Chapter 84. End Stage Renal Disease Treatment Facilities

Subchapter A. General Provisions

§8401. Acronyms and Definitions

A. The following words and terms, when used in this Chapter, shall have the following meanings, unless the context clearly indicates otherwise:

Abuse—any act or failure to act that caused or may have caused injury to a patient knowingly, recklessly, or intentionally, including incitement to act. Injury may include, but is not limited to: physical injury, mental disorientation, or emotional harm, whether it is caused by physical action or verbal statement. Patient abuse includes:

a. any sexual activity between facility personnel and a patient;

b. corporal punishment;

c. efforts to intimidate;

d. the use of any form of communication to threaten, curse, shame, or degrade a patient;

e. restraints that do not conform to standard practice;

f. coercive or restrictive actions that are illegal or not justified by the patient's condition, taken in response to the patient's request for discharge or refusal of medication or treatment; and

g. any other act or omission classified as abuse by Louisiana law.

Acronyms (Federal)-

a. CFR—Code of Federal Regulations

b. CMS—Centers for Medicare and Medicaid Services

c. Network (13)—Federal ESRD Quality Assurance Supplier

d. PRO-Peer Review Organization

Adequacy of Dialysis—term describing the outcome of dialysis treatment as measured by clinical laboratory procedures.

Adequate/Sufficient—reasonable, enough: e.g., personnel to meet the needs of the patients.

Advertise—to solicit or induce to purchase the services provided by a facility.

Assessment—gathering of information relative to physiological, behavioral, sociological, spiritual, functional and environmental impairments and strengths of the patient using the skills, education, and experience of one's professional scope of practice.

Board(s)—entities responsible for licensing/certification of specific professions (e.g., nursing, counselors, social workers, physicians, etc.).

Chronic Maintenance Dialysis—dialysis that is regularly furnished to an End Stage Renal Disease (ESRD) patient in a hospital-based, independent (free-standing), or home setting.

Consultation—professional oversight, advice, or services provided under contract.

Consumer/Patient—person assigned or accepted for treatment furnished by a licensed facility as specified.

Delegation of Tasks—assignment of duties by a registered nurse to a licensed practical nurse, or other personnel with respect to their training, ability and experience. The registered nurse cannot delegate complex nursing tasks that have not been approved as appropriate for delegation, responsibility, or tasks requiring judgment.

Department—the Louisiana Department of Health and Hospitals (DHH). The following is a list of pertinent sections of DHH.

a. *Health Standards Section (HSS)*—the section within the Bureau of Health Services Financing that is responsible for conducting surveys, issuing licenses, and serving as the regulatory body for health care facilities in the state.

b. *Office for Public Health (OPH)*Xthe office that is responsible for the development and enforcement of public health regulations and codes.

c. *Division of Architectural Services*—the office that is responsible for the professional review of all facility floor plans and site plans prior to licensing to assure compliance with state laws and codes.

d. *Program Integrity Section*—the section within the Bureau of Health Services Financing that is responsible for investigating alleged fraud and abuse.

Dialysis—a process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

End-Stage Renal Disease (ESRD)—that stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

End-Stage Renal Disease Treatment Facility—a facility that presents to the public as a supplier of chronic dialysis services including, at least, hemodialysis, but may also include peritoneal dialysis, home training, or home support.

Exploitation—any act or process to use (either directly or indirectly) the labor or resources of a patient for monetary or personal benefit, profit, or gain of another individual or organization. Examples of exploitation include:

a. use of a patient's personal resources such as credit cards, medical assistance cards, or insurance cards to bill for inappropriate services; b. use of the patient's food stamps or other income to purchase food or services used primarily by others; and

c. using the patient to solicit money or anything of value from the public.

Facility—a supplier of services, including all employees, consultants, managers, owners, and volunteers as well as the premises and activities.

Medication Administration—the preparation and giving of legally prescribed individual doses of medication to a patient, including the observation and monitoring of the patient's response to the medication.

Medication Dispensing—the compounding, packaging, and giving of legally prescribed multiple doses of medication to a patient.

Neglect—failure to provide adequate health care or failure to provide a safe environment that is free from abuse or danger; failure to maintain adequate numbers of appropriately trained staff; or any other act or omission classified as neglect by Louisiana law.

Office of the State Fire Marshal(OSFM)Xthe office that is responsible for establishing and enforcing the regulations governing building codes, including Life Safety Codes for healthcare facilities.

On Call—immediately available for telephone consultation.

Sexual Exploitation—a pattern, practice, or scheme of conduct that can reasonably be construed as being for the purpose of sexual arousal or gratification or sexual abuse of any person. It may include sexual contact, a request for sexual contact, or a representation that sexual contact or exploitation is consistent with or part of treatment.

Site/Premises—an identifiable location owned, leased, or controlled by a facility where any element of treatment is offered or provided.

Staff—individuals who provide services for the facility in exchange for money or other compensation, including employees, contract providers/suppliers, and consultants.

Standards—policies, procedures, rules, and other guidelines (i.e., standards of current practice) contained in this document for the licensing and operation of end-stage renal disease treatment facilities.

Supervision—occupational oversight, responsibility and control over employees and/or service delivery by critically watching, monitoring, and providing direction.

Unethical Conduct—conduct prohibited by the ethical standards adopted by DHH, state or national professional organizations or by a state licensing agency.

Unprofessional Conduct—any act or omission that violates commonly accepted standards of behavior for individuals or organizations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2117.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:2191 (October 2002).

§8403. Licensing

A. Any facility that presents itself to the public as a supplier of chronic dialysis treatment services and/or dialysis training to individuals diagnosed with end stage renal disease is required to have a valid and current license. The facility shall not provide services without the appropriate license and shall advertise (or otherwise notify the public or other referral entities) only for services that the facility is licensed to provide. Each licensed facility must comply with the minimum requirements in order to remain licensed. In addition, each facility is required to have a copy of the minimum standards on site, and all administrative and professional staff shall be familiar with the minimum standards.

B. In order to be licensed as an ESRD facility in Louisiana the facility must also be in continuous compliance with federal regulatory requirements applicable to ESRD facilities, including but not limited to: 42CFR §405.2135-2140; 42 CFR §405.2150, and §2160-2164.

C. The initial application process assures that the facility is capable of organizing and planning an operation to provide dialysis services as designated on the license. The application packet and procedures may be obtained from DHH/HSS.

D. Renewal. A license must be renewed at least annually.

E. License Types

1. Full License. A full license is issued to agencies that are in compliance with the minimum standards and all other licensing requirements. The license is valid until the date of expiration unless it is revoked or suspended prior to the date of expiration, or the license renewal is denied.

2. Provisional License. A provisional license is issued to facilities that are not in compliance with the minimum standards and whose license will be terminated if systemic changes fail to correct identified problems. Cited deficiencies shall not be detrimental to the health and safety of clients. A provisional license is valid for six months or until a designated termination date.

F. The current license shall be displayed on-site at each facility. Any license issued by DHH supersedes all other licenses and those previously issued licenses are deemed invalid. Any facility displaying and/or using an invalid or altered license will be sanctioned.

G. Notification of Change. Failure to report any of the following changes in writing to HSS within 10 days of the occurrence of the change is considered delinquent and subject to sanction. Written approval of changes by DHH is required for the facility to remain in compliance with licensing standards. An on-site survey, at the discretion of HSS, may be required prior to issuance of a new license.

1. Change of Ownership. A license is non-transferrable. The new owners must apply for a new license

and submit a new application form, copy of the bill of sale, licensing fee, disclosure of ownership form, and information regarding relocation, name change, etc.

2. New Construction. All plans must have prior approval of the OSFM and Division of Architectural Services.

3. Renovations. All plans must have prior approval of the OSFM and Division of Architectural Services, when required.

4. Change of Address. Address changes require the issuance of a replacement license and must be prior authorized. Authorization is based on the submission of requested information to HSS.

5. Change in Services. Providing additional services requires the submission of an application packet appropriate to the new service. Interim approval may be granted based on the review of the submitted documentation. Permanent approval will be granted automatically at the next on-site survey unless the facility is found to be out of compliance. Deleting existing services requires the submission of written notification to HSS.

6. Days of Operation. Written notification to HSS is required in advance of a change in the facility's days of operation.

7. Change in Stations. Facilities wishing to increase or decrease the number of stations shall be required to submit in writing to HSS at least 30 days in advance of the change.

H. If at any time the facility decides to cease operations, the facility shall notify HSS of the date of the cessation of services, the permanent location of the records and surrender the license.

1. All active patients and pertinent information shall be referred/transferred to the nearest appropriate treatment facility.

2. Written notification and the license shall be sent to HSS within five working days.

3. Notice of intent to cease operation shall be published in the local newspaper with the widest circulation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2117.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:2192 (October 2002).

§8405. Fees, Fines, and Assessments

A. All fees must be submitted to DHH in the form of a company or certified check or money order, and made payable to the Department of Health and Hospitals. All fees are non-refundable and non-transferable.

1. The current fee schedule is available upon request.

2. The fee for the initial application and licensing process shall be submitted prior to review and consideration of the licensing application.

3. The annual renewal fee is payable in advance of the issuance of the renewal license.

4. A fee must accompany any request requiring the issuance of a replacement license.

5. A renewal or other fee is considered delinquent after the due date and an additional fee shall be assessed beginning on the day after the date due. No license will be issued until applicable fees are paid.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2117.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:2193 (October 2002).

§8407. Survey

A. All surveys, except the initial licensing survey, shall be unannounced. This survey may be conducted with other agency personnel and/or personnel from other local, state or federal agencies. A survey of all aspects of the facility's operation is required prior to issuing a license.

B. Initial Survey. DHH shall determine through an onsite review if the facility is capable of becoming fully operational. The procedures for the on-site review may be obtained from HSS.

C. Annual Survey. An on-site survey of the facility is performed or an attestation from the facility is received annually to assure continuous adherence to standards.

D. Follow-up Surveys. An on-site visit is performed or documentation is requested for a desk review to ensure that corrective actions have been taken as stated in the plan of corrections and to assure continued compliance between surveys.

E. DHH shall determine the type and extent of investigation to be made in response to complaints in accordance with R.S. 40: 2009.13 et seq.

1. The facility may be required to do an internal investigation and submit a report to HSS.

2. HSS and other federal, state and local agencies may conduct an on-site focused or complete survey as appropriate.

F. Written plans of correction shall be submitted to HSS to describe actions taken by the facility in response to cited violations. The plan must be submitted within 10 days of the date of the receipt of the notice of deficiencies, or the provider may be sanctioned. All components of the corrective action plan must be specific and realistic, including the dates of completion.

1. The correction plan shall include the following components:

a. the actions taken to correct any problems caused by a deficient practice directed to a specific patient;

b. the actions taken to identify other patients who may also have been affected by a deficient practice, and to

assure that corrective action will have a positive impact for all patients;

c. the systemic changes made to ensure that the deficient practice will not recur;

d. a monitoring plan developed to prevent recurrence; and

e. the date(s) when corrective action will be completed.

G. Corrections must be completed within 60 days of the survey unless HSS directs that corrective action be completed in less time due to danger or potential danger to patients or staff.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2117.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:2193 (October 2002), amended LR 30:432 (March 2004).

§8409. Adverse Actions

A. DHH reserves the right to suspend, deny (initial or renewal), or revoke any license at the discretion of the secretary or his/her designee.

B. Provisional License Designation. See §8403.E.2.

C. Denial of Initial Licensing. An initial license request may be denied in accordance with R.S. 40:2117.5(A).

D. A license may be revoked or denied for any of the following nonexclusive reasons. See also R.S. 40:2117.5:

1. cruelty or indifference to the welfare of the patients;

2. misappropriation or conversion of the property of the patients; or

3. violation of any provision of the End Stage Renal Disease Facilities statute R.S.40:2117 et seq. or of the minimum standards, rules, and regulations, as follows:

a. providing services to more stations than authorized by license;

b. repeated failure to adhere to rules and regulations that resulted in the issuance of a provisional license or other sanction;

c. serious violation of these standards or current professional standards of practice;

d. failure to submit corrective action plans for identified violations;

e. reasonable cause to suspect that patient health and/or safety is jeopardized;

f. reliable evidence that the facility has:

i. falsified records;

ii. bribed, solicited or harassed any person to use the services of any particular facility;

g. failure to submit required fees in a timely manner;

h. failure to cooperate with a survey and/or investigation by DHH and/or authorized agencies; or

i. failure to meet operational requirements as defined in §8423.C;

4. permitting, aiding, or abetting the unlawful, illicit, or unauthorized use of drugs or alcohol within the facility;

5. conviction or plea of nolo contendere by the applicant for a felony. If the applicant is an agency, the head of that agency must be free of such conviction. If a subordinate employee is convicted of a felony, the matter must be handled administratively to the satisfaction of HSS;

6. documented information of past or present conduct or practices of the facility that are detrimental to the welfare of the patients.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2117.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:2194 (October 2002).

§8411. Appeals

A. The Health Standards Section shall give at least 30 days notice of the denial of renewal or revocation of license unless it determines that the health and/or safety of patients is in jeopardy. In the event that it is determined that the health and/or safety of patients is in jeopardy, the license may be revoked immediately with appeal rights granted after the facility ceases operation and patients are transferred to another facility. The facility may appeal within 30 days following the revocation.

B. Requests for an administrative reconsideration must be submitted in writing to HSS within 15 days of the receipt of the denial of renewal or revocation notice.

C. Requests for an administrative appeal must be submitted in writing to DHH, Office of the Secretary within 15 days of the receipt of the denial of renewal or revocation notice. Requests for administrative reconsideration do not affect the timeframes for requesting an administrative appeal.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2117.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:2194 (October 2002), amended LR 30:432 (March 2004).

Subchapter B. Facility Operations

§8423. Operational Procedures

A. Each facility shall establish facility-specific, written policy and implement such policy in these areas:

1. procedures to ensure the health, safety, and wellbeing of patients; 2. The procedure to ensure sound patient care in conformity with current standards of practice;

3. protocols to assure uniform and quality assessment, diagnosis, evaluation, and referral to the appropriate level of care;

4. procedures to assure operational capability and compliance;

5. procedures to assure that only qualified personnel are providing care within their respective scope of practice;

6. procedures to assure that patient information is collected, maintained, and stored according to current standards of practice; and

7. standards of conduct for all personnel in the facility.

B. Continuous Quality Program (CQP). The facility shall:

1. have ongoing programs to assure that the overall function of the facility is in compliance with federal, state, and local laws, and is meeting the needs of the citizens of the area as well as attaining the goals and objectives developed from the mission statement established by the facility;

2. focus on improving patient outcomes and patient satisfaction;

3. have objective measures to allow tracking of performance over time to ensure that improvements are sustained;

4. develop and/or adopt quality indicators that are predictive of desired outcomes and can be measured, analyzed and tracked;

5. identify its own measure of performance for the activities that are identified as priorities in quality assessment and performance improvement strategy;

6. immediately correct problems that are identified through its quality assessment and improvement program that actually or potentially affect the health and safety of the patients;

7. develop and implement an annual internal evaluation procedure to collect necessary data for formulation of a plan. In addition, conduct quarterly meetings of a professional staff committee (at least 3 individuals) to select and assess continuous quality activities, to set goals for the quarter, to evaluate the activities of the previous quarter, and to immediately implement any changes that would protect the patients from potential harm or injury;

8. implement a quarterly utilization review of 5 percent of the active patient records (minimum of 10 records) by professional staff;

9. complete an annual documented review of policies, procedures, financial data, patient statistics, and survey data by the governing board/regional administrator; and

10. participate as requested with state and federal initiatives to assure quality care.

C. Operational Requirements. The facility shall:

1. be fully operational for the business of providing dialysis as indicated on the approved original application or notice of change;

2. be in compliance with R.S.40:2007, if the facility is operated within another health care facility;

3. have active patients at the time of any survey after the initial survey;

4. utilize staff to provide services based on the needs of their current patients;

5. have required staff present in the facility at all times whenever patients are undergoing dialysis;

6. develop, implement, and enforce policies and/or procedures that eliminate or greatly reduce the risk of patient care errors; and

7. develop procedures to communicate to staff and to respond immediately to market warnings, alerts, and recalls.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2117.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:2194(October 2002).

§8425. Facility Records

A. Record keeping shall be in accordance with accepted standards to assure the development and implementation of facility specific policies and procedures to adhere to all licensing standards. Specific facility records shall contain:

1. personnel information including:

a. annual health screens in accordance with CDC/OPH guidelines and facility policy;

b. actual hours of work;

c. orientation/training/in-services;

d. disciplinary actions;

e. verification of professional credentials, licensing/certification and renewals; and

f. job descriptions/performance expectations;

2. operational information including:

a. organizational chart;

b. payment methods in accordance with the Wage and Hour Board;

c. proof of general and professional liability insurance in the amount of at least, \$500,000;

d. projected plan of operations based on the findings of the facility specific continuous improvement program; and

e. written agreements with other entities to assure adherence to licensing standards and continuity of care, e.g., transplant services, lab services, waste removal, hospital, etc.; 3. identification of a governing body composed of adults who have legal authority over the policies and activities of the facility as required by 42 CFR §405.2136. All private providers must comply with this requirement.

B. Required Facility Reports. The facility director shall report the following incidents either verbally or by facsimile to HSS within 24 hours of discovery. If reporting is verbal, it will be confirmed in writing within seven calendar days.

1. fire and/or natural disasters;

2. any substantial disruption of program operation;

3. any inappropriate treatment or service resulting in death or serious injury; and

4. serious violations of laws, rules, and professional and ethical codes of conduct, e.g. abuse, neglect, exploitation by facility personnel/volunteers that resulted in harm or the potential for harm to the patient(s). Patient to patient abuse shall also be reported to the agency.

C. The facility shall post a legible copy of the following documents in full view of patients, visitors, and employees:

1. patient bill of rights/responsibilities;

2. escape routes;

3. facility specific rules, responsibilities and grievance procedures;

4. current license and variances; and

5. current licensing survey findings.

D. The facility shall maintain the following operational records:

- 1. equipment maintenance;
- 2. water testing logs;
- 3. reprocessing logs;
- 4. fire and safety logs;
- 5. in-services/attendance records;
- 6. personnel records; and
- 7. disinfection logs.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2117.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:2195 (October 2002).

§8427. Health and Safety

A. Infection Control

1. The facility shall protect staff, patients, and visitors from potential and/or actual harm from infectious disease by utilizing the following policies and procedures.

a. Development and implementation of a universal precautions program that includes education and practice.

b. Development and implementation of a infection control program to report, evaluate, and maintain

documentation pertaining to the spread of infectious disease, including data collection and analysis, corrective actions, and assignment of responsibility to designated medical staff person (including "access infections").

c. The facility shall strictly adhere to all sanitation requirements.

2. The facility shall establish and maintain a clean environment by the implementation of the following housekeeping policies and procedures:

a. supplies and equipment shall be available to staff and/or patients;

b. consistent and constant monitoring and cleaning of all areas of the facility shall be practiced; and

3. the facility may contract for services necessary to maintain a clean environment.

B. Sanitation

1. Food and waste shall be stored, handled, and removed in a way that will not spread disease, cause odors, or provide a breeding place for pests.

2. If there is evidence of pests, the facility shall contract for pest control.

C. Environmental Safety

1. The entire facility (including grounds, buildings, furniture, appliances, and equipment) shall be structurally sound, in good repair, clean, and free from health and safety hazards.

2. The facility shall comply with the Americans with Disabilities Act (ADA).

3. The facility shall prohibit firearms and/or other weapons.

4. Poisonous, toxic and flammable materials shall be properly labeled, stored, and used safely.

5. The facility shall take all possible precautions to protect the staff, patients and visitors from accidents or unnecessary injuries or illnesses.

D. The facility shall respond effectively during a fire or other emergency. Every facility shall:

1. have emergency evacuation procedures that include provisions for the handicapped;

2. hold simulated fire drills on each shift at least quarterly to familiarize facility personnel with the signals and emergency actions required; patients shall not be moved during drills;

3. be able to evacuate the building in a timely manner whenever necessary;

4. conspicuously post exit diagrams throughout the facility;

5. post emergency numbers by all phones; and

6. have adequate first aid supplies that are visible and easy to access whenever necessary.

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E. The facility shall have a written facility specific disaster plan. The staff shall be able to access and implement the plan when required.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2117.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:2196 (October 2002).

§8429. Physical Plant Requirements

A. For licensing, an ESRD treatment facility applicant shall have architectural plans and specifications reviewed by the DHH Division of Engineering and Architectural Services using the current edition of the *American Institute of Architect's Guidelines for Construction for Hospital and Health Care Facilities*.

B. The Office of the State Fire Marshal shall determine fire safety review requirements based upon applicable regulations.

C. Required Inspections

1. The facility shall pass all required inspections and keep a current file of reports and other documentation needed to demonstrate compliance with applicable laws and regulations. The inspections must be signed, dated, and free of any outstanding violations/citations. The following inspections are required:

a. annual fire marshal inspection;

b. annual inspection by the Office of Public Health (local health unit);

c. annual inspection and maintenance of fire extinguishers by personnel licensed or certified to perform those duties; and

d. regular inspections of elevators, if applicable.

2. The following documentation shall be on file in the facility:

a. certificate of occupancy as required by the local authorities;

b. DHH approval of the water supply/system; and

c. documentation that any liquefied petroleum supply has been inspected and approved.

D. Exterior Space Requirements. The facility shall:

1. ensure that all structures on the grounds of the facility that are accessible to patients are maintained in good repair and are free from identified hazards to health or safety;

2. maintain the grounds of the facility in an acceptable manner and ensure that the grounds are free from any hazard to health or safety;

3. store garbage and rubbish securely in noncombustible, covered containers that are emptied on a regular basis; 4. separate trash collection receptacles and incinerators from patient activity areas and locate all containers so that they are not a nuisance to neighbors; and

5. store and dispose of all medical waste in accordance with local, state, and federal guidelines.

E. Interior Space Requirements

1. Bathrooms. Minimum facilities shall include:

a. adequate operational fixtures that meet *Louisiana State Plumbing Code*. All fixtures must be functional and have the appropriate drain and drain trap to prevent sewage gas escape back into the facility;

b. an adequate supply of hot water. Hot water temperature at the point of service to patients shall be between $105^{\circ}F$ and $120^{\circ}F$;

c. toilets with seats;

d. an adequate supply of toilet paper, towels, and soap;

e. doors to allow for individual privacy;

f. external emergency release mechanism;

g. safe and adequate supply of cold running water; and

h. functional toilets, wash basins, and other plumbing or sanitary facilities which shall be maintained in good operating condition and kept free of any materials that might clog or otherwise impair their operation.

2. Administrative and Counseling Space

a. Administrative office(s) for records, secretarial work and bookkeeping shall be separate and secure from patient areas.

b. Space shall be designated to allow for private discussions and counseling sessions.

3. Doors and Windows. Outside doors, windows and other features of the structure necessary for the safety and comfort of patients shall be secured for safety within 24 hours after they are found to be in a state of disrepair. Total repair should be completed as soon as possible.

4. Storage. The facility shall:

a. ensure that there are sufficient and appropriate storage facilities; and

b. secure all potentially harmful materials.

F. Exits

1. Exit doors and routes shall be lighted and unobstructed at all times.

2. There shall be an illuminated "EXIT" sign over each exit. Where the exit is not visible, there shall be an illuminated "EXIT" sign with an arrow pointing the way.

3. Rooms for 50 or more people shall have exit doors that swing out.

4. No door may require a key for emergency exit.

5. In facilities initially licensed after March 20, 2004, at least one window shall be provided in every treatment area.

6. Every building shall have at least two exits that are well separated.

7. Every multiple-story building shall have at least two fire escapes (not ladders) on each story that are well separated. Fire escapes shall:

a. be made of non-combustible material;

b. have sturdy handrails or walls on both sides; and

c. provide a safe route to the ground.

8. Stairs and ramps shall be permanent and have non-slip surfaces.

9. Exit routes higher than 30 inches (such as stairs, ramps, balconies, landings, and porches) shall have full-length side guards.

G. Electrical Systems. All electrical equipment, wiring, switches, sockets and outlets shall be maintained in good order and safe operating condition. All rooms, corridors, stairways and exits within a facility shall be sufficiently illuminated.

1. The facility shall have an illuminating system that provides lighting levels to support tasks performed by staff and the independent functioning of patients without the need for additional lighting.

2. Lighting shall be provided outside the building and in parking lots.

3. Light bulbs shall have shades, wire guards or other shields.

4. Emergency lighting shall illuminate $AEXIT\cong$ routes.

H. Ventilation

1. The facility shall not use open flame heating equipment, floor furnaces, unvented space heaters, or portable heating units.

2. Occupied parts of the building shall be air conditioned and the temperature should remain between 65EF and 85EF.

3. The entire facility shall be adequately ventilated with fresh air. Windows used for ventilation shall be screened.

4. The facility shall take all reasonable precautions to ensure that heating elements, including exposed hot water pipes, are insulated and installed in a manner that ensures the safety of patients and staff.

I. Plumbing. The plumbing systems shall be designed, installed, operated and maintained in a manner that ensures an adequate and safe supply of water for all required facility

operations and to facilitate the complete and safe removal of all storm water and waste water.

J. Finishes and Surfaces

1. Lead-based paint or materials containing asbestos shall not be used.

2. Floor coverings must promote cleanliness, must not present unusual problems for the handicapped and have flame-spread and smoke development ratings appropriate to the use area (e.g. patient's room versus exit corridor).

3. All variances in floors shall be easily identified by markings, etc. to prevent falls.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2117.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:2196 (October 2002), amended LR 30:432 (March 2004).

Subchapter C. Personnel

§8439. General Provisions

A. Administration

1. The administrative staff shall be qualified and adequate to assure adherence to all licensing standards.

2. Qualifications of all facility staff shall meet or exceed those required by federal regulations.

3. Facility compliance with licensing standards shall determine adequacy of available administrative oversight.

4. Facilities shall be organized so that administrative personnel do not perform any clinical duties and/or make clinical decisions, unless the individual is licensed or certified to make clinical decisions.

B. Referrals, Credentials, and Contract Services

1. Facility personnel shall report referral violations of laws, rules, and professional and ethical codes of conduct to HSS and to appropriate licensing boards when applicable. The facility shall maintain records and have written policies governing staff conduct and reporting procedures that comply with this requirement.

2. The facility administrator is responsible for assuring that all credentials are from accredited institutions, are legal, and have been verified to deter the fraudulent use of credentials.

3. The facility must have formal written agreements with outside professionals or other entities retained to provide contract services. Written agreements shall express the responsibilities between the two parties, be signed by both parties and shall either be time-limited or remain in effect until either party terminates the agreement in writing.

C. Staffing Criteria. Each facility shall develop and implement staffing level criteria to assure compliance with all licensing standards and to provide quality care within the established parameters of current standards of practice. 1. Consideration for determination of adequate nursing staffing levels will include:

a. acuity of patients;

b. physical design of facility;

c. equipment design and complexity; and

d. additional pertinent information as needed.

2. A registered nurse or physician shall be present during and after treatment and until the last patient has left the facility.

3. Any experience used to qualify for any position must be counted by using one year of experience equals 12 months of full-time work.

4. A person may hold more than one position within the facility if that person is qualified to function in both capacities, and the required hours for each job are separate and apart for each position.

5. Social work staffing shall be based on the staffing guidelines developed by the Council of Nephrology Social Workers which addresses the following:

a. treatment setting;

b. number of patients seen or anticipated to be seen in a year;

c. their psychological risk (acuity); and

d. the number of mutually agreed upon social work functions, including, but not limited to:

- i. psycho-social evaluations;
- ii. casework counseling;
- iii. group work;
- iv. information and referral;
- v. facilitating community agency referral;
- vi. team care planning and collaboration;
- vii. transfer planning;
- viii. pre-admission planning;
- ix. discharge planning

x. facilitating use of hospital and/or facility services

- xi. patient/family education;
- xii. financial assistance;
- xiii. staff consultation; and
- xiv. community health services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2117.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:2197 (October 2002), amended LR 30:433 (March 2004).

§8441. Training

A. Each employee shall complete appropriate orientation to the facility and to his/her work responsibilities prior to providing direct patient care/contact. The content of the basic orientation provided to all employees at the time of employment/annual review shall include:

1. policies/procedures and objectives of the facility;

- 2. duties and responsibilities of the employee;
- 3. organizational/reporting relationships;
- 4. ethics and confidentiality;
- 5. patient's rights;
- 6. standards of conduct required by the facility;

7. information on the disease process and expected outcomes;

8. emergency procedures including the disaster plan and evacuation procedures;

9. principals and practices of maintaining a clean, healthy and safe environment;

10. specific information as appropriate to the employee's job duties;

11. universal precautions;

12. violent behavior in the workplace;

13. abuse/neglect and exploitation;

14. overview of ESRD licensing standards; and

15. basic emergency care of ill or injured persons until trained personnel can arrive.

B. In-service training is an educational offering that shall assist the direct care/contact workers in providing current treatment modalities, and serve as refresher for subjects covered in orientation. Documentation of attendance for at least three in-services per quarter is required. Additional educational programs are encouraged.

C. Patient Care Technician (PCT) or Dialysis Technician. Training and orientation shall reflect the American Nephrology Nurses Association (ANNA) standards of clinical practice, including but not limited to:

- 1. anatomy and physiology of the renal system;
- 2. principles of water treatment;
- 3. dialyzer reprocessing;
- 4. basics of nutrition in renal failure;

5. understanding of ethical issues impacting on nephrology practice;

6. communication and interpersonal skills;

7. standard precautions, as recommended by the Center for Disease Control;

8. concepts and principles of hemodialysis;

9. arteriovenous puncture for dialysis access techniques;

10. use of heparin in dialysis procedures;

11. use of isotonic saline in dialysis;

12. maintenance of the delivery system:

a. integrity of extra corporeal circuit;

- b. pressure monitor readings;
- c. anticoagulant delivery;
- d. blood flow rate;
- e. alarm limits and/or conditions;

13. observation and reports of complications to the registered nurse;

14. post-treatment access care guidelines;

15. disposal of supplies in compliance with standard precautions; and

16. agency policy regarding the cleaning of equipment and treatment area.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2117.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:2198 (October 2002).

§8443. Personnel Qualifications and Responsibilities

A. Chief Executive Officer or Administrator

1. Qualifications are as cited in the CFR and designated in writing by the governing body.

2. Responsibilities include:

a. enforcement of local, federal and state requirements;

b. overall management of the facility;

c. annual documented review and appropriate actions taken on all policies, procedures, facility rules, goals, grievances, budget, internal and external evaluations (including all survey findings);

d. implementation and enforcement of codes of conduct to ensure professional, ethical and legal operations; and

e. implementation and enforcement of facility practices that ensure that employees have the necessary administrative support to provide therapeutic milieu for patients (including adequate staff, supplies, and other support).

B. Clinical Nursing Supervisor

1. Qualifications

a. currently licensed as a registered nurse in the state of Louisiana;

b. eighteen months or more of clinical experience as a registered nurse; and

c. six months or more of clinical experience which must include: nursing care of a patient with permanent kidney failure or who is undergoing kidney transplantation, including training in and experience with the dialysis process.

2. Responsibilities include:

a. supervising the clinical nursing functions of the facility;

b. performing the liaison duties between others, including facility staff, physicians and patients;

c. supervising the training and performance of the technicians and non-medical staff in order to ensure safe care;

d. functioning as a patient advocate; and

e. accepting responsibility and accountability for the assessment, planning, intervention, teaching, supervision, and evaluation of care to ensure that the patient receives safe and effective dialysis treatment according to the prescribed treatment plan and in accordance with LAC 46:XLVII.3901-3913.

C. Charge Nurse

1. Qualifications

a. currently licensed as registered nurse in the state of Louisiana;

b. six months or more of clinical experience as a registered nurse; and

c. three months or more of the clinical experience must include nursing care of a patient with permanent kidney failure or who is undergoing kidney transplantation, including training in and experience with the dialysis process.

2. Responsibilities include:

a. accepting responsibility and accountability for the assessment, planning, intervention, teaching, supervision, and evaluation of care to ensure that the patient will receive safe and effective dialysis treatment according to the prescribed treatment plan and in accordance with LAC 46:XLVII.3901-3913;

b. performing initial verification and biannual validation of cannulating skills of dialysis technicians and LPN's;

c. providing supervision and assistance as needed to RN's, LPN's and dialysis technicians; and

d. being on site and available in the treatment area to provide patient care during all dialysis treatments, but may leave the immediate area for meals and breaks. However, during these periods of absence the facility must insure that all necessary care can be delivered by the licensed person on duty. D. Registered Nurse

1. Qualifications. Possession of a current valid license or be an RN applicant with a temporary permit to practice in Louisiana.

2. Responsibilities include:

a. accepting responsibility and accountability for the assessment, planning, intervention, teaching, supervision, and evaluation of care to ensure that the patient will receive safe and effective dialysis treatment according to the prescribed treatment plan and in accordance with LAC 46:XLVII.3901-3913;

b. conducting admission nursing assessments with each visit prior to delegating any task other than collection of data (vital signs only);

c. reassessing patients as needed to determine a change in the patient's status or at the patient's request;

d. participating in the team review of a patient's progress;

e. recommending changes in treatment based on the patient's current needs;

f. providing oversight and direction to dialysis technicians and LPN's; and

g. participating in continuous quality improvement activities.

3. Registered nurses may perform the duties of the nursing positions cited above for which they are qualified and designated.

E. Dietitian/Nutritionist

1. Qualifications. Possession of a currently valid license with the Louisiana Board of Dietitians/Nutritionists.

2. Responsibilities include:

a. those duties defined in R.S. 37:3081-3094;

b. providing in-service and staff training, consultation to professionals and paraprofessionals, and direct supervision as needed to improve the overall quality of care being provided;

c. conducting individual and/or group didactic and counseling interaction with patients as needed to achieve compliance with dietary restrictions;

d. documenting direct communication with other dietitians who may be involved in the patient's care, such as dietitians at the nursing home, assisted living, etc;

e. providing continuous learning opportunities for patients and/or care givers, including regionally appropriate recipes when possible; and

f. providing adequate knowledge to staff to reinforce patient education.

F. Social Worker

1. Qualifications. Currently licensed by the Louisiana State Board of Social Work Examiners as a Licensed Clinical Social Worker or certified by the board as either a graduate social worker (GSW) or provisional graduate social worker (provisional GSW).

2. Responsibilities include those duties defined in R.S. 37:2701-2723 including, but not limited to:

a. Assessment—identification and evaluation of an individual's strengths, weaknesses, problems, and needs for the development of the treatment plan.

b. Case Management—function in which services, agencies, resources, or people are brought together within a planned framework of action directed toward the achievement of established goals. It may involve liaison activities and collateral contracts with other facilities.

c. Patient Education—function in which information is provided to individuals and groups concerning the disease process and treatment, positive lifestyle changes, and available services and resources. Facility orientation may be included with information given regarding rules governing patient conduct and infractions that can lead to disciplinary action or discharge from the facility, availability of services, costs, and patient's rights.

d. Counseling (Individual/Group)—services to provide appropriate support to the patient and/or family to assist individuals, families, or groups in achieving objectives through:

i. exploration of a problem and its ramifications;

ii. examination of attitudes and feelings;

iii. consideration of alternative solutions; and

iv. decision making and problem solving.

e. Referral—assisting patient and/or family to optimally utilize the available support systems and community resources.

f. Treatment Planning—function in which all disciplines and the patient:

i. identify and rank problems needing resolution;

ii. establish agreed upon immediate objectives and long-term goals; and

iii. decide on a treatment process, frequency, and the resources to be utilized.

G. Medical Director. Every facility shall have a designated medical director.

1. Qualifications

a. the medical director shall have a current, valid license to practice medicine in Louisiana;

b. be board certified in Internal Medicine or Pediatrics, or board eligible, or board certified in Nephrology; c. have completed an accredited Nephrology training program;

d. have at least 12 months of experience or training in the care of patients at ESRD facilities; and

EXCEPTION: In emergency situations, such as, isolated rural areas, natural disasters, or the death of the qualified director, DHH may approve the interim appointment (for a limited time period) of a licensed physician who does not meet the above criteria.

2. Responsibilities include:

a. providing services as required by the facility to meet the standards;

b. providing oversight to ensure that the facility's policies/procedures and staff conform with the current standards of medical practice;

c. performing liaison duties between others, including facility staff, physicians, and patients;

d. ensuring that each patient at the facility receives medical care and supervision appropriate to his/her needs; and

e. ensuring that each patient is under the care of a physician.

H. Physician Services.

1. Each patient shall be under the care of a physician on the medical staff.

2. At a minimum, each patient receiving dialysis in the facility shall be seen by a physician, physician's assistant, or advanced practice nurse at least once every 30 days; home patients shall be seen at least every three months. There shall be evidence of monthly assessment for new and recurrent problems and review of dialysis adequacy.

3. At a minimum, each patient, whether receiving dialysis in the facility or at home, shall be seen by a physician once every twelve months.

4. If advanced practice nurses or physicians assistants are utilized:

a. there shall be evidence of communication with the treating physician whenever the advanced practice registered nurse or physicians assistant changes treatment orders;

b. the advanced practice nurse or physicians assistant may not replace the physician in participating in patient care planning or in quality management activities; and

c. the treating physician shall be notified and direct the care of patient medical emergencies.

I. Patient Care Technician (PCT) or Dialysis Technician

1. Qualifications include basic general education (high school or equivalent) and dialysis training as specified in §8441.C.

2. Responsibilities include:

a. performing patient care duties only under the direct and on-site supervision of qualified registered nurses;

b. performing only those patient care duties that are approved by facility management and included in the policy and procedure manual; and

c. performing only those patient care duties for which they have been trained and are documented as competent to perform.

J. Reuse Technician

1. Qualifications. Basic general education (high school or equivalent), facility orientation program, and completion of education and training to include the following:

a. health and safety training, including universal precautions;

b. principles of reprocessing, including dangers to the patient;

c. procedures of reprocessing, including precleaning, processing, storage, transporting, and delivery;

d. maintenance and safe use of equipment, supplies, and machines;

e. general principles of hemodialysis and in-depth information on dialyzer processing; and

f. competency certification on a biannual basis by a designated facility employee.

2. Responsibilities. The reuse technician is responsible for the transport, cleaning, processing, and storage of dialyzers to limit the possibility of cross contamination, and to avoid improper care of multiple use dialyzers.

3. Any technician or professional staff who performs reprocessing shall have documented training in the procedure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2117.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:2198 (October 2002), amended LR 30:433 (March 2004).

Subchapter D. Patient Care

§8455. Patient's Rights

A. Facilities are required to develop, post, and implement rules and policies that protect the rights of patients and encourage patient responsibility.

1. The facility shall have an operational/documented patient advice process in place that gives feedback to the administration of the facility.

B. Patient's Rights. Each facility shall develop and implement policies that protect the rights of their patients including, but not limited to, the right to:

1. be fully informed of rights, responsibilities and all rules governing conduct related to patient care and services;

2. be fully educated and supported concerning their illness;

3. adequate, safe and efficient dialysis treatment;

4. protection from unsafe and/or unskilled care by any person associated with the facility;

5. protection from unqualified persons providing services under the auspices of treatment;

6. consideration and respect toward the patient, family and visitors;

7. timely resolution of problems or grievances without threat or fear of staff intimidation or retaliation;

8. protection of personal property approved for use by the facility; and

9. protection from retaliation for the exercise of individual rights.

C. Grievance Procedure. The facility must have a grievance process and must indicate who the patient can contact to express a grievance. Records of all grievances, steps taken to investigate them, and results of interventions must be available to surveyors upon request. It is recommended that the facility appoint a grievance committee with patient representation to resolve major or serious grievances.

D. Abuse, Neglect, and Exploitation

1. The facility is responsible for taking necessary action to protect patients from an employee accused of abuse, neglect, or exploitation, for referring any licensed personnel to their respective professional boards, and/or contacting local authorities for investigation when indicated.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2117.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:2201 (October 2002).

§8457. Treatment Services

A. The facility must provide outpatient dialysis services as well as adequate lab, social, and dietetic services to meet the needs of ESRD patients. The facility must provide one or both of the following services.

1. Hemodialysis—a method of dialysis in which blood from a patient's body is circulated through an external device or machine and then returned to the patient's bloodstream.

2. Peritoneal Dialysis—a procedure that introduces dialysate into the abdominal cavity to remove waste products through the peritoneum (a membrane which surrounds the intestines and other organs in the abdominal cavity).

B. In addition, the following services may be provided by a facility:

1. home training—home visits, teaching, and professional guidance to teach patients to provide self-dialysis;

2. home support—provision of professional support to assist the patient who is performing self-dialysis.

C. Dialyzer Reprocessing. Reuse shall meet the requirements of 42 CFR.§405.2150. Additionally, the facility shall:

1. develop, implement, and enforce procedures that eliminate or reduce the risk of patient care errors including, but not limited to, a patient receiving another patient's dialyzer, or a dialyzer that has failed performance checks;

2. develop procedures to communicate with staff and to respond immediately to market warnings, alerts, and recalls;

3. develop and utilize education programs that meet the needs of the patient and/or family members to make informed reuse decisions; and

4. be responsible for all facets of reprocessing, even if the facility participates in a centralized reprocessing program.

D. Water treatment shall be in accordance with the *American National Standard, Hemodialysis Systems* published by the Association for the Advancement of Medical Instrumentation (AAMI Standards) and adopted by reference 42 CFR. §405.2140.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2117.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:2201 (October 2002), amended LR 30:433 (March 2004).

§8459. Treatment Requirements

A. Admission

1. Each facility shall develop and implement written criteria to apply when any patient is referred for dialysis treatment or seeks admission, to include:

a. payment guidelines, and alternate resources;

b. exceptions to apply when the patient would have to travel great distances, or suffer undue hardship to be treated at another facility; and

c. consideration of the patient's health and welfare.

2. Each facility shall develop a process that includes:

a. perpetual logging of applicants to assure that all patients are treated equally and offered equal access;

b. referral to appropriate facilities or outside resources;

c. written contracts with those patients who have a history of problems at other facilities, such as disruptive, threatening and abusive behavior to staff or other patients; and

d. professional interaction with other facilities when a patient has financial or behavior problems that cannot be resolved.

B. Patient CareXMiscellaneous

1. Patients must be informed whenever there is an error or incident that exposes them to an infectious illness or the potential for death or serious illness.

2. Facility staff should inform patients of current changes in the dialysis field when those changes could positively or negatively affect the patient.

C. Discharge/Transfer

1. Each facility shall develop and implement written criteria to apply when a patient is discharged without consent to include:

a. reason for discharge (such as, non-compliance or illegal behavior);

b. progressive procedures to assist the patient in making improvements;

c. assistance to aid the patient in finding a new facility; and

e. evaluation of each situation to improve outcomes.

2. A written, patient specific discharge process plan shall be accessible that provides reasonable protection and continuity of services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2117.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:2201 (October 2002), amended LR 30:434 (March 2004).

§8461. Patient Records.

A. The facility is required to maintain a clinical record according to current professional standards for each patient.

1. This record shall:

a. contain all pertinent past and current medical, psychological, social and other therapeutic information, including the treatment plan;

b. be protected from unauthorized persons, loss, and destruction; and

c. be a central location for all pertinent patient information and be easily accessible to staff providing care.

2. Patient records can be copied and/or transferred from one facility to another provided that the patient signs the authorization for transfer of the records and provided that confidentiality of information is strictly enforced.

3. Patient records shall be maintained at the facility where the patient is currently active and for six months after discharge. Records may then be transferred to a centralized location for maintenance in accordance with standard practice and state and federal laws.

4. Confidentiality. Records shall:

a. be inaccessible to anyone not trained in confidentiality, unless they are granted access by legal authority such as surveyors, investigators, etc.; and

b. not be shared with any other entity unless approved in writing by the patient, except in medical emergencies.

5. Record Keeping Responsibility. A person who meets or exceeds the federal requirements, shall be designated as responsible for the patient records.

6. Contents. Patient records shall accurately document all treatment provided and the patient's response in accordance with professional standards of practice. The minimum requirements are as follows:

a. admission and referral information, including the plan/prescription for treatment;

b. patient information/data - name, race, sex, birth date, address, telephone number, social security number, school/employer, and next of kin/emergency contact;

c. medical limitations, such as major illnesses and allergies;

d. physician's orders;

e. psycho-social history/evaluation; and

treatment plan. The plan is a written list of the f. problems and needs based on admission patient's information and updated as indicated by progress or lack of progress. Additionally, the plan shall:

> i. contain long and short term goals;

be reviewed and revised as required, or more ii. frequently as indicated by patient needs;

iii. contain patient-specific, measurable goals that are clearly stated in behavioral terms;

iv. contain realistic and specific expected achievement dates:

indicate how the facility will provide strategies/activities to help the patient achieve the goals;

vi. be followed consistently by all staff members; and

contain complete, pertinent information related vii. to the mental, physical, and social needs of the patient.

g. diagnostic laboratory and other pertinent information, when indicated;

h. progress notes by all disciplines; and

i. other pertinent information related to the individual patient as appropriate.

7. Computer data storage of pertinent medical information must:

a. meet the above criteria;

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b. be easily retrievable and accessible when the patient is receiving dialysis; and

c. be utilized by care givers during dialysis treatment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and R.S. 40:2117.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:2202 (October 2002).

Chapter 85. Intermediate Care Facilities for Persons with Developmental Disabilities

Subchapter A. General Provisions

§8501. Introduction

A. These rules and regulations contain the minimum licensure standards for intermediate care facilities for persons with developmental disabilities (ICF/DD), pursuant to R.S. 40:2180 et seq.

B. Standards are established to ensure minimum compliance under the law, equity among those served, provision of authorized services, and proper disbursement. It is the ICF/DD facility's responsibility to keep these standards current. The standards are the basis for surveys by the state agency, and are necessary for the ICF/DD to remain in compliance with state regulations for licensure.

C. Monitoring of an ICF/DD's compliance with state regulations is the responsibility of Department of Health and Hospitals, Health Standards Section (HSS).

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2180-2180.5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 38:3181 (December 2012).

§8503. Definitions

Administrator—the person appointed by the governing body who is responsible for the day to day functions of the ICF/DD. The administrator can also be called a chief executive officer (CEO).

Bedroom Space—a distinct area used as a sleeping area.

Building Systems-plumbing, mechanical and electrical systems necessary for the complete operations of a facility.

Curator—a person appointed by the court when an individual is interdicted to act as guardian with either limited or full powers over the individual's estate and/or person, depending on the needs of the individual interdicted.

Department—the Louisiana Department of Health and Hospitals (DHH).

Developmental Disabilities (DD)—severe, chronic disabilities which are attributable to mental retardation, cerebral palsy, autism, epilepsy, or any other condition, other than mental illness, found to be closely related to mental

retardation. This condition results in an impairment of general intellectual functioning or adaptive behavior similar to that of mental retardation, and requires treatment or services similar to those required for MR/DD, are manifested before the person reaches age 22 and are likely to continue indefinitely.

Discipline—training that is expected to produce a specified character or pattern of behavior, and especially is expected to produce moral or mental improvement.

Discipline—a field of study, a branch of instruction or learning, or a branch of knowledge or teaching.

Direct Service Management—the act of controlling the various aspects of ICF/DD involving direct services to individuals in order to ensure effective care and treatment.

Direct Service Worker-an employee of an ICF/DD who works directly with individuals as a major function of his/her job.

Existing Licensed Facility—a structure which has been licensed by the department and has received occupancy approval from the local/parish authorities or occupancy approval from Louisiana State Facility Planning and Control and the Office of the State Fire Marshal prior to the effective date of promulgation of these provisions as a final Rule.

Family—the natural or adoptive father, mother, brother, and sister, but may be interpreted broadly to include any person, whether related to the individual by blood or not, who resides in the individual's home and takes part in the individual's family life.

Governing Body—a person or persons with the ultimate responsibility for conducting the affairs of the ICF/DD. The governing body is responsible for appointing an administrator of the ICF/DD.

Intermediate Care Facility for Persons with Developmental Disabilities (ICF/DD)—any 24-hour residential facility, whether public or private, that provides services to individuals that meet the criteria to reside in that facility.

Individual—a person who receives services from an ICF/DD.

Legally Responsible Person—as appropriate, the parent(s) or tutor of a minor or the curator of an interdicted individual.

License—a written certification, whether provisional or regular, of an ICF/DD's authorization to operate under state law.

Living Units—an integral living space utilized by a particular group of individuals who reside in that space.

Major Renovation—any repair or replacement of building materials or equipment which does not meet the definition of *minor alteration*.

Minor Alteration—repair or replacement of building materials and equipment with materials and equipment of a similar type that does not diminish the level of construction