CHAPTER 155
LICENSURE STANDARDS FOR SUBSTANCE ABUSE AND PROBLEM GAMBLING TREATMENT PROGRAMS

[Prior to 7/27/88, see Substance Abuse, Iowa Department of[805] Ch 3]
[Prior to 3/29/06, see 643—Ch 3]

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

"Accreditation body" means a national or not-for-profit body or organization recognized by the committee as meeting the criteria of the committee for deemed status.

"Acute intoxication or withdrawal potential" is a category to be considered in the ASAM-PPC-2R criteria. This category evaluates client/patient's current status of intoxication and potential for withdrawal complications. Historical information about client/patient's withdrawal patterns may also be considered.

"Administration" means the direct application of a prescription drug, whether by injection, inhalation, ingestion, or any other means, to the body of a client/patient or research subject by one of the following:

1. A practitioner or the practitioner's authorized agent.
2. The client/patient or research subject at the direction of a practitioner.

"Admission" means the point in an individual's relationship with the program at which the screening process has been completed and the individual is entitled to receive treatment services.

"Admission criteria" means specific ASAM-PPC-2R criteria to be considered in determining appropriate client/patient placement and resultant referral to a level of care (substance abuse treatment only). Criteria vary in intensity and are organized into categories to be used by treatment programs for assessment, to determine appropriate level of care, and for treatment planning.

"Affiliation agreement" means a written agreement between the governing authority of the program and another organization under the terms of which specified services, space or personnel are provided to one organization by the other, but without exchange of moneys.

"Applicant" means any treatment program which has applied for a license or renewal thereof.

"Application" means the process through which a treatment program applies for a license or renewal as outlined in the application procedures.

"ASAM-PPC-2R" means the American Society of Addiction Medicine Patient Placement Criteria for the Treatment of Substance-Related Disorders, Second Edition, Revised.

"Assessment" means the ongoing process of identifying a diagnosis, ruling out other diagnoses, and determining the level of care needed by the client/patient.

"Biomedical conditions and complications" means one category to be considered in the ASAM-PPC-2R criteria. This category evaluates client/patient's current physical condition. Historical information on client/patient's medical/physical functioning may also be considered. This category includes biological and physical aspects of the medical assessment and treatment of a client/patient. Physical problems may be the direct result of a substance use disorder, or be independent of and interactive with such a disorder, thus affecting the total treatment plan and prognosis.

"Board" means the state board of health created pursuant to Iowa Code chapter 136.

"Case management" means the process of using predefined criteria to evaluate the necessity and appropriateness of client/patient care.

"Chemical dependency" means alcohol or drug dependence or psychoactive substance use disorder as defined by the current Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM IV), criteria or by other standardized and widely accepted criteria.

"Chemical dependency rehabilitation services" means those individual or group services that are directly related to chemical dependency or the individual treatment plan. These services include individual, group and family counseling, educational services, self-help groups and structured recreational activities. They do not include active employment or education courses beyond the secondary level.

"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.

"Client/patient" means an individual who is a substance abuser or a problem gambler or is chemically dependent, has been assessed as appropriate for services, and for whom screening procedures have been completed.

"Clinical oversight" means oversight provided by an individual who, by virtue of education, training and experience, is capable of assessing the psychosocial history of a client/patient to determine the most appropriate treatment plan. The person providing oversight shall be designated by the treatment program.

"Clinically managed high-intensity residential services (Level III.5)" means high-intensity residential services designed to address significant problems with living skills. The prime example of Level III.5 care is the therapeutic community, which provides a highly structured recovery environment in combination with moderate- to high-intensity professional clinical services to support and promote recovery. Client/patients must participate in at least 50 hours of structured chemical dependency rehabilitation services per week.

"Clinically managed low-intensity residential services (halfway house) (Level III.1)" means low-intensity professional addiction treatment services offered at least five hours per week. Treatment is directed toward applying recovery skills, preventing relapse, promoting personal responsibility and reintegrating the resident into the worlds of work, education and family life. The services may include individual, group and family therapy. Mutual/self-help meetings are available on site.

"Clinically managed medium-intensity residential services (Level III.3)" are frequently referred to as extended or long-term care. Level III.3 programs provide a structured recovery environment in combination with medium-intensity professional clinical services to support and promote recovery. Client/patients must participate in at least 30 hours of structured chemical dependency rehabilitation services per week.

"Clinically managed services" means clinically managed services in which treatment is directed by addiction specialists rather than by medical professionals. They serve residents whose problems in the area of emotional/behavioral concerns, treatment acceptance, relapse potential, or recovery environment are the primary focus of treatment and problems in the areas of intoxication/withdrawal (Dimension 1) and biomedical concerns (Dimension 2), if any, are minimal.

"Committee" means the substance abuse and gambling treatment program committee appointed by the state board of health pursuant to Iowa Code section 136.3(13). The committee shall consist of three board members who are recommended by the board chairperson and approved by the board, including two members who have direct experience with substance abuse treatment or prevention and one member who represents the general public. The committee chairperson shall be one of the members who has substance abuse treatment or prevention experience as recommended by the board chairperson and approved by the board.

"Concerned family member" or *"concerned person"* means an individual who is seeking treatment services due to problems arising from the person's involvement or association with a substance abuser, chemically dependent individual, problem gambler or client/patient and who is negatively affected by the behavior of the substance abuser, chemically dependent individual, problem gambler or client/patient.

"Continuing care" means a Level I service of the ASAM-PPC-2R criteria, which provides a specific period of structured therapeutic involvement designed to enhance, facilitate and promote transition from primary care to ongoing recovery. There shall not be any required frequency of review for continuing care or frequency of review of treatment plan by client/patient and counselor.

"Continuing service and discharge criteria" means, in accordance with ASAM-PPC-2R, during the process of client/patient assessment, certain problems and priorities are identified as justifying admission to a particular level of care and the resolution of those problems and priorities determines when a client/patient can be treated at a different level of care or discharged from treatment. New problems may require services that can be provided effectively at the same level of care or may require a more intensive or less intensive level of care.

"Continuum of care" means a structure of interlinked treatment modalities and services designed so that a client/patient's changing needs will be met as the client/patient moves through the treatment and recovery process.

"Contract" means a formal legal document adopted by the governing authority of the program and any other organization, agency, or individual that specifies services, personnel or space to be provided to the program as well as the moneys to be expended in the exchange.

"Counselor" means an individual who, by virtue of education, training or experience, provides treatment, which includes advice, opinion, or instruction to an individual or in a group setting to allow an opportunity for a person to explore the person's problems related directly or indirectly to substance abuse, chemical dependence or problem gambling.

"Culturally and environmentally specific" means integrating into the assessment and treatment process the ideas, customs, beliefs, and skills of a given population, as well as an acceptance, awareness, and celebration of diversity regarding conditions, circumstances and influences surrounding and affecting the development of an individual or group.

"Deemed status" means that the committee and division will accept a committee-approved, outside accreditation body's review, assessment and accreditation of a program, component or service of a program/organization's operations and services. Programs which received deemed status approval are exempt from routine licensure requirements; however, such programs are subject to all other provisions of this chapter.

"Department" means the Iowa department of public health.

"Designee" means the staff person or counselor who is delegated tasks, duties and responsibilities normally performed by the treatment supervisor, treatment director or executive director.

"Detoxification" means the process of withdrawing a person from a specific psychoactive substance in a safe and effective manner. ASAM-PPC-2R detoxification levels of care include Levels I-D, II-D, III.2-D, III.7-D, and IV-D.

"Director" means the director of the Iowa department of public health.

"Discharge planning" means the process, begun at admission, of determining a client/patient's continued need for treatment services and of developing a plan to address ongoing client/patient posttreatment needs. Discharge planning may or may not include a document identified as a discharge plan.

"Division" means the division of behavioral health.

"Emergency admission" means an admission due to an emergency situation with placement screening criteria being applied as soon after admission as possible.

"Emotional, behavioral or cognitive conditions and complications" is a category to be considered in the ASAM-PPC-2R criteria. This category evaluates client/patient's current emotional, behavioral, and cognitive status. Emotional, behavioral or cognitive status may include, but is not limited to, psychiatric conditions, psychological or emotional/behavioral complications, poor impulse control, changes in mental status, or transient neuropsychiatric complications and the behavior that accompanies or follows these emotional states. Historical information on client/patient's emotional/behavioral functioning may also be considered.

"Evaluation" means the process to evaluate the client/patient's strengths, weaknesses, problems, and needs for the purpose of defining a course of treatment. This includes use of the standardized placement screening and any additional client/patient profile information and development of a comprehensive treatment plan.

"Extended outpatient treatment" means a Level I service of the ASAM-PPC-2R criteria, which is an organized, nonresidential service. Extended outpatient treatment services usually are provided in regularly scheduled sessions which include less than nine treatment hours a week for adults or less than six treatment hours a week for adolescents. For problem gambling client/patients, extended outpatient treatment services may be offered in conjunction with transitional housing.

"Facility" means a hospital, detoxification center, institution or program licensed under Iowa Code section 125.13 or 2009 Iowa Code Supplement section 135.150 providing care, maintenance and

treatment for client/patients. Facility also includes the physical areas such as grounds, buildings, or portions thereof under direct administrative control of the program.

"Focused reviews" means a survey conducted during the licensing process to assess the degree to which a program has improved its level of compliance relating to specific recommendations. The subject matter of the review is typically in area(s) of identified deficiency in compliance; however, other performance areas may also be assessed by a surveyor(s), including areas not covered in deemed status.

"Follow-up" means the process for determining the status of an individual who has been referred to an outside resource for services or who has been discharged from services.

"Governing body" means the individual(s), group, or agency that has ultimate authority and responsibility for the overall operation of the facility.

"HIPAA" means the Health Insurance Portability and Accountability Act of 1996.

"Intake" means gathering additional assessment information at the time of admission to services.

"Intensive outpatient treatment (Level II.1)" means intensive outpatient programs (IOP) that provide a minimum of nine hours for adults or a minimum of six hours for adolescents of structured programming per week, consisting primarily of counseling and education. For problem gambling client/patients, the service may be offered in conjunction with transitional housing.

"Iowa board of certification" means the professional certification board that certifies substance abuse counselors and prevention specialists, problem gambling treatment specialists and other addiction treatment specialists in the state of Iowa.

"Levels of care" is a general term that encompasses the different options for treatment that vary according to the intensity of the services offered. Each treatment option in the ASAM-PPC-2R is a level of care.

"Licensee" means any program licensed by the department.

"Licensure" means the issuance of a license by the department and the committee which validates the licensee's compliance with treatment program standards and authorizes the licensee to operate a treatment program in the state of Iowa.

"Licensure weighting report" means the report that is used to determine the type of license a program qualifies for based on point values assigned to areas reviewed and total number of points attained. In addition, a minimum percent value in each of three categories shall be attained to qualify a program for a license as follows: 95 percent or better rating in clinical, administrative and programming for a three-year license; 90 percent or better rating in clinical, administrative and programming for a two-year license; or less than 90 percent but no less than 70 percent rating in clinical, administrative and programming for a one-year license. The determination of length of license for programs licensed through deemed status shall be made by the accreditation body.

"Maintenance" means the prolonged scheduled administration of methadone or other approved controlled substances intended as a substitute or antagonist to abused substances in accordance with federal and state regulations.

"Management of care" means the process to ensure the appropriate level of care is utilized by implementing ASAM-PPC-2R criteria during placement screening, continuing service and discharge. This process includes discharge planning that begins at admission to meet the immediate, ongoing and posttreatment needs of the client/patient.

"May" means a term used in the interpretation of a standard to reflect an acceptable method that is recognized but not necessarily preferred.

"Medically managed intensive inpatient treatment (Level IV)" is an organized ASAM-PPC-2R service staffed by designated addiction physicians or addiction credentialed clinicians. Level IV care involves a planned regimen of 24-hour medically directed evaluation, care and treatment of substance-related disorders in an acute-care inpatient setting. Such a service functions under a defined set of policies and procedures and has permanent facilities that include inpatient beds. Services involve daily medical care in which diagnostic and treatment services are directly provided by a licensed physician.

"Medically monitored intensive inpatient treatment (Level III.7)" is an organized ASAM-PPC-2R service delivered by an interdisciplinary staff to client/patients whose subacute biomedical and

emotional/behavioral problems are sufficiently severe to require inpatient care. Twenty-four-hour observation, monitoring and treatment are available. However, the full resources of an acute care general hospital or a medically managed inpatient treatment service system are not necessary. Services are provided by an interdisciplinary staff of nurses, counselors, social workers, addiction specialists and other health care professionals and technical personnel, under the direction of licensed physicians. Medical monitoring is provided through an appropriate mix of direct patient contact, review of records, team meetings, 24-hour coverage by a physician, and quality assurance programs.

"Outreach" means public speaking engagements and other similar activities and functions that inform the public of available programs and services offered by a treatment program. In addition, outreach is a process or series of activities that identifies individuals in need of services, engages them and links them with the most appropriate resource or service provider. Such activities may include, but are not limited to, the following: individual client/patient recruitment through street outreach and organized informational sessions at churches, community centers, recreational facilities, and community service agencies.

"OWI" means operating while intoxicated, in violation of Iowa Code chapter 321J.

"Partial hospitalization (day treatment) (Level II.5)" means a program which provides 20 or more hours of clinically intensive programming per week based on individual treatment plans. Programs have ready access to psychiatric, medical and laboratory services and thus are better able than Level II.1 programs to meet client/patient needs. Partial hospitalization/day treatment is a generic term encompassing day, night, evening and weekend treatment programs that employ an integrated, comprehensive and complementary schedule of recognized treatments.

"Physician" means any individual licensed under Iowa Code chapter 148, 150, or 150A.

"Prevention" means a proactive process to eliminate unnecessary disease, disability, and premature death caused by (1) acute disease, (2) chronic disease, (3) intentional or unintentional injury or disease associated with environmental, home and workplace hazards, and (4) controllable risk factors such as poor nutrition; lack of exercise; alcohol, tobacco, and other drug use; inadequate use of preventive health services; and other risk behaviors.

"Primary care modality" means a treatment component or modality including continuing care, halfway house, extended outpatient treatment, intensive outpatient treatment, primary extended residential treatment, medically monitored intensive inpatient treatment, and medically managed intensive inpatient treatment services.

"Primary scope of practice" means the area in which a counselor maintains a professional license or certification.

"Prime programming time" means any period of the day when special attention or supervision is necessary, for example, upon awakening in the morning until departure for school, during meals, after school, transition between activities, evenings and bedtime, or weekends and holidays, in order to maintain continuity of program and care. Prime programming time shall be defined by the facility.

"Problem gambling" means a pattern of gambling behavior which may compromise, disrupt or damage family, personal or vocational pursuits.

"Program" means any partnership, corporation, association, governmental subdivision or public or private organization.

"Protected classes" means classes of people who have required special legislation to ensure equality.

"Quality improvement" means the process of objectively and systematically monitoring and evaluating the quality and appropriateness of client/patient care to improve client/patient care and resolve identified problems.

"Readiness to change" is a category to be considered in the ASAM-PPC-2R criteria. This category evaluates the client/patient's current emotional and cognitive awareness of the need to change and level of commitment to change.

"Recovery/living environment" is a category to be considered in the ASAM-PPC-2R criteria. This category evaluates client/patient's current recovery/living environment as it impacts on level of care decision making and treatment planning. Recovery/living environment may include, but is not limited to, current relationships and degree of support for recovery, current housing, employment situation, and

availability of alternatives. Historical information on client/patient's recovery/living environment may also be considered.

"Recovery oriented system of care" means person-centered and self-directed approaches to care that build on the strengths and resilience of individuals, families and communities to take responsibility for their sustained health, wellness, and recovery from mental illness, alcohol and drug problems, and problem gambling. A recovery oriented system of care offers a comprehensive menu of services and supports that can be combined and readily adjusted to meet the individual's needs and chosen pathway to recovery.

"Rehabilitation" means the restoration of a client/patient to the fullest physical, mental, social, vocational, and economic usefulness of which the client/patient is capable. Rehabilitation may include, but is not limited to, medical treatment, psychological therapy, occupational training, job counseling, social and domestic rehabilitation and education.

"Relapse" means progressive irresponsible, inappropriate and dysfunctional behavior patterns that could lead to resumption of alcohol or drug use or problem gambling. "Relapse" also refers to the resumption of alcohol or drug use or problem gambling.

"Relapse, continued-use or continued-problem potential" is a category to be considered in the ASAM-PPC-2R criteria. This category evaluates client/patient's current factors that contribute to relapse potential as it impacts on level of care decision making and treatment planning. Relapse potential may include, but is not limited to, current statements by client/patient about relapse potential, reports from others on potential for client/patient's relapse, and assessment by clinical staff. Historical information on client/patient's relapse potential may also be considered. This category may include the client/patient's understanding of skills in coping with addictive or mental disorders, recognition of relapse triggers, skills to control impulses and ways to cope with relapse potential.

"Residential program" means a 24-hour, live-in, seven-day-a-week treatment program facility offering intensive rehabilitation services to individuals who are considered unable to live or work in the community due to social, emotional, or physical disabilities resulting from substance abuse or problem gambling. The ASAM-PPC-2R levels of care may include III.1, III.3, III.5 or III.7.

"Rule" means each statement of general applicability that implements, interprets, or prescribes division law or policy, or that describes the organization procedure or practice requirements of the division. The term includes the amendment or repeal of existing rules as specified in the Iowa Code.

"Screening" means the process by which a client/patient is determined appropriate and eligible for admission to a particular program or level of care. The focus is on the minimum criteria necessary for appropriateness/eligibility.

"Self-administration of medication" means the process where a properly trained staff member observes a client/patient inject, inhale, ingest, or by any other means take, medication which has been prescribed by a licensed physician.

"Shall" means the term used to indicate a mandatory statement, the only acceptable method under the present standards.

"Should" means the term used in the interpretation of a standard to reflect the commonly accepted method, yet allowing for the use of effective alternatives.

"Sole practitioner" means an individual incorporated under the laws of the state of Iowa, or an individual in private practice who is providing substance abuse treatment services independent from a program that is required to be licensed in accordance with Iowa Code section 125.13(1).

"Specialized certification" means a substance abuse- or problem gambling-related credential acceptable to the department for providing treatment according to these rules.

"Staff" means any individual who provides services to the treatment program on a regular basis as a paid employee, agent or consultant or as a volunteer.

"Standards" means specifications representing the minimal characteristics of a treatment program which are acceptable for the issuance of a license.

"Subspecialty" means a secondary scope of practice, either substance abuse treatment or problem gambling treatment, approved in accordance with these rules. To maintain expertise within the

subspecialty, the counselor shall complete a minimum of an additional 20 hours of training within the subspecialty every two years.

"Substance abuser" means a person who habitually lacks self-control as to the use of chemical substances or uses chemical substances to the extent that the person's health is substantially impaired or endangered or that the person's social or economic function is substantially disrupted.

"Time frames" means the period of time within which the assessment and treatment plan must be completed after admission, frequency of review of the treatment plan by the client/patient and counselor, and frequency of reviews for continuing service and discharge. The time frames for Levels I and III.1 shall be every 30 days; for Levels II.1, II.5, III.3 and III.5, every 7 days; and for Levels III.7 and IV, daily. For Level I continuing care/aftercare, there shall not be any required frequency of review for continuing service or frequency of review of treatment plan by client/patient and counselor.

"Transitional housing" means housing that may be offered to individuals who are problem gamblers and who have no other housing alternatives or whose housing alternatives are not conducive to problem gambling recovery. Problem gamblers receiving transitional housing must also be receiving problem gambling treatment services.

"Treatment" means the broad range of planned and continuing inpatient, outpatient, and residential care services, including diagnostic evaluation, counseling, and medical, psychiatric, psychological, and social service care, which may be extended to substance abusers, problem gamblers, concerned persons, concerned family members, or significant others. Treatment is geared toward influencing the behavior of such individuals to achieve a state of rehabilitation.

"Treatment days" means days in which the treatment program is open for services or actual working days.

"Treatment planning" means the process by which a counselor and client/patient identify and rank problems, establish agreed-upon goals, and decide on the treatment process and resources to be utilized.

"Treatment program" means a program licensed under these rules. A treatment program may be a substance abuse treatment program, a problem gambling treatment program, or a substance abuse and problem gambling treatment program.

"Treatment supervisor" means an individual who, by virtue of education, training or experience, is capable of assessing the psychosocial history of a client/patient to determine the treatment plan most appropriate for the client/patient. This person shall be designated by the treatment program.

[**ARC 8792B**, IAB 6/2/10, effective 7/1/10; **ARC 9534B**, IAB 6/1/11, effective 7/6/11]

641—155.2(125,135) Licensing. A single license will be issued to each qualifying treatment program. A program shall apply for a license to provide substance abuse treatment, problem gambling treatment, or combined substance abuse and problem gambling treatment.

155.2(1) *Categories of services.* The license will delineate one or more categories of services the program is authorized to provide. Although a program may have more than one facility, only one license will be issued to the program. The categories of services for which licenses will be issued are:

a. Narcotic detoxification/chemical substitute, antagonist maintenance chemotherapy;
b. Assessment and evaluation;
c. OWI correctional residential;
d. OWI correctional outpatient;
e. Correctional residential treatment;
f. Correctional outpatient treatment;
g. Medically managed intensive inpatient services: Level IV;
h. Residential/inpatient services: Levels III.1, III.3, III.5 and III.7;
i. Intensive outpatient/partial hospitalization services: Levels II.1 and II.5; and
j. Outpatient extended and continuing care services: Level I.

155.2(2) *Licensing body.* The committee shall:

a. Consider and approve or disapprove all applications for a license and all cases involving the renewal, denial, suspension, or revocation of a license;

b. Advise the department on policies governing the performance of the department in the discharge of any duties imposed on the department by law;

c. Advise or make recommendations to the board relative to substance abuse and gambling treatment, intervention, education, and prevention programs in this state; and

d. Perform other duties as assigned by the board.

[**ARC 8792B**, IAB 6/2/10, effective 7/1/10; **ARC 9534B**, IAB 6/1/11, effective 7/6/11]

641—155.3(125,135) Type of licenses.

155.3(1) *Issuance of licenses.*

a. Licenses may be issued for up to three years. A license may be renewed for one, two, or three years. An initial license may be issued for 270 days. A license issued for 270 days shall not be renewed or extended.

b. Licenses shall expire one or two calendar years from the date of issue, and a renewal of the license shall be issued only on application.

c. The renewal of a one-year or two-year license shall be contingent upon demonstration of continued compliance with licensure standards and in accordance with the licensure weighting report criteria.

d. The renewal of a three-year license shall be contingent upon demonstration of substantial continued compliance with licensure standards and in accordance with the licensure weighting report criteria or continuation in deemed status.

e. Failure to apply for renewal of the license within 30 days after the expiration date shall result in immediate termination of license and require reapplication.

155.3(2) *Corrective action.* Following the issuance of a license, the treatment program may be requested by the committee to provide a written plan of corrective action and to bring into compliance all areas found in noncompliance during the on-site visit. The corrective action plan shall be placed in the program's permanent file with the division and used as reference during future on-site inspections.

[**ARC 8792B**, IAB 6/2/10, effective 7/1/10; **ARC 9534B**, IAB 6/1/11, effective 7/6/11]

641—155.4(125,135) Nonassignability; program closure.

155.4(1) A license issued by the department for the operation of a treatment program applies both to the applicant program and the premises upon which the program is to be operated. Licenses are not transferable.

155.4(2) A discontinued program is one which has terminated the services for which it has been licensed. When a program is discontinued, its current license is void immediately and shall be returned to the department.

155.4(3) Any person or other legal entity acquiring a licensed facility for the purpose of operating a treatment program shall apply for a new license.

155.4(4) Any person or legal entity having acquired a license and desiring to fundamentally alter the treatment philosophy or transfer to a different premises must notify the committee 30 days prior to said action in order for the department to review the site change and to determine appropriate action.

155.4(5) A licensee shall, if possible, notify the department of impending closure of the licensed program at least 30 days prior to such closure. The licensee shall be responsible for the removal and placement of client/patients and for the preservation of all records. Upon closing all facilities and terminating all service delivery activities, the licensee shall immediately return the license to the department.

[**ARC 8792B**, IAB 6/2/10, effective 7/1/10; **ARC 9534B**, IAB 6/1/11, effective 7/6/11]

641—155.5(125,135) Application procedures. The department shall provide an application to all applicants for licensure. An on-site visit for licensure of an initial applicant shall occur before the program opens and admits client/patients for services. For initial applicants, if technical assistance has been provided, the on-site visit may be waived at the discretion of the department. The division shall prepare a report with a recommendation for licensure to be presented at a committee meeting within 60 days from the site visit. Public notice for committee meetings will be made in accordance

with Iowa Code section 21.4. The division shall provide notice to the program ten days prior to the committee meeting notifying the program director and program board chairperson of the time, place, and date the committee will review and act upon the application for the program along with the results of the inspection. The division shall provide to all committee members reports of the on-site program licensure inspection and a final recommendation for each application to be acted upon at the next committee meeting.

155.5(1) *Application information for comprehensive programs.* An applicant for licensure shall submit the following information on forms available at the Iowa Department of Public Health, Division of Behavioral Health, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319-0075.

a. The name and address of the applicant treatment program.

b. The name and address of the executive director of such treatment program.

c. The names, titles, dates of employment, education, and years of current job-related experience of staff and a copy of the table of organization. Where multiple components and facilities exist, the relationship between components and facilities must be shown, as well as a description of the screening and training process for volunteer workers.

d. The names and addresses of members of the governing body, sponsors, or advisory boards of such treatment program and current articles of incorporation and bylaws.

e. The names and addresses of all physicians, other professionally trained personnel, medical facilities, and other individuals or organizations with whom the treatment program has a direct contractual or affiliation agreement.

f. A description of the treatment services provided by the treatment program and a description of weekly activities for each treatment modality or component.

g. Copies of reports substantiating compliance with federal, state and local rules and laws for each facility, to include appropriate Iowa department of inspections and appeals rules, state fire marshal's rules and fire ordinances, appropriate local health, fire, occupancy code, and safety regulations.

h. Information required 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 budget and insurance program.

j. Insurance coverage related to professional and general liability; building; workers' compensation; and fidelity bond.

k. The address and facility code of each office, facility, or program location.

l. The program's current written policies and procedures manual to include the staff development and training program, and personnel policies. Applications for licensure will not be considered complete until a complete policies and procedures manual has been submitted to the division.

m. The application information for an initial application for licensure shall be complete and shall be reviewed by the department prior to a scheduled on-site inspection.

155.5(2) *Application information for substance abuse assessment and evaluation programs.* An applicant for licensure shall submit the following information on forms available at the Iowa Department of Public Health, Division of Behavioral Health, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319-0075.

a. The name and address of the applicant substance abuse assessment and evaluation program.

b. The name and address of the executive director or sole practitioner of such substance abuse program.

c. The names, titles, dates of employment, education, and years of current job-related experience of staff and a copy of the table of organization (if applicable). If multiple components and facilities exist, the relationship between components and facilities must be shown, as well as a description of services.

d. The names and addresses of members of the governing body, sponsors, or advisory boards of such substance abuse assessment and evaluation program and current articles of incorporation and bylaws. (This requirement does not apply to a sole practitioner.)

e. The name(s) and address(es) of person(s) entered into the affiliation agreement for clinical oversight.

f. A description of the assessment and evaluation services.

g. Copies of reports substantiating compliance with federal, state and local rules and laws for each facility, to include appropriate state fire marshal's rules and fire ordinances, occupancy code, and safety regulations.

h. Information required under Iowa Code section 125.14A.

i. Insurance coverage related to professional and general liability; building; workers' compensation; and fidelity bond.

j. The address and facility code of each office, facility, or program location.

k. The program's current written policies and procedures manual which shall include the staff development and training program, and personnel policies. Applications for licensure will not be considered complete until a complete policies and procedures manual has been submitted to the division.

The application information for an initial application for licensure shall be complete and shall be reviewed by the department prior to a scheduled on-site inspection.

155.5(3) *Renewal.* An application for renewal shall be submitted on forms provided by the department at least 60 calendar days before expiration of the current license. An application for licensure renewal will not be considered complete until a current policies and procedures manual has been submitted to the department by the applicant treatment program.

155.5(4) *Application update or revision.* The department shall be notified, and a request of an application for licensure for update or revision shall be made, by an existing licensed program 30 days prior to any change(s) of address of offices, facilities, or program locations; or additions or deletions of the type(s) of services or programs provided and licensed. A new licensure application form shall be completed to reflect change of address of offices, facilities, or program locations, or additions or deletions of the type(s) of services or program(s) provided or licensed and shall be returned to the division within 10 working days from the date the forms are received. When applicable, as determined by the department, an on-site licensure inspection of a new component, service, program or facility may be conducted by the department within six months, upon receipt of the updated or revised application or during an existing licensed program's scheduled relicensure on-site inspection, whichever occurs first.
[**ARC 8792B**, IAB 6/2/10, effective 7/1/10; **ARC 9534B**, IAB 6/1/11, effective 7/6/11]

641—155.6(125,135) Application review. An applicant for licensure shall submit a completed application to the department within 30 days from the date the forms are received. The department shall review the application for completion and request any additional material as needed.

Applicants failing to return the forms shall be notified by registered mail that all programs must be licensed.
[**ARC 8792B**, IAB 6/2/10, effective 7/1/10]

641—155.7(125,135) Inspection of licensees. The department shall inspect the facilities and review the policies and procedures utilized by each program. The examination and review may include case record audits and interviews with staff and clients, consistent with the confidentiality safeguards of state and federal laws.

155.7(1) *Technical assistance.* A program applying for an initial license to operate a treatment program in the state of Iowa will be visited by the department for the purpose of providing needed technical assistance regarding the licensure criteria and procedures. The program may waive technical assistance in order to expedite the licensing process. Requests shall be submitted in writing to the division.

a. Following the issuance of a license, the treatment program may request technical assistance from the department so as to bring into conformity areas reported to be in noncompliance to these rules. Such technical assistance shall be scheduled within 30 days of the applicant's request depending on the availability of staff. The department may also request that technical assistance be provided to the program if deficiencies are noted during a site visit.

b. Reserved.

155.7(2) *On-site visit for licensure.* A licensure on-site inspection shall be scheduled after the department's receipt of the program's application to operate a treatment program. The department shall not be required to provide advance notice to the program of the on-site visit for licensure.

a. The on-site visit team will consist of designated members of the division staff, as approved by the director.

b. The team will inspect the program in order to verify information contained in the application and ensure compliance with all laws, rules and regulations.

c. The inspection team shall send a written report, return receipt requested, of their findings to the applicant within 20 working days after the completion of the inspection.

155.7(3) *Effective date of license.* The effective date of a license shall begin on the date the committee reviews the program's written report/application and acts to issue a license.
[**ARC 8792B**, IAB 6/2/10, effective 7/1/10; **ARC 9534B**, IAB 6/1/11, effective 7/6/11]

641—155.8(125,135) Licenses—renewal. Upon approval of an application for licensing by the committee, a license shall be issued by the department. Licenses shall be renewed pursuant to rule 641—155.5(125,135).

155.8(1) *Committee meeting preparation.* The division shall prepare a report with a final recommendation for licensing to be presented at a committee meeting within 80 days from the site visit. Public notice of committee meetings shall be made in accordance with Iowa Code section 21.4.

a. The division shall send notice to the program by certified mail, return receipt requested, ten days prior to the committee meeting notifying the program director and program board chairperson of the time, place, and date the committee will review and act upon the application for the program along with the results of the inspection.

b. The division shall mail to all committee members the following information on each application to be processed at the next committee meeting:

(1) Reports of the on-site program licensure inspections; and

(2) A final recommendation for licensing.

155.8(2) *Committee meeting format.*

a. The chairperson or designee shall call the meeting to order at the designated time.

b. The presiding officer will read each application and protocols.

c. Opportunity shall be given all concerned parties to respond, present evidence, and arguments on each application.

d. After all concerned parties are heard, the committee will make a decision as to whether the applicant should be finally approved or initially denied a license to operate a substance abuse treatment program.
[**ARC 8792B**, IAB 6/2/10, effective 7/1/10; **ARC 9534B**, IAB 6/1/11, effective 7/6/11]

641—155.9(125,135) Corrective action plan. Programs approved for a license for 270 days by the committee shall submit a corrective action plan to the director no later than 30 days following the committee meeting. The corrective action plan shall include, but not be limited to:

1. Specific problem areas.
2. A delineation of corrective measures to be taken by the program.
3. A delineation of target dates for completion of corrective measures for each problem area.
4. A follow-up on-site visit will be required to review the implemented corrective action with a subsequent report to the committee.

Programs issued a license for a period of one or two years shall submit a corrective action plan for those standards found to be in noncompliance following a licensure inspection. Technical assistance on a corrective action plan shall not be required for one- or two-year licenses. The corrective action plan shall be submitted within 30 days of receipt of the licensure inspection report.
[**ARC 8792B**, IAB 6/2/10, effective 7/1/10; **ARC 9534B**, IAB 6/1/11, effective 7/6/11]

641—155.10(125,135) Grounds for denial of initial license.

155.10(1) *Denial of application for licensure.* All programs applying for an initial license shall submit complete application information and shall be inspected by the department prior to the program's opening and offering services. A recommendation by the department of a denial of an initial application for licensure to the committee may be made based on the following reasons:

a. The application for licensure is incomplete or does not have the information required by 641—155.5(125).

b. On-site inspection report results based on the licensure weighting report indicate a score below minimum required for a recommendation of a 270-day license. A program applying for a 270-day license shall have a minimum score of 70 percent in each of the following standards: clinical, administrative and programming.

c. Violation of any of the grounds for discipline pursuant to 641—155.11(125,135).

155.10(2) *On-site visit for licensure.* The on-site visit for licensure of an initial applicant shall occur prior to the program opening and admitting client/patients. The department shall not be required to provide advance notice to the program of the on-site visit for licensure.

a. The on-site visit team will consist of designated members of the division staff, as approved by the director.

b. The team will inspect the program that has applied for a license in order to verify information contained in the application, ensure compliance with all laws, rules and regulations.

c. The inspection team shall send a written report, return receipt requested, of their findings to the applicant within 20 working days after the completion of the inspection.

d. The application information for an initial application for licensure shall be complete and shall be reviewed by the department prior to a scheduled on-site inspection.

155.10(3) *Committee action.* The committee shall meet to consider all cases involving issuance of a license. Upon approval of an application for licensure by the committee, a license shall be issued by the department.

a. Committee hearing preparation. The division will prepare all documents with a final recommendation for licensing determination to be presented at a committee meeting within 120 days from the site visit. The division shall provide public notice of the date, time, and place of the meeting and the names of applicants to be reviewed and processed.

(1) The division shall provide notice to the program 30 days prior to the committee meeting notifying the program director and program board chairperson of the time, place, and date the committee will review and act upon the application for the program along with the results of the inspection.

(2) The division shall provide to all committee members the following information on each application to be processed at the next committee meeting: reports of the on-site program licensure inspections, and a final recommendation for licensing.

b. Committee meeting format.

(1) The chairperson or designee shall call the meeting to order at the designated time.

(2) The presiding officer or designee shall give summary of each application and protocols.

(3) Opportunity shall be given all concerned parties to respond and present evidence and arguments on each application.

(4) After all concerned parties are heard, the committee will make a decision as to whether the applicant should be finally approved or initially denied a license to operate a substance abuse treatment program.

[**ARC 8792B**, IAB 6/2/10, effective 7/1/10; **ARC 9534B**, IAB 6/1/11, effective 7/6/11]

641—155.11(125,135) Suspension, revocation, or refusal to renew a license.

155.11(1) The committee may suspend or revoke a license or refuse to renew a license for any of the following reasons:

a. Failure to adequately complete the application or renewal application process or submission of fraudulent or misleading information in the application or renewal process.

b. Failure to obtain the minimum score required for a one-, two- or three-year license.

c. Violation by a program, program employee or agent of any statute or rule pertaining to treatment programs, including a violation of any provision of this chapter.

d. Failure to comply with licensure, inspection, health, fire, occupancy, safety, sanitation, zoning, or building code or regulations required by federal, state, or local law.

e. Receiving a report from an accreditation body sanctioning, modifying, terminating, or withdrawing the accreditation of the program.

f. Suspension, revocation, refused renewal, or refused issuance of a federal registration to distribute or dispense methadone or other controlled substances.

g. Committing or permitting or aiding or abetting the commission of an unlawful act within a facility.

h. Conviction of a member of the governing body, a director, administrator, chief executive officer, or other managing staff member, of a felony or misdemeanor involving the management or operation of the facility or which is directly related to the operation or integrity of the facility.

i. Use of untruthful or improbable statements in advertising.

j. Conduct or practices found by the committee to be detrimental to the general health, safety, or welfare of a client/patient or member of the general community.

k. Violating a client/patient's confidentiality or willful, substantial, or repeated violations of a client/patient's rights.

l. Defrauding a client/patient, potential client/patient, or third-party payor.

m. Inappropriate conduct by program staff, including sexual or other harassment or exploitation of a program client/patient, volunteer, trainee or employee.

n. Utilization of treatment techniques which endanger the health, safety, or welfare of a client/patient.

o. Discrimination or retaliation against a client/patient or employee who has submitted a complaint or information to the department.

p. Failure to allow an employee or agent of the department access to the facility for the purpose of inspection, investigation, or other information collection duties necessary to the performance of the department's duties.

q. Failure to submit an acceptable written plan of corrective action or failure to comply with a written plan of corrective action issued pursuant to 155.3(2), 641—155.9(125,135), or 155.16(4)*"e."*

r. Violating an order of the committee or violating the terms or conditions of a consent agreement or informal settlement between a program and the committee.

155.11(2) Initial notice from committee. When the committee determines to deny a renewal, suspend or revoke a license, the committee shall notify the licensee by certified mail, return receipt requested, of the committee's intent to suspend, revoke, or refuse to renew the license and the changes that must be made in the licensee's operation to avoid such action. The initial notice shall further provide the licensee the opportunity to submit either a written plan of corrections or written objections to the department within 20 days from the receipt of notice from the committee.

155.11(3) Correction of issues or objections.

a. Written plan of corrections. If a licensee submits a written plan of corrections, the licensee shall have 60 days from the date of submission within which to show compliance with the plan of corrections. The licensee shall submit any information to the committee that the licensee deems pertinent to show compliance with the plan of corrections.

b. Objections. If a licensee submits written objections, the licensee shall submit to the committee any information that the licensee deems pertinent which supports the licensee's defense.

155.11(4) Decision of committee. Following receipt of a written plan of corrections and expiration of the 60-day time period, or following receipt of written objections, or when objections or notice of corrections have not been received within the 20-day time period, the committee may meet to determine whether to proceed with the disciplinary action. The licensee shall receive notice of this meeting in the same manner as provided by 155.8(1)*"a."*

155.11(5) Notice of decision and opportunity for contested case hearing.

a. When the committee determines to suspend, revoke or not renew a license, the licensee shall be given written notice by restricted certified mail.

b. The licensee may request a hearing on the determination. The request must be in writing and mailed to the department address within 30 days of the notice issued by the committee. The request shall

be sent by certified mail, return receipt requested. Failure to request a hearing will result in final action by the committee.

155.11(6) Summary suspension. If the committee finds that the health, safety or welfare of the public is endangered by continued operation of a treatment program, summary suspension of a license may be ordered pending proceedings for revocation or other actions. These proceedings shall be promptly instituted and determined.

[**ARC 8792B**, IAB 6/2/10, effective 7/1/10; **ARC 9534B**, IAB 6/1/11, effective 7/6/11]

641—155.12(125,135) Contested case hearing. Programs that wish to contest the denial, suspension, revocation or refusal to renew their license shall be afforded an opportunity for a hearing before an administrative law judge from the Department of Inspections and Appeals. The program will be notified in writing, return receipt requested, of the date of the hearing, no less than 30 days before the hearing.

155.12(1) *Failure to appear.* If a party fails to appear in a contested case hearing proceeding after proper service of notice, the administrative law judge shall, in such a case, enter a default judgment against the party failing to appear.

155.12(2) *Conduct of hearing.* Opportunity shall be afforded all parties to respond and present evidence and argument on all issues involved and to be represented by counsel at their own expense.

a. The hearing shall be informal and all relevant evidence admissible. Effect will be given to the rules of privilege recognized by law. Objections to evidentiary offers may be made and shall be noted in the record. When the hearing will be expedited and the interests of the parties will not be prejudiced substantially, any part of the evidence may be required to be submitted in verified written form.

b. Documentary evidence may be received in the form of copies or excerpts if the original is not readily available. Upon request, parties shall be given an opportunity to compare the copy with the original, if available.

c. Witnesses present at the hearing shall be subject to cross-examination by any party as necessary for a full and true disclosure of the facts.

d. The record in a contested case shall include:

(1) All pleadings, motions and intermediate rulings.

(2) All evidence received or considered and all other submissions.

(3) A statement of all matters officially noticed.

(4) All questions and offers of proof, objections and rulings therein.

(5) All proposed findings and exceptions.

(6) Any decision, opinion or report by the officer presiding at the hearing.

e. Oral proceedings shall be open to the public and shall be recorded either by mechanized means or by certified shorthand reporters. Oral proceedings or any part thereof shall be transcribed at the request of any party with the expense of the transcription charged to the requesting party. The recording or stenographic notes of oral proceedings or the transcription thereof shall be filed with and maintained by the agency for at least five years from the date of decision.

f. Findings of fact shall be based solely on the evidence in the record and on matters officially noticed in the record.

155.12(3) *Continuance.* For good cause, the administrative law judge may continue hearings beyond the time originally scheduled or recessed. Requests for continuance shall be made to the administrative law judge in writing at least three days prior to the scheduled hearing date. Continuances will not be granted less than three days before the hearing except for exigent circumstances.

155.12(4) *Decision.* Findings of fact shall be based solely on the evidence in the record and upon matters officially noticed in the record.

a. The decision of the administrative law judge shall be the final decision unless there is an appeal to the board within 20 days of the receipt of the decision.

b. A proposed or final decision or order in a contested case hearing shall be in writing. A proposed or final decision shall include findings of fact and conclusions of law, separately stated. Parties will be promptly notified of each proposed or final decision or order by the delivery to them of a copy of such

decision or order by certified mail, return receipt requested. In the case of a proposed decision, parties shall be notified of the right to appeal the decision to the board.

155.12(5) *Appeal to the board.*

a. Either party may request the board review the proposed decision. The request shall be in writing and mailed within 20 days of receipt of the proposed decision.

b. The parties shall have an opportunity to submit briefs to the board. The board will review the record and any briefs. No new evidence shall be admitted unless requested and allowed by the board.

c. Oral presentation will be made to the board at a time set by the board.

d. The board shall issue its decision in writing within 30 days after conclusion of the hearing.

[**ARC 8792B**, IAB 6/2/10, effective 7/1/10]

641—155.13(125,135) Rehearing application. Any party may file an application for rehearing, stating the specific grounds therefor and the relief sought, within 20 days after the issuance of any final decision by the board in a contested case. A copy of such application shall be timely mailed by the applicant to all parties of record not joining therein. Such an application for rehearing shall be deemed to have been denied unless the board grants the application within 20 days after its filing.

[**ARC 8792B**, IAB 6/2/10, effective 7/1/10]

641—155.14(125,135) Judicial review. A licensee who is aggrieved or adversely affected by the board's final decision and who has exhausted all adequate administrative remedies may seek judicial review of the board's decision pursuant to and in accordance with Iowa Code section 17A.19.

[**ARC 8792B**, IAB 6/2/10, effective 7/1/10]

641—155.15(125,135) Reissuance or reinstatement. After suspension, revocation or refusal to renew a license, the affected licensee shall not have the license reissued or reinstated within one year of the effective date of the suspension, revocation or expiration upon refusal to renew, unless by order of the committee. After that time, proof of compliance with the licensure standards must be presented to the committee prior to reinstatement or reissuance of a license.

[**ARC 8792B**, IAB 6/2/10, effective 7/1/10; **ARC 9534B**, IAB 6/1/11, effective 7/6/11]

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 mailed or delivered to the division director at the Division of Behavioral Health, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319-0075. A complaint form may be downloaded on-line at: http://www.idph.state.ia.us/bh/common/pdf/substance_abuse/complaint_form.pdf. 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 upon the committee's own motion pursuant to evidence received by the department. Timely filing of complaints is required in order to ensure the availability of witnesses and to avoid initiation of an investigation under conditions which may have been significantly altered during the period of delay.

155.16(2) *Evaluation and investigation.* Upon receipt of a complaint, the department shall make a preliminary review of the allegations contained in the complaint. Unless the department concludes that the complaint is intended solely to harass a program or lacks a reasonable basis, it shall conduct an on-site investigation of the program which is the subject of the complaint as soon as is practicable. The program which is the subject of the complaint shall be given an opportunity to informally respond to the allegations contained in the complaint either in writing or through a personal interview or conference.

155.16(3) *Investigative report.* Within 30 working days after completion of the investigation, the department shall prepare a written investigative report and shall submit the report to the executive director of the program, the chairperson of the governing body, and the committee. This report shall 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 committee shall review the investigative report at its next regularly scheduled meeting and shall determine appropriate action.

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

b. Referral for further investigation. If the committee determines that the case warrants further investigation, it shall refer the case to the department for further investigation.

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

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

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 plans of corrective action, and all notices and orders issued pursuant to rule 641—155.11(125,135) shall refer to client/patients by number and shall not include any other client/patient identifying information. Investigative reports, written plans of corrective action, 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.

[**ARC 8792B**, IAB 6/2/10, effective 7/1/10; **ARC 9534B**, IAB 6/1/11, effective 7/6/11]

641—155.17 Reserved.

641—155.18(125,135) Deemed status. The committee shall grant deemed status to programs accredited either by a recognized national or not-for-profit accreditation body when the committee determines that the accreditation is for the same services. Problem gambling treatment components shall not be granted deemed status under this rule, unless specifically reviewed by the accreditation body.

155.18(1) National accreditation bodies. The national accreditation bodies currently recognized as meeting committee criteria for possible deemed status are:

a. Joint Commission.

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

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

d. American Osteopathic Association (AOA).

155.18(2) Credentials and expectations of accreditation bodies.

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

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

155.18(3) Responsibilities of programs granted deemed status.

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

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

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

d. A program shall submit to the division accreditation corrective plans or written conditions to accreditation.

e. A program shall be currently accredited by a committee-approved national accreditation body for services that are outlined in this chapter.

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

g. All survey reports for the hospital-based or freestanding community-based treatment program from the accrediting or licensing body shall be sent to the division.

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

155.18(4) The committee and division shall retain the following responsibilities and rights when deemed status is granted to program/organizations:

a. The division may conduct site follow-up visits as determined appropriate.

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

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

155.18(5) *Continuation of deemed status.* The program shall submit a copy of all CARF, Joint Commission, COA, or AOA behavioral health accreditation survey reports to the division. Applications for continuation of deemed status shall be submitted pursuant to 155.5(3).

[**ARC 8792B**, IAB 6/2/10, effective 7/1/10; **ARC 9534B**, IAB 6/1/11, effective 7/6/11]

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

[**ARC 8792B**, IAB 6/2/10, effective 7/1/10]

641—155.20(125,135) Inspection. Each 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 premises of programs for which a license has been either 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 facility 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 licensee. A facility shall not be licensed which does not permit inspection by the department or examination of all records, including financial records, methods of administration, general and special dietary programs, the disbursement of drugs and methods of supply, and any other records the committee deems relevant to the establishment of such a system.

[**ARC 8792B**, IAB 6/2/10, effective 7/1/10; **ARC 9534B**, IAB 6/1/11, effective 7/6/11]

641—155.21(125,135) General standards for all treatment programs. The following standards shall apply to all treatment programs in the state of Iowa regardless of the category of treatment services provided by such programs. In situations where differences between general standards for all treatment programs and specific standards occur, both general and specific standards must be met.

155.21(1) *Governing body.* Each program shall have a formally designated governing body that is representative of the community being served, complies with Iowa Code chapter 504, and is the ultimate authority for the overall program operations. Persons in private practice as sole practitioners shall be exempt from this subrule except for requirements to have malpractice and liability insurance.

a. The governing body shall develop and adopt written bylaws and policies that define the powers and duties of the governing body, its committees, advisory groups, and the executive director. These bylaws 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. Minutes of all meetings shall be kept and 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, the following:

(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) Establish an effective control which will ensure that quality services are delivered;

(3) Review and approve the program's annual budget; and

(4) Approve all contracts.

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

f. The governing body shall be responsible for all funds, equipment, supplies and the facility in which the program operates. 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 will include, but not necessarily be limited to, the following items:

(1) The name, address, occupation, and place of employment of each governing body member;

(2) Any family relationships which a member of the governing body may have to a program staff member; and

(3) Where applicable, the name and address of all owners or controlling parties whether they are individuals, partnerships, corporation body, or subdivision of other bodies, such as a public agency, or religious group, fraternity, or other philanthropic organization.

h. The governing body shall assume responsibility in seeing that the program has malpractice and liability insurance and a fidelity bond.

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

155.21(3) *Clinical oversight.* The program shall have appropriate clinical oversight to ensure quality of clinical services provided to client/patients. This may be provided in-house or through consultation.

Clinical oversight may include assisting the program in developing policies and procedures relating to the assessment and treatment of psychopathology, assisting in the training of the staff and providing

assistance to the clinical staff in assessment or treatment. The executive director or designee shall be ultimately responsible for clinical services and implementation of treatment services to client/patients.

155.21(4) *Staff development and training.* There shall be written policies and procedures that establish staff development. Staff development shall include orientation for staff and opportunities for continuing job-related education. For corporations organized under Iowa Code chapter 496C and sole practitioners, documentation of continuing education to maintain professional license or certification as specified in 155.21(8) will meet the requirements of this subrule.

a. Evidence of professional education, certification as specified in 155.21(8), licensing, or orientation which includes the following: psychosocial, medical, pharmacological, confidentiality, and tuberculosis and blood-borne pathogens; an orientation to the program and community resources; counseling skill development; HIV/AIDS (human immunodeficiency virus/acquired immune deficiency syndrome) information/education; and the attitudes, values and lifestyles of racially diverse cultures, other cultures and special populations.

b. The program shall establish on-site training programs or enter into relationships with outside resources capable of meeting staff training needs.

c. The staff development program shall take steps to ensure that staff members are kept informed of new developments in the field of assessment, evaluation, placement, treatment and rehabilitation.

d. In-service training programs shall be instituted when program operations or functions are changed and shall be designed to allow staff members to develop new skills so that they may effectively adapt to such changes.

e. Staff development activities and participation in state, national and regional training shall be planned and scheduled. These activities shall be documented in order to evaluate their scope, effectiveness, attendance, and amount of time spent on such efforts. The written plan for on-site staff development and activities for professional growth and development of personnel shall be based on the annual needs assessment and shall be available to all personnel.

f. Minutes shall be kept of on-site training activities and shall include, but not necessarily be limited to:

(1) Date of the meeting;

(2) Names of persons attending; and

(3) Topics discussed, to include name and title of presenters.

g. The individual responsible for supervising staff development activities shall conduct at least an annual needs assessment.

155.21(5) *Management information system.* Programs receiving Medicaid or state funding and programs performing OWI evaluations in accordance with 641—Chapter 157 shall submit client/patient data to the Iowa Department of Public Health, Division of Behavioral Health, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319-0075, in accordance with reporting system procedures.

155.21(6) *Procedures manual.* All programs shall develop and maintain a procedures manual. This manual shall define the program's policies and procedures to reflect the program's activities. Revisions shall be entered with the date, name and title of the individual making the entries. This manual shall contain all of the required written policies, procedures, definitions, and all other documentation outlined throughout these standards. The manual shall contain a working table of contents covering all policies and procedures mandated by this chapter.

155.21(7) *Fiscal management.* The program shall ensure proper fiscal management which shall include the following:

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. The fiscal management system shall be maintained in accordance with generally accepted accounting principles, including internal controls to reasonably protect agency assets. This shall be verified by an independent fiscal audit of the program by the state auditor's office or certified public accountant based on an agreement entered into by the governing body. An annual fiscal audit shall not be required for programs with an annual budget of $75,000 or less.

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

d. Assessment and evaluation programs shall make public the OWI evaluation fees, and the client/patient shall be informed of the fee at the time of scheduling the appointment for the evaluation.

155.21(8) *Personnel.* Written personnel policies and procedures shall be developed by all programs except for sole practitioners. All program staff shall subscribe to a code of conduct found in professional certification or licensure as specified in 155.21(8).

a. All programs shall have written policies and procedures that address the following areas:

(1) Recruitment, selection, and certification of staff members;

(2) Recruitment and selection of volunteers;

(3) Wage and salary administration;

(4) Promotions;

(5) Employee benefits;

(6) Working hours;

(7) Vacation and sick leave;

(8) Lines of authority;

(9) Rules of conduct;

(10) Disciplinary actions and termination of employees;

(11) Methods for handling cases of inappropriate client/patient care;

(12) Work performance appraisal;

(13) Employee accidents and safety;

(14) Employee grievances; and

(15) Policy on staff persons suspected of using or abusing substances.

b. The written personnel policies and practices shall include an equal employment opportunity policy and an affirmative action plan for hiring members of protected classes that minimally comply with Iowa civil rights commission rules and any local ordinances.

c. There shall be written job descriptions that reflect the actual duties of the employee.

d. Job descriptions shall accurately reflect the actual job situation and shall be reviewed when necessary by the executive director or whenever there is a change in required qualifications or duties.

e. All positions shall have job descriptions included in the personnel section of the procedures manual or personnel record of the staff member.

f. The written personnel policies and practices shall include a mechanism for written evaluation of personnel performance on at least an annual basis. There shall be evidence that this evaluation is reviewed with the employee and that the employee is given the opportunity to respond to this evaluation.

g. There shall be a personnel record kept on each staff member. These records shall contain as applicable:

(1) Verification of training, experience, and all professional credentials relevant to the position;

(2) Job performance evaluations;

(3) Incident reports;

(4) Disciplinary actions taken; and

(5) Documentation of review and adherence to confidentiality laws and regulations. This review and agreement shall occur prior to assumption of duties.

h. There shall be written policies and procedures designed to ensure confidentiality of personnel records and a delineation of authorized personnel who have access to various types of personnel information.

i. Appropriately credentialed counselors.

(1) Any person providing screening, evaluations, assessments or treatment in accordance with this chapter shall meet at least one of the following conditions:

1. Currently maintain a substance abuse- or problem gambling-related credential acceptable to the department for providing treatment according to these rules.

2. Currently maintain active status as a licensed marital and family therapist (LMFT) licensed under Iowa Code chapters 154D and 147; a licensed mental health counselor (LMHC) licensed under Iowa Code chapters 154D and 147; a licensed independent social worker (LISW) licensed under Iowa Code chapters 154C and 147; or another licensed professional authorized by the Iowa Code to diagnose and treat DSM-IV disorders.

3. Currently maintain active status as a licensed master social worker (LMSW) licensed under Iowa Code chapters 154C and 147.

4. For a person beginning employment on or after July 1, 2010, at a program licensed in Iowa pursuant to this chapter who does not currently maintain one of the credentials described in "1" to "3" above, successfully complete and maintain one of those credentials within two years of the date on which the person begins to provide services.

5. Be employed before July 1, 2010, as a counselor at a program licensed in Iowa pursuant to this chapter. Those deemed qualified remain qualified only for work for that licensed program.

(2) Any person providing screening, evaluations, assessments or treatment in accordance with this chapter shall maintain a minimum of 30 hours of training within the person's primary scope of practice every two years, including a minimum of three hours of ethics training. In addition to practicing within their primary scope of practice, certified or licensed personnel may practice within a subspecialty in accordance with this chapter by maintaining a minimum of an additional 20 hours of training within the subspecialty every two years.

j. The program shall notify the department in writing within ten working days when a certified or licensed staff member has been sanctioned or disciplined by a certifying or licensing body.

k. There shall be written policies related to the prohibition of sexual harassment.

l. There shall be written policies related to the implementation of the Americans with Disabilities Act.

155.21(9) *Child abuse/dependent adult abuse/criminal history background check.*

a. Written policies and procedures shall prohibit mistreatment, neglect, or abuse of children and dependent adults and shall specify reporting and enforcement procedures for the program. Alleged violations shall be reported immediately to the director of the facility and appropriate department of human services personnel. Written policies and procedures on reporting alleged violations regarding substance abuse client/patients shall be in compliance with HIPAA and DHHS, 42 CFR Part 2, regulations on Confidentiality of Alcohol and Drug Abuse Patient Records. Written policies and procedures on reporting alleged violations regarding problem gambling client/patients shall be in compliance with HIPAA and the Iowa Code. Any employee found to be in violation of Iowa Code sections 232.67 through 232.70, as substantiated by a department of human services' investigation shall be subject to the program's policies concerning dismissal.

b. For each employee working within a juvenile services area 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 at a minimum:

(1) Documentation of a criminal history background check with the Iowa division of criminal investigation on all new applicants for employment. 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 applicant for employment which discloses any substantiated reports of child abuse, neglect or sexual abuse or dependent adult abuse.

(3) Documentation of a check after hiring on probationary or temporary status, but prior to permanently employing the individual, 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 employees hired 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 employed, unless an evaluation of the crime or founded child abuse or founded dependent adult abuse has been made by the department of human services which 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 Form 470-2310, Record Check Evaluation. In its evaluation, the department of human services shall 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. Each treatment staff member shall complete two hours of training relating to the identification and reporting of child abuse and dependent adult abuse within six months of initial employment and at least two hours of additional training every five years thereafter.

155.21(10) *Client/patient case record maintenance.* There shall be written policies and procedures governing the compilation, storage and dissemination of individual client/patient case records.

a. These policies and procedures shall ensure that:

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

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

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

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

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

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

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

f. The governing body shall establish policies that specify the conditions under which information on applicants or client/patients may be released and the procedures to be followed for releasing such information. Even if a program is not federally funded, all such policies and procedures regarding substance abuse client/patients shall be in accordance with HIPAA and the federal confidentiality regulations, "Confidentiality of Alcohol and Drug Abuse Patient Records," 42 CFR Part 2, effective June 9, 1987, which implement federal statutory provisions, 42 U.S.C. 290dd-3 applicable to alcohol abuse client/patient records, and 42 U.S.C. 290ee-3 applicable to drug abuse client/patient records, and state confidentiality laws and regulations. All such policies and procedures regarding problem gambling client/patients shall be in accordance with HIPAA and Iowa Code chapter 228.

g. Confidentiality of alcohol and drug abuse client/patient records. The confidentiality of alcohol and drug abuse client/patient records maintained by a program is protected by HIPAA and the "Confidentiality of Alcohol and Drug Abuse Patient Records" regulations, 42 CFR Part 2, effective June 9, 1987, which implement federal statutory provisions, 42 U.S.C. 290dd-3 applicable to alcohol abuse client/patient records, and 42 U.S.C. 290ee-3 applicable to drug abuse client/patient records.

h. Confidentiality of problem gambling client/patient records. The confidentiality of problem gambling client/patient records maintained by a program is protected by HIPAA and Iowa Code chapter 228.

i. The provision of treatment to a client/patient through any electronic means, including the Internet, telephone, or the Iowa communications network or any fiberoptic media, regardless of the location of the licensee, shall constitute the practice of treatment in the state of Iowa and shall be subject to regulation in accordance with Iowa Code chapter 125 and 2009 Iowa Code Supplement section 135.150 and these rules. A licensee who provides services via electronic media shall inform the client/patient of the limitations and risks associated with such services and shall document in the client/patient case record that such notice has been provided.

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

155.21(11) *Placement screening, admission, assessment and evaluation.*

a. The program shall conduct an initial assessment for substance abuse client/patients which shall include evaluation of the American Society of Addiction Medicine Patient Placement Criteria for the Treatment of Substance-Related Disorders, Second Edition, Revised, or other national or recognized criteria approved by the department upon granting a variance by the director in accordance with 641—Chapter 178 for determining the eligibility of individuals for placement and admission. The program shall utilize a recognized diagnostic test/tool to determine substance abuse or dependence as defined in the DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition).

b. The program shall conduct an initial assessment for problem gambling client/patients that shall utilize a recognized diagnostic test/tool to determine pathological gambling as defined in the DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition). The client/patient is a problem gambler if the client/patient meets any of the diagnostic criteria for pathological gambling.

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

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

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

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

d. Following admission, the comprehensive assessment (psychosocial history) shall be an analysis and synthesis of the client/patient's status and shall address the client/patient's strengths and needs, which may be documented in the comprehensive assessment or in the treatment plan, and areas of clinical concern. Sufficient information shall be collected so that a comprehensive treatment plan can be developed. The comprehensive treatment plan shall be developed within the period of time between admission and the first review date specified for that particular level of care within the management of care review process, or within 30 days for problem gambling client/patients.

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

(1) General nature and goals of the program;

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

(3) In a nonresidential program, the hours during which services are available;

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

(5) Client/patient's rights and responsibilities;

(6) Confidentiality laws, rules and regulations;

(7) HIV/AIDS information; and

(8) Safety and emergency procedures for residential, halfway house, inpatient and treatment services with housing.

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

155.21(12) *Treatment plans.* Based upon the initial assessment, an individualized written treatment plan shall be developed and recorded in the client/patient case record. The program shall have written policies and procedures governing a uniform process for treatment planning.

a. A treatment plan shall be developed as soon after the client/patient's admission as is clinically feasible and within the period of time between admission and the next review date specified for that particular level of care within the management of care review process.

b. The individualized treatment plan shall minimally contain:

(1) A clear and concise statement of the client/patient's current strengths and needs, which may be documented in the treatment plan or in the comprehensive assessment;

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

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

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

(5) Treatment plans shall be culturally and environmentally specific so as to meet the needs of the client/patient. Treatment plans shall be written in a manner readily understandable to the client/patient, with assistance if necessary.

c. Treatment plans shall be developed in partnership with the client/patient and shall be reviewed by the primary counselor and the client/patient as often as necessary and in accordance with the time frames specified within the management of care review process.

d. The reviews shall consist of: a reassessment of the client/patient's current status in conjunction with the continued stay review criteria, accomplishments and needs, and a redefining of treatment goals when appropriate. The date of the review, as well as any changes, shall be recorded in the record.

e. The use of abstract terms, technical jargon, or slang should be avoided in the treatment plan. The program should provide the client/patient with copies of all treatment plans upon request.

155.21(13) *Progress notes.* A client/patient's progress and current status in meeting the goals set in the treatment plan shall be recorded in the client/patient case record. Information will be noted following each individual counseling session and a summary of group counseling services shall be documented at least weekly.

a. Entries shall be filed in chronological order and shall include the date services were provided or observations made, the date the entry was made, and the signature or initials and staff title of the individual rendering the services. All progress notes shall be legibly entered into the client/patient case record in permanent pen, by typewriter, or by computer. In those instances where records are maintained electronically, a staff identification code number authorizing access shall be accepted in lieu of a signature.

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

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

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

155.21(14) *Client/patient case record contents.* There shall be a case record for each client/patient that contains:

a. Results of all examinations, tests, and screening and admissions information;

b. Reports from referring sources;

c. Treatment plans;

d. Continued stay and discharge reviews;

e. Medication records, which shall allow for the monitoring of all medications administered and self-administered and the detection of adverse drug reactions. All medication orders in the client/patient case records shall define at least the name of the medication, dose, route of administration, frequency of administration, the name of the physician who prescribed the medication, and the name of the person administering or dispensing the medication;

f. Reports from outside resources shall be dated and include the name of the resource;

g. Multidisciplinary case conference and consultation notes, including the date of the conference or consultation, recommendations made, actions taken, and individuals involved;

h. Correspondence related to the client/patient, including all letters and dated notations of telephone conversations relevant to the client/patient's treatment;

i. Treatment consent forms, if applicable;

j. Information release forms;

k. Progress notes;

l. Records of services provided;

m. Discharge summaries of services provided shall be completed within 30 days of discharge and shall be sufficiently detailed to identify the types of services the client/patient has received and action taken to address specific problems identified. General terms such as "counseling" or "activities" shall be avoided in describing services;

n. Management information system or other appropriate data forms; and

o. Incident reports.

p. Records of financial counseling services for problem gambling client/patients. The treatment program shall offer financial counseling services to problem gambling client/patients. Financial counseling services shall be provided in-house or through consultation. If the treatment program determines that the problem gambling client/patient has financial problems, then financial counseling services shall include assisting the client/patient in preparing a budget and discussing financial debt options, including restitution and bankruptcy.

155.21(15) *Drug screening.* All programs serving client/patients who are receiving treatment for use or abuse of a controlled substance shall establish policies and procedures, if applicable, for the collection of urine specimens and utilization of urinalysis results.

a. Urine specimens obtained from client/patients shall be collected under direct supervision and analyzed as indicated by the program, or the program shall have a policy in place to reduce the client/patient's ability to skew the test.

b. Any laboratory used by the program for urine testing and analysis shall comply, if applicable, with all federal and state proficiency testing programs.

c. Any program conducting on-site urine testing shall comply with the Clinical Laboratory Improvement Act regulations.

d. Client/patient records shall reflect the manner in which urine test results are utilized in treatment.

e. For programs with a urinalysis service, policies shall be developed concerning measures to be employed when urine specimens of client/patients are found to contain substances.

155.21(16) *Medical services.* The treatment program shall have policies and procedures developed in conjunction with a physician to examine and evaluate client/patients/concerned persons seeking or undergoing treatment or rehabilitation.

a. Individuals who enter an inpatient, residential, halfway house, chemotherapy or emergency care facility (ASAM Levels III.1, III.3, III.5, III.7 and IV) shall undergo a medical history and physical examination. Laboratory examinations may be performed as deemed necessary by the physician. The medical history, physical examination, and necessary laboratory examinations shall be performed as soon as possible, however minimally, as follows:

(1) Inpatient medically managed and medically monitored residential treatment services (ASAM Levels IV and III.7) within 24 hours of admission;

(2) Primary residential and extended residential treatment (Levels III.5 and III.3) within 7 calendar days of admission; and

(3) Halfway house services (Level III.1) within 21 calendar days of admission.

b. For individuals who enter a Level I or Level II service, a medical history shall be obtained upon admission.

c. A program may accept medical history and physical examination results from referral sources if the medical history and examination were completed no more than 90 days prior to admission.

d. Rescinded IAB 10/3/12, effective 11/7/12.

155.21(17) *Emergency medical services.* The program shall ensure, by affiliation agreement, or contract, that emergency medical services at a general hospital are available on a 24-hour basis.

a. The program will maintain emergency medical service coverage on a 24-hour, seven days a week, basis.

b. The program shall ensure that all community service providers, medical facilities, law enforcement agencies, and other appropriate personnel are informed of the 24-hour emergency services and treatment available.

155.21(18) *Medication control.* Policies and procedures shall be developed to ensure that prescription and over-the-counter drugs are administered or self-administered safely and properly in accordance with federal, state and local laws and regulations. The written policies and procedures shall include, but not be limited to, the following:

a. Authorized personnel who administer medications shall be qualified, and an updated list of such personnel shall be maintained. Only the following are designated by 657—8.32(124,155A) as qualified individuals to whom a physician can delegate the administration of controlled substances:

(1) Persons who have successfully completed a medication administration course reviewed by the board of pharmacy examiners.

(2) Advanced emergency medical technicians and paramedics.

(3) Licensed physician assistants.

(4) Licensed pharmacists.

(5) Nurse, intern or other qualified individual delegated the responsibility to administer a prescription drug by a practitioner, licensed by the appropriate state board, to administer drugs to patients, in accordance with Iowa Code section 155A.4(2)*"c."*

b. Medications shall be administered only in accordance with the instructions of the attending physician. The type and amount of the medication, the time and date, and the staff member administering the medication shall be documented in the client/patient's record.

c. Self-administration of prescription medication shall be observed by a staff member who has been oriented to the program's policies and procedures on self-administration. Self-administration of prescription medications shall be permitted only when the client/patient's medication is clearly labeled. There shall be written policies and procedures relative to self-administration of prescription medications by client/patients and only when:

(1) Medications are prescribed by a physician.

(2) The physician agrees that the client/patient can self-administer the drug.

(3) What is taken, how, and when, are documented in the record of the client/patient.

d. Drugs/medications shall be prescribed by a physician or other practitioner authorized to prescribe under Iowa law.

e. Prescription drugs shall not be administered or self-administered to a client/patient without a written order signed by a physician or other practitioner authorized to prescribe under Iowa law. All prescribed medications shall be clearly labeled indicating the client/patient's full name, physician's name, prescription number, name and strength of the medication, dosage, directions for use, date of issue; and name, address and telephone number of the pharmacy or physician issuing the medication. Medications shall be packaged and labeled according to state and federal guidelines.

f. If the medications the client/patient brings to the program are not to be used, they shall be packaged, sealed and stored. The sealed packages of medications shall be returned to the client/patient, family or significant others at the time of discharge.

g. 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 member in charge of medications shall provide for monthly inspection of all storage units.

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

(5) Unused prescription drugs prescribed for residents who have left the facility without their medication shall be destroyed by the person in charge with a witness and notation made on the resident's record. When a resident is discharged or leaves the facility, medications currently being administered shall be sent, in the original container, with the resident or with a responsible agent, and with the approval of the physician.

h. 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 client/patient shall be stored in the original containers.

(5) All potent 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 persons.

i. Dispensed from a licensed pharmacy. Medication provided to a client/patient shall be dispensed only from a licensed pharmacy in the state of Iowa in accordance with the pharmacy laws in the Code of Iowa, or from a licensed pharmacy in another state according to the laws of that state, or by a licensed physician.

j. Use of medications. Prescription medications prescribed for one resident may not be administered to or allowed in the possession of another resident.

k. Patient reaction. Any unusual client/patient reaction to a medication shall be documented in the client/patient record and reported to the attending physician immediately.

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

155.21(19) *Management of care.* The program shall ensure appropriate level of care utilization by implementing and maintaining the written placement screening, continuing service, and discharge criteria process developed by the department.

a. The program shall also address underutilization, overutilization, and the effective use of levels of care available.

b. The time frames for management of care activities minimally shall be implemented within 30 days for Levels I and III.1; within 7 days for Levels II.1, II.5, III.3 and III.5; and daily for Levels III.7 and IV.

c. The discharge planning process shall begin at admission and shall include a determination of the client/patient's continued need for treatment services and development of a plan to address ongoing client/patient needs posttreatment. Discharge planning may or may not include a document identified as a discharge plan.

155.21(20) *Quality improvement.* The program shall have an ongoing quality improvement program designed to objectively and systematically monitor and evaluate the quality and appropriateness of client/patient care, pursue opportunities to improve client/patient care, and resolve identified problems. Quality improvement efforts shall be facilitywide in scope and include review of clinical and professional services.

a. There shall be a written plan for a quality improvement program that describes the objectives, organization, scope, and mechanisms for overseeing the effectiveness of monitoring, evaluation, and problem-solving activities.

b. The program shall establish written policies and procedures to both describe and document the quality improvement of the program's monitoring and evaluation activities. The policies and procedures shall ensure that:

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

(2) Objective criteria shall be utilized in the development and application of criteria relating to the care or service it provides; and

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

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

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

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

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

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

155.21(21) *Building construction and safety.* All buildings in which client/patients receive screenings, evaluations, assessments or treatment shall be designed, constructed, equipped, and maintained in a manner that provides for the physical safety of client/patients, personnel, and visitors.

a. If required by local jurisdiction, all programs 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.

c. 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.

d. All programs shall have written policies and procedures to provide a safe environment for client/patients, personnel, and visitors and to monitor that environment. The program shall document implementation of the procedures. The written policies and procedures shall include, but not be limited to, the following:

(1) The process for the identification, development, implementation, and review of safety policies and procedures for all departments or services.

(2) The promotion and maintenance of an ongoing, facilitywide hazard surveillance program to detect and report all safety hazards related to client/patients, visitors, and personnel.

(3) The process by which the staff is to dispose of biohazardous waste within the clinical service areas.

(4) All program areas.

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

2. Radiators, registers, and steam and hot water pipes shall have protective covering or insulation. Electrical outlets and switches shall have wall plates.

3. For juvenile facilities, fuse boxes shall be under lock and key or six feet above the floor.

4. Facilities shall have written procedures for the handling and storage of hazardous materials.

5. Facilities shall have policies and procedures for weapons removal.

6. Swimming pools shall conform to state and local health and safety regulations. Adult supervision shall be provided at all times when children are using the pool.

7. Facilities shall have policies regarding fishing ponds, lakes, or any bodies of water located on or near the program and accessible to the client/patient.

155.21(22) *Outpatient facility.* The outpatient facility shall be safe, clean, well ventilated, properly heated, free from vermin and rodents and in good repair.

a. The facility shall be appropriate for providing services available from the program and for protecting confidentiality.

b. Furniture shall be in good repair.

c. There shall be a written plan outlining procedures to be followed in the event of fire or tornado. These plans shall be conspicuously displayed at the facility.

155.21(23) *Therapeutic environment.* All programs shall establish an environment that enhances the positive self-image of client/patients and preserves their human dignity. The grounds of the program shall have adequate space for the program to carry out its stated goals. When client/patient needs or program goals involve outdoor activities, these activities and programs shall be appropriate to the ages and clinical needs of the client/patient.

a. All services shall be accessible to people with disabilities or the program shall have written policies and procedures that describe how people with disabilities can attain access to the facility for necessary services. All programs shall comply with the Americans with Disabilities Act.

b. The waiting or reception areas shall be of adequate size, have appropriate furniture and be located so as to ensure confidentiality of client/patients in session or receiving services.

c. Program staff shall be available in waiting or reception areas so as to address the needs of the client/patients and visitors.

d. The program shall have written policies and procedures regarding chemical substances in the facility.

e. Smoking shall be prohibited within any facilities or any portion of a facility used for outpatient drug and alcohol treatment services and programs. Smoking shall be prohibited, except in designated areas within facilities or portions of facilities used for inpatient and residential drug and alcohol treatment services.

f. A program or person shall not sell, give, or otherwise supply any tobacco, tobacco products, or cigarettes to any person under 18 years of age, and a person under 18 years of age shall not smoke, use, purchase, or attempt to purchase, any tobacco, tobacco products, or cigarettes.

g. There shall be written policies and procedures to address the following:

(1) There shall be a policy to inform client/patients of their legal and human rights at the time of admission;

(2) Client/patient communication, opinions, or grievances, with a mechanism for redress;

(3) Prohibition of sexual harassment; and

(4) Client/patient rights to privacy.

[**ARC 8792B**, IAB 6/2/10, effective 7/1/10; **ARC 9774B**, IAB 10/5/11, effective 11/9/11; **ARC 0365C**, IAB 10/3/12, effective 11/7/12]

641—155.22(125,135) Inpatient, residential, and halfway house safety. Specific safety standards for inpatient, residential and halfway house safety.

155.22(1) *Health and fire safety inspections.* Inpatient, residential and halfway house substance abuse treatment facilities shall comply with appropriate department of inspections and appeals rules, state fire marshal's rules and fire ordinances, and appropriate local health, fire, occupancy code, and safety regulations. The program shall maintain documentation of such compliance.

a. Inpatient, residential and halfway house substance abuse treatment facilities required to be licensed by the department of public health shall comply with standards for food service sanitation in accordance with rules promulgated by the department of inspections and appeals pursuant to 481—Chapter 32 of the Iowa Administrative Code and Iowa Code chapter 137B.

b. Food service operations in substance abuse inpatient, residential, and halfway house treatment facilities shall be inspected on an annual basis by the department of inspections and appeals or appropriate local boards of health having agreements with the department of inspections and appeals to conduct such inspections.

c. The use of door locks or closed sections shall be approved by the fire marshal, professional staff and governing body.

155.22(2) *Emergency preparedness.* The inpatient, residential and halfway house programs shall have an emergency preparedness program designed to provide for the effective utilization of available resources so that client/patient care can be continued during a disaster.

[**ARC 8792B**, IAB 6/2/10, effective 7/1/10]

641—155.23(125,135) Specific standards for inpatient, residential, and halfway house service. An inpatient, residential, and halfway house service shall be designed to provide comprehensive diagnostic, treatment and rehabilitation services in a 24-hour therapeutic setting.

155.23(1) *Hours of operation.* An inpatient, residential, and halfway house service shall operate seven days per week, 24 hours a day.

155.23(2) *Meals.* Inpatient and residential programs shall provide a minimum of three meals per day to each client/patient enrolled in the program. Inpatient, residential, and other programs where client/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 client/patients are allowed to prepare meals, the program shall document conformity with all commonly accepted policies and procedures of state health regulations and food hygiene.

155.23(3) *Consultation with counsel.* An inpatient, residential, and halfway house program shall have policies and procedures which will ensure that all client/patients in a facility have opportunity for and access to consultation with legal counsel at any reasonable time.

155.23(4) *Visitation with family and friends.* An inpatient, residential, and halfway house program shall have policies and procedures which will ensure opportunities for continuing contact with family and friends. If such visiting opportunities are clinically contraindicated, they shall be approved on an individual basis by the treatment supervisor and subject to review by the executive director. The justification for restrictions shall be documented in the client/patient record. If clinical indications require restrictions on visitation, such restrictions shall be evaluated for continuing therapeutic effectiveness every seven days by the treatment supervisor and primary counselor.

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

155.23(5) *Telephone use.* An inpatient, residential, and halfway house program shall have policies and procedures which allow client/patients to conduct private telephone conversations with family and friends at the facility. If such are clinically contraindicated, they shall be approved on an individual basis by the treatment supervisor and subject to review by the executive director. The justification for restrictions shall be documented in the client/patient record. If clinical indications require restrictions, such shall be evaluated for continuing therapeutic effectiveness every seven days by the treatment supervisor and primary counselor. Access to the telephone shall be available during reasonable hours as defined by the program in written policies and procedures except for emergency calls, which may be received at the time of the call, or made when necessary.

155.23(6) *Written communication.* An inpatient, residential, and halfway house program shall have policies and procedures which ensure that neither mail nor other communications to or from a client/patient in a facility is intercepted, read, or censored.

155.23(7) *Facility.* An inpatient, residential, and halfway house facility shall be safe, clean, well-ventilated, properly heated, in good repair, and free from vermin to ensure the well-being of residents.

a. Client/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) Windows in bedrooms shall have curtains or window blinds.

b. Sleeping areas shall include:

(1) Doors for privacy;

(2) Partitioning or placement of furniture to provide privacy for all client/patients;

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

(4) Client/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 client/patient's right to privacy by knocking on the door of the client/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 shall provide residents with facilities necessary for personal hygiene and personal privacy, including:

(1) A safe supply of hot and cold running water which is potable;

(2) Clean towels, electric hand dryers or paper towel dispensers, and an available supply of toilet paper and soap;

(3) Natural or mechanical ventilation capable of removing odors;

(4) Tubs or showers shall have slip-proof surfaces;

(5) Partitions with doors which provide privacy if a bathroom has multiple toilet stools;

(6) Toilets, wash basins, and other plumbing or sanitary facilities shall at all times be maintained in good operating condition; and

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

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

e. There shall be a written plan outlining procedures to be followed in the event of fire or tornado. These plans shall be conspicuously displayed on each floor or dormitory area that client/patients, residents, or visitors occupy at the facility and shall be explained to all inpatient, residential, and halfway house client/patients as a part of their orientation to the program. Fire drills shall be conducted at least monthly and tornado drills conducted during the tornado season from April through October.

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

g. Smoking shall not be permitted in bedrooms.

h. Every facility shall have an adequate water supply from an approved source. A municipal water system shall be considered as meeting this requirement. Private water sources shall be tested annually.

i. The facility shall allow for the following:

(1) Areas in which a client/patient may be alone when appropriate; and

(2) Areas for private conversations with others.

j. Articles of grooming and personal hygiene that are appropriate to the client/patient's age, developmental level, and clinical state shall be readily available in a space reserved near the client/patient's sleeping area. If clinically indicated as determined by the treatment supervisor, a client/patient's personal articles may be kept under lock and key by staff. If access to potentially dangerous grooming aids or other personal articles is contraindicated for clinical reasons, a member of the professional staff shall explain to the client/patient the conditions under which the articles may be used; and the clinical rationale for these conditions shall be documented in the client/patient case record.

k. Housekeeping. If client/patients take responsibility for maintaining their own living quarters and for day-to-day housekeeping activities of the program, these responsibilities shall be clearly defined in writing and be a part of the client/patient orientation program. Staff assistance and equipment shall be provided as needed.

l. Clothing. Client/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. In addition, a laundry room shall be accessible so client/patients may wash their clothing.

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

n. Recreation and outdoor activities. The program shall provide recreation and outdoor activities, unless contraindicated for therapeutic reasons.

155.23(8) *Religion-culture.* The inpatient, residential, and halfway house program shall have a written description of its religious orientation, particular religious practices that are observed, and any religious restrictions. This description shall be provided to the client/patients, parent(s) or guardian, and the placing agency at the time of admission in compliance with HIPAA and DHHS, 42 CFR Part 2, regulations on Confidentiality of Alcohol and Drug Abuse Patient Records. This information shall also be available to adults during orientation. The client/patient shall have the opportunity to participate

in religious activities and services in accordance with the client/patient's own faith or that of a minor client/patient's parent(s) or guardian. The facility shall, when necessary and reasonable, arrange transportation for religious activities.
[**ARC 8792B**, IAB 6/2/10, effective 7/1/10]

641—155.24(125,135) Specific standards for inpatient, residential, and halfway house services for juveniles. An inpatient, residential, and halfway house program that houses one or more juveniles under the age of 18 must also comply with the following standards.

155.24(1) *Personal possessions.* The inpatient, residential, and halfway house program shall allow a child to bring personal belongings. However, the inpatient, residential, and halfway house program shall, as necessary, limit or supervise the use of these items. In addition, the program shall ensure that each child has adequate, clean, well-fitting, attractive, and seasonable clothing as required for health, comfort, and physical well-being. The clothes should be appropriate to age, sex and individual needs.

155.24(2) *Family involvement.* There shall be written policies and procedures for family involvement that shall encourage continued involvement of the family.

155.24(3) *Children's money.* Money earned or received as a gift or as an allowance by a child in care shall be deemed to be that child's personal property. The program shall have a written policy on the child's use of funds. The program shall maintain a separate accounting system for children's money.

155.24(4) *Discipline.* The inpatient, residential, and halfway house program shall have written policies and procedures regarding methods used for control and discipline of children which shall be available to all staff and to the child's family. Agency staff shall be in control of and responsible for discipline at all times. Discipline shall not include the withholding of basic necessities such as food, clothing, or sleep.

a. The program shall have a policy that clearly prohibits staff or the children from utilizing corporal punishment as a method of disciplining or correcting children. This policy is to be communicated, in writing, to all staff of the facility.

b. Behavior expectations. The program shall make available to the child and the child's parents or guardian written policies regarding the following areas:

(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 7 days per week, 24-hour per day coverage. The number and qualifications of the staff will vary depending on the needs of the children.

a. Inpatient, residential, halfway house programs, and community residential facilities as defined in 441—Chapter 114, shall have an on-call system operational 24 hours a day to provide supervisory consultation. The program shall have a written plan documenting this system. During prime programming time, there shall be at least a one-to-eight, staff-to-client/patient ratio.

b. Comprehensive residential facilities, as defined in 441—Chapter 115, shall have at least a one-to-five, staff-to-client/patient ratio during prime programming time. A staff person shall be in each living unit at all times when children 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. Policies and procedures for nighttime checks shall be in writing.

c. The program's prime programming time shall be defined in writing.

155.24(6) *Illness, accident, death, or absence from the inpatient, residential, and halfway house program.* The program shall have written policies and procedures to notify the child's parent(s), guardian, and responsible agency of any serious illnesses, incidents involving serious bodily injury or absence, or circumstances causing removal of the child from the facility in compliance with HIPAA and DHHS, 42 CFR Part 2, regulations on Confidentiality of Alcohol and Drug Abuse Patient Records. In the event of the death of a child, the program shall immediately notify the physician, the child's parent(s) or guardian, the placing agency, and the appropriate state authority.

155.24(7) *Educational services.* An educational program shall be available for each child in accordance with abilities and needs. The educational and teaching standards established by the state department of public instruction shall be met.

155.24(8) *Needs of the juvenile.* Program services and rules shall be designed to meet individual needs of the juvenile.
[**ARC 8792B**, IAB 6/2/10, effective 7/1/10]

641—155.25(125,135) Specific standards for assessment and evaluation programs.

155.25(1) *Definitions.* Rescinded IAB 6/2/10, effective 7/1/10.

155.25(2) *Governing body.* Each program shall have a formally designated governing body that is representative of the community being served, complies with Iowa Code chapter 504 and is the ultimate authority for the overall program operations. Persons in private practice as sole practitioners shall be exempt from this subrule except for the requirements to have malpractice and liability insurance.

a. The governing body shall develop and adopt written bylaws and policies that define the powers and duties of the governing body, its committees, advisory groups, and the executive director. These bylaws 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. Minutes of all meetings shall be kept and 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, the following:

(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) Establish an effective control which will ensure that quality services are delivered;

(3) Review and approve the program's annual budget; and

(4) Approve all contracts.

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

f. The governing body shall be responsible for all funds, equipment, supplies and the facility in which the program operates. 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 will include, but not necessarily be limited to, the following items:

(1) The name, address, occupation, and place of employment of each governing body member;

(2) Any family relationship which a member of the governing body may have to a program staff member; and

(3) Where applicable, the names and addresses of all owners or controlling parties whether they are individuals, partnerships, corporation body, or subdivision of other bodies, such as a public agency, or religious group, fraternity, or other philanthropic organization.

h. The governing body shall assume responsibility in seeing that the program has malpractice and liability insurance and a fidelity bond.

155.25(3) *Executive director.* This individual shall have primary responsibility for the overall program operations. The duties of the executive director shall be clearly defined by the governing authority, when applicable.

155.25(4) *Clinical oversight.* The program shall have appropriate clinical oversight to ensure quality of clinical services provided to client/patients. This may be provided in house or through a consultation agreement.

155.25(5) *Staff development and training.* There shall be written policies and procedures that establish staff development. Staff development shall include orientation for staff and opportunities for continuing job-related education. For corporations organized under Iowa Code chapter 496C and sole practitioners, documentation of continuing education to maintain a professional license or substance abuse certification as specified in 155.21(8) will meet the requirement of this subrule.

a. Evidence of professional education, substance abuse certification or licensing as specified in 155.21(8), or orientation which includes the following: psychosocial, medical, pharmacological, confidentiality, tuberculosis, community resources; screening, evaluation, HIV/AIDS (human immunodeficiency virus/acquired immune deficiency syndrome) information/education; and the attitudes, values and lifestyles of racially diverse cultures, other cultures and special populations.

b. Staff development shall ensure that staff members are kept informed of new developments in the field of substance abuse screening, evaluation and placement.

155.25(6) *Management information system.* Programs receiving Medicaid or state funding and programs performing OWI evaluation in accordance with 641—Chapter 157 shall submit client/patient data to the Iowa Department of Public Health, Division of Behavioral Health, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319-0075, in accordance with substance abuse reporting system procedures.

155.25(7) *Procedures manual.* All programs shall develop and maintain a procedures manual. This manual shall define the program's policies and procedures to reflect the program's activities. Revisions shall be entered with the date, name and title of the individual making the entries. This manual shall contain all of the required written policies, procedures, definitions, and all other documentation required by these standards in the following areas:

a. Legal authority and organization;
b. Personnel policies, except for sole practitioner;
c. Emergency medical services;
d. Staff development;
e. Maintenance of client/patient case records;
f. Confidentiality of client/patient records;
g. Clinical services, such as placement screening, evaluation and assessment; and
h. Relationship with other providers.

155.25(8) *Fiscal management.* The program shall ensure proper fiscal management.

a. The fiscal management system shall be maintained in accordance with generally accepted accounting principles, including internal controls to reasonably protect the agency assets.

b. The OWI evaluation fee schedule shall be made public, and the client/patient shall be informed of the fee schedule at the time of scheduling the evaluation.

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

155.25(9) *Personnel.* Written personnel policies and procedures shall be developed, except for the sole practitioner.

a. These policies and procedures shall address the following areas:
(1) Recruitment, selection, and certification of staff members;
(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 of employees;
(10) Methods for handling cases of inappropriate client/patient care;
(11) Work performance appraisal;

(12) Employee accidents and safety;

(13) Employee grievances; and

(14) Policy on staff persons suspected of using or abusing substances.

b. The written personnel policies and practices shall include an equal employment opportunity policy and an affirmative action plan for hiring members of protected classes that minimally comply with Iowa civil rights commission rules and any local ordinances.

c. There shall be written job descriptions that reflect the actual job situation.

d. The written personnel policies and practices shall include a mechanism for a written evaluation of personnel performance on at least an annual basis. There shall be evidence that this evaluation is reviewed with the employee and that the employee is given the opportunity to respond to this evaluation.

e. There shall be a personnel record kept on each staff member. These records shall contain as applicable:

(1) Verification of training, experience, and all professional credentials relevant to the position;

(2) Job performance evaluations;

(3) Incident reports;

(4) Disciplinary actions taken; and

(5) Documentation of review and adherence to confidentiality laws and regulations. This review and agreement shall occur prior to assumption of duties.

f. There shall be written policies and procedures designed to ensure confidentiality of personnel records and a delineation of authorized personnel who have access to various types of personnel information.

155.25(10) *Professional qualifications.*

a. Personnel conducting screenings, placements, and assessments in accordance with this chapter shall meet the requirements of 155.21(8)*"i."*

b. The sole practitioner shall subscribe to a code of conduct found in professional certification or licensure as specified in 155.21(8).

155.25(11) *Child abuse/dependent adult abuse/criminal history background check.*

a. Written policies and procedures shall prohibit mistreatment, neglect, or abuse of children and dependent adults and shall specify reporting and enforcement procedures for the program. Alleged violations shall be reported immediately to the director of the facility and appropriate department of human services personnel. Written policies and procedures on reporting alleged violations regarding substance abuse client/patients shall be in compliance with HIPAA and DHHS, 42 CFR Part 2, regulations on Confidentiality of Alcohol and Drug Abuse Patient Records. Any employee found to be in violation of Iowa Code sections 232.67 through 232.70, as substantiated by a department of human services' investigation shall be subject to the program's policies concerning dismissal.

b. For each employee working within a juvenile services area as set forth in Iowa Code section 125.14A or with dependent adults as set forth in Iowa Code chapter 235B, the following, at a minimum, shall be documented:

(1) Documentation of a criminal history background check with the Iowa division of criminal investigation on all new applicants for employment. 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 applicant for employment which discloses any substantiated reports of child abuse, neglect, or sexual abuse or dependent adult abuse.

(3) Documentation of a check after hiring on probationary or temporary status, but prior to permanently employing the individual, 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 employees hired on or after July 1, 1994, pursuant to Iowa Code chapter 235B.

(4) A person who has a record of a criminal conviction or founded child abuse report or founded dependent adult abuse report shall not be employed, unless an evaluation of the crime or founded child abuse or founded dependent adult abuse has been made by the department of human services which 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 exists, the person shall be offered the opportunity to complete and submit Form 470-2310, Record Check Evaluation. In its evaluation, the department of human services shall 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.

c. Each treatment staff member shall complete two hours of training relating to the identification and reporting of child abuse and dependent adult abuse within six months of initial employment, and at least two hours of additional training every five years thereafter.

155.25(12) *Client/patient case record maintenance.* There shall be written policies and procedures governing the compilation, storage and dissemination of individual client/patient case records.

a. These policies and procedures shall ensure that:

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

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

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

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

c. Appropriate records shall be readily accessible to those staff members providing services directly to the client/patient and other individuals specifically authorized by program policy.

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

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

f. Policies shall be established that specify the conditions under which information on applicants or client/patients may be released and the procedures to be followed for releasing such information. All such policies and procedures shall be in accordance with HIPAA and the federal confidentiality regulations, "Confidentiality of Alcohol and Drug Abuse Patient Records," 42 CFR Part 2, effective June 9, 1987, which implement federal statutory provisions, 42 U.S.C. 290dd-3 applicable to alcohol abuse client/patient records, and 42 U.S.C. 290ee-3 applicable to drug abuse client/patient records, and state confidentiality laws and regulations.

g. Confidentiality of alcohol and drug abuse client/patient records. The confidentiality of alcohol and drug abuse client/patient records maintained by a program is protected by HIPAA and the "Confidentiality of Alcohol and Drug Abuse Patient Records" regulations, 42 CFR Part 2, effective June 9, 1987, which implement federal statutory provisions, 42 U.S.C. 290dd-3 applicable to alcohol abuse client/patient records, and 42 U.S.C. 290ee-3 applicable to drug abuse client/patient records.

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

155.25(13) *Placement screening, evaluation and assessment.* There shall be clearly stated written criteria for determining the eligibility of individuals for placement screening evaluation and assessment.

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

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

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

b. The program shall conduct a screening, which shall include evaluation of the ASAM-PPC-2 for determining the recommendation of individuals for placement into a level of care.

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

(1) Evaluation costs to be borne by the client/patient, if any;

(2) Client/patient's rights and responsibilities; and

(3) Confidentiality laws, rules and regulations.

d. Sufficient information shall be collected during the screening and evaluation process so that a recommendation can be made for placement into a level of care.

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

f. Programs conducting screenings and evaluations on persons convicted of operating a motor vehicle while intoxicated (OWI), Iowa Code section 321J.2, and persons whose driver's license or nonresident operating privileges are revoked under chapter 321J, shall do so in accord with and adhere to 641—Chapter 157.

155.25(14) *Client/patient case record contents.* There shall be a case record for each client/patient that contains:

a. Results of all examinations, tests, and screening and admissions information;

b. Reports from referring sources when applicable;

c. Reports from outside resources shall be dated and include the name of the resource;

d. Multidisciplinary case conference and consultation notes, including the date of the conference or consultation, recommendations made, actions taken, and individuals involved when applicable;

e. Correspondence related to the client/patient, including all letters and dated notations of telephone conversations relevant to the client/patient's treatment;

f. Information release forms;

g. Records of services provided; and

h. Management information system or other appropriate data forms.

155.25(15) *Emergency medical services.* The program shall ensure that emergency medical services are available through an affiliation agreement or contract or policy and procedure.

155.25(16) *Management of care.* The program shall ensure appropriate level of care utilization by implementing and maintaining the written placement screening.

155.25(17) *Building construction and safety.* All buildings in which client/patients receive treatment shall be designed, constructed, equipped, and maintained in a manner that provides for the physical safety of client/patients, personnel, and visitors.

a. All programs shall have written policies and procedures to provide a safe environment for client/patients, personnel and visitors. The program shall have written policies and procedures for the maintenance, supervision, and safe use of all its grounds and equipment.

b. Safety education shall include orientation of new employees to general facilitywide safety practices.

155.25(18) *Outpatient facility.* The outpatient facility shall be safe, clean, well-ventilated, properly heated and in good repair.

a. The facility shall be appropriate for providing services available from the program and for protecting client/patient confidentiality.

b. Furniture shall be clean and in good repair.

c. There shall be a written plan outlining procedures to be followed in the event of fire and tornado. This plan shall be conspicuously displayed at the facility.

d. All services shall be accessible to people with disabilities, or the program shall have written policies and procedures that describe how people with disabilities can gain access to the facility for necessary services.

e. The program shall ensure confidentiality of client/patients receiving services.

f. Smoking shall be prohibited.

155.25(19) *Client/patient rights.* The program shall maintain written policies and procedures that ensure that the legal and human rights of client/patients participating in the program are observed and protected.

a. There shall be procedures to inform all client/patients of their legal and human rights at the time of evaluation.

b. There shall be documentation of the implementation of these procedures.

c. There shall be written policies and procedures for:

(1) Client/patient communications, e.g., opinions, recommendations;

(2) Client/patient grievances, with a mechanism for redress;

(3) Prohibition of sexual harassment; and

(4) Implementation of the Americans with Disabilities Act.

d. There shall be procedures designed to protect client/patients' rights and privacy.

155.25(20) *Administrative and procedural standards.* The program shall comply with the following rules:

a. 641—155.2(125,135) Licensing.

b. 641—155.3(125,135) Type of licenses.

c. 641—155.4(125,135) Nonassignability.

d. 641—155.5(125,135) Application procedures.

e. 641—155.6(125,135) Application review.

f. 641—155.7(125,135) Inspection of licensees.

g. 641—155.8(125,135) Licenses—renewal.

h. 641—155.9(125,135) Corrective action plan.

i. 641—155.10(125,135) Grounds for denial of initial license.

j. 641—155.11(125,135) Suspension, revocation, or refusal to renew a license.

k. 641—155.12(125,135) Contested case hearing.

l. 641—155.13(125,135) Rehearing application.

m. 641—155.14(125,135) Judicial review.

n. 641—155.15(125,135) Reissuance or reinstatement.

o. 641—155.16(125,135) Complaints.

p. 641—155.17 Reserved.

q. 641—155.18(125,135) Deemed status.

r. 641—155.19(125,135) Funding.

s. 641—155.20(125,135) Inspection.

This rule is intended to implement Iowa Code section 125.13.

[**ARC 8792B**, IAB 6/2/10, effective 7/1/10]

641—155.26 to **155.34** Reserved.

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

155.35(1) *Definitions.*

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

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

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

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

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

"Detoxification treatment" means the dispensing of an opioid agonist treatment medication in decreasing doses to an individual to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of an opioid drug and as a method of bringing the individual to a drug-free state within such a period.

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

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

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

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

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

"Opiate addiction" means a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opiates despite significant opiate-induced problems. Opiate dependence is characterized by an individual's repeated self-administration of opiates that usually results in opiate tolerance, withdrawal symptoms, and compulsive drug-taking. Dependency may occur with or without the physiological symptoms of tolerance and withdrawal.

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

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

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

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

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

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

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

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

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

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

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

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

a. Definitions. For purposes of this subrule:

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

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

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

(1) The disclosure is made when:

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

(2) The disclosure is limited to:

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

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

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

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

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

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

155.35(4) *Admission requirements.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

155.35(5) *Placement, admission and assessment.* The program shall have written criteria for considering an individual for placement and admission. In addition, the program shall maintain current procedures to ensure that patients are admitted to maintenance treatment by qualified staff who have determined by using accepted medical criteria such as those outlined in the Diagnostic and Statistical Manual for Mental Disorders (DSM IV) that the person is currently addicted to an opioid drug.

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

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

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

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

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

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

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

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

(1) General nature and goals of the program;

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

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

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

(5) Client/patient rights and responsibilities;

(6) Confidentiality laws, rules and regulations; and

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

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

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

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

(1) A complete medical history;

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

(3) A physical examination including examination for:

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

(4) Laboratory tests including:

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

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

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

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

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

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

c. The individualized treatment plan shall minimally contain:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

155.35(8) *Rehabilitative services.* The program shall have policies and procedures on the minimum attendance for rehabilitative services relative to the client/patient's progress and length of involvement in treatment. The minimum frequency of rehabilitative services shall occur at the same frequency of on-site dosing for client/patients receiving more than two take-home dosages a week in the first year. The minimum frequency for rehabilitative services for client/patients receiving two or fewer take-home dosages shall be weekly. The program shall provide rehabilitative services that are appropriate for

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

155.35(9) *Medication dispensing.*

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

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

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

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

c. Administration.

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

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

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

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

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

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

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

(2) Regular attendance at the clinic;

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

(4) Absence of recent criminal activity;

(5) Stable home environment and social relationships;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

rule shall be in compliance with all applicable federal proficiency testing and licensing standards and all applicable state standards.

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

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

a. These policies and procedures shall ensure that:

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

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

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

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

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

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

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

(1) The client/patient consents in writing;

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

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

(4) The disclosure is required by law.

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

155.35(13) *Diversion prevention plan.*

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

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

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

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

155.35(14) *Quality improvement.* The program shall have an ongoing quality improvement process designed to objectively and systematically monitor and evaluate the quality and appropriateness of client/patient care, pursue opportunities to improve client/patient care, and resolve identified

problems. Quality improvement efforts shall be facilitywide in scope and include review of clinical and professional services.

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

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

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

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

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

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

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

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

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

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

155.35(15) *Interim maintenance treatment.*

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

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

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

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

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

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

d. Minimum standards for interim maintenance treatment. The program may admit a client/patient who is eligible for comprehensive maintenance treatment to interim maintenance treatment if the client/patient cannot be placed in a public or private nonprofit comprehensive program within a reasonable geographic area and within 14 days of application for services. An initial drug screen, and at least two others, shall be taken from the client/patient during the maximum admission period of 120 days. A program shall establish and follow reasonable criteria for determining the transfer of client/patients to comprehensive maintenance treatment. These transfer criteria shall be in writing, available for inspection, and shall include at a minimum a preference for the transfer of

pregnant client/patients. Interim maintenance shall be conducted in accordance with all applicable federal regulations and state rules. The program shall notify the division when a client/patient begins interim treatment; when a client/patient leaves interim treatment, and when a client/patient transfers to comprehensive maintenance treatment. Such notifications shall be documented by the program in the client/patient's case record. All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions:

(1) The medication is required to be administered daily under observation;

(2) Take-home medication is not allowed;

(3) Initial and comprehensive treatment plans are not required;

(4) A primary counselor is not required to be assigned to the client/patient; and

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

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

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

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

(1) Joint Commission.

(2) Council on Accreditation of Rehabilitation Facilities (CARF).

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

(4) American Osteopathic Association (AOA).

b. Credentials and expectations of accreditation bodies.

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

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

c. Responsibilities of programs granted deemed status.

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

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

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

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

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

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

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

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

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

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

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

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

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

155.35(18) *Personnel qualifications.*

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

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

[**ARC 8792B**, IAB 6/2/10, effective 7/1/10; **ARC 9534B**, IAB 6/1/11, effective 7/6/11]

TUBERCULOSIS (TB) SCREENING:
HEALTH CARE WORKERS AND RESIDENTS

641—155.36(125,135) Purpose. The purpose of these rules is to outline procedures for conducting tuberculosis (TB) screening for health care workers and residents at substance abuse and problem gambling treatment program facilities. Facilities will need to conduct a risk assessment to determine the risk classification of the facility and to identify appropriate screening criteria. The screening criteria are consistent with those of the U.S. Centers for Disease Control and Prevention (CDC), TB Elimination Division, as outlined in the MMWR December 30, 2005/Vol. 54/No. RR-17, "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005."

[**ARC 0365C**, IAB 10/3/12, effective 11/7/12]

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

"Bacille Calmette-Guerin (BCG) vaccination" means a vaccine for 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 greater than three weeks. 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 the infection control team, or designated other, determines that 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 that 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.

[**ARC 0365C**, IAB 10/3/12, effective 11/7/12]

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 and laryngeal TB that 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 shall 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 shall 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 shall 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 shall 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 shall 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 shall be classified as medium risk.

d. Classification criteria—potential ongoing transmission. If evidence of ongoing *M. tuberculosis* transmission exists at a facility, the facility shall 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 clients or residents after a negative TB symptom screen (i.e., no symptoms of active TB disease) and a negative TST (i.e., first step) or negative IGRA. The second TST may be performed after the staff member starts working with clients or residents.

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. Prior 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 shall 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).

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

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1 Effective date of Ch 3 delayed by the Administrative Rules Review Committee 70 days from 8/2/78.
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2 Effective date of 643—3.35(125) delayed 70 days by the Administrative Rules Review Committee at its meeting held April 11, 1994; on June 15, 1994, the Committee voted to delay the rule until adjournment of the 1995 General Assembly.