

Regulatory Analysis

Notice of Intended Action to be published: 641—Chapter 155

“Licensure Standards for Substance Use Disorder and Problem Gambling Treatment Programs”

Iowa Code section(s) or chapter(s) authorizing rulemaking: 125 and 135

State or federal law(s) implemented by the rulemaking: Iowa Code chapters 125 and 135 and 2024 Iowa Acts, House File 2673

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

June 3, 2025
2 p.m.

Microsoft Teams
Meeting ID: 264 402 551 733
Passcode: Y5xc3X4A

Public Comment

Any interested person may submit written or oral comments concerning this Regulatory Analysis, which must be received by the Department of Health and Human Services no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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Purpose and Summary

This proposed chapter provides licensure requirements for substance use disorder/problem gambling (SUD/PG) treatment programs throughout Iowa. The proposed chapter also sets forth the specific standards required for opioid use disorder treatment programs. Finally, it outlines the process and requirements for tuberculosis screening for individuals working at SUD/PG treatment program facilities as well as for residents of those facilities.

This proposed chapter underwent a Red Tape Review pursuant to Executive Order 10. The Department deleted restrictive terms, added dates certain, and consolidated appeals language to refer to 441—Chapter 7, the Department’s appeals chapter.

The Department also used this opportunity to implement changes necessitated by 2024 Iowa Acts, House File 2673, and government realignment under 2023 Iowa Acts, Senate File 514.

Analysis of Impact

1. Persons affected by the proposed rulemaking:

- **Classes of persons that will bear the costs of the proposed rulemaking:**

Owners and operators of SUD/PG treatment programs may incur administrative costs associated with compliance with this proposed chapter.

- **Classes of persons that will benefit from the proposed rulemaking:**

Individuals with substance use disorder, including opioid use disorder; individuals with problem gambling disorder; and residents at SUD/PG disorder treatment facilities will benefit from this rulemaking.

2. Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:

- **Quantitative description of impact:**

In calendar year 2024, there were 17,194 unique individuals admitted to substance use disorder treatment programs at 112 locations across Iowa.

- **Qualitative description of impact:**

This proposed chapter helps ensure the general health, safety, and welfare of SUD/PG treatment patients, potential patients, concerned persons, visitors, staff, and members of the public.

3. Costs to the State:

- **Implementation and enforcement costs borne by the agency or any other agency:**

The Department incurs personnel and other administrative costs associated with enforcing this proposed chapter.

- **Anticipated effect on state revenues:**

This proposed chapter has no effect on state revenues.

4. Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:

Rulemaking is both required and appropriate to help ensure safe treatment of SUD/PG in Iowa.

5. Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:

Not applicable.

6. Alternative methods considered by the agency:

- **Description of any alternative methods that were seriously considered by the agency:**

Not applicable.

- **Reasons why alternative methods were rejected in favor of the proposed rulemaking:**

Not applicable.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.

- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.

- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.

- Establish performance standards to replace design or operational standards in the rulemaking for small business.

- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

This proposed rulemaking has no impact on small business.

Text of Proposed Rulemaking

ITEM 1. Rescind 641—Chapter 155 and adopt the following new chapter in lieu thereof:

CHAPTER 155
LICENSURE STANDARDS FOR SUBSTANCE USE DISORDER AND PROBLEM GAMBLING
TREATMENT PROGRAMS

641—155.1(125,135) Definitions. Unless otherwise indicated, the following definitions apply to the specific terms used in these rules:

“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).

“Addictive disorder” means a substance use disorder and problem gambling.

“Addictive disorder professional” means an individual who is qualified by virtue of certification or license and education, training and experience to provide program services.

“Administration” means the direct application of a prescription medication to a patient by a prescriber or the prescriber’s authorized agent.

“Admission” means the point at which an initial assessment has been completed sufficient to determine the patient’s need and eligibility for program services and the patient has agreed to begin treatment.

“Admission, continued service, and discharge criteria” means the ASAM criteria dimensions to be considered in determining the level of care appropriate for the patient.

“Applicant” means a person, facility, or legal entity that has applied for an initial license, renewal of a license, or a license under deemed status pursuant to these rules.

“Application” means the process through which an applicant requests an initial license, renewal of a license, or a license under deemed status pursuant to these rules.

“ASAM criteria” means the clinical guide for the treatment of addictive, substance use and co-occurring conditions as published by the American Society of Addiction Medicine (ASAM) and as amended to August 1, 2025.

“Assessment” means the ongoing process of evaluating a patient’s strengths, resources, preferences, limitations, problems, and needs; determining the licensed program services needed by the patient; determining the patient’s eligibility for program services; and identifying treatment plan priorities, in accordance with the ASAM criteria and accepted standards of practice.

“Care coordination” or *“case management”* means the collaborative process that assesses, plans, implements, coordinates, monitors and evaluates the options and services, both internal and external to the program, to meet patient needs, using communication and available resources to promote quality care and effective outcomes.

“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.

“Chemical substance” means alcohol, wine, spirits and beer as defined in Iowa Code chapter 123 and controlled substances as defined in Iowa Code section 124.101.

“Chemical substitutes and antagonists program” means an opioid treatment program that provides opioid treatment services in accordance with Iowa Code section 125.21 and rule 641—155.35(125,135).

“Clinically managed” means that program services are directed by addictive disorder professionals.

“Clinically managed high-intensity residential treatment” means the ASAM criteria level of care totaling at least 50 hours of clinically managed inpatient treatment services per week.

“Clinically managed low-intensity residential treatment” means the ASAM criteria level of care totaling at least five hours of clinically managed inpatient treatment services per week.

“Clinically managed medium-intensity residential treatment” means the ASAM criteria level of care totaling at least 30 hours of clinically managed inpatient treatment services per week.

“Clinical oversight” means oversight provided by an individual who, by virtue of certification or license and education, training and experience is qualified to oversee treatment services in accordance with subrule 155.21(3).

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

“Concerned person” means an individual who is seeking treatment services due to problems arising from a personal relationship with an individual with an addictive disorder.

“Confidentiality” means protection of patient information in compliance with state and federal law.

“Crisis stabilization” means medically monitored subacute inpatient services for individuals with urgent addictive disorder needs requiring immediate intervention, assessment, and mobilization of family, community and program resources.

“Culturally and environmentally specific” means integrating into assessment and treatment the customs and beliefs of a given population, as well as awareness and acceptance of diversity regarding conditions, circumstances and influences affecting an individual or group.

“Data reporting” means the required submission of certain patient demographic and program services information to the department by a program.

“Dimension” means one of the six ASAM criteria patient biopsychosocial areas to be considered in the assessment process to identify patient needs and determine the appropriate level of care for admission and continued services.

“Discharge” means the point at which the patient ceases participation in licensed program services, marking the end of a specific encounter or episode of care. Discharge does not require termination of the relationship between the patient and the program.

“Discharge planning” means the process, begun at admission, of determining a patient’s continued need for licensed program services and of developing a plan to address ongoing patient needs following discharge.

“DSM” means the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association as amended to August 1, 2025, and all references to the DSM herein are as amended to August 1, 2025.

“Early intervention” means the ASAM criteria level of care which explores and addresses problems or risk factors that appear to be related to an addictive disorder and which helps the individual recognize potential harmful consequences.

“Enhanced program” means a licensee that provides enhanced treatment services in accordance with paragraph 155.2(2) “j” and rule 641—155.34(125,135).

“Enhanced treatment services” means licensed program services provided in accordance with paragraph 155.2(2) “j” and rule 641—155.34(125,135).

“Facility” means an institution or an installation providing care, maintenance or treatment for persons with substance use disorders licensed by the department under Iowa Code section 125.13, hospitals licensed under Iowa Code chapter 135B, or the state mental health institutes designated by Iowa Code chapter 226. “Facility” also means the physical areas such as grounds, buildings, or portions thereof under administrative control of the program.

“Governing body” means the person, group, or legal entity that has ultimate authority and responsibility for the overall operation of the program.

“Inpatient” means 24-hour licensed program services.

“Intensive outpatient treatment” means the ASAM criteria level of care totaling a minimum of nine hours of clinically managed outpatient treatment services per week for adults or a minimum of six hours of clinically managed outpatient treatment services per week for juveniles.

“Interim maintenance treatment” means withdrawal management for a period of more than 30 days but not in excess of 180 days.

“Level of care” or *“level of service”* means the different ASAM criteria service options. “Level of care” also means certain licensed program services under these rules.

“Licensed program services” means the services a licensee may be authorized to provide under these rules.

“Licensee” means a program licensed by the department pursuant to these rules.

“Licensure” means the issuance of a license by the department pursuant to these rules that validates the licensee’s compliance with these rules and authorizes the licensee to operate a program in the state of Iowa.

“Licensure weighting report” means the department’s report that is used to determine an applicant’s level of compliance with these rules and the length of time a license will be in effect.

“Maintenance” means the prolonged, scheduled administration of an opiate agonist medication such as buprenorphine or methadone by an opioid treatment program in accordance with federal and state laws, rules and regulations.

“Maintenance treatment” means the dispensing of a medication for opioid use disorder (MOUD) at stable dosage levels for a period in excess of 21 days in the treatment of an individual for opioid addiction.

“Management of care” means the ongoing application of the ASAM criteria and the coordination of care to ensure the appropriate provision of licensed program services to a patient.

“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. Such delegations will not eliminate the medical director’s responsibility for all medical and behavioral health services provided by the OTP.

“Medically managed” means that the inpatient program services that involve daily medical care in a hospital setting are directed by a prescriber.

“Medically managed intensive inpatient treatment” means the ASAM criteria level of care for medically managed inpatient treatment services.

“Medically monitored” means that the program services are directed by addictive disorder professionals with medical oversight by a prescriber.

“Medically monitored intensive inpatient treatment” means the ASAM criteria level of care for medically monitored subacute inpatient treatment services.

“Medication-assisted treatment” means the medically monitored use of certain substance use disorder medications in combination with other treatment services.

“Medication unit” means an entity that is established as part of, but geographically separate from, an OTP from which appropriately licensed OTP practitioners, contractors working on behalf of the OTP, or community pharmacists may dispense or administer MOUD, collect samples for drug testing or analysis, or provide other OTP services. Medication units can be a brick-and-mortar location or mobile unit.

“Opioid addiction” means a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opioid despite significant opiate-induced problems. Opioid dependence is characterized by an individual’s repeated self-administration of opioids that usually results in opioid 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 as amended to August 1, 2025) 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 program” or *“OTP”* means a substance use disorder treatment program or a substance use disorder and problem gambling treatment program licensed to provide opioid treatment services in accordance with Iowa Code section 125.21 and rules 641—155.2(125,135) and 641—155.35(125,135).

“Opioid treatment services” means medically monitored outpatient maintenance services provided in accordance with federal and state laws, rules and regulations.

“Opioid use disorder treatment” or *“OUD treatment”* means the dispensing of MOUD, along with the provision of a range of medical and behavioral health services, as clinically necessary and based on an individualized assessment and a mutually agreed-upon care plan, to an individual to alleviate the combination of adverse medical, psychological, or physical effects associated with an OUD.

“Outpatient” means non-24-hour licensed program services.

“Outpatient treatment” means the ASAM criteria level of care totaling less than nine hours of clinically managed outpatient treatment services per week for adults and less than six hours of clinically managed outpatient treatment services per week for juveniles.

“OWI evaluation” means an assessment completed solely for the purpose of compliance with the substance abuse evaluation requirements of Iowa Code chapter 321J.

“Partial/day treatment” means the ASAM criteria level of care totaling 20 or more hours of clinically managed outpatient treatment services per week.

“Patient” means an individual who participates in licensed program services.

“Placement” means selection of an appropriate licensed program service, based on ongoing assessment.

“Prescriber” means a licensed health care professional with the authority to prescribe medication in accordance with Iowa law.

“Prevention” means activities aimed at minimizing the use of potentially addictive substances, lowering risk in at-risk individuals, or minimizing potential adverse consequences of substance use or gambling.

“Prime programming time” means any period of the day, as determined by a program treating juveniles, when special attention or supervision is necessary.

“Problem gambling” means a gambling disorder that results in a functional impairment of sufficient impact and duration to meet diagnostic criteria specified within the DSM.

“Program” means a person, facility, institution, building, agency or legal entity that provides one or more of the services stated in subrule 155.2(2) and is required to be licensed under these rules.

“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.

“Quality improvement” means the process of objectively and systematically monitoring and evaluating the quality and appropriateness of patient care and program services and operations to resolve identified problems and to make continued improvements.

“Recovery” means the process of addressing an addictive disorder and working toward personally defined health and well-being.

“Recovery supports” means the broad range of nontreatment services, such as transportation, that assists patients in their recovery efforts.

“Rehabilitation” means the restoration of an optimal state of health by medical, psychological, and social means, including peer group support.

“Residential” means clinically managed inpatient treatment services.

“Resiliency- and recovery-oriented system of care” means coordinated, person-centered approaches to health promotion, prevention, early intervention, treatment and recovery support that build on the protective factors and strengths of individuals to sustain or achieve health and well-being.

“Screening” means the brief review of a patient’s or potential patient’s current risk factors for an addictive disorder or medical or mental health condition to determine if they indicate a need for immediate admission or referral. Screening is not an assessment and is not sufficient to develop a treatment plan, rule out an addictive disorder, or determine that admission to treatment or referral to other services is not indicated.

“Short-term withdrawal management treatment” means withdrawal management treatment for a period not in excess of 30 days.

“Self-administration of medication” means the process whereby a properly trained and qualified staff person observes a patient take medication prescribed by a prescriber.

“Staff” means any individual who conducts an activity on behalf of a program as an employee, agent, consultant, contractor, volunteer or other status.

“Standards category” means the grouping of standards, such as clinical, administrative or programming, in the licensure weighting report.

“State authority” means the department, which regulates the treatment of opioid addiction with opioid drugs.

“Subacute” means medically monitored inpatient services for individuals who require management, supervision and treatment to reduce immediate risk of danger to self or others or severe disability or complication of an addictive disorder or an addictive disorder and a medical or mental health condition.

“Substance abuse treatment and rehabilitation facility” or *“substance abuse treatment program”* means a program required to be licensed under these rules.

“Substance use disorder” means a substance use disorder that results in a functional impairment of sufficient impact and duration to meet diagnostic criteria specified within the DSM.

“Telemedicine” means the same as defined in rule 653—13.11(144E,147,148,272C).

“Time frames” means the periods of time specified throughout the standards.

“Treatment” means the broad range of planned services to identify and change patterns of behavior that are maladaptive, destructive or injurious to health or to restore appropriate levels of physical, psychological or social functioning. Such services may include assessment; care coordination; crisis stabilization; withdrawal management; early intervention; health promotion; individual, group and family counseling; management of care; and medication administration, provided by addictive disorder professionals and a mix of medical, mental health and peer professionals as appropriate to the structure of the program.

“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.

“Treatment planning” means the process, based on ongoing assessment, by which a patient and qualified staff identify and rank problems, establish agreed-upon goals, and decide on the treatment services and resources to be utilized.

“Withdrawal management” means the safe management of intoxication states and withdrawal states in accordance with the ASAM criteria and accepted standards of practice.

641—155.2(125,135) Licensing. In accordance with Iowa Code section 125.13, a person shall not maintain or conduct a substance use disorder program without having first obtained a license for the program from the department, and in accordance with Iowa Code section 135.150, a person shall not maintain or conduct a problem gambling treatment program funded by the department unless the

person has obtained a license for the program from the department. The provision of treatment to a patient through any electronic means, regardless of the location of the program or facility, shall constitute the practice of treatment in the state of Iowa and shall be subject to regulation in accordance with Iowa Code chapter 125, Iowa Code section 135.150, and these rules. An applicant shall apply for one license only. The department will award one license only to an applicant or licensee.

155.2(1) *Program licenses.* The department will offer the following program licenses:

- a.* A substance use disorder assessment and OWI evaluation-only program license.
- b.* A substance use disorder treatment program license.
- c.* A problem gambling treatment program license.
- d.* A substance use disorder and problem gambling treatment program license.

155.2(2) *Licensed program services.* The license will delineate the licensed program service(s) the program is authorized to provide and will specify that each licensed program service is licensed for adults, juveniles, or adults and juveniles. Licensed program services are:

- a.* Substance use disorder assessment and OWI evaluation only, provided by a substance use disorder assessment and OWI evaluation-only program;
- b.* Outpatient treatment, provided by a substance use disorder treatment program, a problem gambling treatment program, or a substance use disorder and problem gambling treatment program;
- c.* Intensive outpatient treatment, provided by a substance use disorder treatment program, a problem gambling treatment program, or a substance use disorder and problem gambling treatment program;
- d.* Partial/day treatment, provided by a substance use disorder treatment program, a problem gambling treatment program, or a substance use disorder and problem gambling treatment program;
- e.* Clinically managed low-intensity residential treatment, provided by a substance use disorder treatment program, a problem gambling treatment program, or a substance use disorder and problem gambling treatment program;
- f.* Clinically managed medium-intensity residential treatment, provided by a substance use disorder treatment program, a problem gambling treatment program, or a substance use disorder and problem gambling treatment program;
- g.* Clinically managed high-intensity residential treatment, provided by a substance use disorder treatment program, a problem gambling treatment program, or a substance use disorder and problem gambling treatment program;
- h.* Medically monitored intensive inpatient treatment, provided by a substance use disorder treatment program or a substance use disorder and problem gambling treatment program;
- i.* Medically managed intensive inpatient treatment, provided by a substance use disorder treatment program or a substance use disorder and problem gambling treatment program;
- j.* Enhanced treatment services, provided by a substance use disorder treatment program or a substance use disorder and problem gambling treatment program;
- k.* Opioid treatment services, provided by a substance use disorder treatment program or a substance use disorder and problem gambling treatment program.

155.2(3) *Licensing body.* The department will consider and approve or deny all license applications, suspensions and revocations.

641—155.3(125,135) Types of licenses.

155.3(1) The department may issue an initial license for 270 days to a new applicant scoring a minimum rating of 70 percent in each standards category on the licensure weighting report. An initial license shall expire in 270 days and shall not be extended or renewed.

155.3(2) The department may issue a license subsequent to an initial license for one, two, or three years based on the applicant's rating on the licensure weighting report.

- a.* An applicant achieving a rating of 95 percent or higher in each standards category may qualify for a three-year license.

b. An applicant achieving a rating of less than 95 percent but not less than 90 percent in each standards category may qualify for a two-year license.

c. An applicant achieving a rating of less than 90 percent but not less than 70 percent in each standards category may qualify for a one-year license.

d. A license for one, two, or three years shall expire on the date noted on the license and shall not be extended but may be renewed upon application.

155.3(3) The department may issue a license under deemed status to an applicant providing required documentation of accreditation by a recognized accreditation body. A deemed-status license will be effective for the same time frame as that of the accreditation granted by the accreditation body, up to three years.

641—155.4(125,135) Nonassignability.

155.4(1) A license issued by the department for the operation of a program applies both to the licensee and the facility in which the program is operated. A license is not transferable.

155.4(2) A closing program is one that intends to cease providing licensed program services. The licensee shall notify the department 30 days before ceasing service provision. The licensee shall be responsible for the transition of patients to another program and for the preservation of all records. The licensee shall include in its notice to the department its plan to transition patients and locate records. When a program closes, the program's license is void on the date the program ceases providing licensed program services and the license shall be returned to the department.

155.4(3) A closed program is one that has ceased providing licensed program services. The licensee shall notify the department immediately of ceased service provision. The licensee shall be responsible for the transition of patients to another program and for the preservation of all records. The licensee shall include in its notice to the department its plan to transition patients and locate records. When a program is closed, the program's license is void on the date the program ceased providing licensed program services and the license shall be returned to the department.

155.4(4) A person, facility or legal entity acquiring a licensed, closing or closed program for the purpose of operating a program shall apply for a license.

641—155.5(125,135) Application procedures. The department will provide license application forms on its website and at its office. An applicant shall submit application materials to the department. The department will proceed with inspection of the applicant upon receipt of a complete application. To be complete, an application must include all required materials and be responsive to all licensure standards, as described in these rules.

155.5(1) *Application information.* An applicant shall submit application materials on the forms provided and in the required format. Application materials shall include but may not be limited to:

a. The name and address of the applicant and, if the applicant is part of a larger organization, the name and address of the larger organization.

b. The name and address of the applicant's executive director and, if the applicant is part of a larger organization, the name and address of the executive director of the larger organization.

c. The names, titles, dates of employment, education, and years of current job-related experience of the applicant's staff and the table of organization. If the applicant is part of a larger organization or has multiple organizational components and physical facilities, the relationships between the larger organization, organizational components and physical facilities must be shown on the table of organization, with the applicant and applicant's staff positions clearly delineated.

d. The names and addresses of members of the applicant's governing body, sponsors, and advisory boards and the current articles of incorporation and bylaws.

e. The names and addresses of individuals, facilities, organizations, and legal entities with which the applicant has a contractual or affiliation agreement pertaining to licensed program services.

f. A description of the licensed program services to be provided by the applicant and a calendar showing program services each week.

g. For each physical facility, copies of reports substantiating compliance with federal, state and local laws, rules and regulations, to include appropriate department of inspections, appeals, and licensing rules; state fire marshal rules and fire ordinances; and local health, fire, occupancy, and safety regulations.

h. Information required for programs admitting juveniles as described under Iowa Code section 125.14A.

i. Fiscal management information, to include a recent audit or opinion of auditor and program board minutes to reflect approval of the program's budget and insurance.

j. Insurance coverage related to professional and general liability; building, if the applicant has a physical location; and workers' compensation and fidelity bond, if the applicant has employees.

k. The address of each physical facility, if applicable.

l. The written policies and procedures manual that covers all the requirements of these rules.

155.5(2) *Application time frame.* An applicant seeking to be licensed subsequent to a 270-day initial license or a licensee seeking to renew a one-, two-, or three-year license or to significantly change a currently licensed program shall submit an application at least 90 days before expiration of the current license or before the program change.

155.5(3) *License under deemed status.* An organization seeking to be licensed under deemed status shall submit an application.

641—155.6(125,135) Technical assistance. The department may provide technical assistance to an applicant or licensee.

155.6(1) An applicant may request technical assistance regarding these rules and the licensure process.

155.6(2) A licensee may request technical assistance regarding these rules and the licensure process or to bring areas of noncompliance with these rules into compliance.

155.6(3) The department may require a licensee to receive technical assistance to bring areas of noncompliance with these rules into compliance.

641—155.7(125,135) Inspection of applicants.

155.7(1) *Inspection of applicants.* The department will inspect each applicant. Inspection will include review of the complete application and may include but may not be limited to review of patient records, review of applicant data reporting, and interviews with staff and patients. Inspection will include on-site inspection unless specifically waived as allowed under these rules. The department will send the applicant a report of inspection findings within 30 business days of the inspection.

155.7(2) *On-site inspection.* The department will schedule an on-site inspection of an applicant within 60 business days of receipt of the applicant's complete application.

a. The department may waive on-site inspection of an applicant that is:

(1) A licensee applying to renew a license when the applicant's licensed program services are limited to substance use disorder assessment and OWI evaluation services only, outpatient treatment, or intensive outpatient treatment.

(2) An applicant applying for a license under deemed status.

b. The department is not required to provide advance notice of the on-site inspection to the applicant.

c. The on-site inspection team will consist of designated employees or agents of the department.

d. The on-site inspection team will inspect the applicant to verify application information and determine compliance with all laws, rules and regulations.

641—155.8(125,135) License—approval. The department will issue a license upon approval of an application. The license will be effective upon approval.

641—155.9(125,135) Written corrective action plan.

155.9(1) A program approved for a license shall submit a written corrective action plan to the department within 30 days following approval to bring any area of noncompliance with these rules into compliance.

155.9(2) The written corrective action plan shall include but may not be limited to:

- a.* Any area of noncompliance specified in the inspection findings report;
- b.* The corrective measures to be taken by the program for each area of noncompliance; and
- c.* The completion date for each corrective measure.

641—155.10(125,135) Grounds for denial of license. The department may deny an application for a license for any of the following reasons:

155.10(1) The application is not complete, is not timely or otherwise does not meet the requirements of these rules.

155.10(2) The applicant fails to achieve the minimum licensure weighting report rating required for a 270-day initial license or a one-, two- or three-year license.

155.10(3) Lack of patients or patient records for review.

155.10(4) Violation of any of the following grounds for discipline:

- a.* Submission of fraudulent or misleading information.
- b.* Violation by a program or staff of any statute or rule pertaining to programs, including violation of any provision of these rules, or failure to adhere to program policies and procedures adopted pursuant to these rules.
- c.* Failure to comply with licensure, inspection, health, fire, occupancy, safety, sanitation, zoning, or building codes or regulations required by federal, state or local law.
- d.* Sanction, modification, termination, withdrawal, refused renewal, suspension, or revocation of accreditation by an accreditation body.
- e.* Sanction, modification, termination, withdrawal, refused renewal, suspension, revocation, or refused issuance of a federal registration to distribute or dispense controlled substances.
- f.* Commission of or permitting, aiding or abetting commission of an unlawful act.
- g.* Conviction of a member of the governing body, a director, administrator, chief executive officer, or other managing staff person of a felony or misdemeanor related to the management, operation or integrity of the program.
- h.* Use of untruthful or improbable statements in advertising.
- i.* Conduct or practices determined to be detrimental to the general health, safety, or welfare of a patient, potential patient, concerned person, visitor, staff or member of the public.
- j.* Violation of a patient's confidentiality or willful, substantial, or repeated violation of a patient's rights.
- k.* Defrauding a patient, potential patient, concerned person, visitor, staff or third-party payor.
- l.* Inappropriate conduct by staff, including sexual or other harassment or exploitation of a patient, potential patient, concerned person, visitor or staff.
- m.* Utilization of treatment techniques that endanger the health, safety, or welfare of a patient, potential patient, concerned person, visitor, staff or member of the public.
- n.* Discrimination or retaliation against a patient, potential patient, concerned person, visitor, staff, or member of the public who has submitted a complaint or information to the department.
- o.* Failure to allow an employee or agent of the department access to the program or facility for the purpose of inspection, investigation, or other activity necessary to the performance of the department's duties.
- p.* Failure to submit an acceptable written corrective action plan or failure to comply with a corrective action plan issued pursuant to rule 641—155.9(125,135) or 641—155.16(125,135).
- q.* Violation of an order of the department or violating the terms or conditions of a consent agreement or informal settlement between a program and the department.

641—155.11(125,135) Denial, suspension or revocation of a license. The department may deny an application for a license. The department may suspend or revoke a license for any of the grounds for discipline pursuant to subrule 155.10(4).

155.11(1) *Initial notice from the department.* When the department determines to deny, suspend or revoke a one-, two-, or three-year license or a license under deemed status, the department will notify the applicant or licensee by certified mail, return receipt requested, in accordance with 441—Chapter 16. Such notice will provide the applicant or licensee the opportunity to submit a written corrective action plan or written objections to the department.

155.11(2) *Submission of corrective action plan or objections.* An applicant notified of denial of a one-, two-, or three-year license or a license under deemed status or a licensee notified of suspension or revocation of a license may submit a written corrective action plan or written objections to the department within 20 days after receipt of the notice.

a. Written corrective action plan. The written corrective action plan must meet the requirements of paragraphs 155.9(1) “a” through “c.” If the applicant or licensee submits a written corrective action plan, the applicant or licensee shall have 90 days from the date of submission within which to show compliance with the plan. The applicant or licensee shall submit any information to the department that the department requests or that the applicant or licensee deems pertinent to show compliance with the plan. The department may inspect the licensee, including on-site inspection, to review the implemented corrective measures.

b. Objections. If the applicant or licensee submits written objections, the applicant or licensee shall submit to the department any information that the department or the applicant or licensee deems pertinent to support the applicant’s or licensee’s defense.

155.11(3) *Decision of department.* Following receipt of a written corrective action plan and expiration of the 90-day compliance period, or following receipt of written objections, or when a written corrective action plan or written objections have not been received within the 20-day time period, the department will determine whether to proceed with the denial, suspension or revocation.

155.11(4) *Notice of decision and opportunity for contested case hearing.*

a. When the department determines to deny, suspend, or revoke a license, the applicant or licensee shall be given written notice by restricted certified mail pursuant to 441—Chapter 16.

b. The applicant or licensee may request a hearing on the determination. The request must be in writing and sent to the department’s address within 30 days of the notice issued by the department. Failure to request a hearing will result in final action by the department.

155.11(5) *Summary suspension.* If the department finds that the health, safety or welfare of the public is endangered by continued operation of a program, the department may order summary suspension of a license, pursuant to Iowa Code sections 17A.18 and 125.15A, pending proceedings for revocation or other actions in accordance with Iowa Code sections 17A.18A and 125.15A and 441—Chapter 7. These proceedings shall be promptly instituted and determined.

641—155.12 to 155.14 Reserved.

641—155.15(125,135) Issuance of a license after denial, suspension or revocation. After denial, suspension, or revocation of a license, the former applicant or licensee shall not have a license issued within one year of the effective date of the denial, suspension or revocation. After one year, the former applicant or licensee may submit an application for a 270-day initial license. For purposes of this rule, “former applicant or licensee” includes any director, officer, administrator, chief executive officer, or other managing staff of the former applicant or licensee.

641—155.16(125,135) Complaints and investigations.

155.16(1) *Complaints.* Any person may file a complaint with the department against any program licensed pursuant to this chapter. The complaint shall be made in writing and shall be emailed, mailed or delivered to the department. The complaint shall include the name and address of

the complainant, the name of the program, and a concise statement of the allegations against the program, including the specific alleged violations of Iowa Code chapter 125 or this chapter, if known. A complaint may also be initiated by the department when an emergency exists that is deemed to endanger the health, safety or welfare of a patient, potential patient, concerned person, visitor, staff or the public, pursuant to evidence received by the department. Timely filing of complaints is required to ensure the availability of witnesses and to avoid initiation of an investigation under conditions that may have been significantly altered during the period of delay.

155.16(2) *Evaluation and investigation.* Upon receipt of a complaint, the department will make a preliminary review of the allegations contained in the complaint. The department may request that the complainant submit the complaint to the program's grievance process. Unless the department concludes that the complaint is intended solely to harass a program or lacks a reasonable basis, or is more reasonably addressed through the program's grievance process, the department will conduct an investigation of the program that is the subject of the complaint as soon as is practicable. The program that is the subject of the complaint will be given an opportunity to informally respond to the allegations contained in the complaint either in writing or through a personal interview or conference with department staff.

155.16(3) *Investigative report.* Within 30 days after completion of the investigation, the department will prepare a written investigative report and submit it to the executive director of the program and the chairperson of the governing body of the program. This report will include the nature of the complaint and shall indicate if the complaint allegations were substantiated, unsubstantiated, or undetermined; the basis for the finding; the specific statutes or rules at issue; a response from the program, if received; and a recommendation for action.

155.16(4) *Review of investigations.* The department will review the investigative report and determine appropriate action.

a. Closure. If the department determines that the allegations contained in the complaint are unsubstantiated, the department will close the case and promptly notify the complainant and the program by letter.

b. Further investigation. The department may determine that the complaint warrants further investigation and may conduct an additional investigation.

c. Written corrective action plan. If the department determines that the allegations contained in the complaint are substantiated and corrective action is warranted, the department may require the program to submit and comply with a written corrective action plan. A program shall submit a written corrective action plan to the department within 20 business days after receiving a request for such plan. The written corrective action plan shall include a plan for correcting areas of noncompliance as required by the department and a time frame within which such plan shall be implemented. The plan is subject to department approval. Requiring a written corrective action plan is not formal disciplinary action. Failure to submit or comply with a written corrective action plan may result in formal disciplinary action against the program.

d. Disciplinary action. If the department determines the allegations contained in the complaint are substantiated and disciplinary action is warranted, the department may proceed with such action in accordance with rule 641—155.11(125,135).

155.16(5) *Confidential information and public information.* Information contained in a complaint may be confidential pursuant to Iowa Code section 22.7(2), 22.7(18), or 125.37 or any other provision of state or federal law. Investigative reports, written corrective action plans, and all notices and orders issued pursuant to rule 641—155.11(125,135) shall refer to patients by number and shall not include patient identifying information. Investigative reports, written corrective action plans, and all notices and orders issued pursuant to rule 641—155.11(125,135) shall be available to the public as open records pursuant to Iowa Code chapter 22.

641—155.17(125,135) License revision. A licensee shall submit a written request to the department to revise a license at least 30 days prior to any change of address, executive director, clinical oversight

staff, facility, or licensed program service. The department will determine if the requested revision can be approved or if the change is significant enough to require the submission of an application for license renewal by the licensee.

641—155.18(125,135) Deemed status.

155.18(1) Accreditation. The department will approve a license under deemed status for an applicant accredited by a recognized national accreditation body when it determines that the accreditation is for the same licensed program services as those addressed by these rules and when such accreditation is consistent with these rules.

a. An applicant for a license under deemed status shall submit a copy of the entire accreditation body survey or inspection report, certificate of accreditation, accreditation conditions, and corrective action requirements and plans with the applicant's application.

b. The department may review and accept an accreditation body's survey or inspection report, certificate of accreditation, and conditions or corrective action plans as meeting the requirements for inspection for those licensed program services described in these rules.

c. An applicant for a license under deemed status shall be licensed only for licensed program services that are described in these rules.

d. A program licensed under deemed status shall be licensed for the same period of time as that for which the program is accredited, up to three years.

155.18(2) National accreditation bodies. The national accreditation bodies recognized for the purposes of licensure under deemed status 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).

155.18(3) Credentials and expectations of accreditation bodies. The accreditation credentials of an accreditation body shall specify the types of organizations, programs and services the body accredits.

155.18(4) Responsibilities of programs licensed under deemed status.

a. A program licensed under deemed status shall meet all requirements of these rules and all applicable laws and regulations.

b. A program licensed under deemed status may submit an application for licensure of licensed program services covered by these rules that are not covered by the accreditation.

155.18(5) Rights and responsibilities of department. The department retains the following responsibilities and rights for deemed status applicants and licensees:

a. The department may inspect the applicant or licensee.

b. The department will investigate complaints in accordance with these rules and recommend and require corrective action or other sanctions. Complaints, findings, and required corrective action may be reported to the accreditation body.

c. The department will review and act upon a license under deemed status when complaints have been founded, when the national accreditation body identifies noncompliance with accreditation, when accreditation expires without renewal, or when accreditation is sanctioned, modified, terminated, withdrawn, suspended or revoked.

641—155.19(125,135) Funding. The issuance of a license shall not be construed as a commitment on the part of either the state or federal government to provide funds to such licensee.

641—155.20(125,135) Inspection. An applicant or licensee agrees as a condition of licensure:

155.20(1) To permit properly designated representatives of the department to enter into and inspect any and all programs and facilities for which a license has been applied or issued to verify information contained in the application or to ensure compliance with all laws, rules, and regulations

relating thereto, during all hours of operation of said applicant or licensee and at any other reasonable hour.

155.20(2) To permit properly designated representatives of the department to audit and collect statistical data from all records maintained by the applicant or licensee. An applicant or licensee that does not permit inspection by the department or examination of all records, including financial records, records pertaining to methods of administration, general and special dietary programs, and the disbursement of medications and methods of supply, and any other records the department deems relevant, will not be licensed.

641—155.21(125,135) General standards for all programs. The following standards apply to all programs. For programs for which both the general standards and specific standards apply, both sets of standards shall be met.

155.21(1) Governing body. The program shall have a formally designated governing body that complies with Iowa Code chapter 504 and that is the ultimate authority for program operations.

a. The governing body shall develop and adopt written bylaws and policies that define the powers and duties of the governing body, its committees, its advisory groups, and the executive director. These bylaws and policies shall be reviewed and revised by the governing body as necessary.

b. The bylaws shall minimally specify the following:

- (1) The type of membership;
- (2) The term of appointment;
- (3) The frequency of meetings;
- (4) The attendance requirements; and
- (5) The quorum necessary to transact business.

c. The governing body shall maintain minutes of all meetings, and the minutes shall be available for review by the department and shall include but not necessarily be limited to:

- (1) Date of the meeting;
- (2) Names of members attending;
- (3) Topics discussed; and
- (4) Decisions reached and actions taken.

d. The duties of the governing body shall include but not necessarily be limited to:

- (1) Appointment of a qualified executive director, who shall have the responsibility and authority for the management of the program in accordance with the governing body's established policies;
- (2) Establishment of effective controls to ensure that quality services are provided;
- (3) Review and approval of the program's annual budget; and
- (4) Approval of all contracts.

e. The governing body shall approve policies and procedures for the effective operation of the program.

f. The governing body shall be responsible for all funds, equipment, and supplies and the facility in which the program operates, if applicable. The governing body shall be responsible for the appropriateness and adequacy of services provided by the program.

g. The governing body shall at least annually prepare a report, which shall include but not necessarily be limited to:

- (1) The name, address, occupation, and place of employment of each governing body member;
- (2) Disclosure of any family relationship a member of the governing body has with a program staff member;
- (3) The names and addresses of any owners or controlling parties whether they are individuals, partnerships, a corporation body, or a subdivision of other bodies;
- (4) Disclosure of any potential conflict of interest a member of the governing body may have.

h. The governing body shall ensure that the program has malpractice, liability and workers' compensation insurance for all staff and a fidelity bond that covers all staff, if applicable.

155.21(2) *Executive director.* The executive director shall have primary responsibility for program operations. The duties of the executive director shall be clearly defined in accordance with the policies established by the governing body.

155.21(3) *Clinical oversight.* The program shall designate a treatment supervisor to oversee provision of licensed program services.

155.21(4) *Policies and procedures manual.* The program shall maintain and implement a written policies and procedures manual that documents the program's compliance with these rules. The manual shall describe the program's licensed program services and related activities, specify the policies and procedures to be followed, and govern all staff.

a. The manual shall have a table of contents.

b. Revisions to the manual shall be entered with the date and with the name and title of the staff person making the revisions.

155.21(5) *Staff development and training.* The program's policies and procedures shall establish a staff development and training plan that encompasses all staff and all licensed program services, considers the professional continuing education requirements of certified and licensed staff, and is available to all staff.

a. The program shall designate a staff person responsible for the staff development and training plan.

b. The staff person responsible for the staff development and training plan shall conduct an annual needs assessment.

c. The staff development and training plan shall describe orientation for new staff that includes an overview of the program and licensed program services, confidentiality, tuberculosis and blood-borne pathogens, including HIV/AIDS, and culturally and environmentally specific information. Orientation shall also address the specific responsibilities of each staff person and community resources specific to the staff person's responsibilities.

d. The staff development and training plan shall address training when program operations or licensed program services change.

e. The staff development and training plan may include on-site training activities. The program shall maintain minutes of on-site training that include the name and date of the training, the training topic, the name and title of the trainer, and the names of staff attending the training.

155.21(6) *Data reporting.* The program's policies and procedures shall describe how the program reports required data to the department in accordance with department requirements and processes.

155.21(7) *Fiscal management.* The program's policies and procedures shall ensure proper fiscal management, which shall include:

a. The preparation and maintenance of an annual written budget, which shall be reviewed and approved by the governing body prior to the beginning of the budget year.

b. A fiscal management system maintained in accordance with generally accepted accounting principles, including internal controls to reasonably protect program assets. This shall be verified by an annual independent fiscal audit of the program by the state auditor's office or a certified public accountant based on an agreement entered into by the governing body. A program with an annual budget of \$100,000 or less shall conduct a fiscal audit no less than every three years.

c. An insurance program that provides for the protection of the physical and financial resources of the program and provides coverage for all people, buildings, and equipment. The insurance program shall be reviewed annually by the governing body.

155.21(8) *Personnel.* The program shall have personnel policies and procedures.

a. Personnel policies and procedures shall address:

(1) Recruitment and selection of staff;

(2) Wage and salary administration;

(3) Promotions;

(4) Employee benefits;

- (5) Working hours;
- (6) Vacation and sick leave;
- (7) Lines of authority;
- (8) Rules of conduct;
- (9) Disciplinary actions and termination;
- (10) Methods for handling cases of inappropriate patient care;
- (11) Work performance appraisal;
- (12) Staff accidents and safety;
- (13) Staff grievances;
- (14) Prohibition of sexual harassment;
- (15) Implementation of the Americans with Disabilities Act as amended to August 1, 2025;
- (16) Implementation of the Drug-Free Workplace Act as amended to August 1, 2025;
- (17) Use of social media; and
- (18) Implementation of equal employment opportunity.

b. The program shall have for each position and each staff person a written job description that describes the duties of each position and staff and the qualifications required for each position.

(1) A staff person providing screening, OWI evaluation, assessment or treatment services in accordance with these rules shall be qualified as an addictive disorder professional by meeting at least one of the following conditions:

1. Be certified or licensed as a substance use disorder or problem gambling counselor by a national or state organization approved by the department.

2. Be licensed as a marital and family therapist or a mental health counselor under Iowa Code chapters 154D and 147, an independent social worker under Iowa Code chapters 154C and 147, or another independent professional authorized by the Iowa Code to diagnose and treat mental disorders as specified in the DSM.

3. Be licensed as a master social worker under Iowa Code chapters 154C and 147.

4. Be licensed as a bachelor social worker under Iowa Code chapters 154C and 147.

5. Be temporarily or provisionally certified or licensed as allowed under a certification or license acceptable to the department. Such staff person must meet all requirements of the temporary or provisional certification or license, must be supervised by a staff person meeting one of the requirements of paragraphs “1” to “4” above, and must be fully certified or licensed within two years of the date on which the person began to provide licensed program services.

6. A staff person employed on and after July 1, 2010, who is not qualified as described in any of the paragraphs “1” to “5” above shall be deemed qualified while the person is in the process of being certified or licensed under a certification or license acceptable to the department. Such staff must meet the requirements of the certification or licensure process, must be supervised by a staff person meeting one of the requirements of paragraphs “1” to “4” above, and must be fully certified or licensed within two years of the date on which the person began to provide licensed program services. The two-year time frame is continuous from the person’s date of first employment by the program, including if the person changes employment from one program to another.

7. A person employed before July 1, 2010, and continuously since that date at a program licensed pursuant to this chapter, who is not qualified as described in any of the paragraphs “1” to “5” above, shall be deemed qualified as long as such person remains employed by that program and that program remains licensed. Such staff shall maintain a minimum of 30 hours of training every two years, including a minimum of 3 hours of ethics training, and shall be supervised by a staff person meeting at least one of the conditions of paragraphs “1” to “4” above.

- (2) The program shall review job descriptions annually and whenever there is a change in a position’s duties or required qualifications.

- (3) The program shall include job descriptions in the personnel section of the policies and procedures manual.

c. The program shall conduct a written evaluation of job performance with each staff person at least annually. The evaluation shall include the opportunity for the staff person to comment.

d. The program shall maintain a personnel record on each staff person. The record shall contain, as applicable:

- (1) Verification of training, experience, qualifications, and professional credentials;
- (2) Job performance evaluations;
- (3) Incident reports;
- (4) Disciplinary action taken; and
- (5) Documentation of review of and agreement to adhere to confidentiality laws and regulations.

This review and agreement shall occur prior to the staff person's assumption of duties.

e. The personnel policies and procedures shall ensure confidentiality of personnel records and shall specify staff authorized to have access to personnel information.

f. The program shall notify the department in writing within ten days of being informed that a staff person has been sanctioned or disciplined by a certifying or licensing body. Such notice shall include the sanction or discipline order.

155.21(9) *Child abuse, dependent adult abuse and criminal history background checks.* The program's policies and procedures shall address child abuse, dependent adult abuse and criminal history background checks.

a. The program shall prohibit mistreatment, neglect, or abuse of children and dependent adults and shall specify reporting and enforcement procedures. Alleged violations shall be reported immediately to the program's executive director and appropriate department personnel. Policies and procedures on reporting alleged violations shall be in compliance with subrule 155.21(10). A staff person found to be in violation of Iowa Code sections 232.67 through 232.70, as substantiated by a department investigation, shall be subject to the program's policies concerning termination.

b. For each staff person working with juveniles as set forth in Iowa Code section 125.14A or with dependent adults as set forth in Iowa Code chapter 235B, the personnel record shall contain:

(1) Documentation of a criminal history background check with the Iowa division of criminal investigation on all new staff applicants. The background check shall include asking whether the applicant has been convicted of a crime.

(2) A written, signed and dated statement furnished by a new staff applicant that discloses any substantiated report of child abuse, neglect or sexual abuse or dependent adult abuse.

(3) Documentation of a check prior to permanent acceptance of a person as staff, with the Iowa central registry for any substantiated reports of child abuse, neglect or sexual abuse pursuant to Iowa Code section 125.14A or substantiated reports of dependent adult abuse for all staff hired or accepted on or after July 1, 1994, pursuant to Iowa Code chapter 235B.

c. A person who has a record of a criminal conviction or founded child abuse report or founded dependent adult abuse report shall not be hired or accepted as staff unless an evaluation of the crime or founded child abuse or founded dependent adult abuse has been made by the department that concludes that the crime or founded child abuse or founded dependent adult abuse does not merit prohibition of employment. If a record of criminal conviction or founded child abuse or founded dependent adult abuse does exist, the person shall be offered the opportunity to complete and submit a Record Check Evaluation form. In its evaluation, the department will consider the nature and seriousness of the crime or founded abuse in relation to the position sought, the time elapsed since the commission of the crime or founded abuse, the circumstances under which the crime or founded abuse was committed, the degree of rehabilitation and the number of crimes or founded abuses committed by the person involved.

d. A staff person providing screening, OWI evaluation, assessment or treatment in accordance with this chapter shall complete the department's core training curriculum pursuant to Iowa Code sections 232.69 and 235B.16 within six months of initial employment or self-employment and every three years thereafter.

155.21(10) *Patient records.* The program's policies and procedures shall describe compilation, storage and dissemination of patient records and release or disclosure of information.

a. The policies and procedures shall ensure that:

(1) The program protects the patient record against loss, tampering or unauthorized disclosure of information;

(2) The content and format of patient records are uniform;

(3) All entries in the patient record are in chronological order, signed, dated and legible. When records are maintained electronically, a staff identification code number authorizing access shall be accepted in lieu of a signature;

(4) Each entry in the patient record is made in permanent ink, by typewriter, or by computer; and

(5) Entries in the patient record use language consistent with generally accepted standards of practice and do not include abstract terms, technical jargon or slang.

b. The program shall provide adequate physical facilities for the secure storage, processing and handling of patient records.

c. Appropriate patient records shall be readily accessible to staff as specifically authorized by program policy.

d. The program shall appropriately maintain and dispose of patient records. Patient records shall be maintained for not less than seven years from the date they are officially closed.

e. Each file cabinet or storage area containing patient records shall be locked.

f. The program shall release or disclose information on individuals seeking program services or on patients in strict accordance with the Health Insurance Portability and Accountability Act (HIPAA) as amended to August 1, 2025, and state and federal confidentiality laws, rules and regulations.

(1) The confidentiality of substance use disorder patient records and information is protected by HIPAA as amended to August 1, 2025, and the regulations on confidentiality of alcohol and drug abuse patient records, 42 CFR Part 2 as amended to August 1, 2025, which implement federal statutory provisions, 42 U.S.C. 290dd-2 applicable to alcohol abuse patient records, and 42 U.S.C. 290ee-3 both as amended to August 1, 2025, applicable to drug abuse patient records.

(2) The confidentiality of problem gambling patient records and information is protected by HIPAA as amended to August 1, 2025, Iowa Code chapter 228 and section 22.7(35).

g. A program that provides licensed program services via electronic means shall inform the patient of the limitations and risks associated with such services and shall document in the patient record that such notice has been provided.

h. Upon receipt of a properly executed written release of information or authorization to disclose signed by the patient, the program shall release patient records in a timely manner. A program shall not refuse to release patient records related to continuation of care solely because payment has not been received. A program may refuse to release patient records that 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.

155.21(11) *Assessment and admission.* The program's policies and procedures shall address screening, assessment, referral and admission and documentation of such activities in the patient record.

a. The program shall conduct an assessment with each patient prior to admission unless the patient's current risk factors indicate a need for immediate admission.

(1) If the program admits a patient based on a screening or initial assessment that indicates the patient requires immediate admission, that screening or initial assessment must be updated and expanded to a full assessment when the patient's current risk factors are stabilized.

(2) The assessment shall be documented in the patient record and shall be organized in a manner that supports development of a treatment plan by the program or by any program to which the patient is referred.

b. The program shall implement a uniform assessment process that describes:

- (1) The information to be gathered;
- (2) Procedures for accepting a referral from another program, agency or organization;
- (3) Procedures for referring a patient to another program, agency or organization.

c. A substance use disorder treatment program, problem gambling treatment program, or substance use disorder and problem gambling treatment program shall update the assessment on an ongoing basis, when clinically indicated, and within the periods of time specified for each level of care in the management-of-care review process.

d. The results of each assessment shall be clearly explained to the patient, and to the patient's family when appropriate, and such explanation shall be documented in the patient record.

e. At the time of admission, a substance use disorder treatment program, problem gambling treatment program, or substance use disorder and problem gambling treatment program shall document that the patient has been informed of:

- (1) The general nature and goals of the program;
- (2) Rules governing patient conduct and infractions that can lead to disciplinary action or discharge from the program;
- (3) The hours during which services are available;
- (4) The costs to be borne by the patient;
- (5) Patient rights and responsibilities;
- (6) Confidentiality laws, rules and regulations; and
- (7) Safety and emergency procedures.

155.21(12) *Treatment plans.* The policies and procedures for substance use disorder treatment programs, problem gambling treatment programs, and substance use disorder and problem gambling treatment programs shall describe the program's uniform process for developing individualized treatment plans based on ongoing assessment and documentation of such plans in the patient record.

a. Staff shall initiate development of the treatment plan as soon after the patient's admission as is clinically feasible and within the period of time between admission and the review date specified for that level of care in the management-of-care review process.

b. The treatment plan shall minimally contain:

- (1) A summary of assessment findings;
- (2) Patient short- and long-term goals;
- (3) The type and frequency of planned treatment activities;
- (4) The staff responsible for the patient's treatment; and
- (5) Culturally and environmentally specific considerations.

c. Staff shall develop each treatment plan in partnership with the patient, with patient participation documented in the patient record. The treatment plan shall be written in a manner clearly understandable to the patient. Staff shall give the patient a copy of each treatment plan. The patient and staff shall review and revise the treatment plan when clinically indicated and in accordance with the time frames specified in the management-of-care review process.

d. Treatment plan reviews shall be based on ongoing assessment and shall specify the indicated level of care and licensed program services and any revision of treatment plan goals. The date of the review and any revision of the treatment plan shall be documented in the patient record.

155.21(13) *Progress notes.* The policies and procedures for substance use disorder treatment programs, problem gambling treatment programs, and substance use disorder and problem gambling treatment programs shall describe the program's uniform process for reviewing a patient's current status and progress in meeting treatment plan goals and documenting such review in the patient record.

a. Progress notes shall include the date each service was provided or observation was made and the name and title of the staff person providing each service.

b. Staff shall enter a progress note following each individual counseling session.

c. Staff shall enter a summary progress note at least weekly for group counseling sessions.

d. Progress notes that involve subjective interpretations of a patient's status or progress should be supplemented with a description of the behavioral observations that were the basis for the interpretation.

155.21(14) Patient record contents. The program's policies and procedures shall require that a record be maintained for each patient and shall specify the contents of the patient record.

a. The patient record shall include:

- (1) Any screening;
- (2) Each assessment;
- (3) Results of any physical examination or laboratory test;
- (4) Admission information;
- (5) Any report from a referring source or outside resource;
- (6) Notes from any case conference, consultation, care coordination or case management;
- (7) Any correspondence related to the patient, including letters, electronic communications and telephone conversations;
- (8) Any treatment consent form;
- (9) Any release of information or authorization to disclose;
- (10) Notes on any service provided; and
- (11) Any incident report.

b. For substance use disorder treatment programs, problem gambling treatment programs, and substance use disorder and problem gambling treatment programs, the patient record shall also include:

- (1) Treatment plans;
- (2) Management-of-care reviews;
- (3) Medication records, which shall allow for the monitoring of all medications administered and self-administered and detection of adverse drug reactions;
- (4) Progress notes;
- (5) Discharge summaries completed within 30 days of discharge, which shall be sufficiently detailed to identify the types of services the patient received, action taken to address specific problems identified, and plans for services and referrals postdischarge.

c. For problem gambling treatment programs and substance use disorder and problem gambling treatment programs, the patient record shall also include documentation of financial counseling services that assist problem gambling patients in preparing a budget and addressing financial debt options, including restitution and bankruptcy.

155.21(15) Drug screening. The program's policies and procedures shall address collection of drug-screening specimens and utilization of drug-screening results. Such policies may state that the program does not conduct drug screening.

a. A specimen obtained from a patient shall be collected under direct supervision and analyzed in accordance with program policies, or the program shall have a policy in place to reduce the patient's ability to alter the drug screening.

b. Any laboratory used by the program for drug screening and analysis shall comply with federal and state requirements.

c. A program conducting on-site drug screening shall comply with the Clinical Laboratory Improvement Act regulations as amended to August 1, 2025.

d. The manner in which drug-screening results are utilized shall be documented in the patient record.

155.21(16) Medical and mental health services. The program's policies and procedures shall address patient medical and mental health conditions.

a. In addition to assessment of biomedical conditions and complications as described in the ASAM criteria, the program shall take a medical history and perform a physical examination and necessary laboratory tests as follows for patients admitted to the level of care specified:

(1) Medically managed intensive inpatient treatment and medically monitored intensive inpatient treatment: within 24 hours of admission.

(2) Clinically managed high-intensity residential treatment and clinically managed medium-intensity residential treatment: within seven days of admission.

(3) Clinically managed low-intensity residential treatment: within 21 days of admission.

(4) Crisis stabilization services and opioid treatment program services: within 24 hours of admission.

b. A program may accept a medical history or physical examination from a qualified source if the history or examination was completed no more than 90 days prior to the patient's current admission.

c. In addition to assessment of emotional, behavioral, and cognitive conditions and complications as described in the ASAM criteria, a program may accept a mental health history from a qualified source if the history was completed no more than three days prior to the patient's current admission.

155.21(17) *Emergency services.* The program's policies and procedures shall address the availability of emergency services for substance use disorders and medical and mental health conditions.

a. Emergency services shall be available 24 hours a day, seven days a week.

b. Emergency services may be provided by the program or by any other qualified individual, institution, facility, or other legal entity.

c. The program shall communicate the availability of emergency services by posting notice at facilities, having a recorded message on the program's telephone system, posting notice on the program's website and through program materials.

155.21(18) *Medication control.* The program's policies and procedures shall describe how medications are administered or self-administered in accordance with federal, state and local laws, rules and regulations. Such policies may state that the program does not conduct medication administration or self-administration.

a. Staff authorized to administer medications shall be qualified, and a current list of such staff shall be maintained.

b. Medication shall be administered only in accordance with the instructions of the attending prescriber. The type and amount of the medication, the time and date, and the staff person administering the medication shall be documented in the patient record.

c. Self-administration of medication shall be observed by a staff person who has been oriented to the program's policies and procedures on self-administration. Self-administration of medication shall be permitted only when the patient's medication is clearly labeled. The policies and procedures on self-administration shall include:

(1) Medications are ordered or prescribed by a prescriber.

(2) The prescriber agrees that the patient can self-administer the medication.

(3) The medication taken and how and when the medication is taken are documented in the patient record.

d. Prescription medication shall not be administered to or self-administered by a patient without a written order signed by a prescriber. All prescribed medications shall be clearly labeled indicating the patient's full name, the prescriber's name, the prescription number, the name and strength of the medication, the dosage, the directions for use, and the date of issue and the name, address and telephone number of the pharmacy or prescriber issuing the medication. Medications shall be packaged and labeled according to state and federal guidelines.

e. If a medication the patient brings to the program is not used, it shall be packaged, sealed and stored. The sealed package of medication shall be returned to the patient, family or designee at the time of discharge.

f. Accountability and control of medications.

(1) There shall be a specific routine for medication administration, indicating dose schedules and standardization of abbreviations.

(2) There shall be specific methods for control and accountability of medication products throughout the program.

(3) The staff person in charge of medications shall provide for monthly inspection of all storage units.

(4) Prescription medication containers having soiled, damaged, illegible, or makeshift labels shall be returned to the issuing pharmacist, pharmacy, or prescriber for relabeling or disposal.

(5) Unused prescription medication prescribed for a patient who leaves a program without the patient's medication shall be destroyed by a staff person with a staff witness, and a notation shall be made in the patient record. When a patient is discharged or leaves the program, medication currently being administered shall be sent, in the original container, with the patient or with a responsible agent, as approved by a prescriber.

g. Medication storage shall be maintained in accordance with the security requirements of federal, state and local laws.

(1) All medication shall be maintained in locked storage. Controlled substances shall be maintained in a locked box within the locked cabinet.

(2) Medications requiring refrigeration shall be kept in a refrigerator and separated from food and other items.

(3) Disinfectants and medication for external use shall be stored separately from internal and injectable medications.

(4) The medication for each patient shall be stored in the original container.

(5) All poisonous or caustic medication shall be plainly labeled; stored separately from other medication in a specific well-illuminated cabinet, closet, or storeroom and made accessible only to authorized staff.

h. Prescription medication provided to a patient shall be dispensed only from a licensed pharmacy in the state of Iowa in accordance with the pharmacy laws in the Iowa Code, from a licensed pharmacy in another state according to the laws of that state, or by a licensed prescriber.

i. Prescription medication prescribed for one patient shall not be administered to or allowed to be in the possession of another patient.

j. Any unusual patient reaction to a medication shall be documented in the patient record and reported to the prescriber immediately.

k. Dilution or reconstitution and labeling of medication shall be done only by a licensed pharmacist.

155.21(19) *Management of care and discharge planning.* The program's policies and procedures shall use the ASAM criteria for assessment, admission, continued service and discharge decisions and shall describe management-of-care processes.

a. The program shall conduct care coordination to meet each patient's needs and promote effective outcomes.

b. The program shall conduct management-of-care activities at least minimally within the time frames specified for each level of care.

(1) Medically managed intensive inpatient treatment and medically monitored intensive inpatient treatment: daily.

(2) Clinically managed high-intensity residential treatment, clinically managed medium-intensity residential treatment, partial/day treatment, and intensive outpatient treatment: within seven days of the patient's admission.

(3) Clinically managed low-intensity residential treatment and outpatient treatment: within 30 days of the patient's admission.

c. The program shall coordinate patient care with other programs for any licensed program service for which the program is not licensed and with qualified individuals and organizations for any

related services the program does not provide, such as crisis stabilization, medical services, mental health services, and social services.

d. At the time of the patient's admission, the program shall initiate discharge planning that includes a determination of the patient's continued need for licensed program services and development of a plan to address ongoing patient needs postdischarge.

155.21(20) *Quality improvement.* The program's policies and procedures shall describe a written quality improvement plan that encompasses all licensed program services and related program operations.

a. The program shall designate a staff person responsible for the quality improvement plan.

b. The quality improvement plan shall describe and document monitoring, problem-solving and evaluation activities designed to systematically identify and resolve problems and make continued improvements.

(1) The quality improvement plan shall include specific goals, objectives, and methods.

(2) The quality improvement plan shall include objective criteria to measure its effectiveness.

c. The program shall document whether the quality of patient care and program operations are improved and identified problems are resolved.

d. The program shall communicate quality improvement plan activities and findings to all staff.

e. Quality improvement plan findings are used to detect trends, patterns of performance, and potential problems that affect patient care and program operations.

f. The program shall evaluate the effectiveness of the quality improvement plan at least annually and revise the plan as necessary.

155.21(21) *Facility safety and cleanliness.* The program's policies and procedures shall ensure that program physical facilities are clean, well-ventilated, heated, free from vermin, and appropriately furnished and are designed, constructed, equipped, and maintained in a manner that provides for the physical safety of patients, concerned persons, visitors and staff.

a. If required by local jurisdiction, the program shall maintain a certification of occupancy.

b. During all phases of construction or alterations of buildings, the level of life safety shall not be diminished in any occupied area. The construction shall be in compliance with all applicable federal, state, and local codes. New construction shall comply with Iowa Code chapter 104A and all applicable federal and local codes and provide for safe and convenient use by disabled individuals.

c. The program shall have specific policies and procedures for each of the following:

(1) Identification, development, implementation, maintenance and review of safety policies and procedures.

(2) Promotion and maintenance of an ongoing, facilitywide hazard surveillance program to detect and report all safety hazards.

(3) Safe and proper disposal of biohazardous waste.

(4) Stairways, halls, and aisles that shall be of substantial, nonslippery material, maintained in a good state of repair, adequately lighted and kept free from obstructions at all times. All stairways shall have handrails.

(5) Radiators, registers, and steam and hot water pipes, each of which shall have protective covering or insulation. Electrical outlets and switches shall have wall plates.

(6) For programs serving juveniles, fuse boxes that shall be under lock and key or six feet above the floor.

(7) Safe and proper handling and storage of hazardous materials.

(8) Prohibition against weapon possession; safe and proper removal of weapons.

(9) Swimming pools that shall conform to state and local health and safety rules and regulations. Adult supervision shall be provided at all times when juveniles are using the pool.

(10) Ponds, lakes, or any bodies of water located on or near the program and accessible to patients, concerned persons, visitors and staff.

(11) The written plan to be followed in the event of fire or tornado. The plan shall be conspicuously displayed at the facility.

155.21(22) *Therapeutic environment.* The program's policies and procedures shall provide for the establishment of an environment that preserves human dignity. Program facilities shall have adequate space for the program to provide licensed program services.

a. The program's policies and procedures shall include a description of how all licensed program services are accessible to people with disabilities or how the program provides accommodations for people with disabilities. All programs shall comply with the Americans with Disabilities Act as amended to August 1, 2025.

b. The waiting or reception areas shall be of adequate size and be located so as to ensure patient confidentiality.

c. Staff shall be available in waiting or reception areas to address the needs of the patients, potential patients, concerned persons, and visitors.

d. The program's policies and procedures shall include:

- (1) Possession and use of chemical substances in the facility.
- (2) Prohibition of smoking.
- (3) Prohibition of the sale or other provision of any tobacco product.
- (4) Informing patients of their legal and human rights at the time of admission.
- (5) Patient communication, opinions, or grievances, with a mechanism for redress.
- (6) Prohibition of sexual harassment.
- (7) Patient right to privacy.

641—155.22(125,135) Inpatient and residential program facilities. Specific standards apply for programs providing clinically managed low-intensity residential treatment, clinically managed medium-intensity residential treatment, clinically managed high-intensity residential treatment, medically monitored intensive inpatient treatment, and medically managed intensive inpatient treatment. The program's policies and procedures shall address each standard.

155.22(1) *Health and fire safety inspections.* Inpatient and residential programs shall comply with applicable department of inspections, appeals, and licensing rules; state fire marshal's rules and fire ordinances; and applicable local health, fire, occupancy, and safety regulations. The program shall maintain documentation of such compliance.

a. Inpatient and residential programs shall comply with standards for food service sanitation in accordance with rules promulgated by the department of inspections, appeals, and licensing pursuant to 481—Chapter 30 and Iowa Code chapter 137B.

b. The use of door locks or closed sections shall be documented in written policies and procedures approved by the fire marshal and governing body.

155.22(2) *Emergency preparedness.* Inpatient and residential programs shall have a written emergency preparedness plan for continuation of licensed program services during an emergency or disaster.

641—155.23(125,135) Specific standards for inpatient and residential programs. The program's policies and procedures shall address each standard.

155.23(1) *Hours of operation.* Inpatient and residential programs shall operate seven days per week, 24 hours per day.

155.23(2) *Meals.* Inpatient and residential programs shall provide a minimum of three meals per day to each patient. A program where patients are not present during mealtime shall make provisions to make available the necessary meals. Menus shall be prepared in consultation with a dietitian. If patients are allowed to prepare meals, the program shall document conformity with all commonly accepted policies and procedures of state health rules and regulations and food hygiene.

155.23(3) *Consultation with counsel.* Patients shall have opportunity for and access to consultation with legal counsel at any reasonable time.

155.23(4) *Visitation with family and friends.*

a. Each patient shall have opportunities for continuing contact with family and friends. If such contact is clinically contraindicated, it may be restricted. Any restriction shall be approved by the treatment supervisor and the executive director. Justification for the restriction shall be documented in the patient record. Any restriction shall be reviewed within three calendar days by the treatment supervisor, who may continue or end the restriction. Continuation of a restriction shall be documented in the patient record and shall be reviewed by the treatment supervisor every three calendar days.

b. The program shall establish visiting hours, which shall be conspicuously displayed at the facility in such a manner to be visible to those entering the facility.

155.23(5) *Telephone use.*

a. Each patient shall have opportunities to conduct private telephone conversations. If such conversations are clinically contraindicated, they may be restricted. Any restriction shall be approved by the treatment supervisor and the executive director. Justification for the restriction shall be documented in the patient record. Any restriction shall be reviewed within three calendar days by the treatment supervisor, who may continue or end the restriction. Continuation of a restriction shall be documented in the patient record and shall be reviewed by the treatment supervisor every three calendar days.

b. The program shall establish telephone hours. Emergency telephone conversations may be received at the time of the call or made when necessary.

155.23(6) *Written communication.*

a. Each patient shall have opportunities to conduct private written communications. If such communications are clinically contraindicated, they may be restricted. Any restriction shall be approved by the treatment supervisor and the executive director. Justification for the restriction shall be documented in the patient record. Any restriction shall be reviewed within three calendar days by the treatment supervisor, who may continue or end the restriction. Continuation of a restriction shall be documented in the patient record and shall be reviewed by the treatment supervisor every three calendar days.

b. The program shall establish access to written communications. The program shall not intercept, read, or censor the U.S. mail.

155.23(7) *Facility.* Inpatient and residential program facilities shall be appropriate for 24-hour occupancy.

a. Patient bedrooms shall include:

- (1) A sturdily constructed bed;
- (2) A clean mattress protected with a clean mattress pad;
- (3) A designated space for personal possessions and for hanging clothing in proximity to the sleeping area; and
- (4) Curtains or window blinds on any windows.

b. Sleeping areas.

- (1) Sleeping areas shall include doors for privacy.
- (2) Sleeping areas shall include partitioning or placement of furniture to provide privacy for all patients.

(3) The number of patients in a room shall be appropriate to the goals of the facility and to the ages, developmental levels, and clinical needs of the patients.

(4) Patients will be allowed to keep and display personal belongings and add personal touches to the decoration of their rooms in accordance with program policy.

(5) Staff shall respect the patient's right to privacy by knocking on the door of the patient's room before entering.

c. Clean linen, towels and washcloths shall be available minimally on a weekly basis and more often as needed.

d. Bathrooms.

(1) Bathrooms shall provide the facilities necessary for patients' personal hygiene and personal privacy, including:

1. A safe supply of hot and cold running potable water;
2. Clean towels, electric hand dryers or paper towel dispensers, toilet paper and soap;
3. Natural or mechanical ventilation capable of removing odors;
4. Tubs or showers that have slip-proof surfaces;
5. Partitions with doors that provide privacy if a bathroom has multiple toilet stools; and
6. Toilets, wash basins, and other plumbing or sanitary facilities that shall at all times be maintained in good operating condition.

(2) The ratio of bathroom facilities to inpatient and residential patients shall be one tub or shower head per 12 patients, one wash basin per 12 patients and one toilet per 8 patients.

(3) If the facility is coeducational, the program shall designate and so identify separate bathrooms for male and female patients.

e. The written plan to be followed in the event of fire or tornado shall be conspicuously displayed on each floor or in each area that patients, concerned persons, staff or visitors occupy at the facility and shall be explained to all inpatient and residential patients as a part of their orientation to the program. Fire drills shall be conducted at least monthly, and tornado drills shall be conducted monthly from April through October.

f. Written reports of annual inspections by state or local fire safety officials or private fire protection companies approved by the department shall be maintained with records of corrective action taken by the program based on recommendations articulated in such reports.

g. Every facility shall have an adequate water supply from an approved source. A municipal water system shall meet this requirement. Private water sources shall be tested annually.

h. The facility shall allow for the following:

- (1) Areas in which a patient may be alone when appropriate; and
- (2) Areas for private conversations with others.

i. Articles of grooming and personal hygiene that are appropriate to the patient's age, developmental level, and clinical state shall be readily available in a space reserved near the patient's sleeping area. If access to such articles is clinically contraindicated as approved by the treatment supervisor, a patient's personal articles may be kept under lock and key by staff. Staff shall explain to the patient the conditions under which the articles may be used. Justification for this restriction shall be documented in the patient record.

j. If patients maintain their own living quarters or perform day-to-day housekeeping activities, these responsibilities shall be clearly defined in writing and be a part of the patient orientation program. Staff assistance and equipment shall be provided as needed.

k. Patients shall be allowed to wear their own clothing in accordance with program rules. If clothing is provided by programs, it shall be suited to the climate and appropriate. A laundry room shall be accessible so patients may wash their clothing.

l. The program shall ensure that the use and location of noise-producing equipment and appliances, such as television sets, radios, computers, and CD players, do not interfere with clinical and therapeutic activities.

m. The program shall provide recreation and outdoor activities unless clinically contraindicated.

155.23(8) Religion-culture. Program policies and procedures shall include a written description of any religious orientation, religious practice, or religious restrictions. For juvenile patients, this description shall be provided to the patient, parent(s) or guardian, and placing agency at the time of admission in compliance with HIPAA as amended to August 1, 2025, and U.S. Department of Health and Human Services (DHHS), 42 CFR Part 2 as amended to August 1, 2025, regulations on the confidentiality of alcohol and drug abuse patient records. For adult patients, this information shall be available during orientation. The patient shall have the opportunity to participate in religious activities and services in accordance with the patient's faith or that of a patient's parent(s) or guardian if the patient is a minor. The program shall, when necessary and reasonable, arrange transportation to religious activities.

641—155.24(125,135) Specific standards for inpatient and residential programs licensed to provide services to juveniles. Inpatient and residential programs that provide services to juveniles under the age of 18 shall also comply with the following standards. The program's policies and procedures shall address each standard.

155.24(1) *Personal possessions.* A program shall allow a patient to bring personal belongings. The program may limit or supervise the use of these items. The program shall ensure that each patient has adequate, clean, well-fitting, attractive, and seasonable clothing as required for health, comfort, and physical well-being. The clothes should be appropriate to the patient's individual needs, age, and sex.

155.24(2) *Family involvement.* The program shall encourage family involvement.

155.24(3) *Money.* Money earned or received as a gift or as an allowance by a patient shall be that patient's personal property. The program shall maintain a separate accounting system for patient money and shall address the patient's use of funds.

155.24(4) *Discipline.* The program's methods for control and discipline of juveniles shall be available to all staff and to the juvenile's family. Staff shall be in control of and responsible for discipline at all times. Discipline shall not include withholding basic necessities such as food, clothing, or sleep.

a. The program shall prohibit staff or patients from utilizing corporal punishment as a method of disciplining or correcting patients. This policy shall be communicated in writing to all staff.

b. The program's written policies on behavior expectations shall be made available to the patient and the patient's parent(s) or guardian, including:

(1) The general expectations of behavior, including the program's rules and practices.

(2) The range of reasonable consequences that may be used to deal with inappropriate behavior.

155.24(5) *Number of staff.* The program shall have staff coverage seven days per week, 24 hours per day. The number and qualifications of the staff will vary depending on the needs of the patients.

a. The program shall have a 24-hour supervisory consultation on-call system. During prime programming time, there shall be at least a one-to-eight staff-to-patient ratio.

b. Comprehensive residential facilities, as defined in 441—Chapter 115, shall have at least a one-to-five staff-to-patient ratio during prime programming time. A staff person shall be in each living unit at all times when juveniles are in residence, and there shall be a minimum of three nighttime checks between the hours of 12 midnight and 6 a.m. These checks shall be logged. The program's policies and procedures shall address nighttime checks.

c. The program shall define its prime programming time.

155.24(6) *Illness, accident, death, or absence from the inpatient or residential program.* The program shall notify the patient's parent(s), guardian, and responsible agency of any serious illness, incident involving serious bodily injury, absence, or removal of the juvenile from the facility in compliance with HIPAA as amended to August 1, 2025, and DHHS, 42 CFR Part 2 as amended to August 1, 2025, regulations on the confidentiality of alcohol and drug abuse patient records. In the event of the death of a patient, the program shall immediately notify the prescriber, the patient's parent(s) or guardian, the placing agency, and the appropriate state authority.

155.24(7) *Educational services.* The program's educational program shall meet the requirements of the department of education and shall be available for each patient in accordance with abilities and needs.

641—155.25(125,135) Specific standards for substance use assessment and OWI evaluation-only programs. Programs that provide substance use assessment and OWI evaluation-only services shall also comply with the following standards. The program's policies and procedures shall address each standard.

155.25(1) A program conducting OWI evaluations on persons convicted of operating a motor vehicle while intoxicated (OWI) pursuant to Iowa Code section 321J.2 and on persons whose driver's

license or nonresident operating privileges are revoked under Iowa Code chapter 321J shall do so in accordance with 641—Chapter 157.

155.25(2) The program shall make its fees public and shall inform potential patients of the fee at the time the assessment or evaluation is scheduled.

641—155.26 to 155.33 Reserved.

641—155.34(125,135) Specific standards for enhanced treatment services.

155.34(1) *Standards.* Substance use disorder and problem gambling treatment programs licensed to provide enhanced treatment services shall also comply with the following standards. The program's policies and procedures shall address each standard.

155.34(2) *Personnel.* The program shall meet the requirements in subrule 155.21(8). In addition:

a. The program's policies and procedures shall include job descriptions for positions that provide prevention services for substance use disorders and problem gambling, treatment for substance use disorders and problem gambling, services for medical conditions, and services for mental health conditions.

b. The program shall have staff on site who are qualified to provide prevention and early intervention services for substance use disorders and problem gambling, treatment for substance use disorders and problem gambling, services for medical conditions, and services for mental health conditions.

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, 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 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 telemedicine 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 telemedicine. When using telemedicine, the following caveats apply:

(1) In evaluating patients for treatment with Schedule II medications (such as methadone), audiovisual telemedicine 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 section. 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).

TUBERCULOSIS (TB) SCREENING: HEALTH CARE WORKERS AND RESIDENTS

641—155.36 Reserved.

641—155.37(125,135) Definitions. For the purpose of these rules, the following definitions shall apply:

“Bacille Calmette-Guerin vaccination” or *“BCG vaccination”* means a vaccine for tuberculosis (TB). BCG is used in many countries with a high prevalence of TB to prevent childhood tuberculosis meningitis and military disease. BCG is not generally recommended for use in the United States because of the low risk of infection with *Mycobacterium tuberculosis*, the variable effectiveness of the vaccine against adult pulmonary TB, and the vaccine's potential interference with tuberculin skin test reactivity.

“Baseline TB screening” means the screening of staff and residents for latent tuberculosis infection (LTBI) and TB disease at the beginning of employment or upon admission to a facility. Baseline TB screening includes a symptom screen for all staff and residents and tuberculin skin tests (TSTs) or interferon-gamma release assay (IGRA) for *Mycobacterium tuberculosis* for those staff and residents with previous negative test results for *M. tuberculosis* infection.

“Baseline TST” or *“baseline IGRA”* means the TST or IGRA, respectively, that is administered at the beginning of employment to newly hired staff or upon admission to residents of facilities.

“Boosting” means a phenomenon in which a person has a negative TST (i.e., false-negative) result years after infection with *M. tuberculosis* and then a positive subsequent TST result. The positive TST result is caused by a boosted immune response of previous sensitivity rather than by a new infection (false-positive TST conversion). Two-step testing reduces the likelihood of mistaking a boosted reaction for a new infection.

“Extrapulmonary TB” means TB disease in any part of the body other than the lungs (e.g., kidney, spine, or lymph nodes).

“Interferon-gamma release assay” or *“IGRA”* means a whole-blood test that can aid in diagnosing *Mycobacterium tuberculosis* infection.

“*Laryngeal TB*” means a form of TB disease that involves the larynx and may be highly infectious.

“*Latent TB infection*” or “*LTBI*” means infection with *M. tuberculosis* without symptoms or signs of disease having manifested.

“*Mantoux method*” means a skin test performed by intradermally injecting 0.1 mL of purified protein derivative (PPD) tuberculin solution into the volar or dorsal surface of the forearm.

“*Pulmonary TB*” means TB disease that occurs in the lung parenchyma, usually producing a cough that lasts three weeks or longer. Pulmonary TB is usually infectious.

“*Purified protein derivative (PPD) tuberculin*” means a material used in diagnostic tests for detecting infection with *M. tuberculosis*.

“*Risk classification*” means the category on which the infection control team, or designated other, determines the setting’s TB risk classification is based, as a result of the TB risk assessment.

“*Serial screening*” refers to TB screening performed at regular intervals following baseline TB screening. Serial TB screening, also called annual or ongoing TB testing, consists of two components: (1) assessing for current symptoms of active TB disease, and (2) testing for the presence of infection with *M. tuberculosis* by administering either a TST or single IGRA.

“*Symptom screen*” means a procedure used during a clinical evaluation in which patients are asked if they have experienced any departure from normal in function, appearance, or sensation related to TB disease (e.g., cough).

“*TB patient*” means a person who had undiagnosed infectious pulmonary or laryngeal TB while in the facility during the preceding year. “TB patient” does not include persons with LTBI (treated or untreated), extrapulmonary TB disease, pulmonary, or laryngeal TB who have met criteria for noninfectiousness.

“*TB risk assessment*” means an initial and ongoing evaluation of the risk for transmission of *M. tuberculosis* in a particular health care setting.

“*TB screening*” means an administrative control measure in which evaluation for LTBI and TB disease is performed through baseline and serial screening of staff and residents of facilities.

“*TB screening plan*” means a plan that facilities develop and implement that comprises four major components: (1) baseline testing for *M. tuberculosis* infection, (2) serial testing for *M. tuberculosis* infection, (3) serial screening for signs or symptoms of TB disease, and (4) TB training and education.

“*Treatment for LTBI*” means treatment that prevents the progression of *M. tuberculosis* infection into TB disease.

“*Tuberculin skin test*” or “*TST*” means a diagnostic aid for finding *M. tuberculosis* infection. The Mantoux method is the recommended method to be used for the TST.

“*Tuberculosis*” or “*TB*” means the namesake member organism of *M. tuberculosis* complex and the most common causative infectious agent of TB disease in humans. In certain instances, the species name refers to the entire *M. tuberculosis* complex, which includes *M. bovis* and *M. african*, *M. microti*, *M. canetti*, *M. caprae*, and *M. pinnipedii*.

“*Tuberculosis disease*” or “*TB disease*” means a condition caused by infection with a member of the *M. tuberculosis* complex that has progressed to causing clinical (manifesting symptoms or signs) or subclinical (early stage of disease in which signs or symptoms are not present, but other indications of disease activity are present) illness.

“*Two-step tuberculin skin test*” or “*two-step TST*” means the procedure used for the baseline skin testing of persons who will receive serial TSTs to reduce the likelihood of mistaking a boosted reaction for a new infection.

641—155.38(125,135) Tuberculosis screening of staff and residents.

155.38(1) *TB risk assessment.* Annually, each facility shall conduct a TB risk assessment to evaluate the risk for transmission of *M. tuberculosis*, regardless of whether a person with suspected or confirmed TB disease is expected to be encountered in the facility. The TB risk assessment shall be utilized to determine the types of administrative, environmental, and respiratory protection controls

needed and serves as an ongoing evaluation tool of the quality of TB infection control and for the identification of needed improvements in infection control measures. The risk assessment shall include:

- a. The community rate of TB,
- b. The number of persons with infectious TB encountered in the facility, and
- c. The speed with which persons with infectious TB are suspected, isolated, and evaluated to determine if persons with infectious TB exposed staff or others in the facility. TB cases include persons who had undiagnosed infectious pulmonary or laryngeal TB while in the facility during the preceding year. This does not include persons with LTBI (treated or untreated), persons with extrapulmonary TB disease, or persons with pulmonary or laryngeal TB who have met criteria for noninfectiousness.

155.38(2) Facility risk classification. The infection control team or designated staff in a facility is responsible for determining the type of risk classification of the facility. The facility risk classification is used to determine the frequency of TB screening. The facility risk classification may change due to an increase or decrease in the number of TB cases during the preceding year.

a. *Types of risk classifications.*

(1) “Low risk” means that a facility is one in which persons with active TB disease are not expected to be encountered and in which exposure to TB is unlikely.

(2) “Medium risk” means that a facility is one in which health care workers will or might be exposed to persons with active TB disease or to clinical specimens that might contain *M. tuberculosis*.

(3) “Potential ongoing transmission” means that a facility is one in which there is evidence of person-to-person transmission of *M. tuberculosis*. This classification is a temporary classification. If it is determined that this classification applies to a facility, the facility shall consult with the department’s TB control program.

b. *Classification criteria—low risk.*

(1) Inpatient settings with 200 or more beds. If a facility has fewer than six TB patients for the preceding year, the facility will be classified as low risk.

(2) Inpatient settings with fewer than 200 beds. If a facility has fewer than three TB patients for the preceding year, the facility will be classified as low risk.

(3) Outpatient, outreach, and home-based health care settings. If a facility has fewer than three TB patients for the preceding year, the facility will be classified as low risk.

c. *Classification criteria—medium risk.*

(1) Inpatient settings with 200 or more beds. If a facility has six or more TB patients for the preceding year, the facility will be classified as medium risk.

(2) Inpatient settings with fewer than 200 beds. If a facility has three or more TB patients for the preceding year, the facility will be classified as medium risk.

(3) Outpatient, outreach, and home-based health care settings. If a facility has three or more TB patients for the preceding year, the facility will be classified as medium risk.

d. *Classification criteria—potential ongoing transmission.* If evidence of ongoing *M. tuberculosis* transmission exists at a facility, the facility will be classified as potential ongoing transmission, regardless of the facility’s previous classification.

155.38(3) Baseline TB screening procedures for facilities.

a. All facility staff members shall receive baseline TB screening upon hire. Baseline TB screening consists of two components: (1) assessing for current symptoms of active TB disease and (2) using a two-step TST or a single IGRA to test for infection with *M. tuberculosis*.

b. A staff member may begin working with patients after a negative TB symptom screen (i.e., no symptoms of active TB disease) and a negative TST (i.e., first step) or a negative IGRA. The second TST may be performed after the staff member starts working with patients.

c. A staff member with a new positive test result for *M. tuberculosis* infection (i.e., TST or IGRA) shall receive one chest radiograph result to exclude TB disease. Repeat radiographs are not

needed unless symptoms or signs of TB disease develop or unless recommended by a clinician. Treatment for LTBI should be considered in accordance with CDC guidelines.

d. A staff member with documentation of past positive test results (i.e., TST or IGRA) and documentation of the results of a chest radiograph indicating no active disease, dated after the date of the positive TST or IGRA test result, does not need another chest radiograph at the time of hire.

e. TB, TST or IGRA tests for *M. tuberculosis* infection do not need to be performed for staff with a documented history of TB disease, documented previously positive test result for *M. tuberculosis* infection, or documented completion of treatment for LTBI or TB disease. Documentation of a previously positive test result for *M. tuberculosis* infection can be substituted for a baseline test result if the documentation includes a recorded TST result in millimeters or IGRA result, including the concentration of cytokine measured (e.g., interferon-gamma (IFN-g)). All other staff should undergo baseline testing for *M. tuberculosis* infection to ensure that the test result on record in the setting has been performed and measured using the recommended diagnostic procedures.

f. A second TST is not needed if the staff member has a documented TST result from any time during the previous 12 months. If a newly employed staff member has had a documented negative TST result within the previous 12 months, a single TST can be administered in the new setting. This additional TST represents the second stage of two-step testing. The second test decreases the possibility that boosting on later testing will lead to incorrect suspicion of transmission of *M. tuberculosis* in the setting.

g. Previous BCG vaccination is not a contraindication to having an IGRA, a TST or two-step skin testing administered. Health care workers with previous BCG vaccination should receive baseline and serial testing in the same manner as those without BCG vaccination. Evaluation of TST reactions in persons vaccinated with BCG should be interpreted using the same criteria for those not BCG-vaccinated. A health care worker's history of BCG vaccination should be disregarded when administering and interpreting TST results. Previous BCG vaccination does not cause a false-positive IGRA test result.

155.38(4) *Serial TB screening procedures for facilities.*

a. *Facilities classified as low risk.* After baseline testing of staff for infection with *M. tuberculosis*, additional TB screening of staff is not necessary unless an exposure to *M. tuberculosis* occurs.

b. *Facilities classified as medium risk.*

(1) After undergoing baseline testing for infection with *M. tuberculosis*, staff should receive TB screening annually (i.e., symptom screen for all staff members and testing for infection with *M. tuberculosis* for staff members with baseline negative test results).

(2) Staff members with a baseline positive or new positive test result for *M. tuberculosis* infection or documentation of previous treatment for LTBI or TB disease shall receive one chest radiograph result to exclude TB disease. Instead of participating in serial testing, staff should receive a symptom screen annually. This screen should be accomplished by educating the staff about symptoms of TB disease and instructing the staff members to report any such symptoms immediately to the occupational health unit. Treatment for LTBI should be considered in accordance with CDC guidelines.

c. *Facilities classified as potential ongoing transmission.* Testing for infection with *M. tuberculosis* may need to be performed every eight to ten weeks until lapses in infection control have been corrected and no additional evidence of ongoing transmission is apparent. The potential ongoing transmission classification should be used only as a temporary classification. This classification warrants immediate investigation and corrective steps. After a determination that ongoing transmission has ceased, the setting will be reclassified as medium risk for a minimum of one year.

155.38(5) *Screening of staff who transfer to other facilities.*

a. *Staff transferring from a low-risk facility to another low-risk facility.* After a baseline result for infection with *M. tuberculosis* is established and documented, serial testing for *M. tuberculosis* infection is not necessary for staff transferring from a low-risk facility to another low-risk facility.

b. Staff transferring from a low-risk facility to a medium-risk facility. After a baseline result for infection with *M. tuberculosis* is established and documented, annual TB screening, including a symptom screen and TST or IGRA for persons with previously negative test results, should be performed for staff transferring from a low-risk facility to a medium-risk facility.

155.38(6) *Baseline TB screening procedures for residents of residential, inpatient, and halfway house facilities.*

a. TB screening is a formal procedure to evaluate residents for LTBI and TB disease. Baseline TB screening consists of two components: (1) assessing for current symptoms of active TB disease and (2) using a two-step TST or a single IGRA to test for infection with *M. tuberculosis*.

b. All residents shall be assessed for current symptoms of active TB disease upon admission. Within 72 hours of a resident's admission, baseline TB testing for infection shall be initiated unless baseline TB testing occurred within three months prior to the resident's admission.

c. Residents with a new positive test result for *M. tuberculosis* infection (i.e., TST or IGRA) shall receive one chest radiograph result to exclude TB disease. Repeat radiographs are not needed unless symptoms or signs of TB disease develop or unless recommended by a clinician.

d. Residents with documentation of past positive test results (i.e., TST or IGRA) and documentation of the results of a chest radiograph indicating no active disease, dated after the date of the positive TST or IGRA test result, do not need another chest radiograph at the time of admission.

e. TB, TST or IGRA tests for *M. tuberculosis* infection do not need to be performed for residents with a documented history of TB disease, a documented previously positive test result for *M. tuberculosis* infection, or documented completion of treatment for LTBI or TB disease. Documentation of a previously positive test result for *M. tuberculosis* infection can be substituted for a baseline test result if the documentation includes a recorded TST result in millimeters or IGRA result, including the concentration of cytokine measured (e.g., IFN-g). All other residents should undergo baseline testing for *M. tuberculosis* infection to ensure that the test result on record in the setting has been performed and measured using the recommended diagnostic procedures.

f. A second TST is not needed if the resident has a documented TST result from any time during the previous 12 months. If a new resident has had a documented negative TST result within the previous 12 months, a single TST can be administered in the new setting. This additional TST represents the second stage of two-step testing. The second test decreases the possibility that boosting on later testing will lead to incorrect suspicion of transmission of *M. tuberculosis* in the setting.

g. After baseline TB screening is accomplished, serial TB screening of the residents is not recommended.

155.38(7) *Serial TB screening procedures for residents of residential, inpatient, and halfway house facilities.*

a. If a resident is discharged and readmitted to a facility and less than 12 months have passed since the last TB screening, residents should receive a symptom screen upon readmittance. This screen should be accomplished by educating the resident about symptoms of TB disease and instructing the resident to report any such symptoms immediately to the infection control team or designated other staff. If symptoms or signs of TB disease are documented, then a medical evaluation to include a chest X-ray to rule out TB disease is required.

b. If a resident is discharged and readmitted to a facility and more than 12 months have passed since the last TB screening, baseline TB screening should be repeated as outlined in subrule 155.38(6).

These rules are intended to implement Iowa Code sections 125.13, 125.21 and 135.150.