641—155.35 (125,135) Specific standards for opioid treatment programs. All programs that use methadone or other medications approved by the Food and Drug Administration under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and the state of Iowa for use in the treatment of opioid addiction shall comply with this rule, HIPAA and Part II, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, 42 CFR Part 8, Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction, effective May 18, 2001.

155.35(1) *Definitions.*

"Accredited opioid treatment program" means an opioid treatment program that is the subject of a current, valid accreditation from an accreditation body approved by the Substance Abuse and Mental Health Services Administration (SAMHSA).

"Certification" means the process by which SAMHSA determines that an opioid treatment program is qualified to provide opioid treatment under the federal opioid treatment standards.

"Certification application" means the application filed by an opioid treatment program for purposes of obtaining certification from SAMHSA.

"Certified opioid treatment program" means an opioid treatment program that is the subject of a current, valid certification.

"Comprehensive maintenance treatment" means maintenance treatment provided in conjunction with a comprehensive range of appropriate medical and rehabilitative services.

"Detoxification treatment" means the dispensing 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 within such a period.

"Interim maintenance treatment" means detoxification treatment for a period of more than 30 days but not in excess of 180 days.

"Maintenance treatment" means the dispensing of an opioid agonist treatment medication at stable dosage levels for a period in excess of 21 days in the treatment of an individual for opioid addiction.

"Medical and rehabilitative services" means services such as medical evaluations, counseling, and rehabilitative and other social programs (e.g., vocational and educational guidance, employment placement) that are intended to help patients in opioid treatment programs become or remain productive members of society.

"Medical director" means a physician who is licensed to practice medicine in accordance with Iowa Code chapter 148, 150, or 150A and who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and health care professionals functioning under the medical director's direct supervision.

"Medication unit" means a facility established as part of, but geographically separate from, an opioid treatment program from which licensed private practitioners or community pharmacists dispense or administer opioid agonist treatment medications or collect samples for drug testing or analysis.

"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 dependence is characterized by an individual's repeated self-administration of opiates that usually results in opiate tolerance, withdrawal symptoms, and compulsive drug-taking. Dependency may occur with or without the physiological symptoms of tolerance and withdrawal.

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

"Opioid drug" means any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

"Opioid treatment" means the dispensing of an opioid agonist treatment medication, along with a comprehensive range of medical and rehabilitative services, when clinically necessary, to an individual to alleviate the adverse medical, psychological, or physical effects incident to opiate addiction. This term encompasses detoxification treatment, short-term detoxification treatment, long-term detoxification treatment, maintenance treatment, comprehensive maintenance treatment, and interim maintenance treatment.

"Opioid treatment program" or *"OTP"* means a program or practitioner engaged in opioid treatment or interim maintenance treatment.

"Patient" or *"client/patient"* means any individual who undergoes treatment in an opioid treatment program.

"Program sponsor" means the person responsible for the operation of the opioid treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

"Short-term detoxification treatment" means detoxification treatment for a period not in excess of 30 days.

"State authority" means the Iowa department of public health, division of behavioral health, which regulates the treatment of opiate addiction with opioid drugs.

"Treatment plan" means a plan that outlines for each patient attainable short-term treatment goals that are mutually acceptable to the patient and the opioid treatment program and that specifies the services to be provided and the frequency and schedule for their provision.

155.35(2) *Required approvals.* All opioid treatment programs shall be licensed or approved by the board and shall maintain all other approvals required by the Drug Enforcement Administration, Substance Abuse and Mental Health Services Administration and the Iowa board of pharmacy examiners in order to provide services.

155.35(3) *Central registry system.* To prevent simultaneous enrollment of a client/patient in more than one program, all opioid treatment programs shall participate in a central registry as established by the division.

Prior to admission of an applicant to an opioid treatment program, the program shall submit to the registry the applicant's name, birth date, and date of intended admission, and any other information

required for the clearance procedure. No person shall be admitted to a program who is found by the registry to be participating in another such program. All opioid treatment programs shall report all admissions, discharges, and transfers to the registry immediately. All information reported to the registry from the programs and all information reported to the programs from the registry shall be treated as confidential in accordance with HIPAA and "Confidentiality of Alcohol and Drug Abuse Patient Records" regulations, 42 CFR Part 2, effective June 9, 1987.

a. Definitions. For purposes of this subrule:

"Central registry" means the system through which the Iowa department of public health, division of behavioral health, obtains client/patient identifying information about individuals applying for maintenance or detoxification treatment for the purpose of preventing an individual's concurrent enrollment in more than one such program.

"Opioid treatment program" means a detoxification or maintenance treatment program which is required to report client/patient identifying information to the central registry and which is located in the state.

b. Restrictions on disclosure. A program may disclose client/patient identifying information to a central registry for the purpose of preventing multiple enrollment of a client/patient only if:

(1) The disclosure is made when:

1. The client/patient is admitted for treatment; or
2. The treatment is interrupted, resumed or terminated.

(2) The disclosure is limited to:

1. Client/patient identifying information; and
2. Relevant dates of admission.

(3) The program shall inform the client/patient of the required disclosure prior to admission.

c. Use of information limited to prevention of multiple enrollments. Any information disclosed to the central registry to prevent multiple enrollments may not be redisclosed by the registry or such information used for any other purpose than the prevention of multiple enrollments unless so authorized by court order in accordance with HIPAA and 42 CFR Part 2, effective June 9, 1987.

d. Permitted disclosure by the central registry to prevent a multiple enrollment. If a program petitions the central registry, and an identified client/patient is enrolled in another program, the registry may disclose:

(1) The name, address, and telephone number of the program in which the client/patient is currently enrolled to the inquiring program; and

(2) The name, address, and telephone number of the inquiring program to the program in which the client/patient is currently enrolled. The programs may communicate as necessary to verify that no error has been made and to prevent or eliminate any multiple enrollment.

155.35(4) *Admission requirements.*

a. Prior to or at the time of a client/patient's admission to an opioid treatment program, the program shall conduct a comprehensive assessment so as to determine appropriateness for admission.

b. The program shall verify, to the extent possible, the client/patient's name, address, and date of birth.

c. The program physician shall determine and document in the client/patient's record that the client/patient is physiologically dependent on narcotic substances and has been so dependent for at least one year prior to admission. A one-year history of addiction means that the client/patient was physiologically dependent on a narcotic at a time one year before admission to a program and was addicted for most of the year preceding admission.

(1) When physiological addiction cannot be clearly documented, the program physician or an appropriately trained staff member designated and supervised by the physician shall record in the client/patient's record the criteria used to determine the client/patient's current physiologic dependence and history of addiction. In the latter circumstance, the program physician shall review, date, and countersign the supervised staff member's evaluation to demonstrate the physician's agreement with the evaluation. The program physician shall make the final determination concerning a client/patient's physiologic dependence and history of addiction. The program physician also shall sign, date, and record a statement that the physician has reviewed all the documented evidence to support a one-year history of addiction and the current physiologic dependence and that in the physician's reasonable clinical judgment the client/patient fulfills the requirements for admission to maintenance treatment. Before the program administers any medication to the client/patient, the program physician shall complete and record the statement documenting addiction and current physiologic dependence.

(2) When a client/patient has voluntarily left an opioid treatment program in good standing and seeks readmission within two years of discharge, the program shall document the following information:

1. Prior opioid treatment of six months or more; and

2. The program physician shall enter in the client/patient's record that in the physician's medical judgment treatment is warranted.

d. The program shall collect a drug screening sample for analysis. Where dependence is substantially verified through other indicators, a negative drug screen will not necessarily preclude admission to the program.

e. Prior to admission, the program shall confirm with the central registry that the client/patient is not currently enrolled in another opioid treatment program.

f. If a potential client/patient has previously been enrolled in another program, the admitting program shall request from the previous program a copy of the client/patient's assessment data, treatment plan, and discharge summary including the type of or reason for discharge. All programs subject to these rules shall promptly respond to such a request upon receipt of a valid release of information.

g. A person under the age of 18 is required to have had two documented attempts at short-term detoxification or drug-free treatment to be eligible for maintenance treatment. A one-week waiting period is required after such a detoxification attempt, however, before an attempt is repeated. The program physician shall document in the client/patient's record that the client/patient continues to be, or is again, physiologically dependent on narcotic drugs.

h. Program staff shall ensure that a client/patient is voluntarily participating in the program, and the client/patient shall sign a Consent to Treatment Form.

i. Pregnant client/patients may be admitted to opioid treatment with the following provisions:

(1) Evidence of current physiological dependency is not needed if the program physician certifies the pregnancy and, in the physician's reasonable judgment, finds treatment to be justified. Documentation of all findings and justifications for admission shall be documented in the client/patient's record by the program physician prior to the initial dose of methadone.

(2) Pregnant client/patients shall be offered comprehensive prenatal care. If the program cannot provide prenatal services, the program shall assist the client/patient in obtaining such services and shall coordinate ongoing care with the collateral provider.

(3) The program physician shall document that the client/patient has been informed of the possible risks to the unborn child from the use of medication and the risks of continued use of illicit substances.

(4) Should a program have a waiting list for admission to the program, pregnant client/patients shall be given priority.

155.35(5) *Placement, admission and assessment.* The program shall have written criteria for considering an individual for placement and admission. In addition, the program shall maintain current procedures to ensure that patients are admitted to maintenance treatment by qualified staff who have

determined by using accepted medical criteria such as those outlined in the Diagnostic and Statistical Manual for Mental Disorders (DSM IV) that the person is currently addicted to an opioid drug.

a. The program shall have written policies and procedures governing a uniform process that defines:

(1) The types of information to be gathered on all individuals upon admission;

(2) Procedures to be followed when accepting referrals from outside agencies or organizations;

(3) The types of records to be kept on all individuals applying for services.

b. The client/patient assessment (psychosocial history) shall be an analysis and synthesis of the client/patient's status, and shall address the client/patient's strengths, problems, and areas of clinical concern.

It shall be developed within the period of time between admission and the first review date specified for that particular level of care within the continued stay review process. This initial assessment upon admission to treatment services is an expansion of information on the six categories contained within the placement screening document.

c. When an individual refuses to divulge information or to follow the recommended course of treatment, this refusal shall be noted in the case record.

d. At the time of admission, documentation shall be made that the individual has been informed of:

(1) General nature and goals of the program;

(2) Rules governing client/patient conduct and infractions that can lead to disciplinary action or discharge from the program;

(3) The hours during which the services are available;

(4) Treatment costs, if any, to be borne by the client/patient;

(5) Client/patient rights and responsibilities;

(6) Confidentiality laws, rules and regulations; and

(7) Information on preventing exposure to and transmission of human immunodeficiency virus.

e. Sufficient information shall be collected during the admission process so that the assessment process allows for the development of a complete assessment of the client/patient's status and a comprehensive plan of treatment can be developed.

f. The results of the screening and admission process shall be clearly explained to the client/patient, and to the client/patient's family when appropriate. This shall be documented in the client/patient record.

g. The program physician or designee, who is a qualified medical professional, shall complete a medical evaluation and a current psychological/mental status evaluation of the client/patient prior to the administration of the initial dose of medication. If the history and current psychological/mental status evaluation is completed by an individual other than the program physician, the program shall document in the client/patient's case record that this information was reviewed by the program physician prior to the initial dosage of medication. The medical evaluation shall include but not be limited to:

(1) A complete medical history;

(2) An assessment of the client/patient's current psychological and mental status;

(3) A physical examination including examination for:

1. Pulmonary, liver, or cardiac abnormalities;
2. Infectious disease; and
3. Dermatologic sequela of addiction.

(4) Laboratory tests including:

1. Serological test for syphilis; and
2. Urine screening for drugs.

(5) Intradermal PPD (tuberculosis skin test) and review of tetanus immunization status; and

(6) When indicated, an EKG, chest X-ray, pap smear, pregnancy test, sickle cell screening, complete blood count and white cell differential, multiphasic chemistry profile, routine and microscopic urinalysis, or other tests indicated by the client/patient's condition.

155.35(6) *Treatment plans.* Based upon the initial assessment, an individualized written treatment plan shall be developed and recorded in the client/patient's case record.

a. A treatment plan shall be developed and shall delineate the client/patient's immediate needs and actions required to meet these needs.

b. The treatment plan shall be developed as soon after the client/patient's admission as is clinically feasible, but no later than 30 days following admission to an outpatient opioid maintenance treatment program.

c. The individualized treatment plan shall minimally contain:

(1) A clear and concise statement of client/patient's current strengths and needs;

(2) Clear and concise statements of the short- and long-term goals the client/patient will be attempting to achieve;

(3) Type and frequency of therapeutic activities in which the client/patient will be participating;

(4) The staff person(s) to be responsible for the client/patient's treatment; and

(5) The specific criteria to be met for successful completion of treatment.

d. Treatment plans shall be developed in partnership with the client/patient. Comprehensive treatment plans shall be reviewed by the primary counselor and the client/patient as often as necessary, but no less than every 90 days during the first year and semiannually each subsequent year for opioid treatment modalities. Treatment plans shall be reviewed by the program physician on an annual basis.

e. The reviews shall consist of a reassessment of the client/patient's current status to include accomplishments and needs and a redefining of treatment goals when appropriate. The date of the review and any change, as well as the individuals involved in the review, shall also be recorded.

f. The use of abstract terms, jargon, or slang should be avoided in the treatment plan, and the plan should be written in a manner readily understandable to the average client/patient. The program shall provide the client/patient with copies of all treatment plans upon request.

g. Treatment plans shall be culturally and environmentally specific so as to meet the needs of the client/patient. Treatment plans shall be written in a manner readily understandable to the average person or with assistance available to illiterate, handicapped, or mentally impaired client/patients.

155.35(7) *Progress notes.* A client/patient's progress and current status in meeting the goals set in the treatment plan, as well as efforts by staff members to help the client/patient achieve these stated goals, shall be recorded in the client/patient's case record. Such information will be noted following each individual counseling session. Group therapy progress notes shall be recorded following each session or summarized at least weekly.

a. Entries shall be filed in chronological order and shall include the date services were provided or observations made, the date the entry was made, the signature or initials and staff title of the individual rendering the services. All progress notes shall be entered into the client/patient case record in permanent pen, typewriter, or by computer.

b. All entries that involve subjective interpretations of a client/patient's progress should be supplemented with a description of the actual behavioral observations which were the basis for the interpretation.

c. The use of abstract terms, jargon, or slang should be avoided in progress notes.

d. If a client/patient is receiving services from an outside resource, the program shall attempt to secure a written copy of status reports and other client/patient records from that resource.

e. The program shall develop a uniform progress notes format to be used by all clinical staff.

155.35(8) *Rehabilitative services.* The program shall have policies and procedures on the minimum attendance for rehabilitative services relative to the client/patient's progress and length of involvement in treatment. The minimum frequency of rehabilitative services shall occur at the same frequency of

on-site dosing for client/patients receiving more than two take-home dosages a week in the first year. The minimum frequency for rehabilitative services for client/patients receiving two or fewer take-home dosages shall be weekly. The program shall provide rehabilitative services that are appropriate for the client/patient based on needs identified during the assessment process. The program may provide rehabilitative services through collateral agreements with other service providers. A client/patient who does not comply with the program's rehabilitative service requirements shall be placed on a period of probation as defined by the program, or be required to immediately increase the frequency of clinic attendance for medication and rehabilitative services. If, during a period of probation, the client/patient continues to be in noncompliance with rehabilitation services, the program shall continue to increase the attendance requirement until daily attendance is obtained or the client/patient complies with rehabilitative services. This requirement shall not preclude the program's ability to determine that discharge of a client/patient is warranted for therapeutic reasons or program needs.

155.35(9) *Medication dispensing.*

a. The program physician shall determine the client/patient's initial and subsequent dose of medication and clinic dosing schedule and shall assume responsibility for the amount of the narcotic drug administered or dispensed and shall record, date, and sign in each client/patient's case record each change in the dosage schedule. The physician shall directly communicate orders to the pharmacy or registered or licensed personnel supervising medication dispensing. The program physician may communicate such orders verbally; however, orders shall be reduced in writing and countersigned within 72 hours by the program physician.

b. The initial dose of medication shall not exceed 30 milligrams, and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the client/patient's case record that 40 milligrams did not suppress opiate abstinence symptoms. A client/patient transferring into the program or on a guest-dosing status may receive an initial dosage of no more than the last daily dosage authorized by the former or primary program.

(1) Medication shall be administered by a professional authorized by law.

(2) No medication shall be administered unless the client/patient has completed admission procedures, unless the client/patient enters the program on a weekend and the central registry cannot be contacted. If, in the clinical judgment of the program physician, a client/patient is experiencing an emergency situation, the admission procedures may be completed on the following workday.

c. Administration.

(1) Take-home medication shall be labeled in accordance with state and federal law and have childproof caps.

(2) A dispensing log shall be kept in the dispensing area and in the client/patient case records which shall document the amount of medication dispensed and include the signature of the staff member authorized to dispense the medication. No dose shall be dispensed until the client/patient has been positively identified and the dosage amount is compared with the currently ordered and documented dosage level.

(3) Ingestion shall be observed and verified by the staff person authorized to dispense the medication.

(4) The program physician shall record, date, and sign in each client/patient's case record each change in the dosage schedule. Daily dosages of medications in excess of 100 milligrams shall be dispensed only with the approval of the program physician and shall be documented and justified in the client/patient's case record.

155.35(10) *Take-home or unsupervised medication use.*

a. Take-home medication may be given to client/patients who demonstrate a need for a more flexible schedule in order to enhance and continue rehabilitative progress. For client/patients receiving take-home medication, the program shall document the following requirements:

(1) Absence of recent abuse of drugs (narcotic or nonnarcotic), including alcohol;

(2) Regular attendance at the clinic;

(3) Attendance at a licensed or approved treatment program for rehabilitative services (e.g., programs are considered approved when licensed or approved in accordance with Iowa Code chapter 125);

(4) Absence of recent criminal activity;

(5) Stable home environment and social relationships;

(6) Active employment or participation in school, or similar responsible activities related to employment, education or vocation; and

(7) Assurance that medication can be safely transported and stored by the client/patient for the client/patient's own use.

b. Prior to granting take-home privileges, the program physician shall document in the client/patient's case record that all the above criteria have been considered and that, in the physician's professional judgment, the risk of diversion or abuse is outweighed by the rehabilitative benefits to be derived.

c. If the client/patient meets the above criteria, the client/patient may receive take-home medication according to the following guidelines:

(1) During the first 90 days of treatment, the take-home supply is limited to a single dose each week;

(2) During the second 90 days of treatment, the take-home supply is limited to two doses per week;

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

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

(5) After two years of continuous treatment, a patient may be given a maximum one-month supply of take-home medication; and

(6) Take-home medication shall not be dispensed to patients in interim maintenance treatment or detoxification.

d. If a client/patient is unable to conform to the applicable mandatory schedule, a revised schedule may be permitted provided the program receives an exception to these rules from the division and SAMHSA, when applicable. A copy of the written exception shall be placed in the client/patient's case record. The division will consider exceptions only in unusual circumstances. When a program is applying for less frequent pickups for client/patients, approval will be based on considerations in addition to distance when another program exists within 25 miles of the client/patient's residence.

e. Should a patient receiving take-home medication provide a drug screen that is confirmed either positive for substances or negative for the prescribed medication, the program shall ensure that when test results are used, presumptive laboratory results are distinguished from results that are definitive.

(1) The program physician shall place the client/patient on three months' probation, as defined by the program, or increase the client/patient's frequency of clinic dosing after considering the client/patient's overall progress and length of involvement in the program.

(2) Should the client/patient provide a drug screen that is positive for substances or negative for medication during a period of probation, the program physician shall increase the client/patient's frequency of clinic attendance for dosage pickup for at least three months. If after the three-month period the client/patient meets the eligibility criteria, the client/patient may return to the previous take-home schedule.

f. Take-home or unsupervised dosages of medication in excess of 100 milligrams may be dispensed by the program physician when the need for those dosages is carefully reviewed and considered and justified in the client/patient's case record based on the physician's clinical judgment.

155.35(11) *Drug testing.* Each program shall establish policies and procedures for the collection of drug-screening specimens and utilization of results.

a. The program shall ensure that an initial drug-screening test or analysis is completed for each prospective client/patient and that at least eight additional random tests or analyses are performed on each client/patient during the first year in maintenance treatment and that at least quarterly random tests or analyses are performed on each client/patient in maintenance treatment for each subsequent year. When a sample is collected from each client/patient for such a test or analysis, it shall be done in a manner that minimizes opportunity for falsification. Each test or analysis shall be analyzed for opiates, methadone, amphetamines, cocaine, and barbiturates. In addition, if any other drug or drugs have been determined by a program to be abused in that program's locality, or as otherwise indicated, each test or analysis must be analyzed for any of those drugs as well. Any laboratory that performs the testing required under this rule shall be in compliance with all applicable federal proficiency testing and licensing standards and all applicable state standards.

b. The program shall ensure that test results are not used as the sole criterion to force a client/patient out of treatment but are used as a guide to change treatment approaches. The program shall also ensure that when test results are used, presumptive laboratory results are distinguished from results that are definitive.

155.35(12) *Client/patient case records.* The program shall have written policies and procedures governing the compilation, storage and dissemination of individual client/patient case records.

a. These policies and procedures shall ensure that:

(1) The program exercises its responsibility for safeguarding and protecting the client/patient case records against loss, tampering, or unauthorized disclosure of information;

(2) Content and format of client/patient case records are kept uniform; and

(3) Entries in the client/patient case record are signed and dated.

b. The program shall provide adequate physical facilities for the storage, processing, and handling of client/patient case records. These facilities shall include suitably locked, secured rooms or file cabinets.

c. Appropriate records shall be readily accessible to those staff members providing services directly to the client/patient and other individuals specifically authorized by program policy. Records should be kept in proximity to the area in which the client/patient normally receives services.

d. The program shall have a written policy governing the disposal and maintenance of client/patient case records. Client/patient case records shall be maintained for not less than seven years from the date they are officially closed.

e. Confidentiality of alcohol and drug abuse client/patient case records. The confidentiality of alcohol and drug abuse client/patient case records maintained by a program is protected by HIPAA and the "Confidentiality of Alcohol and Drug Abuse Patient Records" regulations, 42 CFR Part 2, effective June 9, 1987, which implement federal statutory provisions, 42 U.S.C. 290dd-3 applicable to alcohol abuse client/patient records, and 42 U.S.C. 290ee-3 applicable to drug abuse client/patient records. The program is precluded from identifying that a client/patient attends the program or disclosing any information identifying a client/patient as an alcohol or drug abuser unless:

(1) The client/patient consents in writing;

(2) The disclosure is allowed by a court order;

(3) The disclosure is made to medical personnel in a medical emergency; or

(4) The disclosure is required by law.

f. Confidentiality and transfer of records. Upon receipt of a properly executed written release of information signed by the client/patient, the program shall release client/patient records in a timely manner. A program shall not refuse to transfer or release client/patient records related to continuation of care solely because payment has not been received. A program may refuse to release client/patient records which are unrelated to continuation of care if payment has not been received. A program may refuse to file the reporting form required by 641—subrule 157.3(1), "Notice Iowa Code 321J—Confidential Medical Record," reporting screening, evaluation, and treatment completion, if payment has not been received for such services.

155.35(13) *Diversion prevention plan.*

a. The program shall develop a diversion identification and prevention plan that:

(1) Outlines methods by which the program shall detect possible diversion of take-home medication; and

(2) Actions to be taken when diversion is identified or suspected.

b. The program shall establish and implement proactive procedures to reduce the likelihood or possibility of diversion.

155.35(14) *Quality improvement.* The program shall have an ongoing quality improvement process designed to objectively and systematically monitor and evaluate the quality and appropriateness of client/patient care, pursue opportunities to improve client/patient care, and resolve identified problems. Quality improvement efforts shall be facilitywide in scope and include review of clinical and professional services.

a. The program shall have a written plan for a quality improvement process. The written plan shall describe the objectives, organization, scope, and mechanisms for overseeing the effectiveness of monitoring, evaluation, and problem-solving activities.

b. The program shall establish written policies and procedures to describe and document the quality improvement process, including the monitoring and evaluation activities of the program. The policies and procedures shall ensure that:

(1) Information is collected or screened by a designated individual, individuals, or committee. Quality improvement activities may be contracted through all outside resources;

(2) Objective criteria are utilized in the development and application of criteria relating to the care or service the program provides; and

(3) Objective criteria are utilized in the evaluation of the information collected in order to identify important problems in, or opportunities to improve, client/patient care and clinical performance.

c. The program shall document that the quality of client/patient care is improved and identified problems are resolved through appropriate actions taken by the program's administrative and supervisory staff and through professional staff functions.

d. Necessary information shall be communicated among program components, modalities, or services when problems or opportunities to improve client/patient care involve more than one program component or service.

e. The program shall ensure that the status of identified problems is tracked to ensure improvement or resolution.

f. The program shall ensure that information from program components or services and the findings of discrete quality improvement activities are used to detect trends, patterns of performance, and potential problems that affect more than one program component or service.

g. The objectives, scope, organization, and effectiveness of the quality improvement process are evaluated at least annually and revised as necessary.

155.35(15) *Interim maintenance treatment.*

a. An approved program may offer interim maintenance treatment when, due to capacity, the program cannot place the client/patient in a program offering comprehensive services within 14 days of the client/patient's application for admission.

b. An approved program may provide interim maintenance treatment only if the program also provides comprehensive maintenance treatment to which interim maintenance treatment client/patients may be transferred.

c. Interim maintenance treatment program approval. Before a public or nonprofit private narcotic treatment program may provide interim maintenance treatment, the program must receive approval of both the U.S. Food and Drug Administration and the division of behavioral health and:

(1) The program director must certify that the program seeking such authorization is unable to place client/patients in a public or private nonprofit program within a reasonable geographic area within 14 days of the client/patient's application for admission; and

(2) That interim maintenance treatment will not reduce the capacity of the program's comprehensive maintenance treatment.

(3) Client/patients admitted to interim maintenance treatment shall be transferred to comprehensive maintenance treatment within 120 days of admission.

d. Minimum standards for interim maintenance treatment. The program may admit a client/patient who is eligible for comprehensive maintenance treatment to interim maintenance treatment if the client/patient cannot be placed in a public or private nonprofit comprehensive program within a reasonable geographic area and within 14 days of application for services. An initial drug screen, and at least two others, shall be taken from the client/patient during the maximum admission period of 120 days. A program shall establish and follow reasonable criteria for determining the transfer of client/patients to comprehensive maintenance treatment. These transfer criteria shall be in writing, available for inspection, and shall include at a minimum a preference for the transfer of pregnant client/patients. Interim maintenance shall be conducted in accordance with all applicable federal regulations and state rules. The program shall notify the division when a client/patient begins interim treatment; when a client/patient leaves interim treatment, and when a client/patient transfers to comprehensive maintenance treatment. Such notifications shall be documented by the program in the client/patient's case record. All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions:

(1) The medication is required to be administered daily under observation;
(2) Take-home medication is not allowed;
(3) Initial and comprehensive treatment plans are not required;
(4) A primary counselor is not required to be assigned to the client/patient; and
(5) Interim maintenance cannot be provided for longer than 120 days in any 12-month period.

155.35(16) *Complaints, investigations, suspension and revocation.* The rules relating to complaints, investigations, suspension and revocation as outlined in 641—155.11(125,135) through 641—155.16(125,135) shall apply to opioid treatment programs.

155.35(17) *Deemed status.* The board shall grant deemed status to programs accredited either by a recognized national or not-for-profit accreditation body when the board determines that the accreditation is for the same services.

a. National accreditation bodies. The national accreditation bodies currently recognized as meeting board criteria for possible deemed status are:

(1) Joint Commission.
(2) Council on Accreditation of Rehabilitation Facilities (CARF).
(3) Council on Accreditation of Children and Family Services (COA).
(4) American Osteopathic Association (AOA).

b. Credentials and expectations of accreditation bodies.

(1) The accreditation credentials of the bodies shall specify the types of organizations, programs, and services the bodies accredit and targeted population groups, if appropriate.

(2) Deemed status means that the board and division shall recognize, in lieu of their own review, an outside body's review, assessment and accreditation of a hospital-based or freestanding community-based substance abuse program's operations, functioning, and services that correspond to those described in this chapter.

c. Responsibilities of programs granted deemed status.

(1) When a program receives accreditation and is then granted licensure through deemed status, the program shall continue to be responsible for meeting all requirements in accordance with this chapter and all applicable laws and regulations.

(2) If a program that is nationally accredited requests deemed status for services not covered by the national accreditation body's standards, but covered by this chapter, the licensing for those services shall be conducted by the division.

(3) Copies of the entire CARF, Joint Commission, COA or AOA behavioral health accreditation survey/inspection report and certificate of accreditation shall be submitted to the division with the application for deemed status provided by the division.

(4) The program shall submit to the division accreditation corrective plans or written conditions to accreditation.

(5) The program shall be currently accredited by a board-approved national accreditation body for services that are outlined in this chapter.

(6) The program shall advise the division of any changes in the program's accreditation status, address, executive director/CEO, facility locations, or any other changes to the program/organization within 30 days of such changes.

(7) All survey reports for the hospital-based or freestanding community-based substance abuse treatment program from the accrediting or licensing body shall be sent to the division.

(8) For a program granted deemed status, the period of deemed status shall coincide with the period of time that program is awarded accreditation by the national accreditation body. However, under no circumstances shall it be longer than three years.

d. The board and division shall retain the following responsibilities and rights when deemed status is granted to program/organizations:

(1) The division may conduct focused or general on-site follow-up visits as determined appropriate.

(2) The division shall investigate all complaints that are under the authority of this chapter and recommend and require corrective action or other sanctions in accordance with 641—155.16(125,135). All complaints, findings and required corrective action may be reported to the accreditation body.

(3) The board shall review and act upon deemed status if necessary when complaints have been founded, when national accreditation bodies find instances of noncompliance with accreditation, when the accreditation status of the program expires without renewal, when the program's accreditation status is downgraded or withdrawn by the accreditation body, or when focused reviews find instances of noncompliance.

e. Continuation of deemed status. The program shall submit a copy of all CARF, Joint Commission, COA or AOA behavioral health accreditation survey reports to the division.

155.35(18) *Personnel qualifications.*

a. Personnel providing screening, evaluations, assessments or treatment in accordance with this chapter shall meet the requirements of 155.21(8)*"i."*

b. Personnel in opioid treatment programs shall subscribe to a code of conduct found in professional certification or licensure as specified in 155.21(8).

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