

CHAPTER 3
LICENSURE STANDARDS FOR SUBSTANCE ABUSE TREATMENT PROGRAMS

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

643—3.1(125) Definitions. Unless otherwise indicated, the following definitions shall apply to the specific terms used in these rules:

“*Acute intoxication or withdrawal potential*” is a category to be considered in client/patient placement, continued stay, and discharge criteria. This category evaluates patient/client’s current status of intoxication and potential for withdrawal complications as it impacts on level of care decision making. 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 patient or research subject by one of the following:

1. A practitioner or the practitioner’s authorized agent.
2. The 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 criteria developed by the department to be considered in determining appropriate client/patient placement and resultant referral to a level of care. Criteria vary in intensity and are organized into six categories: acute intoxication or withdrawal potential, biomedical conditions or complications, emotional/behavioral conditions or complications, treatment resistance/acceptance, relapse potential, and recovery environment.

“*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 substance abuse treatment program which has applied for a license or renewal thereof.

“*Application*” means the process through which a substance abuse treatment program applies for a license or renewal as outlined in the application procedures.

“*Assessment*” means the ongoing process of identifying a diagnosis, ruling out other diagnoses, and determining the level of care needed by the client.

“*Biomedical condition or complication*” means one category to be considered in client/patient placement, continued stay, and discharge criteria. This category evaluates client/patient’s current physical condition as it impacts on level of care decision making. Historical information on client/patient’s medical/physical functioning may also be considered.

“*Case management*” means the process of using predefined criteria to evaluate the necessity and appropriateness of client care.

“*Chemical dependency*” means alcohol or drug dependence or psychoactive substance use disorder as defined by current diagnostic statistical measurement (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 drugs as defined in Iowa Code section 203A.2, subsection 3, which when used improperly could result in chemical dependency or a substance abuse problem.

“*Client*” means an individual who has a substance abuse problem or is chemically dependent, has been assessed as appropriate for services, and for whom screening procedures have been completed.

“Clinical privileges” means authorization by the governing body to provide specific client care and treatment services in the facility within well-defined limits, based on the individual’s license, education, training, experience, competence, and judgment.

“Commission” means the Iowa commission on substance abuse.

“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 or chemically dependent individual or client, and is negatively affected by the behavior of the substance abuser, chemically dependent individual, or client.

“Continued stay criteria” means specific criteria to be considered in determining appropriate client/patient placement for continued stay at a level of care or referral to a more appropriate level of care. Criteria vary in intensity and are organized into six categories: acute intoxication or withdrawal potential; biomedical conditions or complications; emotional/behavioral conditions or complications; treatment resistance/acceptance; relapse potential; and recovery environment.

“Continuing care” means Level I of client/patient placement criteria, which provides a specific period of structured therapeutic involvement designed to enhance, facilitate and promote transition from primary care to ongoing recovery.

“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 or dependence.

“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.

“Day treatment” is Level IV of client/patient placement criteria substance abuse treatment services provided to clients during a day for a minimum of eight hours of chemical dependency rehabilitation services.

“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 eliminating the toxic effects of drugs and alcohol from the body. Supervised detoxification methods include social detoxification and medical monitoring or management and are intended to avoid withdrawal complications.

“Director” means the director of the Iowa department of public health.

“Discharge criteria” means specific criteria to be considered in determining appropriate client/patient placement for discharge or referral to a different level of care. Criteria vary in intensity and are organized into six categories: acute intoxication or withdrawal potential; biomedical conditions or complications; emotional/behavioral conditions or complications; treatment resistance/acceptance; relapse potential; and recovery environment.

“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 post-treatment needs. Discharge planning may or may not include a document identified as a discharge plan.

“Division” means the division of substance abuse and health promotion.

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

“Emotional/behavioral conditions or complications” is a category to be considered in client/patient placement criteria. This category evaluates client/patient’s current emotional/behavioral status as it impacts on level of care decision making. Emotional/behavioral status may include, but is not limited to, anxiety, depression, impulsivity, and guilt and the behavior that accompanies or follows these emotional states. Historical information on client/patient emotional/behavioral functioning may also be considered.

“Evaluation” means the process to evaluate the client’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 patient/client profile information and development of a comprehensive treatment plan.

“Extended outpatient treatment” means Level III of client/patient placement criteria, which is an organized, nonresidential service. Services usually are provided in regularly scheduled sessions which do not exceed ten treatment hours a week.

“Extended residential program” means one of the two treatment modes described in Level V of client/patient placement criteria, where addiction treatment is provided in a residential setting offering primary treatment followed by a combination of chemical dependency rehabilitation and community ancillary services averaging 30 hours of service per week.

“Facility” means a hospital, detoxification center, institution or program licensed under Iowa Code section 125.13 providing care, maintenance and treatment for substance abusers. Facility also includes the physical areas such as grounds, buildings, or portions thereof under direct administrative control of the program.

“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.

“Halfway house” means Level II of client/patient placement criteria, which is low-intensity addiction treatment in a supportive living environment to facilitate the individual’s reintegration into the community, most often following completion of primary treatment. Clients/patients participate in at least five hours of chemical dependency rehabilitation services weekly.

“Inpatient treatment” means Level VII of client/patient placement criteria. See “Medically managed inpatient treatment.”

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

“Intensive outpatient treatment” means Level IV of client/patient placement criteria, which is an organized, outpatient treatment service with scheduled sessions that provide a range of 11 or more treatment hours per week.

“Iowa board of substance abuse certification” means the professional certification board that certifies substance abuse counselors and prevention 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 client/patient placement criteria 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 substance abuse commission which validates the licensee’s compliance with substance abuse program standards and authorizes the licensee to operate a substance abuse 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: 90 percent or better rating in clinical, administrative and programming for a two-year license; less than 90 percent but no less than 70 percent rating in clinical, administrative and programming for a one-year license. Also, in order to receive a two-year license, a program must re-

ceive a rating of 80 percent or better in each of the two categories of quality assurance and building construction and safety. In order to receive a one-year license, a program must receive a rating of 60 percent or better in each of those two categories.

“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.

“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 detoxification” is the detoxification service offered in Level VII of client/patient placement criteria. This intensity of service is reserved for potentially life-threatening detoxification situations.

“Medically managed inpatient treatment” is Level VII of client/patient placement criteria, which is addiction and chemical dependency treatment provided to a patient/client whose medical condition is such that a physical examination by a physician is required within 24 hours of admission. The program provides 24-hour medical management of treatment and detoxification services.

“Medically monitored detoxification” means the detoxification service offered in Level VI of client/patient placement criteria. This level of care is appropriate for acute detoxification situations.

“Medically monitored residential treatment” is Level VI of client/patient placement criteria, which is addiction and chemical dependency treatment. Client/patient’s medical condition is such that a physical examination by a physician is required within 24 hours of admission. The program provides 24-hour medical monitoring of treatment and detoxification services; and 50 or more hours of chemical dependency rehabilitation services per week are provided. Programs providing this level of care may provide detoxification services or residential chemical dependency treatment services, or both.

“Outpatient treatment” means Levels III and IV of client/patient placement criteria. See “Extended outpatient and intensive outpatient treatment.”

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

“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 substance abuse treatment component or modality including continuing care, halfway house, extended outpatient treatment, intensive outpatient treatment, primary extended residential treatment, medically monitored residential treatment, and medically managed inpatient treatment services.

“Primary residential program” means one of the two treatment modes described in Level V of client/patient placement criteria, which is addiction treatment provided by a program with 50 or more hours of chemical dependency rehabilitation services per week. A client/patient’s medical condition is such that a physical examination by a physician is required within seven calendar days of admission.

“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.

“Program” means any individual, 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 care to improve client care and resolve identified problems.

“Recovery environment” means one category to be considered in client/patient placement, continued stay and discharge criteria. This category evaluates client/patient’s current recovery environment as it impacts on level of care decision making. Recovery 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 environment may also be considered.

“Rehabilitation” means the restoration of a client to the fullest physical, mental, social, vocational, and economic usefulness of which the client 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. *“Relapse”* also refers to the resumption of alcohol or drug use.

“Relapse potential” means a category to be considered in client/patient placement, continued stay, and discharge criteria. This category evaluates client/patient’s current relapse potential as it impacts on level of care decision making. Relapse potential may include, but is not limited to, current statements by client/patient about relapse potential, reports from others on potential for patient/client relapse, and assessment by clinical staff. Historical information on client/patient’s relapse potential may also be considered.

“Residential detoxification” means the detoxification service offered in Level VI of client/patient placement criteria. This intensity of service is appropriate for subacute detoxification situations.

“Residential program” means a 24-hour live-in, seven-day-a-week substance abuse 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.

“Residential treatment” is Level V of client/patient placement criteria where addiction and chemical dependency treatment is provided in a residential setting. Primary residential provides 50 or more hours of chemical dependency rehabilitation services per week. Client/patient’s medical condition is such that a physical examination by a physician is required within seven days of admission. Extended residential treatment combines chemical dependency and community ancillary services averaging 30 hours of service per week.

“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 patient/client 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.

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

“*Standards*” means specifications representing the minimal characteristics of a substance abuse treatment program which are acceptable for the issuance of a license.

“*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.

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

“*Treatment acceptance/resistance*” is a category to be considered in client/patient placement, continued stay, and discharge criteria. This category evaluates client/patient’s current treatment acceptance/resistance as it impacts on level of care decision making. Treatment acceptance/resistance may include, but is not limited to, current statement by client/patient about treatment acceptance/resistance, reports from others on client/patient treatment acceptance/resistance, and assessment by clinical staff on client/patient motivation. Historical information on client/patient may also be considered.

“*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 supervisor*” means an individual who, by virtue of education, training or experience, is capable of assessing the psychosocial history of a substance abuser to determine the treatment plan most appropriate for the client. This person shall be designated by the applicant.

643—3.2(125) Licensing. A single license will be issued to each qualifying substance abuse treatment program. 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:

1. Inpatient;
2. Residential;
3. Halfway house;
4. Outpatient;
5. Chemical substitute, antagonist and detoxification; and
6. Intake and assessment.

643—3.3(125) Type of licenses.

3.3(1) Issuance of licenses.

a. Licenses may be issued for up to two years. A license may be renewed for one or two 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 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 two-year license shall be contingent upon demonstration of substantial continued compliance with licensure standards and in accordance with the licensure weighting report criteria.

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.

3.3(2) Corrective action. Following the issuance of a license, the treatment program may be requested by the commission 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.

643—3.4(125) Nonassignability. A license issued by the department for the operation of a substance abuse program applies both to the applicant program and the premises upon which the program is to be operated. Licenses are not transferable. A discontinued program is one which has terminated its 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. Any person or other legal entity acquiring a licensed facility for the purpose of operating a substance abuse program shall make an application as provided for a new license. Similarly, any person or legal entity having acquired a license and desiring to fundamentally alter the treatment philosophy or transfer to different premises must notify the commission 30 days prior to said action in order for the department to review the site change and to determine appropriate action.

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 patients or clients 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.

643—3.5(125) Application procedures. The department will mail an application form to all applicants for licensure.

3.5(1) Application information. An applicant for licensure shall submit the following information on forms available at the Iowa Department of Public Health, Division of Substance Abuse, Lucas State Office Building, Des Moines, Iowa 50319.

- a.* The name and address of the applicant substance abuse treatment program.
- b.* The name and address of the executive director of such substance abuse 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 substance abuse 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 substance abuse treatment program has a direct contractual or affiliation agreement.
- f.* A description of the treatment services provided by the substance abuse 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 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.

3.5(2) *Renewal.* An application for renewal shall be submitted on forms provided by the department at least 90 calendar days before expiration of the current license.

Applications for licensure renewal will not be considered complete until a current policies and procedures manual has been submitted to the department by the applicant substance abuse treatment program.

3.5(3) *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 returned to the division within 10 working days from the date the forms are received. After receipt of an updated or revised application for licensure, the division shall conduct an on-site visit within 60 days to verify information contained in the application. 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.

643—3.6(125) *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.

643—3.7(125) *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.

3.7(1) *Technical assistance.* All treatment programs applying for an initial license to operate a substance abuse 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.

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.

3.7(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 substance abuse 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.

643—3.8(125) Licenses—renewal. Upon approval of an application for licensing by the commission, a license shall be issued by the department. Licenses shall be renewed pursuant to rule 643—3.5(125).

3.8(1) Commission hearing preparation. The division will prepare all documents with a final recommendation for licensing determination to be presented at a commission meeting within 120 days from the site visit. The division shall send public notice of the date, time, place and name of applicants to be reviewed and processed.

a. The division shall send notice to the program by certified mail, return receipt requested, 30 days prior to the commission meeting notifying the program director and board chairperson of the time, place, and date the commission will review and act upon the application for the program along with the results of the inspection.

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

- (1) Reports of the on-site program licensure inspections; and
- (2) A final recommendation for licensing.

3.8(2) Commission 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 commission 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.

643—3.9(125) Corrective action plan. Programs approved for a license for 270 days by the commission will submit a corrective action plan to the director no later than 30 days following the commission 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 commission.

643—3.10(125) Grounds for denial of initial license.

3.10(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 opening and offering services. A recommendation by the department of a denial of an initial application for licensure to the commission may be made based on the following reasons:

a. The application for licensure is incomplete in accordance with information required as outlined in 643—3.5(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.

c. Permitting, aiding or abetting the commitment of an unlawful act within the facilities maintained by the program or permitting, aiding or abetting the commitment of an unlawful act involving chemical substances within the program.

d. Conduct or practices found by the department to be detrimental to the general health or welfare of a participant in the program or the general community.

3.10(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 patients/clients. 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.

3.10(3) Commission action. The commission shall meet to consider all cases involving issuance of a license. Upon approval of an application for licensure by the commission, a license shall be issued by the department.

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

(1) The division shall send notice to the program by certified mail, return receipt requested, 30 days prior to the commission meeting notifying the program director and board chairperson of the time, place, and date the commission will review and act upon the application for the program along with the results of the inspection.

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

b. Commission 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 commission 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.

643—3.11(125) Suspension, revocation, or refusal to renew a license. The commission may suspend or revoke a license for any of the following reasons:

1. Violation by the program, its director or staff, of any rule promulgated by the department pertaining to substance abuse treatment programs.

2. Permitting, aiding or abetting the commitment of an unlawful act within the facilities maintained by the program or permitting, aiding or abetting the commitment of an unlawful act involving chemical substances within the program.

3. Conduct or practices found by the department to be detrimental to the general health or welfare of a participant in the program or the general community.

4. The renewal application for licensure is incomplete or does not include all necessary and required information for verification.

5. On-site inspection report results based on the licensure weighting report indicate a score below minimum required for a recommendation for a one- or two-year license.

3.11(1) *Initial notice from commission.* When the commission determines to deny a renewal, suspend or revoke a license, the commission shall notify the licensee by certified mail, return receipt requested, of the commission'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 objections or plan of corrections to the department within 30 days from the receipt of notice from the commission.

3.11(2) *Objections or corrections of issues.* Where a licensee submits objections or plan of corrections to the department, the licensee shall have an opportunity to correct and resolve issues provided by the department within 90 days of the department's receipt of objections or plan of corrections.

3.11(3) *Decision of commission.* Where objections or notice of corrections has not been received or a recommendation is made based upon review of information received by the department, the commission shall meet to determine whether the license in question should be suspended, revoked, or not renewed. The licensee shall receive notice of this meeting in the same manner as provided by subrule 3.8(1), paragraph "a."

3.11(4) *Notice of decision and opportunity for contested case hearing.*

a. When the commission 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, mailed to the department address within 30 days of the notice issued by the commission. Failure to request a hearing will result in final action by the commission.

3.11(5) *Summary suspension.* If the commission finds that the health, safety or welfare of the public is endangered by continued operation of a substance abuse 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.

643—3.12(125) *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.

3.12(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.

3.12(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.

3.12(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.

3.12(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 commission 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 commission.

3.12(5) Appeal to the commission.

a. Either party may request the commission 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 commission. The commission will review the record and any briefs. No new evidence shall be admitted unless requested and allowed by the commission.

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

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

643—3.13(125) 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 commission 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 commission grants the application within 20 days after its filing.

643—3.14(125) Judicial review. A licensee who is aggrieved or adversely affected by the commission's final decision and who has exhausted all adequate administrative remedies may seek judicial review of the commission's decision pursuant to and in accordance with Iowa Code section 17A.19.

643—3.15(125) 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 commission. After that time, proof of compliance with the licensure standards must be presented to the commission prior to reinstatement or reissuance of a license.

643—3.16(125) Complaints. Any person may request an inspection of a program licensed pursuant to Iowa Code chapter 125 by filing with the department a complaint of any alleged violation of applica-

ble requirements of the Iowa Code or the rules adopted pursuant to it. The complaint shall state in a specific manner the basis of the complaint and the full name and address of the complainant. The complaint may be delivered personally or by mail to the division director at Lucas State Office Building, Des Moines, Iowa 50319. The executive director of the program involved shall be notified that the department shall conduct a complaint investigation within 48 hours of the on-site visit. Timely filing is required in order to ensure availability of witnesses and to avoid initiation of an investigation under conditions which may have been significantly altered during the period of delay.

3.16(1) *Evaluation of complaints.* Upon receipt of a complaint the department shall make a preliminary review of the complaint. Unless the department concludes that the complaint is intended to harass a program, or is without reasonable basis, it shall conduct an on-site investigation of the program which is the subject of the complaint as soon as practicable. The program complained of may be given an opportunity to informally present a position or defense regarding the allegations of the complaint during the on-site investigation. The complainant shall be properly informed of the results of any action taken by the department in this matter.

3.16(2) *Reports.* A written report shall be submitted by certified mail, return receipt requested, to the executive director of the facility, the chairperson of the governing body, and to the commission within 20 working days after completion of the complaint investigation. This report shall indicate if the complaint was substantiated, the basis for substantiation or nonsubstantiation, the specific statutes or rules violated, a response by the program receiving the complaint, and a recommendation for corrective action with specific time lines. If a recommendation is made to revoke or suspend the program's license, the commission shall proceed as required by rule 3.11(125).

3.16(3) *Response to report.* Within 20 working days after receiving a report substantiating violations, the program shall send a written response to the department acknowledging that the report has been received and stating that the violations will be corrected within the time specified by the department. Failure to respond to this report may constitute the basis for the program's license to be revoked or suspended.

3.16(4) *Informal response.* The program complained of may be given an opportunity to informally present a position or defense in regard to the allegations of the complaint. This position or defense may be submitted in writing or presented in a personal conference with the director or designee.

3.16(5) *Confidential records.* Written complaint investigation reports by the department, information provided to or obtained by the department through complaints or investigations concerning any program shall be maintained confidentially and not available to the public as outlined in Iowa Administrative Code 643—paragraph 5.13(2)“b.”

643—3.17(125) Variances. Variances from these rules may be granted by the director of the department of public health or designee for good and sufficient reason when the need for variance has been established; no danger to the health, safety, or welfare of any resident results; alternate means are employed or compensating circumstances exist and the variance will apply only to an individual program. Variances will be reviewed at the discretion of the director of the department of public health.

3.17(1) To request a variance, the licensee shall:

- a. Apply for variance in writing on a form provided by the department;
- b. Cite the rule or rules from which a variance is desired;
- c. State why compliance with the rule or rules cannot be accomplished;
- d. Explain alternate arrangements or compensating circumstances which justify the variance;
- e. Demonstrate that the requested variance will not endanger the health, safety, or welfare of any resident or client.

3.17(2) Upon receipt of a request for variance, the director of public health shall proceed as follows:

- a. Examine the rule from which variance is requested to determine that the request is necessary and reasonable;

- b. If the request meets the above criteria, evaluate the alternate arrangements or compensating circumstances against the requirement of the rules;
- c. Examine the effect of the requested variance on the health, safety, or welfare of the residents; and
- d. Consult with the applicant if additional information is required.

3.17(3) Based upon these studies, approval of the variance will be either granted or denied within 45 days of receipt.

643—3.18 Reserved.

643—3.19(125) 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.

643—3.20(125) Inspection. Each applicant or licensee agrees as a condition of licensure:

3.20(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.

3.20(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 commission deems relevant to the establishment of such a system.

643—3.21(125) General standards for all substance abuse treatment programs. The following standards shall apply to all substance abuse 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.

3.21(1) Governing body. Each program shall have a formally designated governing body that is representative of the community being served, complies with the Iowa Code, and is the ultimate authority for the overall program operations.

a. The governing body shall develop and adopt written bylaws and policies that define the powers and duties of the governing body, its committees, 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 qualifications of the memberships;
- (2) The type of membership;
- (3) The method of selecting members;
- (4) The term of appointment or election of members, officers and chairpersons of committees;
- (5) The number of the membership;
- (6) The frequency of meetings;
- (7) The attendance requirements; and
- (8) 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;
- (4) Decisions reached and actions taken; and

- (5) A summary of all reports presented to the governing body.
- 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.

3.21(2) *Executive director.* The governing body shall appoint an executive director whose qualifications, authority, and duties are appropriate to the administrative and treatment requirements of the program. This individual shall have primary responsibility for the overall program operations in accordance with the policies established by the governing body.

a. The duties of the executive director shall include, but not necessarily be limited to, the following:

- (1) The developing and organizing of administrative and procedural functions of the program;
- (2) Public relations;
- (3) Establishing a formal means of staff accountability;
- (4) Control and conservation of the physical and financial assets of the program;
- (5) Personnel administration; and
- (6) Review of policies on an annual basis and updating as appropriate.

b. The executive director shall assist the governing body in formulating policies and shall prepare, present, and interpret all relevant information as deemed appropriate by the governing body which may include:

- (1) Reports describing the program's operation;
- (2) Evaluation reports dealing with the efficiency and effectiveness of the program;
- (3) Plans based upon the nature and extent of substance abuse problems within the service area, the nature and extent of funding, and other resources available, and federal, state and local developments affecting substance abuse treatment; and
- (4) Budget and financial statements.

3.21(3) *Treatment supervisor services.* The program shall have available consultation from a treatment supervisor to ensure quality of clinical services provided to clients/patients. This individual will assist the program in developing policies and procedures relating to the assessment and treatment of psychopathology. The treatment supervisor will assist in the training of the staff and providing assistance to the clinical staff in client treatment. The executive director or designee shall be ultimately responsible for clinical services and implementation of treatment services to clients.

3.21(4) *Staff development and training.* There shall be written policies and procedures that establish a staff development program. The staff development program shall include orientation for entry-level staff, on-the-job training, in-service education, and opportunities for continuing job-related education.

a. Initial training is recommended for all staff, which for each treatment staff member shall include structured scheduled orientation in the following areas: 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. In addition, 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.

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 substance abuse 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;
- (3) Topics discussed, to include name and title of presenters; and
- (4) Recommendations made.

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

h. The local program shall document staff attendance and participation at local, regional, state and national training opportunities.

3.21(5) *Management information system.* All programs funded by the department shall submit client data to the Iowa Department of Public Health, Division of Substance Abuse and Health Promotion, Lucas State Office Building, Des Moines, Iowa 50319-0075, in accordance with substance abuse reporting system procedures.

3.21(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 required by these standards in the following areas:

- a.* Legal authority and organization of the governing body;
- b.* Fiscal management;
- c.* Personnel policies;
- d.* Medical services;
- e.* Staff training;
- f.* Treatment planning;

- g. Client case records;
- h. Supportive and professional services;
- i. Follow-up services;
- j. Client rights;
- k. Confidentiality of client records;
- l. Discharge planning;
- m. All clinical services, such as placement screening and initial assessment, outpatient services, primary residential treatment, extended residential treatment;
- n. Treatment philosophy;
- o. Objectives;
- p. Table of organization;
- q. The role of the coordinator/director in charge of this service; and
- r. Interrelationship with other service components and providers.

3.21(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 the 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.
- 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.

3.21(8) Personnel. Written personnel policies and procedures shall be developed by all programs.

- a. These policies and procedures shall 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 care;
 - (12) Work performance appraisal;
 - (13) Employee accidents and safety;
 - (14) Arbitration of employee grievances;
 - (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.
- c. There shall be written job descriptions for all positions. Each job description shall identify specifically:
 - (1) Job title;
 - (2) Tasks and responsibilities of the job;
 - (3) The skills, knowledge, training, education and experience required for the job; and
 - (4) Lines of authority.

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 the evaluating of personnel performance on at least an annual basis. This evaluation shall be in writing. 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. Any wages paid to clients engaged in vocational training or work within the program shall be in accord with local, state and federal requirements.

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

- (1) The application for employment;
- (2) Verification of training, experience, and all professional credentials relevant to the position;
- (3) Wage and salary information, including all changes;
- (4) Job performance evaluations;
- (5) Incident reports;
- (6) Disciplinary actions taken; and
- (7) Documentation of review and adherence to confidentiality laws and regulations. This review and agreement shall occur prior to assumption of duties.

i. For each employee working within a juvenile service area, these personnel records shall contain:

(1) Documentation of a criminal records check with the Iowa division of criminal investigation on all new applicants for employment 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 that may exist on the applicant.

(3) Documentation of a check after hiring on probationary or temporary status, but prior to permanently employing the individual with the Iowa central child abuse registry for any substantiated reports of child abuse, neglect, or sexual abuse.

(4) A person who has a record of a criminal conviction or founded child abuse report shall not be employed, unless an evaluation of the crime or founded child abuse has been made by the Department of Human Services which concludes that the crime or founded child abuse does not merit prohibition of employment. If a record of criminal conviction or founded child abuse exists, the person shall be offered the opportunity to complete and submit Form 470-2310, Record Check Evaluation. In its evaluation, the DHS 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.

j. 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.

k. Personnel providing treatment shall be certified through the Iowa board of substance abuse certification, or certified by an international certification and reciprocity consortium member board in the states of Illinois, Minnesota, Nebraska, Missouri, South Dakota, and Wisconsin; or be eligible for certification or have education, training, or experience in the substance abuse field.

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

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

3.21(9) *Child abuse.* Written policies and procedures shall prohibit mistreatment, neglect, or abuse of children and specify reporting and enforcement procedures for the program. Alleged violation 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 shall be in compliance with DHHS, 42 CFR, Part 2, Regulations on Confidentiality of Alcohol and Drug Abuse Client Records. Any employee found to be in violation of Iowa Code chapter 232, division III, part 2, as substantiated by the department of human services' investigation shall be subject to the agency's policies concerning dismissal.

3.21(10) *Client case record maintenance.* There shall be written policies and procedures governing the compilation, storage and dissemination of individual client case records.

a. These policies and procedures shall ensure that:

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

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

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

b. The program shall provide adequate physical facilities for the storage, processing, and handling of client 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 and other individuals specifically authorized by program policy. Records should be kept in proximity to the area in which the client normally receives services.

d. There shall be a written policy governing the disposal and maintenance of client case records. Client case records shall be maintained for not less than five 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 clients 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 shall be in accordance with 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 patient records, and 42 U.S.C. 290ee-3 applicable to drug abuse patient records, and state confidentiality laws and regulations.

g. Confidentiality of alcohol and drug abuse patient records. The confidentiality of alcohol and drug abuse patient records maintained by a program is protected by 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 patient records, and 42 U.S.C. 290ee-3 applicable to drug abuse patient records.

3.21(11) *Placement screening, admission, and assessment.* There shall be clearly stated written criteria for determining the eligibility of individuals for placement and admission.

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 assessment (psychosocial history) shall be an analysis and synthesis of the client's status, and shall address the client'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 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, if any;
- (5) Client's rights and responsibilities; and
- (6) Confidentiality laws, rules and regulations.

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'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 and to the client's family when appropriate. This shall be documented in the client record.

3.21(12) Treatment plans. Based upon the initial assessment, an individualized written treatment plan shall be developed and recorded in the client's case record.

a. A treatment plan shall be developed as soon after the client'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 continued stay reviews.

b. The individualized treatment plan shall minimally contain:

- (1) A clear and concise statement of client's current strengths and needs;
- (2) Clear and concise statements of the short- and long-term goals the client will be attempting to achieve;
- (3) Type and frequency of therapeutic activities in which the client will be participating;
- (4) The staff person(s) to be responsible for the client's treatment;
- (5) The specific criteria to be met for successful completion of treatment; and
- (6) Treatment plans shall be culturally and environmentally specific so as to meet the needs of the client. Treatment plans shall be written in a manner readily understandable to the client, with assistance if necessary.

c. Treatment plans shall be developed in partnership with the client and shall be reviewed by the primary counselor and the client as often as necessary and in accordance with the time frames specified within the continued stay reviews.

d. The reviews shall consist of: a reassessment of the client'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, any changes, as well as the individuals involved in the review shall also be recorded in the continued stay review process.

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

3.21(13) Progress notes. A client's progress and current status in meeting the goals set in the treatment plan shall be recorded in the client's 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, the signature or initials and staff title of the individual rendering the services. All progress notes shall be entered into the client case record in permanent pen, 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'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.

3.21(14) Client case record contents. There shall be a case record for each client 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 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, including all letters and dated notations of telephone conversations relevant to the client'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 sufficiently detailed to identify the types of services the client has received and action taken to address specific problems identified. General terms such as "counseling" or "activities" shall be avoided in describing services; and
- n. Management information system or other appropriate data forms.

3.21(15) Urinalysis. All programs serving clients 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 clients shall be collected under direct supervision and analyzed as indicated by the program.
- 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 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 clients are found to contain substances.

3.21(16) Medical services. The applicant shall have policies and procedures developed in conjunction with a physician to examine and evaluate substance abusers/concerned persons seeking or undergoing treatment or rehabilitation. Individuals who enter an inpatient, residential, halfway house facility, chemotherapy or emergency care facility 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:

- Inpatient and medically monitored residential treatment services (Levels VI & VII) within 24 hours of admission;
- Primary residential treatment and extended residential treatment (Level V) within seven calendar days of admission; and

- Halfway house services (Level II) within 21 calendar days of admission.

A program may accept medical history and physical examination results from referral sources which were conducted no more than 90 days prior to admission. All residential and halfway house residents are required to receive tuberculosis testing within 5 calendar days of admission, and all identified high-risk outpatient clients are required to receive testing within 14 calendar days. On individuals who enter a Level I program or any outpatient program, a medical history shall be obtained upon admission.

3.21(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.

3.21(18) *Medication control.* Policies and procedures shall be developed to ensure that prescription and over-the-counter medical 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—10.16(124) 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 patient/client’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 patient/client’s medication is clearly labeled. There shall be written policies and procedures relative to self-administration of prescription medications by patients/clients and only when:

(1) Medications are prescribed by a physician.

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

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

d. Drugs/medications shall be prescribed by a physician licensed to practice in the state of Iowa or other practitioner authorized to prescribe under Iowa law.

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

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

g. Accountability and control of medications.

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

(2) There shall be specific methods for control and accountability of drug 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. Drug storage shall be maintained in accordance with the security requirements of federal, state and local laws.

(1) All drugs 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 drugs for external use are stored separately from internal and injectable medications.

(4) The medication for each client shall be stored in the original containers.

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

i. Dispensed from a licensed pharmacy. Drugs provided to patients/clients 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. No prescription medications prescribed for one resident may be administered to or allowed in the possession of another resident.

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

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

3.21(19) Management of care. The program shall ensure appropriate level of care utilization by implementing and maintaining the written placement screening, continued stay, and discharge criteria process developed by the department. The programs shall also address underutilization, overutilization, and the effective use of levels of care available.

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

3.21(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 care, pursue opportunities to improve client care, and resolve identified problems. Quality im-

provement efforts shall be facilitywide in scope and include review of clinical, professional, and administrative 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 develop and implement a plan to put into operation outcome measures or performance indicators, as determined by the department.

c. Relevant findings from the quality improvement activities (as defined by program) may be considered as part of the performance evaluations for all professional, clinical, and administrative staff members.

d. 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 care and clinical performance.

e. The program shall document that the quality of client 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, which may include, but not be limited to:

(1) Activities of the governing body;

(2) Activities of the program, program component, modality, or service;

(3) Revisions to written policies and procedures for program and professional services and staff composition.

f. The findings, conclusions, recommendations, actions taken, and results of actions taken shall be documented and reported through processes established by the program.

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

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

i. 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.

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

3.21(21) *Building construction and safety.* All buildings in which clients receive treatment are designed, constructed, equipped, and maintained in a manner that is designed to provide for the physical safety of clients, 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.

3.21(22) *Facility grounds.* All programs shall maintain facility grounds in a manner that is designed to provide safe access to and a safe environment for clients, personnel, and visitors.

a. The program shall have written policies and procedures for the maintenance, supervision, and safe use of all its grounds and equipment, including special activity areas such as swimming pools, tennis courts, and gymnasiums.

b. Safe access and a safe environment shall be maintained during phases of construction or alterations of the grounds.

c. New construction shall provide for safe and convenient use of the grounds by disabled individuals and comply with Iowa Code chapter 104A, federal and local codes.

3.21(23) *General safety.* All programs shall have written policies and procedures to provide a safe environment for clients, personnel, and visitors and to monitor that environment. The written policies and procedures shall include, but not be limited to, the following:

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

b. The promotion and maintenance of an ongoing, facilitywide hazard surveillance program to detect and report all safety hazards related to clients, visitors, and personnel.

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

d. 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 not keep firearms and ammunition on the premises.

(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 children.

3.21(24) *Safety education.* All programs shall have an organized safety education program.

a. The safety education program shall include, but not be limited to, orientation of new employees to general facilitywide safety practices and orientation and continuing education regarding safety practices specific to individual departments or services at least annually.

b. The orientation and in-service education programs shall utilize findings of the quality improvement function and other appropriate standing committees, if applicable.

643—3.22(125) Inpatient, residential and halfway house services safety. Specific safety standards for inpatient, residential and halfway house services.

3.22(1) *Health and fire safety inspections.* Inpatient, residential service 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 Iowa 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.

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.

d. Staff shall respect a client's right to privacy by knocking on the door of a client's room before entering.

3.22(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 care can be continued during a disaster.

a. The emergency preparedness plans shall provide for the effective activation of community resources to prevent or minimize the consequences of a disaster.

b. The emergency preparedness plans shall be pertinent to a variety of disasters and be based on the program's capability and limitations.

c. The emergency preparedness program shall address, but not be limited to, the following:

(1) Staff preparedness, including staff requirements and the designation of roles and functions, particularly in terms of capabilities and limitations;

(2) Client management, including modified schedules, criteria for the cessation of nonessential services and client transfer determinations, particularly in terms of discharge and relocation; and

(3) A fire plan which shall address the use and function of fire alarm and detection systems, containment, and the protection of lives, including transfer to areas of refuge, evacuation plans, and fire extinguishment.

1. The fire plan shall be implemented at least quarterly for each work shift of facility personnel in each client-occupied building.

2. Documentation of the implementation of the plan shall include, at a minimum, problems identified during implementation, corrective actions taken, and staff participation.

d. Facility employees and staff shall be provided with appropriate education and training in elements of the emergency preparedness program and in elements of the fire plan.

e. The emergency preparedness program shall be evaluated annually and is updated as needed.

643—3.23(125) Specific standards for inpatient, residential, and halfway house program per established definitions. An inpatient, residential, and halfway house program shall be designed to provide comprehensive diagnostic, treatment and rehabilitation services on a scheduled or nonscheduled basis in a 24-hour therapeutic setting.

3.23(1) Hours of operation. An inpatient, residential, and halfway house program shall operate no less than seven days per week, for no less than 24 hours a day.

3.23(2) Use of chemical substances. An inpatient, residential, and halfway house program shall have written policies regarding the use of chemical substances in the facility.

3.23(3) Program participation. All residents of the inpatient, residential and halfway house program shall be active participants in the therapeutic program.

3.23(4) Meals. Inpatient and residential programs shall provide a minimum of three meals per day to each client enrolled in the program. Inpatient, residential, and other programs where clients are not present during mealtime, shall make provisions to make available the necessary meals. Menus shall be prepared in consultation with a registered dietitian. If clients are allowed to prepare meals, the program shall document conformity with all commonly accepted policies and procedures of state health regulations and food hygiene.

3.23(5) Consultation with counsel. An inpatient, residential, and halfway house program shall have policies and procedures which will ensure that all clients in a facility have opportunity for and access to consultation with legal counsel at any reasonable time.

3.23(6) 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 justi-

fication for restrictions shall be documented in the client 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 will be conspicuously displayed at the facility and in such a manner to be visible to those entering the facility.

3.23(7) Telephone use. An inpatient, residential, and halfway house program shall have policies and procedures which allow clients 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 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.

3.23(8) 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 in a facility may be intercepted, read, or censored.

3.23(9) Inpatient, residential, and halfway house facility. An inpatient, residential, and halfway house facility shall be safe, clean, well-ventilated, properly heated, in good repair, and free from vermin and rodents to ensure the well-being of residents.

a. Client 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 clients;
- (3) The number of clients in a room shall be appropriate to the goals of the facility and to the ages, developmental levels, and clinical needs of the clients;
- (4) Clients will be allowed to keep and display personal belongings and add personal touches to the decoration of their rooms in accordance with program policy.

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 clients.

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 clients, residents, or visitors occupy at the facility and shall be explained to all inpatient, residential, and halfway house clients 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. Fire and tornado drills shall be conducted randomly during all three work shifts.

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. Smoking will be allowed only in designated areas. 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.

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 inpatient, residential, or halfway house facility shall allow for a full range of social activities from individual to group activities which shall include, but not necessarily be limited to:

- (1) Areas in which a client may be alone when appropriate;
- (2) Areas for private conversations with other clients or family members;
- (3) Appropriate furnishings and equipment which are clean and in good repair shall be available; and
- (4) Dining areas shall be comfortable, attractive, and conducive to pleasant dining.

j. Articles of grooming and personal hygiene that are appropriate to the client's age, developmental level, and clinical state shall be readily available in a space reserved near the client's sleeping area. If clinically indicated as determined by the treatment supervisor, a client'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 the conditions under which the articles may be used; and the clinical rationale for these conditions shall be documented in the client's case record.

k. Housekeeping. If clients 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's orientation program. Staff assistance and equipment shall be provided as needed.

l. Clothing. Clients 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 clients 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 record 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. Clients' need to be outdoors may be met through the use of nearby parks and playgrounds, adjacent countryside, and facility grounds.

3.23(10) 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 confidentiality.

b. Furniture shall be clean and in good repair.

c. 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.

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

3.23(11) Therapeutic environment. All programs shall establish an environment that enhances the positive self-image of clients 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 needs or program goals involve outdoor activities, these activities and programs shall be appropriate to the ages and clinical needs of the client.

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 gain access to the facility for necessary services.

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

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

d. The program may designate and identify with signs specific smoking areas, which shall allow smoking only in such designated areas.

3.23(12) 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 parent(s) or guardian, and the placing agency at the time of admission in compliance with DHHS, 42 CFR, Part 2, Regulations on Confidentiality of Alcohol and Drug Abuse Client Records. This information shall also be available to adults during orientation. Children shall have the opportunity to participate in religious activities and services in accordance with the patient's own faith or that of a minor patient's parent(s) or guardian. The facility shall, when necessary and reasonable, arrange transportation for religious activities. Wherever feasible, children shall be permitted to attend religious activities and services in the community.

3.23(13) Client rights. The program shall maintain written policies and procedures that ensure that the legal and human rights of clients participating in the program shall be observed and protected.

a. There shall be procedures to inform all clients of their legal and human rights at the time of admission into the program or when the client is deemed competent to receive them.

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

c. There shall be written policies and procedures for reviewing and responding to clients' communications, e.g., opinions, recommendations, and client grievances, with a mechanism for redress.

d. There shall be procedures designed to protect the clients' rights and privacy with respect to facility visitors, e.g., educational or other individual or group visitations at the program.

643—3.24(125) Specific standards for inpatient, residential, and halfway house substance abuse program admitting 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.

3.24(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.

3.24(2) Family involvement. There shall be written policies and procedures for family involvement that shall encourage continued involvement of the family.

3.24(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.

3.24(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 disci-

pline 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.

3.24(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 ratio.

b. Comprehensive residential facilities as defined in 441—Chapter 115, shall have at least a one-to-five, staff-to-client 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 for nighttime checks shall be in writing.

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

3.24(6) *Illness, accident, death, or absence from the inpatient, residential, and halfway house program.* The program shall notify the child's parent(s), guardian, and responsible agency of any serious illnesses, incidents involving serious bodily injury, or circumstances causing removal of the child from the facility in compliance with DHHS, 42 CFR, Part 2, Regulations on Confidentiality of Alcohol and Drug Abuse Client Records. In the event of the death of a child, a facility shall notify immediately the physician, the child's parent(s) or guardian, the placing agency, and the appropriate state authority. The agency shall cooperate in arrangements made for examination, autopsy, and burial.

3.24(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.

3.24(8) *Needs of the juvenile.* Program services and rules shall be designed to meet individual needs of the juvenile.

643—3.25 to 3.34 Reserved.

643—3.35(125) Specific standards for methadone treatment centers. All programs which use methadone in the treatment of narcotic addicts shall comply with this rule and to the U.S. Food and Drug Administration's methadone regulations as articulated in 21 CFR, Part 5.1, 291.505, effective March 2, 1989.

3.35(1) *Definitions.*

"Methadone detoxification" means a practice of using methadone as part of a planned course of treatment involving reduction in dosage to the point of abstinence followed by drug-free treatment. A patient/client may be enrolled in methadone detoxification for a maximum of 180 days.

"Methadone maintenance" means a practice of using methadone administered over a period of time to relieve withdrawal symptoms, reduce craving and permit normal functioning so that, in conjunction with rehabilitative services, patients/clients can develop productive lifestyles.

"Methadone program" means a detoxification or maintenance treatment program using methadone and offering services for the rehabilitation of persons dependent on opium, morphine, heroin or any other derivative or synthetic drug of that group.

“Program physician” means any individual licensed under Iowa Code chapter 148, 150, or 150A.

3.35(2) Required approvals. All methadone programs shall be licensed or approved by the commission and shall maintain all other approvals required by the U.S. Food and Drug Administration, Drug Enforcement Administration and the Iowa board of pharmacy examiners in order to provide services.

3.35(3) Central registry system. To prevent simultaneous enrollment of a patient/client in more than one methadone program, all methadone programs shall participate in a central registry as established by the division.

Prior to admission of an applicant to a methadone program, the program shall submit to the registry the name, birth date, date of intended admission, and any other information required for the clearance procedure. No person shall be admitted to a methadone program who is found by the registry to be participating in another such program. All methadone 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 “Confidentiality of Alcohol and Drug Abuse Patient Records” regulations, 42 CFR, Part 2, effective June 9, 1987.

a. Definitions. For purposes of this section:

“Central registry” means the system through which the Iowa department of public health, division of substance abuse and health promotion, obtains patient/client 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.

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

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

(1) The disclosure is made when:

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

(2) The disclosure is limited to:

- Patient/client identifying information; and
- Relevant dates of admission.

(3) The program shall inform the patient/client 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 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 patient/client is enrolled in another program, the registry may disclose:

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

(2) The name, address, and telephone number of the inquiring program to the program in which the patient/client 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.

3.35(4) Admission requirements.

a. Prior to or at the time of admission to a methadone program, the program shall conduct a comprehensive assessment so as to determine appropriateness for admission.

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

c. The program physician shall determine and document in the patient's/client's record that the patient/client 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 patient/client 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 patient's/client's record the criteria used to determine the patient's/client'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 their agreement with the evaluation. The program physician shall make the final determination concerning a patient's/client's physiologic dependence and history of addiction. The program physician also shall sign, date, and record a statement that they have reviewed all the documented evidence to support a one-year history of addiction and the current physiologic dependence and that in their reasonable clinical judgment the patient/client fulfills the requirements for admission to maintenance treatment. Before the program administers any methadone to the patient/client, the program physician shall complete and record the statement documenting addiction and current physiologic dependence.

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

- Prior methadone treatment of six months or more; and
- The program physician shall enter in the patient's/client's record that in the physician's medical judgment methadone treatment is warranted.

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

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

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

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

h. Program staff shall ensure that a patient/client is voluntarily participating in the methadone program and the patient/client shall sign the Consent to Methadone Treatment, Form FDA 2635.

i. Pregnant patients/clients may be admitted to methadone 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 patient's/client's record by the program physician prior to the initial dose of methadone.

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

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

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

3.35(5) Placement, admission and assessment. The program shall have written criteria for considering an individual for placement and admission.

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 patient/client assessment (psychosocial history) shall be an analysis and synthesis of the patient's/client's status, and shall address the patient's/client'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 patient/client 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 to be borne by the patient/client, if any;
- (5) Patient/client rights and responsibilities; and
- (6) Confidentiality laws, rules and regulations.

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 patient's/client'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 patient/client, and to the patient's/client's family when appropriate. This shall be documented in the patient/client 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 prior to the administration of the initial dose of methadone. If the history and current psychological/mental status evaluation is completed by an individual other than the program physician, the program shall document in the patient's/client's case record that this information was reviewed by the program physician prior to the initial dosage of methadone. The medical evaluation shall include but not be limited to:

- (1) A complete medical history;
- (2) An assessment of the patient's/client's current psychological and mental status;
- (3) A physical examination including examination for:
 - Pulmonary, liver, or cardiac abnormalities;
 - Infectious disease; and
 - Dermatologic sequela of addiction.
- (4) Laboratory tests including:
 - Serological test for syphilis; and
 - 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 patient's/client's condition.

3.35(6) Treatment plans. Based upon the initial assessment, an individualized written treatment plan shall be developed and recorded in the patient's/client's case record.

a. An initial treatment plan shall be developed upon intake and shall delineate the patient's/client's immediate needs and actions required to meet these needs. This plan shall be in effect until a comprehensive treatment plan is developed.

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

c. The comprehensive individualized treatment plan shall minimally contain:

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

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

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

(4) The staff person(s) to be responsible for the patient's/client'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 patient/client. Comprehensive treatment plans shall be reviewed by the primary counselor and the patient/client as often as necessary, but no less than every 90 days during the first year and semiannually each subsequent year for methadone 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 patient's/client'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 patient/client. The program shall provide the patient/client 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 patient/client. Treatment plans shall be written in a manner readily understandable to the average person or with assistance available to illiterate, handicapped, or mentally impaired patients/clients.

3.35(7) Progress notes. A patient's/client's progress and current status in meeting the goals set in the treatment plan, as well as efforts by staff members to help the patient/client achieve these stated goals, shall be recorded in the patient's/client'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 patient/client case record in permanent pen, typewriter, or by computer.

b. All entries that involve subjective interpretations of a patient's/client'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 patient/client is receiving services from an outside resource, the program shall attempt to secure a written copy of status reports and other patient/client records from that resource.

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

3.35(8) Rehabilitative services. The program shall provide rehabilitative services that are appropriate for the patient/client based on needs identified during the assessment process. The program

may provide rehabilitative services through collateral agreements with other service providers. A patient/client 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 patient/client continues to be in noncompliance with rehabilitative services, the program shall continue to increase the attendance requirement until daily attendance is obtained or the patient/client complies with rehabilitative services. This requirement shall not preclude the program's ability to determine that discharge of a patient/client is warranted for therapeutic reasons or program needs.

3.35(9) Medication dispensing.

a. The program physician shall determine the patient's/client'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 patient's/client'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 patient's/client's case record that 40 milligrams did not suppress opiate abstinence symptoms. A patient/client 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) The medication shall be administered by a professional authorized by law.

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

c. Administration.

(1) Methadone, including take-home doses, shall be dispensed to patients/clients in oral liquid form and in single doses. Take-home bottles 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 patient/client case records which shall document the amount of methadone dispensed and include the signature of the staff member authorized to dispense the medication. No dose shall be dispensed until the patient/client 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 patient's/client's case record each change in the dosage schedule. Daily dosages of methadone in excess of 100 milligrams shall be dispensed only with the approval of the program physician and shall be documented and justified in the patient's/client's case record.

3.35(10) Take-home medication.

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

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

(2) Regular attendance at the clinic;

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

- (4) Absence of recent criminal activity;
- (5) Stable home environment and social relationships;
- (6) Active employment or participation in school, or similar responsible activities related to employment, education or vocation; and
- (7) Assurance that medication can be safely transported and stored by the patient/client for the patient's/client's own use.

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

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

(1) If the patient/client has been admitted for less than three months, daily clinic dosing is required unless the program is closed on Sunday in which case a one-day dosage may be issued for take-home;

(2) If the patient/client has been admitted for more than three months, but less than two years, the patient/client must receive clinic dosing at least three times per week with no more than two take-home dosages issued at a time; and

(3) If the patient/client has been admitted for more than two years, the patient/client must receive clinic dosing at least two times per week with no more than three take-home dosages issued at a time.

(4) If the patient/client has been admitted for more than three years, the patient/client must receive clinic dosing at least one time per week with no more than six take-home dosages issued at one time.

d. If a patient/client 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 FDA. A copy of the written exception shall be placed in the patient's/client's case record. The division will consider exceptions only in unusual circumstances. When applying for less frequent pickups for patients/clients, approval will be based on considerations in addition to distance when another program exists within 25 miles of the patient's/client's residence.

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

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

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

f. Take-home dosages of methadone in excess of 100 milligrams may be dispensed by the program physician when carefully reviewed and considered and justified in the patient's/client's case record based on the physician's clinical judgment; and when prior approval is obtained from the Food and Drug Administration and the Iowa Department of Public Health, Division of Substance Abuse and Health Promotion.

3.35(11) Urinalysis. Each program shall establish policies and procedures for the collection of urine specimens and utilization of urinalysis results.

a. The program shall ensure that an initial drug-screening test or analysis is completed for each prospective patient/client and that at least eight additional random tests or analyses are performed on each patient/client during the first year in maintenance treatment and that at least quarterly random tests or analyses are performed on each patient/client in maintenance treatment for each subsequent year.

Random tests or analyses shall be performed monthly on each patient/client who receives six days of take-home medication. When a sample is collected from each patient/client for such a test or analysis, it shall be done in a manner that minimizes opportunity for falsification. Each test or analysis shall be analyzed for opiates, methadone, amphetamines, cocaine, and barbiturates. In addition, if any other drug or drugs have been determined by a program to be abused in that program's locality, or as otherwise indicated, each test or analysis must be analyzed for any of those drugs as well. Any laboratory that performs the testing required under this rule shall be in compliance with all applicable federal proficiency testing and licensing standards and all applicable state standards.

b. The program shall ensure that test results are not used as the sole criterion to force a patient/client 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.

3.35(12) Patient/client case records. The program shall have written policies and procedures governing the compilation, storage and dissemination of individual patient/client case records.

a. These policies and procedures shall ensure that:

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

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

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

b. The program shall provide adequate physical facilities for the storage, processing, and handling of patient/client 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 patient/client and other individuals specifically authorized by program policy. Records should be kept in proximity to the area in which the patient/client normally receives services.

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

e. Confidentiality of alcohol and drug abuse patient/client case records. The confidentiality of alcohol and drug abuse patient/client case records maintained by a program is protected by 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 patient/client records, and 42 U.S.C. 290ee-3 applicable to drug abuse patient/client records. The program is precluded from identifying that a patient/client attends the program or disclosing any information identifying a patient/client as an alcohol or drug abuser unless:

(1) The patient/client 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.

3.35(13) Interim maintenance treatment.

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

b. An approved program may provide interim maintenance treatment only if the program also provides comprehensive maintenance treatment to which interim maintenance treatment patients/clients 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 substance abuse and health promotion and:

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

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

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

d. Minimum standards for interim maintenance treatment. The program may admit a patient/client who is eligible for comprehensive maintenance treatment to interim maintenance treatment if the patient/client 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 patient/client during the maximum admission period of 120 days. A program shall establish and follow reasonable criteria for determining the transfer of patients/clients 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 patients/clients. Interim maintenance shall be conducted in accordance with all applicable federal regulations and state rules. The program shall notify the division when a patient/client begins interim treatment; when a patient/client leaves interim treatment, and when a patient/client transfers to comprehensive maintenance treatment. Such notifications shall be documented by the program in the patient's/client's case record. All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions:

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

(2) Take-home medication is not allowed;

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

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

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

3.35(14) Complaints, investigations, suspension and revocation. The rules relating to complaints, investigation, suspension and revocation as outlined in 643 IAC 3.11(125) through 3.17(125) shall apply to methadone programs.

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

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