.

Rule Caption (Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.)

In the Matter of:

Temporary amendments to OAR 415-020 regarding outpatient synthetic Opiate Treatment Programs.

Statutory Authority:

ORS 413.042

Other Authority:

Statutes Implemented:

ORS 813.500 - 813.520

Need for the Temporary Rule(s):

These rules prescribe standards for the development and operation of Opioid Treatment Programs approved by the Health Systems Division of the Oregon Health Authority (OHA).

Documents Relied Upon, and where they are available:

Other rules referenced in these rules may be accessed on the website of Oregon's Secretary of State.

Justification of Temporary Rule(s):

These rule amendments must be filed promptly so as to ensure standardized language and citations with other rule amendments recently filed.

Nola Russell

nola.russell@state.or.us

Printed Name

Email Address

**OREGON HEALTH AUTHORITY
HEALTH SYSTEMS DIVISION
ADDICTION SERVICES
DIVISION 20
STANDARDS FOR OUTPATIENT SYNTHETIC OPIATE TREATMENT PROGRAMS**

415-020-0000

Purpose

These rules prescribe standards for the development and operation of Opioid Treatment Programs approved by the Health Systems Division of the Oregon Health Authority.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

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) "Accredited Opioid Treatment Program" means a program that is the subject of a current, valid accreditation from an accreditation body approved by SAMHSA.
- (4) "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.
- (5) "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 and approved service delivery locations of the certificate.
- (6) "Community Mental Health Program (CMHP)" means the organization of all services for persons with mental or emotional disturbances, drug abuse problems, developmental disabilities, and alcoholism and alcohol abuse problems operated by, or contractually affiliated with, a local mental health authority operated in a specific geographic area of the state under an intergovernmental agreement or direct contract with the Oregon Health Authority.
- (7) "Comprehensive maintenance treatment" means opioid agonist medication treatment that includes a broad range of clinically appropriate medical and rehabilitative services.
- (8) "Division" means the Health Systems Division of the Oregon Health Authority (OHA).
- (9) "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.
- (10) "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.
- (11) "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.
- (12) "Federal Opioid Treatment Standards" means the standards established by the Secretary of Health and Human Services that are used to determine whether an opioid treatment program is qualified to engage in opioid treatment.

- (13) "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.
- (14) "Long-Term Medically Supervised Withdrawal Treatment" means treatment for a period of more than 30 days but not exceeding 180 days.
- (15) "Maintenance Treatment" means the administration of an opioid agonist treatment medication at stable dosage levels for a period longer than 21 days.
- (16) "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.
- (17) "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.
- (18) "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.
- (19) "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.
- (20) "Opioid Treatment Program" means a program that dispenses and administers opioid agonist medications in conjunction with appropriate counseling, supportive, and medical services.
- (21) "Patient" means any individual who receives services in an opioid treatment program.
- (22) "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 produced in a contemporaneous printed form, authenticated by signature and date of the person who provided the service, and placed in the patient record.
- (23) "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.
- (24) "Quality Assurance" means the process of objectively and systematically monitoring and evaluating the appropriateness of patient care to identify and resolve identified problems.
- (25) "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.
- (26) "State Methadone Authority" means the State Methadone 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 Methadone Authority for Oregon is the Addictions and Mental Health Division of the Oregon Health Authority.
- (27) "Treatment" means the specific medical and non-medical therapeutic techniques employed to assist the patient in recovering from drug abuse or drug dependence.
- (28) "Urinalysis Test" means an analytical procedure to identify the presence or absence of specific drugs or metabolites in a urine specimen.
- (29) "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.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0010

Program Approval

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

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

(c) Submit documentation of accreditation as an opioid treatment program by an accreditation body approved by SAMHSA under 42 CFR Part 8.

(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.

(6) 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, and the Federal Drug Enforcement Administration.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b), 430.560 - 430.590

415-020-0015

Administrative Requirements

(1) Administrative Rules: An Opioid Treatment Program which obtains reimbursement for publicly funded services shall comply with the public contracting rules including but not limited to:

(a) OAR 309-013-0020;

(b) OAR 309-013-0075 to 309-013-0105;

(c) OAR 309-014-0000 to 309-014-0040;

(d) OAR 309-016-0000 to 309-016-0130;

(e) OAR 410-120-0000 through 410-120-1980; and

(f) OAR 410-141-0000 through 410-141-0860.

(2) Policies and Procedures: An Opioid Treatment Program shall develop and implement written policies and procedures, which describe program operations. This shall include a quality assurance process that ensures that patients receive appropriate treatment services and that the program is in compliance with relevant administrative rules.

(3) Personnel Policies: If two or more staff provide services, the program shall have and implement the following written personnel policies and procedures which are applicable to program staff:

(a) Rules of program staff conduct and standards for ethical practices of treatment program practitioners;

(b) Standards for program staff use and abuse of alcohol and other drugs with procedures for managing incidences of use and abuse that, at a minimum, comply with Drug Free Workplace Standards; and
(c) Compliance with the federal and state personnel regulations including the Civil Rights Act of 1964 as amended in 1972, Equal Pay Act of 1963, the Age Discrimination in Employment Act of 1967, Title I of the Americans with Disabilities Act, Oregon civil rights laws related to employment practices, and any subsequent amendments effective on or before the effective date of these rules. The opioid treatment program shall give individualized consideration to all job applicants who, with or without reasonable accommodation, can perform the essential functions of the job position.

(4) Personnel Records: Personnel records for each member of the program's work force, including staff or volunteers shall be kept and shall include:

(a) Resume or employment application, and job description;

(b) Documentation of applicable qualification standards as described in OAR 415-020-0075;

(c) For volunteers or interns or students, the record need only include information required by subsection (a) of this rule and the written work plan for such person.

(5) Confidentiality and Retention: Personnel records shall be maintained and utilized in such a way as to ensure program staff confidentiality and shall be retained for a period of three years following the departure of a program staff person.

(6) Disabilities Act: Programs receiving public funds must comply with Title 2 of the Americans with Disabilities Act of 1990, 42 USC § 1231 et al.

(7) Insurance: Each program shall maintain malpractice and liability insurance and be able to demonstrate evidence of current compliance with this requirement. If the program is operated by a public body, the program shall demonstrate evidence of insurance or a self-insurance fund pursuant to ORS 30.282.

(8) Prevention of Duplicate Dispensing: Opioid Treatment Programs will participate in any procedures, developed by the Division in consultation with opioid treatment providers, for preventing simultaneous dispensing of opioid agonist medications to the same patient by more than one program.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0017

Patient Records

(1) Patient Recordkeeping: Each program shall:

(a) Accurately record all information about patients as required by these rules in the permanent patient record;

(b) Maintain each patient record to assure identification, accessibility, uniform organization, and completeness of all components required by these rules and in a manner to protect against damage or separation from the permanent patient or program record;

(c) Keep all documentation current .unless specified otherwise, within seven days of delivering the service or obtaining the information;

(d) Include the signature of the person providing the documentation and service;

(e) Not falsify, alter, or destroy any patient information required by these rules to be maintained in a patient record or program records;

(f) Document all procedures in these rules requiring patient consent and the provision of information to the patient on forms describing what the patient has been asked to consent to or been informed of, and signed and dated by the patient. If the program does not obtain documentation of consent or provision of required information, the reasons must be specified in the patient record and signed by the person responsible for providing the service to the patient;

(g) Require that errors in the permanent record be corrected by lining out the incorrect data with a single line in ink, adding the correct information, and dating and initialing the correction. Errors may not be corrected by removal or obliteration through the use of correction fluid or tape so they cannot be read; and

(h) Permit inspection of patient records upon request by the Division to determine compliance with these rules.

(2) Patient and Fiscal Record Retention: Patient records shall be kept for a minimum of seven years. If a program is taken over or acquired by another program, the original program is responsible for assuring compliance with the requirements of 42 CFR § 2.19(a)(1) or (b), whichever is applicable. If a program discontinues operations, the program is responsible for:

(a) Transferring fiscal records required to be maintained under section (1) of this rule to the Division if it is a direct contract or to the community mental health program or managed care plan administering the contract, whichever is applicable; and

(b) Destroying patient records or, with patient consent, transferring patient records to another program. Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0020

Patient Rights

(1) Patient Record Confidentiality: An Opioid Treatment Program 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 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 drugs. 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.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590.

415-020-0025

Admission Policies and Procedures

(1) Admission Criteria: The Opioid Treatment Program 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 or medical director;
- (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 has documentation in the patient record that there is a medical need to administer opioid agonist medications
- (d) Documentation that an effort was made to discover whether the applicant is on probation or parole. For applicants on parole or probation, the program must obtain documentation that the probation and parole officer has provided written approval for admission,
- (e) Documentation that an initial urinalysis test has been completed and screened for opiates, methadone, benzodiazepines, barbiturates, cocaine, amphetamines, and Tetrahydrocannabinol (THC),
- (f) 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.
- (g) 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.

(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 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 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 herself and her 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'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 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 Programs 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.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

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).

(2) The diagnostic assessment shall be documented in the permanent patient record. It shall consist of the elements described in the ASAM PPC 2R 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.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0035

Treatment Planning and Documentation of Treatment Progress

(1) The Opioid Treatment Program shall develop treatment plans, progress notes, and discharge plans consistent with the ASAM PPC 2R.

(2) Treatment Plan: The PTP 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.

(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, and the patient's progress toward the treatment objectives.

(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.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0040

Treatment Services General

(1) Treatment Services: The Opioid Treatment Program 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 her 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, benzodiazepines, and THC.

(7) Frequency of urine testing: The Opioid Treatment Program 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.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

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 with ASAM PPC 2R.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0053

Unsupervised Use of Opioid Agonist Medications

(1) Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays, and state or federal holidays.

(2) Decisions on dispensing opioid treatment medications to patients for unsupervised use shall be made by the program medical director. In determining whether a patient is responsible in handling opioid medications and may be permitted unsupervised use, the medical director shall consider the following criteria;

(a) Absence of drugs of abuse, including alcohol;

(b) Regularity of program attendance;

(c) Absence of serious behavioral problems at the program;

(d) Absence of criminal activity while enrolled at the program;

(e) Stability of the patient's home environment and social relationships;

(f) Length of time in comprehensive maintenance treatment;

(g) Assurance that take-home medication can be safely stored in the patient's home; and

(h) Whether the rehabilitative benefit the patient derives from decreasing the frequency of program attendance outweighs the potential risks of diversion.

(3) Decisions to approve unsupervised use of opioid medications, including the rationale for the approval, shall be documented in the patient record.

(4) If it is determined that a patient is responsible in handling opioid agonist medications, the supply shall be limited to the following schedule;

(a) During the first 90 days of treatment, the take-home supply is limited to a single dose each week, in addition to take-home doses allowed when the clinic is closed;

(b) During the second 90 days of treatment, the take-home supply is limited to two doses per week, in addition to take-home doses allowed when the clinic is closed;

(c) During the third 90 days of treatment, the take-home supply is limited to three doses per week, in addition to take-home doses allowed when the clinic is closed;

(d) In the remaining months of the first year, a patient may be given a maximum 6-day supply of take-home medication;

(e) After one year of continuous abstinence in treatment, a patient may be given a maximum two-week supply of take-home medication;

(f) After two years of continuous abstinence treatment, a patient may be given a maximum one-month supply of take-home medication.

(5) The dispensing restrictions set forth in 4(a) through 4(f) of this rule do not apply to the partial agonist opioid medication, buprenorphine and buprenorphine products. Patients must meet criteria established in 2(a) through 2(h) of this rule for unsupervised use of buprenorphine and buprenorphine products.

Stat. Auth.: ORS 413.042 & 430.256

Stats. Implemented: ORS 430.010 & 430.560 - 430.590

415-020-0054

Diversion Control Plan

Each Opioid Treatment Program shall have a diversion control plan to reduce possibilities for diversion of controlled substances from legitimate treatment to illicit use. The plan shall include the following;

(1) A mechanism for continuous monitoring of clinical and administrative activities, to reduce the risk of medication diversion; and

(2) A mechanism for problem identification, prevention, and correction of diversion problems.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0060

Medically Supervised Withdrawal

(1) This section contains special provisions that apply to medically supervised withdrawal. Except as otherwise noted in this section, all requirements in the other sections of this rule apply to medically supervised withdrawal as well as comprehensive maintenance treatment patients.

(2) Admission Criteria: The opioid treatment program must establish current physical dependence on narcotics or opiates by way of grade 2 withdrawal symptoms. A one year history of dependence is not required for medically supervised withdrawal.

(3) Readmissions: Patients with two or more unsuccessful medically supervised withdrawal episodes within a 12 month period must be assessed by the Opioid Treatment Program physician for other forms of treatment. A program shall not admit a patient for more than two medically supervised withdrawal episodes in one year.

(4) Medically Supervised Withdrawal Contract: Before initial dosing of the patient, the program shall develop a contract with the patient that shall be dated and signed by the counselor and the patient, and shall specify:

(a) Maximum length of medically supervised withdrawal treatment, which may not exceed 180 days, and a rationale for the length chosen. Subsequent changes in length of medically supervised withdrawal must also be accompanied by a rationale.

(b) Required abstinence from alcohol and other drugs during medically supervised withdrawal treatment;

(c) Required counseling contacts;

(d) Take-out dose limits;

(e) Consequences regarding missed doses;

(f) Urine drug screening procedures;

(g) Consequences of failure to carry out the medically supervised withdrawal contract including involuntary termination;

(h) Criteria for involuntary termination

(5) Assessment: The program shall develop and implement a written procedure for assessing each patient's medically supervised withdrawal needs following initial dosing. The procedure shall specify that the assessment and evaluation is the responsibility of a member of the treatment staff, shall be recorded in the patient record, and shall include:

- (a) Alcohol and drug use and problems history;
- (b) Psychological history;
- (c) Presenting problems) and
- (d) History of previous treatment.

(6) Planning: Individualized medically supervised withdrawal planning shall occur and be documented in the patient's record within seven working days to include:

- (a) Initial dose level and a planned reduction schedule that shall be completed within 180 days;
- (b) Referral to appropriate agencies for needs identified during the intake assessment and procedure; and
- (c) Monthly review by the medical director.

(7) Treatment: Each patient shall be assigned a counselor who shall:

- (a) Meet at least weekly with the patient;
- (b) Monitor the patient's response to the withdrawal schedule;
- (c) Make and monitor referrals;
- (d) Maintain the patient's record; and
- (e) Monitor patient compliance with the medically supervised withdrawal contract.

(8) Take-Out Doses: Take-home medication is not allowed for medically supervised withdrawal treatment planned for 30 days or less. For medically supervised withdrawal treatment planned for longer than 30 days the program shall use the time frames and criteria established for maintenance patients.

(9) Discharge: An opioid treatment program shall discharge a patient who misses two consecutive doses unless an adequate explanation for the absences has been reviewed and approved by the medical director.

(10) Urinalysis: The program shall collect and test one random urine drug screen for each patient per week. Documentation of a specific clinical intervention shall accompany documentation of any positive urine sample and shall be followed by documentation of the effectiveness of the intervention in subsequent progress notes.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0065

Opioid Agonist Medication Administration

The Opioid Treatment Program 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 name, address, telephone number, and medical director. All labeling shall be in compliance with the Oregon Board of Pharmacy standards.

(3) Opioid Treatment Programs 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 record, date, and sign in each patient's record each change in the dosage schedule; 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 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 in the opioid agonist treatment medication shall be documented in the patient 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;

(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 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.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0070

Medical Services

- (1) There shall be at least one program physician available to supervise the initial medical evaluation, follow-up care and to supervise the patient medication schedules, who is licensed under the appropriate State law and registered under the appropriate State and Federal laws to order narcotic drugs for patients. The licensed physician assumes responsibility for the amounts of narcotic drugs administered or dispensed and shall record and countersign all changes in the dosage schedule.
- (2) Administering of narcotic agonist medications may be performed by a registered nurse, licensed practical nurse, or other healthcare professional authorized by federal and state law to administer narcotic agonist medications under the direction and supervision of the program administrator.
- (3) Dispensing services may be provided under the direction and supervision of the program physician, provided that the agent is a pharmacist or other healthcare professional authorized under federal and state law to dispense narcotic agonist medications.
- (4) The medical director shall assure that the program's medical services are in full compliance with the standards, ethics, and licensure requirements of the medical profession and these rules.
- (5) The program shall adopt, maintain, and implement written procedures for acquiring patient physical examinations including medical histories and any laboratory tests or other special examination required by the medical director including the required content of those examinations and procedures. The medical director shall review and approve all such examination procedures. Physical examinations must be completed before administering the first dose of an opioid agonist medication.
- (6) The opioid treatment program shall adopt, maintain, and implement a policy and procedure to maintain the health and safety of patients and staff. This shall include:
 - (a) Control measures for infectious diseases such as hepatitis, tuberculosis, and AIDS;
 - (b) Informed consent for testing and medical treatment; and
 - (c) Medication monitoring.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0075

Staffing

- (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 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 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 alcohol and drug treatment including experience in a opioid treatment program 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 a opioid treatment program 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 a opioid treatment program with at least one year in a paid administrative capacity.

(3) Management Staff — Competency: The program administrator 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 conduct the competencies required by this rule and compliance with the program policies and procedures implementing these rules.

(4) Management Staff — Recovering Individuals: For an individual recovering from a substance abuse related disorder, the performance of a program administrator's essential job functions in connection with staff and patients who themselves may be trying to recover from a substance abuse related disorder demands that an applicant or person hired as program administrator be able to demonstrate continuous sobriety under nonresidential, independent living conditions for the immediate past two years.

(5) Clinical Supervisor — Qualifications: Each Opioid Treatment Program 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 a opioid treatment program, 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 a opioid treatment program; 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 a opioid treatment program.

(6) 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, 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 conduct the competencies required by this rule and compliance with the program policies and procedures implementing these rules; and

(c) Except as provided in section (9) of 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.

(7) 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 alcohol/drug abuse counseling;

(b) 270 contact hours of education and training in alcoholism and drug abuse related subjects; and

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

(8) 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 alcohol and drug-related 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

(9) Clinical Supervisors — Existing Staff: Supervisors not having a credential or license that meets the standards identified in section (7) or (8) 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 (7) or (8) of this rule within 24 months of the application date.

(10) Clinical Supervisors — Recovering Individuals: For an individual recovering from the disease of alcoholism /or from other drug dependence, the performance of a clinical supervisor's essential job functions in connection with staff and patients who themselves may be trying to recover from the disease of addiction demands that an applicant or person hired as clinical supervisor be able to demonstrate continuous sobriety under non-residential, independent living conditions for the immediate past two years.

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

(12) Treatment Staff — Competency: All treatment staff shall:

- (a) Have knowledge, skills, and abilities demonstrating competence in the following essential job functions: treatment of substance-related 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 section (15) or (16) of 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.

(13) 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 alcohol/drug abuse counseling;
- (b) 150 contact hours of education and training in alcoholism and drug abuse related subjects; and
- (c) Successful completion of a written objective examination or portfolio review by the certifying body.

(14) 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 alcohol and drug-related 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.

(15) Treatment Staff — Existing Staff: Existing staff who do not hold a certificate or license that meets the standards identified in section (13) or (14) 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 (13) or (14) of this rule within 36 months of the application date.

(16) 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.

(17) Treatment Staff — Recovering Individuals: For an individual recovering from the disease of alcoholism or from other drug dependence, the performance of a counselor's essential job functions demands that an applicant or person hired as a counselor be able to demonstrate continuous sobriety under non-residential, independent living conditions for the immediate past two years.

(18) The Opioid Treatment Program 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.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0080

Volunteers

An Opioid Treatment Program utilizing volunteers shall have the following standards for volunteers:

(1) Policy Required: A written policy regarding the use of volunteers that shall include:

- (a) Specific tasks and responsibilities of volunteers;
- (b) Procedures and criteria used in selecting volunteers, including sobriety requirements for individuals recovering from the disease of alcohol or other drug abuse;
- (c) Specific accountability and reporting requirements of volunteer; and
- (d) Specific procedure for reviewing the performance of volunteers and providing direct feedback to them.

(2) Orientation and Training: The program shall document that the volunteers complete an orientation and training program specific to their responsibilities before they participate in assignments. The orientation and training shall:

- (a) Include a review of the program's philosophical approach to treatment;
- (b) Include information on confidentiality regulations and patient's rights;
- (c) Specify how volunteers are to respond to and follow procedures for unusual incidents;
- (d) Explain the program's channels of communication, reporting requirements, and accountability requirements for volunteers;
- (e) Explain the procedure for reviewing the volunteer's performance and providing feedback to the volunteer; and
- (f) Explain the procedure for discontinuing a volunteer's participation.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0085

Building Requirements

(1) Applicable Codes: Each Opioid Treatment Program shall maintain up-to-date documentation verifying that they meet applicable building codes, and state and local fire and safety regulations. The program must check with local government to make sure all applicable local codes have been met.

(2) Space Where Services Provided: Each Opioid Treatment Program shall provide space for services including but not limited to intake, assessment and , counseling, and telephone conversations that assures the privacy and confidentiality of clients and is furnished in an adequate and comfortable fashion including plumbing, sanitation, heating, and cooling.

(3) Disabled Accessibility: Programs shall be accessible to persons with disabilities pursuant to Title II of the Americans with Disabilities Act if the program receives any public funds or Title III of the Act if no public funds are received.

(4) Emergency Procedures: Programs shall adopt and implement emergency policies and procedures, including an evacuation plan and emergency plan in case of fire, explosion, accident, death or other emergency. The policies and procedures and emergency plans shall be current and posted next to the telephone used by staff. In addition, programs shall maintain a 24 hour telephone answering capability to respond to facility and patient emergencies;

(5) Disaster Plan: The program must develop and regularly update a disaster plan that outlines the program response to disasters of human or natural origin that may render the program's facility unusable. The plan must address the following;

(a) How emergency dosing will be implemented; and

(b) Identification of emergency links to other community agencies.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0090

Variations

Requirements and standards for requesting and granting variations or exceptions are found in OAR 309-008-1600.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 183, 430.560 & 430.590

Secretary of State
STATEMENT OF NEED AND JUSTIFICATION
A Certificate and Order for Filing Temporary Administrative Rules
accompanies this form

FILED
8-10-16 3:31 PM
ARCHIVES DIVISION
SECRETARY OF STATE

Oregon Health Authority, Health Systems Division: Addiction Services
Agency and Division

415
Administrative Rules Chapter Number

Temporary amendments to OAR 415-020 regarding outpatient Opiate Treatment Programs.

Rule Caption (Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.)

In the Matter of:

Temporary amendments to OAR 415-020 regarding outpatient synthetic Opiate Treatment Programs.

Statutory Authority:

ORS 413.042

Other Authority:

Statutes Implemented:

ORS 813.500 - 813.520

Need for the Temporary Rule(s):

These rules prescribe standards for the development and operation of Opioid Treatment Programs approved by the Health Systems Division of the Oregon Health Authority (OHA).

Documents Relied Upon, and where they are available:

Other rules referenced in these rules may be accessed on the website of Oregon's Secretary of State.

Justification of Temporary Rule(s):

These rule amendments must be filed promptly so as to ensure standardized language and citations with other rule amendments recently filed.

Nola Russell

nola.russell@state.or.us

Printed Name

Email Address

**OREGON HEALTH AUTHORITY
HEALTH SYSTEMS DIVISION
ADDICTION SERVICES
DIVISION 20
STANDARDS FOR OUTPATIENT SYNTHETIC OPIATE TREATMENT PROGRAMS**

415-020-0000

Purpose

These rules prescribe standards for the development and operation of Opioid Treatment Programs approved by the Health Systems Division of the Oregon Health Authority.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

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) "Accredited Opioid Treatment Program" means a program that is the subject of a current, valid accreditation from an accreditation body approved by SAMHSA.
- (4) "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.
- (5) "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 and approved service delivery locations of the certificate.
- (6) "Community Mental Health Program (CMHP)" means the organization of all services for persons with mental or emotional disturbances, drug abuse problems, developmental disabilities, and alcoholism and alcohol abuse problems operated by, or contractually affiliated with, a local mental health authority operated in a specific geographic area of the state under an intergovernmental agreement or direct contract with the Oregon Health Authority.
- (7) "Comprehensive maintenance treatment" means opioid agonist medication treatment that includes a broad range of clinically appropriate medical and rehabilitative services.
- (8) "Division" means the Health Systems Division of the Oregon Health Authority (OHA).
- (9) "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.
- (10) "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.
- (11) "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.
- (12) "Federal Opioid Treatment Standards" means the standards established by the Secretary of Health and Human Services that are used to determine whether an opioid treatment program is qualified to engage in opioid treatment.

- (13) "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.
- (14) "Long-Term Medically Supervised Withdrawal Treatment" means treatment for a period of more than 30 days but not exceeding 180 days.
- (15) "Maintenance Treatment" means the administration of an opioid agonist treatment medication at stable dosage levels for a period longer than 21 days.
- (16) "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.
- (17) "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.
- (18) "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.
- (19) "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.
- (20) "Opioid Treatment Program" means a program that dispenses and administers opioid agonist medications in conjunction with appropriate counseling, supportive, and medical services.
- (21) "Patient" means any individual who receives services in an opioid treatment program.
- (22) "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 produced in a contemporaneous printed form, authenticated by signature and date of the person who provided the service, and placed in the patient record.
- (23) "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.
- (24) "Quality Assurance" means the process of objectively and systematically monitoring and evaluating the appropriateness of patient care to identify and resolve identified problems.
- (25) "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.
- (26) "State Methadone Authority" means the State Methadone 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 Methadone Authority for Oregon is the Addictions and Mental Health Division of the Oregon Health Authority.
- (27) "Treatment" means the specific medical and non-medical therapeutic techniques employed to assist the patient in recovering from drug abuse or drug dependence.
- (28) "Urinalysis Test" means an analytical procedure to identify the presence or absence of specific drugs or metabolites in a urine specimen.
- (29) "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.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0010

Program Approval

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

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

(c) Submit documentation of accreditation as an opioid treatment program by an accreditation body approved by SAMHSA under 42 CFR Part 8.

(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.

(6) 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, and the Federal Drug Enforcement Administration.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b), 430.560 - 430.590

415-020-0015

Administrative Requirements

(1) Administrative Rules: An Opioid Treatment Program which obtains reimbursement for publicly funded services shall comply with the public contracting rules including but not limited to:

(a) OAR 309-013-0020;

(b) OAR 309-013-0075 to 309-013-0105;

(c) OAR 309-014-0000 to 309-014-0040;

(d) OAR 309-016-0000 to 309-016-0130;

(e) OAR 410-120-0000 through 410-120-1980; and

(f) OAR 410-141-0000 through 410-141-0860.

(2) Policies and Procedures: An Opioid Treatment Program shall develop and implement written policies and procedures, which describe program operations. This shall include a quality assurance process that ensures that patients receive appropriate treatment services and that the program is in compliance with relevant administrative rules.

(3) Personnel Policies: If two or more staff provide services, the program shall have and implement the following written personnel policies and procedures which are applicable to program staff:

(a) Rules of program staff conduct and standards for ethical practices of treatment program practitioners;

(b) Standards for program staff use and abuse of alcohol and other drugs with procedures for managing incidences of use and abuse that, at a minimum, comply with Drug Free Workplace Standards; and
(c) Compliance with the federal and state personnel regulations including the Civil Rights Act of 1964 as amended in 1972, Equal Pay Act of 1963, the Age Discrimination in Employment Act of 1967, Title I of the Americans with Disabilities Act, Oregon civil rights laws related to employment practices, and any subsequent amendments effective on or before the effective date of these rules. The opioid treatment program shall give individualized consideration to all job applicants who, with or without reasonable accommodation, can perform the essential functions of the job position.

(4) Personnel Records: Personnel records for each member of the program's work force, including staff or volunteers shall be kept and shall include:

(a) Resume or employment application, and job description;

(b) Documentation of applicable qualification standards as described in OAR 415-020-0075;

(c) For volunteers or interns or students, the record need only include information required by subsection (a) of this rule and the written work plan for such person.

(5) Confidentiality and Retention: Personnel records shall be maintained and utilized in such a way as to ensure program staff confidentiality and shall be retained for a period of three years following the departure of a program staff person.

(6) Disabilities Act: Programs receiving public funds must comply with Title 2 of the Americans with Disabilities Act of 1990, 42 USC § 1231 et al.

(7) Insurance: Each program shall maintain malpractice and liability insurance and be able to demonstrate evidence of current compliance with this requirement. If the program is operated by a public body, the program shall demonstrate evidence of insurance or a self-insurance fund pursuant to ORS 30.282.

(8) Prevention of Duplicate Dispensing: Opioid Treatment Programs will participate in any procedures, developed by the Division in consultation with opioid treatment providers, for preventing simultaneous dispensing of opioid agonist medications to the same patient by more than one program.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0017

Patient Records

(1) Patient Recordkeeping: Each program shall:

(a) Accurately record all information about patients as required by these rules in the permanent patient record;

(b) Maintain each patient record to assure identification, accessibility, uniform organization, and completeness of all components required by these rules and in a manner to protect against damage or separation from the permanent patient or program record;

(c) Keep all documentation current unless specified otherwise, within seven days of delivering the service or obtaining the information;

(d) Include the signature of the person providing the documentation and service;

(e) Not falsify, alter, or destroy any patient information required by these rules to be maintained in a patient record or program records;

(f) Document all procedures in these rules requiring patient consent and the provision of information to the patient on forms describing what the patient has been asked to consent to or been informed of, and signed and dated by the patient. If the program does not obtain documentation of consent or provision of required information, the reasons must be specified in the patient record and signed by the person responsible for providing the service to the patient;

(g) Require that errors in the permanent record be corrected by lining out the incorrect data with a single line in ink, adding the correct information, and dating and initialing the correction. Errors may not be corrected by removal or obliteration through the use of correction fluid or tape so they cannot be read; and

(h) Permit inspection of patient records upon request by the Division to determine compliance with these rules.

(2) Patient and Fiscal Record Retention: Patient records shall be kept for a minimum of seven years. If a program is taken over or acquired by another program, the original program is responsible for assuring compliance with the requirements of 42 CFR § 2.19(a)(1) or (b), whichever is applicable. If a program discontinues operations, the program is responsible for:

(a) Transferring fiscal records required to be maintained under section (1) of this rule to the Division if it is a direct contract or to the community mental health program or managed care plan administering the contract, whichever is applicable; and

(b) Destroying patient records or, with patient consent, transferring patient records to another program. Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0020

Patient Rights

(1) Patient Record Confidentiality: An Opioid Treatment Program 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 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 drugs. 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.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590.

415-020-0025

Admission Policies and Procedures

(1) Admission Criteria: The Opioid Treatment Program 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 or medical director;
- (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 has documentation in the patient record that there is a medical need to administer opioid agonist medications
- (d) Documentation that an effort was made to discover whether the applicant is on probation or parole. For applicants on parole or probation, the program must obtain documentation that the probation and parole officer has provided written approval for admission,
- (e) Documentation that an initial urinalysis test has been completed and screened for opiates, methadone, benzodiazepines, barbiturates, cocaine, amphetamines, and Tetrahydrocannabinol (THC),
- (f) 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.
- (g) 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.

(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 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 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 herself and her 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'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 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 Programs 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.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

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).

(2) The diagnostic assessment shall be documented in the permanent patient record. It shall consist of the elements described in the ASAM PPC 2R 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.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0035

Treatment Planning and Documentation of Treatment Progress

(1) The Opioid Treatment Program shall develop treatment plans, progress notes, and discharge plans consistent with the ASAM PPC 2R.

(2) Treatment Plan: The PTP 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.

(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, and the patient's progress toward the treatment objectives.

(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.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0040

Treatment Services General

(1) Treatment Services: The Opioid Treatment Program 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 her 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, benzodiazepines, and THC.

(7) Frequency of urine testing: The Opioid Treatment Program 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.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

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 with ASAM PPC 2R.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0053

Unsupervised Use of Opioid Agonist Medications

(1) Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays, and state or federal holidays.

(2) Decisions on dispensing opioid treatment medications to patients for unsupervised use shall be made by the program medical director. In determining whether a patient is responsible in handling opioid medications and may be permitted unsupervised use, the medical director shall consider the following criteria;

(a) Absence of drugs of abuse, including alcohol;

(b) Regularity of program attendance;

(c) Absence of serious behavioral problems at the program;

(d) Absence of criminal activity while enrolled at the program;

(e) Stability of the patient's home environment and social relationships;

(f) Length of time in comprehensive maintenance treatment;

(g) Assurance that take-home medication can be safely stored in the patient's home; and

(h) Whether the rehabilitative benefit the patient derives from decreasing the frequency of program attendance outweighs the potential risks of diversion.

(3) Decisions to approve unsupervised use of opioid medications, including the rationale for the approval, shall be documented in the patient record.

(4) If it is determined that a patient is responsible in handling opioid agonist medications, the supply shall be limited to the following schedule;

(a) During the first 90 days of treatment, the take-home supply is limited to a single dose each week, in addition to take-home doses allowed when the clinic is closed;

(b) During the second 90 days of treatment, the take-home supply is limited to two doses per week, in addition to take-home doses allowed when the clinic is closed;

(c) During the third 90 days of treatment, the take-home supply is limited to three doses per week, in addition to take-home doses allowed when the clinic is closed;

(d) In the remaining months of the first year, a patient may be given a maximum 6-day supply of take-home medication;

(e) After one year of continuous abstinence in treatment, a patient may be given a maximum two-week supply of take-home medication;

(f) After two years of continuous abstinence treatment, a patient may be given a maximum one-month supply of take-home medication.

(5) The dispensing restrictions set forth in 4(a) through 4(f) of this rule do not apply to the partial agonist opioid medication, buprenorphine and buprenorphine products. Patients must meet criteria established in 2(a) through 2(h) of this rule for unsupervised use of buprenorphine and buprenorphine products.

Stat. Auth.: ORS 413.042 & 430.256

Stats. Implemented: ORS 430.010 & 430.560 - 430.590

415-020-0054

Diversion Control Plan

Each Opioid Treatment Program shall have a diversion control plan to reduce possibilities for diversion of controlled substances from legitimate treatment to illicit use. The plan shall include the following;

(1) A mechanism for continuous monitoring of clinical and administrative activities, to reduce the risk of medication diversion; and

(2) A mechanism for problem identification, prevention, and correction of diversion problems.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0060

Medically Supervised Withdrawal

(1) This section contains special provisions that apply to medically supervised withdrawal. Except as otherwise noted in this section, all requirements in the other sections of this rule apply to medically supervised withdrawal as well as comprehensive maintenance treatment patients.

(2) Admission Criteria: The opioid treatment program must establish current physical dependence on narcotics or opiates by way of grade 2 withdrawal symptoms. A one year history of dependence is not required for medically supervised withdrawal.

(3) Readmissions: Patients with two or more unsuccessful medically supervised withdrawal episodes within a 12 month period must be assessed by the Opioid Treatment Program physician for other forms of treatment. A program shall not admit a patient for more than two medically supervised withdrawal episodes in one year.

(4) Medically Supervised Withdrawal Contract: Before initial dosing of the patient, the program shall develop a contract with the patient that shall be dated and signed by the counselor and the patient, and shall specify:

(a) Maximum length of medically supervised withdrawal treatment, which may not exceed 180 days, and a rationale for the length chosen. Subsequent changes in length of medically supervised withdrawal must also be accompanied by a rationale.

(b) Required abstinence from alcohol and other drugs during medically supervised withdrawal treatment;

(c) Required counseling contacts;

(d) Take-out dose limits;

(e) Consequences regarding missed doses;

(f) Urine drug screening procedures;

(g) Consequences of failure to carry out the medically supervised withdrawal contract including involuntary termination;

(h) Criteria for involuntary termination

(5) Assessment: The program shall develop and implement a written procedure for assessing each patient's medically supervised withdrawal needs following initial dosing. The procedure shall specify that the assessment and evaluation is the responsibility of a member of the treatment staff, shall be recorded in the patient record, and shall include:

- (a) Alcohol and drug use and problems history;
- (b) Psychological history;
- (c) Presenting problems) and
- (d) History of previous treatment.

(6) Planning: Individualized medically supervised withdrawal planning shall occur and be documented in the patient's record within seven working days to include:

- (a) Initial dose level and a planned reduction schedule that shall be completed within 180 days;
- (b) Referral to appropriate agencies for needs identified during the intake assessment and procedure; and
- (c) Monthly review by the medical director.

(7) Treatment: Each patient shall be assigned a counselor who shall:

- (a) Meet at least weekly with the patient;
- (b) Monitor the patient's response to the withdrawal schedule;
- (c) Make and monitor referrals;
- (d) Maintain the patient's record; and
- (e) Monitor patient compliance with the medically supervised withdrawal contract.

(8) Take-Out Doses: Take-home medication is not allowed for medically supervised withdrawal treatment planned for 30 days or less. For medically supervised withdrawal treatment planned for longer than 30 days the program shall use the time frames and criteria established for maintenance patients.

(9) Discharge: An opioid treatment program shall discharge a patient who misses two consecutive doses unless an adequate explanation for the absences has been reviewed and approved by the medical director.

(10) Urinalysis: The program shall collect and test one random urine drug screen for each patient per week. Documentation of a specific clinical intervention shall accompany documentation of any positive urine sample and shall be followed by documentation of the effectiveness of the intervention in subsequent progress notes.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0065

Opioid Agonist Medication Administration

The Opioid Treatment Program 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 name, address, telephone number, and medical director. All labeling shall be in compliance with the Oregon Board of Pharmacy standards.

(3) Opioid Treatment Programs 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 record, date, and sign in each patient's record each change in the dosage schedule; 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 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 in the opioid agonist treatment medication shall be documented in the patient 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;

(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 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.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0070

Medical Services

- (1) There shall be at least one program physician available to supervise the initial medical evaluation, follow-up care and to supervise the patient medication schedules, who is licensed under the appropriate State law and registered under the appropriate State and Federal laws to order narcotic drugs for patients. The licensed physician assumes responsibility for the amounts of narcotic drugs administered or dispensed and shall record and countersign all changes in the dosage schedule.
- (2) Administering of narcotic agonist medications may be performed by a registered nurse, licensed practical nurse, or other healthcare professional authorized by federal and state law to administer narcotic agonist medications under the direction and supervision of the program administrator.
- (3) Dispensing services may be provided under the direction and supervision of the program physician, provided that the agent is a pharmacist or other healthcare professional authorized under federal and state law to dispense narcotic agonist medications.
- (4) The medical director shall assure that the program's medical services are in full compliance with the standards, ethics, and licensure requirements of the medical profession and these rules.
- (5) The program shall adopt, maintain, and implement written procedures for acquiring patient physical examinations including medical histories and any laboratory tests or other special examination required by the medical director including the required content of those examinations and procedures. The medical director shall review and approve all such examination procedures. Physical examinations must be completed before administering the first dose of an opioid agonist medication.
- (6) The opioid treatment program shall adopt, maintain, and implement a policy and procedure to maintain the health and safety of patients and staff. This shall include:
 - (a) Control measures for infectious diseases such as hepatitis, tuberculosis, and AIDS;
 - (b) Informed consent for testing and medical treatment; and
 - (c) Medication monitoring.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0075

Staffing

- (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 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 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 alcohol and drug treatment including experience in a opioid treatment program 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 a opioid treatment program 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 a opioid treatment program with at least one year in a paid administrative capacity.

(3) Management Staff — Competency: The program administrator 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 conduct the competencies required by this rule and compliance with the program policies and procedures implementing these rules.

(4) Management Staff — Recovering Individuals: For an individual recovering from a substance abuse related disorder, the performance of a program administrator's essential job functions in connection with staff and patients who themselves may be trying to recover from a substance abuse related disorder demands that an applicant or person hired as program administrator be able to demonstrate continuous sobriety under nonresidential, independent living conditions for the immediate past two years.

(5) Clinical Supervisor — Qualifications: Each Opioid Treatment Program 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 a opioid treatment program, 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 a opioid treatment program; 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 a opioid treatment program.

(6) 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, 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 conduct the competencies required by this rule and compliance with the program policies and procedures implementing these rules; and

(c) Except as provided in section (9) of 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.

(7) 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 alcohol/drug abuse counseling;

(b) 270 contact hours of education and training in alcoholism and drug abuse related subjects; and

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

(8) 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 alcohol and drug-related 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

(9) Clinical Supervisors — Existing Staff: Supervisors not having a credential or license that meets the standards identified in section (7) or (8) 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 (7) or (8) of this rule within 24 months of the application date.

(10) Clinical Supervisors — Recovering Individuals: For an individual recovering from the disease of alcoholism /or from other drug dependence, the performance of a clinical supervisor's essential job functions in connection with staff and patients who themselves may be trying to recover from the disease of addiction demands that an applicant or person hired as clinical supervisor be able to demonstrate continuous sobriety under non-residential, independent living conditions for the immediate past two years.

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

(12) Treatment Staff — Competency: All treatment staff shall:

- (a) Have knowledge, skills, and abilities demonstrating competence in the following essential job functions: treatment of substance-related 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 section (15) or (16) of 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.

(13) 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 alcohol/drug abuse counseling;
- (b) 150 contact hours of education and training in alcoholism and drug abuse related subjects; and
- (c) Successful completion of a written objective examination or portfolio review by the certifying body.

(14) 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 alcohol and drug-related 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.

(15) Treatment Staff — Existing Staff: Existing staff who do not hold a certificate or license that meets the standards identified in section (13) or (14) 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 (13) or (14) of this rule within 36 months of the application date.

(16) 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.

(17) Treatment Staff — Recovering Individuals: For an individual recovering from the disease of alcoholism or from other drug dependence, the performance of a counselor's essential job functions demands that an applicant or person hired as a counselor be able to demonstrate continuous sobriety under non-residential, independent living conditions for the immediate past two years.

(18) The Opioid Treatment Program 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.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0080

Volunteers

An Opioid Treatment Program utilizing volunteers shall have the following standards for volunteers:

(1) Policy Required: A written policy regarding the use of volunteers that shall include:

- (a) Specific tasks and responsibilities of volunteers;
- (b) Procedures and criteria used in selecting volunteers, including sobriety requirements for individuals recovering from the disease of alcohol or other drug abuse;
- (c) Specific accountability and reporting requirements of volunteer; and
- (d) Specific procedure for reviewing the performance of volunteers and providing direct feedback to them.

(2) Orientation and Training: The program shall document that the volunteers complete an orientation and training program specific to their responsibilities before they participate in assignments. The orientation and training shall:

- (a) Include a review of the program's philosophical approach to treatment;
- (b) Include information on confidentiality regulations and patient's rights;
- (c) Specify how volunteers are to respond to and follow procedures for unusual incidents;
- (d) Explain the program's channels of communication, reporting requirements, and accountability requirements for volunteers;
- (e) Explain the procedure for reviewing the volunteer's performance and providing feedback to the volunteer; and
- (f) Explain the procedure for discontinuing a volunteer's participation.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0085

Building Requirements

(1) Applicable Codes: Each Opioid Treatment Program shall maintain up-to-date documentation verifying that they meet applicable building codes, and state and local fire and safety regulations. The program must check with local government to make sure all applicable local codes have been met.

(2) Space Where Services Provided: Each Opioid Treatment Program shall provide space for services including but not limited to intake, assessment and , counseling, and telephone conversations that assures the privacy and confidentiality of clients and is furnished in an adequate and comfortable fashion including plumbing, sanitation, heating, and cooling.

(3) Disabled Accessibility: Programs shall be accessible to persons with disabilities pursuant to Title II of the Americans with Disabilities Act if the program receives any public funds or Title III of the Act if no public funds are received.

(4) Emergency Procedures: Programs shall adopt and implement emergency policies and procedures, including an evacuation plan and emergency plan in case of fire, explosion, accident, death or other emergency. The policies and procedures and emergency plans shall be current and posted next to the telephone used by staff. In addition, programs shall maintain a 24 hour telephone answering capability to respond to facility and patient emergencies;

(5) Disaster Plan: The program must develop and regularly update a disaster plan that outlines the program response to disasters of human or natural origin that may render the program's facility unusable. The plan must address the following;

(a) How emergency dosing will be implemented; and

(b) Identification of emergency links to other community agencies.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 430.010(4)(b) & 430.560 - 430.590

415-020-0090

Variations

Requirements and standards for requesting and granting variations or exceptions are found in OAR 309-008-1600.

Stat. Auth.: ORS 409.410 & 409.420

Stats. Implemented: ORS 183, 430.560 & 430.590