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 as amended to August 1, 2025) and by the state of Iowa for use in the treatment of opioid addiction shall comply with this rule; HIPAA, as amended to August 1, 2025; and Part II, DHHS, Substance Abuse and Mental Health Services Administration, 42 CFR Part 8, Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Addiction, effective February 2, 2024, and as amended to August 1, 2025.

155.35(1) *Required approvals.* All opioid treatment programs shall be licensed or approved by the department and shall maintain all other approvals required by the federal Drug Enforcement Administration, SAMHSA and the Iowa board of pharmacy in order to provide services.

155.35(2) *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 department.

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 as amended to August 1, 2025, and regulations on the confidentiality of alcohol and drug abuse patient records, DHHS, 42 CFR Part 2 as amended to August 1, 2025.

a. Definitions. For purposes of this subrule:

"Central registry" means the system through which the department obtains patient identifying information about individuals applying for maintenance treatment for the purpose of preventing an individual's concurrent enrollment in more than one such program.

"Opioid treatment program" means a withdrawal management or maintenance treatment program that is required to report patient identifying information to the central registry and that is located in the state.

b. Restrictions on disclosure.

(1) 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:
- The patient is admitted for treatment; or
- The treatment is interrupted, resumed or terminated.
2. The disclosure is limited to:
- Patient identifying information; and
- Relevant dates of admission.

(2) 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 as amended to August 1, 2025, and 42 CFR Part 2 as amended to August 1, 2025.

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(3) *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. Determination and documentation.

(1) An OTP shall maintain current procedures designed to ensure that patients are admitted to treatment by qualified personnel who have determined, using accepted medical criteria, that:

1. The person meets diagnostic criteria for a moderate to severe OUD; or

2. The individual has an active moderate to severe OUD, or OUD in remission, or is at high risk for recurrence or overdose.

(2) Such decisions must be appropriately documented in the patient's clinical record. In addition, a health care practitioner shall ensure that each patient voluntarily chooses treatment with MOUD, that all relevant facts concerning the use of MOUD are clearly and adequately explained to the patient, and that each patient provides informed consent to treatment.

(3) 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.

(4) 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 withdrawal management or drug-free treatment to be eligible for maintenance treatment. A one-week waiting period is required after such a short-term withdrawal management 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. No person under 18 years of age may be admitted to OTP treatment unless a parent, legal guardian, or responsible adult designated by the relevant state authority consents in writing to such treatment.

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(4) *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 DSM.

a. The program shall require each patient to undergo an initial medical examination. The initial medical examination is comprised of two parts:

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

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

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

c. A full in-person physical examination, including the results of serology and other tests that are considered to be clinically appropriate, must be completed within 14 calendar days following a patient's admission to the OTP. The full examination can be completed by a non-OTP practitioner if the examination is verified by a licensed OTP practitioner as being true and accurate and transmitted in accordance with applicable privacy laws.

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

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

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

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

f. 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. A patient's refusal to undergo lab testing for co-occurring physical health conditions should not preclude the patient from access to treatment, provided such refusal does not have potential to negatively impact treatment with medications.

155.35(5) *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(6) *Rehabilitative services.*

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

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

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

155.35(7) *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. For each new patient enrolled in an OTP, the initial dose of methadone shall be individually determined and shall include consideration of the type(s) of opioid(s) involved in the patient's OUD, other medications or substances being taken, medical history, and severity of opioid withdrawal. The total dose for the first day should not exceed 50 milligrams unless the OTP practitioner, licensed under the appropriate state law and registered under the appropriate state and federal laws to administer or dispense MOUD, finds sufficient medical rationale, including but not limited to if the patient is transferring from another OTP on a higher dose that has been verified, and documents in the patient's record that a higher dose was clinically indicated.

(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(8) *Take-home or unsupervised medication use.*

a. Unsupervised (take-home) medication doses may be provided under the following circumstances:

(1) Any patient in comprehensive treatment may receive individualized take-home doses as ordered for days that the clinic is closed for business, including one weekend day (e.g., Sunday) and state and federal holidays, no matter the patient's length of time in treatment.

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

1. Absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose, or the ability to function safely;
2. Regularity of attendance for supervised medication administration;
3. Absence of serious behavioral problems that endanger the patient, the public or others;
4. Absence of known recent diversion activity;
5. Whether take-home medication can be safely transported and stored; and
6. Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health.

(3) Such determinations and the basis for such determinations consistent with the criteria outlined shall be documented in the patient's medical record. If it is determined that a patient is safely able to manage unsupervised doses of MOUD, the dispensing restrictions set forth in this rule apply. The dispensing restrictions set forth in this rule do not apply to buprenorphine and buprenorphine products listed in this rule.

1. During the first 14 days of treatment, the take-home supply is limited to 7 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to seven days, but decisions must be based on the criteria listed in this rule. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record.
2. From 15 days of treatment, the take-home supply is limited to 14 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 14 days, but this determination must be based on the criteria listed in this rule. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record.
3. From 31 days of treatment, the take-home supply provided to a patient is not to exceed 28 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 28 days, but this determination must be based on the criteria listed in this subrule. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record.

(4) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that each individual take-home dose is packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers. Programs must provide education to each

patient on the following: safely transporting medication from the OTP to the patient's place of residence and the safe storage of take-home doses at the individual's place of residence, including child and household safety precautions. The provision of this education should be documented in the patient's clinical record.

b. 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 department and SAMHSA, when applicable. A copy of the written exception shall be placed in the patient's case record. The department 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.

c. 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.

155.35(9) *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 opioids, 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(10) *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(11) *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 department; 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 department 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(12) *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 (COA).

d. The American Osteopathic Association (AOA).

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