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 by 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 providing 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" 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 which outlines for each patient attainable short-term treatment goals that are mutually acceptable to the patient and the opioid treatment program and which 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 committee 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 in order to provide services.

155.35(3) *Central registry system.* To prevent simultaneous enrollment of a 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 DHHS regulations on the confidentiality of alcohol and drug abuse patient records, 42 CFR Part 2.

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 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 patient identifying information to the central registry and which is located in the state.

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

(1) The disclosure is made when:

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

(2) The disclosure is limited to:

1. Patient identifying information; and
2. Relevant dates of admission.

The program shall inform the 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 shall not be redisclosed by the registry nor shall such information be 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.

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

(1) The name, address, and telephone number of the program in which the 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 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 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 patient's name, address, and date of birth.

c. The program physician shall determine and document in the patient's record that the patient is physiologically dependent on narcotic substances and has been physiologically dependent for at least one year prior to the patient's admission. A one-year history of addiction means that the patient was physiologically dependent on a narcotic at a time one year before the patient's 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 patient's record the criteria used to determine the 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 patient's physiologic dependence and history of addiction. The program physician shall also sign, date, and record a statement that the physician has reviewed all the documented evidence to support a one-year history of addiction and current physiologic dependence by the patient and that in the physician's reasonable clinical judgment the patient fulfills the requirements for admission to maintenance treatment. Before the program administers any medication to the patient, the program physician shall complete and record the statement documenting the patient's addiction and current physiologic dependence.

(2) When a 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 about the patient:

1. Prior opioid treatment of six months or more; and
2. That in the physician's medical judgment, treatment of the patient is warranted. Such documentation shall be entered in the patient's record by the program physician.

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 a patient's admission, the program shall confirm with the central registry that the patient is not currently enrolled in another opioid treatment program.

f. If a potential patient has previously been enrolled in another program, the admitting program shall request from the previous program a copy of the 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 patient's record that the patient continues to be, or is again, physiologically dependent on narcotic drugs.

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

i. Pregnant patients may be admitted to opioid treatment in accordance 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 patient's record by the program physician prior to the administration of the initial dose of medication.

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

(3) The program physician shall document that the 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 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, that the person is currently addicted to an opioid drug.

a. The program physician or a designee who is a qualified medical professional shall complete a medical evaluation and a current psychological/mental status evaluation of the 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 patient's case record that this information was reviewed by the program physician prior to administration of the initial dose of medication.

b. The medical evaluation of the patient shall include, but not be limited to:

(1) A complete medical history;

(2) An assessment of the 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) An 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 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 patient's case record.

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

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

c. Treatment plans shall be developed in partnership with the patient. Comprehensive treatment plans shall be reviewed by the primary counselor and the 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.

155.35(7) *Rehabilitative services.* The program shall have policies and procedures on the minimum attendance for rehabilitative services relative to the patient's progress and length of involvement in treatment. The minimum frequency of rehabilitative services shall occur at the same frequency as that of on-site dosing for patients receiving more than two take-home dosages a week in the first year. The minimum frequency for rehabilitative services for patients receiving two or fewer take-home dosages shall be weekly. The program shall provide rehabilitative services that are appropriate for the patient based on needs identified during the assessment process. A 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 shall be required to immediately increase the frequency of clinic attendance for medication and rehabilitative services. If, during a period of probation, the patient continues to be in noncompliance with rehabilitation services, the program shall continue to increase the attendance requirement until daily attendance is obtained or until the patient complies with rehabilitative services. This requirement shall not preclude the program's ability to determine that discharge of a patient is warranted for therapeutic reasons or program needs.

155.35(8) *Medication administration.*

a. The program physician shall determine the patient's initial and subsequent dose of medication and on-site dosing schedule and shall assume responsibility for the amount of the narcotic drug administered or dispensed and shall record, date, and sign in each 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 administration. The program physician may communicate such orders verbally; however, orders shall be reduced to 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 patient's case record that 40 milligrams did not suppress opiate abstinence symptoms. A 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 until the patient has completed admission procedures unless the patient enters the program on a weekend and the central registry cannot be contacted. If, in the clinical judgment of the program physician, a 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 medication administration log shall be kept in the dosing area and in the patient's case record. The amount of medication administered and the signature of the staff member authorized to administer the medication shall also be included in the patient's case record. No dose shall be administered until the patient has been positively identified and the dosage amount has been compared with the currently ordered and documented dosage level.

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

(4) The program physician shall record, date, and sign in each 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 patient's case record.

155.35(9) *Take-home or unsupervised medication use.*

a. Take-home medication may be given to patients who demonstrate a need for a more flexible schedule in order to enhance and continue rehabilitative progress. For 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 patient for the patient's own use.

b. Prior to granting take-home privileges, the program physician shall document in the 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 patient meets the above criteria, the 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) During the third 90 days of treatment, the take-home supply is limited to three doses per week;

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

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

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

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

d. If a patient is unable to conform to the applicable mandatory schedule, a revised schedule may be permitted provided that 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 patient's case record. The division will consider exceptions only in unusual circumstances. When a program is applying for less frequent pickups for patients, approval will be based on considerations in addition to distance if another program exists within 25 miles of the 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 patient on three months' probation, as defined by the program, or increase the patient's frequency of clinic dosing after considering the patient's overall progress and length of involvement in the program.

(2) Should the 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 patient's frequency of clinic attendance for dosage pickup for at least three months. If after the three-month period the patient meets the eligibility criteria, the 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 patient's case record based on the physician's clinical judgment.

155.35(10) *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 patient and that at least eight additional random tests or analyses are performed on each patient during the patient's first year in maintenance treatment and that at least quarterly random tests or analyses are performed on each patient in maintenance treatment for each subsequent year. When a sample is collected from each 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 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(11) *Diversion prevention plan.*

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

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

(2) Describes the 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(12) *Interim maintenance treatment.*

a. An approved program may offer interim maintenance treatment when, due to capacity, the program cannot place the patient in a program offering comprehensive services within 14 days of the 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 patients may be transferred.

c. Interim maintenance treatment program approval.

(1) Before a public or nonprofit private narcotic treatment program may provide interim maintenance treatment:

1. The program must receive approval of both the U.S. Food and Drug Administration and the division of behavioral health; and

2. The program director must certify that the program seeking such authorization is unable to place patients in a public or private nonprofit program within a reasonable geographic area within 14 days of the patient's application for admission and that interim maintenance treatment will not reduce the capacity of the program's comprehensive maintenance treatment.

(2) 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 patient who is eligible for comprehensive maintenance treatment to interim maintenance treatment if the 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 other drug screens shall be taken from the patient during the maximum admission period of 120 days. A program shall establish and follow reasonable criteria for determining the transfer of patients to comprehensive maintenance treatment. These transfer criteria shall be in writing and available for inspection and shall include at a minimum a preference for the transfer of pregnant patients. Interim maintenance shall be conducted in accordance with all applicable federal regulations and state rules. The program shall notify the division when a patient begins interim treatment, when a patient leaves interim treatment, and when a patient transfers to comprehensive maintenance treatment. Such notifications shall be documented by the program in the 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 patient; and

(5) Interim maintenance treatment cannot be provided for longer than 120 days in any 12-month period.

155.35(13) *Accreditation.* All opioid treatment programs shall obtain and retain accreditation by a recognized national accreditation organization. The national accreditation bodies currently recognized as meeting committee criteria are:

a. The Joint Commission.

b. The Council on Accreditation of Rehabilitation Facilities (CARF).

c. The Council on Accreditation of Children and Family Services (COA).

d. The American Osteopathic Association (AOA).

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