

§ 558.405 Standards Specific to Agencies Licensed to Provide Home Dialysis Services

(a) License designation. An agency may not provide peritoneal dialysis or hemodialysis services in a client's residence, independent living environment, or other appropriate location unless the agency holds a license to provide licensed home health or licensed and certified home health services and designated to provide home dialysis services. In order to receive a home dialysis designation, the agency must meet the licensing standards specified in this section and the standards for home health services in accordance with Subchapter C of this chapter (relating to Minimum Standards for All Home and Community Support Services Agencies) and § 558.401 of this subchapter (relating to Standards Specific to Licensed Home Health Services), except for § 558.401(b)(2)(A) and (B) of this subchapter. If there is a conflict between the standards specified in this section and those specified in Subchapter C of this chapter and § 558.401 of this subchapter, the standards specified in this section will apply to the home dialysis services.

(b) Governing body. An agency must have a governing body. The governing body must appoint a medical director and the physicians who are on the agency's medical staff. The governing body must annually approve the medical staff policies and procedures. The governing body on a biannual basis must review and consider for approval continuing privileges of the agency's medical staff. The minutes from the governing body of the agency must be on file in the agency office.

(c) Qualifications and responsibilities of the medical director.

(1) Qualifications. The medical director must be a physician licensed in the State of Texas who:

(A) is eligible for certification or is certified in nephrology or pediatric nephrology by a professional board; or

(B) during the five-year period prior to September 1, 1996, served at least 12 months as director of a dialysis facility or program.

(2) Responsibilities. The medical director must:

(A) participate in the selection of a suitable treatment modality for all clients;

(B) assure adequate training of nurses in dialysis techniques;

(C) assure adequate monitoring of the client and the dialysis process; and

(D) assure the development and availability of a client care policy and procedures manual and its implementation.

(d) Personnel files. An agency must have individual personnel files on all physicians, including the medical director. The file must include the following:

(1) a curriculum vitae which documents undergraduate, medical school, and all pertinent post graduate training; and

(2) evidence of current licensure, and evidence of current United States Drug Enforcement

Administration certification, Texas Department of Public Safety registration, and the board eligibility or certification, or the experience or training described in subsection (c)(1) of this section.

(e) Provision of services. An agency that provides home staff-assisted dialysis must, at a minimum, provide nursing services, nutritional counseling, and medical social service. These services must be provided as necessary and as appropriate at the client's home, by telephone, or by a client's visit to a licensed ESRD facility in accordance with this subsection. The use of dialysis technicians in home dialysis is prohibited.

(1) Nursing services.

(A) An RN, licensed by the State of Texas, who has at least 18 months experience in hemodialysis obtained within the last 24 months and has successfully completed the orientation and skills education described in subsection (f) of this section, must be available whenever dialysis treatments are in progress in a client's home. The agency administrator must designate a qualified alternate to this RN.

(B) Dialysis services must be supervised by an RN who meets the qualifications for a supervising nurse as set out in § 558.244(c)(2) of this chapter (relating to Administrator Qualifications and Conditions and Supervising Nurse Qualifications).

(C) Dialysis services must be provided by a qualified licensed nurse who:

(i) is licensed as an RN by the State of Texas;

(ii) has at least 18 months experience in hemodialysis obtained within the last 24 months; and

(iii) has successfully completed the orientation and skills education described in subsection (f) of this section.

(2) Nutritional counseling. A dietitian who meets the qualifications of this paragraph must be employed by or under contract with the agency to provide services. A qualified dietitian must meet the definition of dietitian in § 558.2 of this chapter (relating to Definitions) and have at least one year of experience in clinical nutrition after obtaining eligibility for registration by the American Dietetic Association, Commission on Dietetic Registration.

(3) Medical social services. A social worker who meets the qualifications established in this paragraph must be employed by or be under contract with the agency to provide services. A qualified social worker is a person who:

(A) is currently licensed under the laws of the State of Texas as a social worker and has a master's degree in social work from a graduate school of social work accredited by the Council on Social Work Education; or

(B) has served for at least two years as a social worker, one year of which was in a dialysis facility or program prior to September 1, 1976, and has established a consultative relationship with a licensed master social worker.

(f) Orientation, skills education, and evaluation.

(1) All personnel providing dialysis in the home must receive orientation and skills education and demonstrate knowledge of the following:

(A) anatomy and physiology of the normal kidney;

(B) fluid, electrolyte, and acid-base balance;

(C) pathophysiology of renal disease;

- (D) acceptable laboratory values for the client with renal disease;
 - (E) theoretical aspects of dialysis;
 - (F) vascular access and maintenance of blood flow;
 - (G) technical aspects of dialysis;
 - (H) peritoneal dialysis catheter, testing for peritoneal membrane equilibration, and peritoneal dialysis adequacy clearance, if applicable;
 - (I) the monitoring of clients during treatment, beginning with treatment initiation through termination;
 - (J) the recognition of dialysis complications, emergency conditions, and institution of the appropriate corrective action. This includes training agency personnel in emergency procedures and how to use emergency equipment;
 - (K) psychological, social, financial, and physical complications of chronic dialysis;
 - (L) care of the client with chronic renal failure;
 - (M) dietary modifications and medications for the uremic client;
 - (N) alternative forms of treatment for ESRD;
 - (O) the role of renal health team members (physician, nurse, social worker, and dietitian);
 - (P) performance of laboratory tests (hematocrit and blood glucose);
 - (Q) the theory of blood products and blood administration; and
 - (R) water treatment to include:
 - (i) standards for treatment of water used for dialysis as described in §3.2.1 (Hemodialysis Systems) and §3.2.2 (Maximum Level of Chemical Contaminants) of the American National Standard, Hemodialysis Systems, March 1992 Edition, published by the Association for the Advancement of Medical Instrumentation (AAMI), 3330 Washington Boulevard, Suite 500, Arlington, Virginia 22201. Copies of the standards are indexed and filed in the Texas Health and Human Services Commission, 701 W. 51st Street, Austin, Texas 78751, and are available for public inspection during regular working hours;
 - (ii) systems and devices;
 - (iii) monitoring; and
 - (iv) risks to clients of unsafe water.
- (2) The requirements for the orientation and skills education period for licensed nurses are as follows.
- (A) The agency must develop an 80-hour written orientation program that includes classroom theory and direct observation of the licensed nurse performing procedures on a client in the home.
 - (i) The orientation program must be provided by an RN qualified under subsection (e)(1) of this section to supervise the provision of dialysis services by a licensed nurse.
 - (ii) The licensed nurse must pass a written skills examination or competency evaluation at the conclusion of the orientation program and prior to the time the licensed nurse delivers independent client care.
 - (B) The licensed nurse must complete the required classroom component as described in paragraph (1)(A) - (E), (K) - (O), (Q) and (R) of this subsection and satisfactorily demonstrate the skills described in paragraph (1)(F) - (J) and (P) of this subsection. The orientation program may be waived by successful completion of the written examination as

described in subparagraph (A)(ii) of this paragraph.

(C) The supervising nurse or qualified designee must complete an orientation competency skills checklist for each licensed nurse to reflect the progression of learned skills, as described in subsection (f)(1) of this section.

(D) Prior to the delivery of independent client care, the supervising nurse or qualified designee must directly supervise the licensed nurse for a minimum of three dialysis treatments and ensure satisfactory performance. Dependent upon the trainee's experience and accomplishments on the skills checklist, additional supervised dialysis treatments may be required.

(E) Continuing education for employees must be provided quarterly.

(F) Performance evaluations must be done annually.

(G) The supervising nurse or qualified designee must provide direct supervision to the licensed nurse providing dialysis services monthly, or more often if necessary. Direct supervision means that the supervising nurse is on the premises but not necessarily immediately present where dialysis services are being provided.

(g) Hospital transfer procedure. An agency must establish an effective procedure for the immediate transfer to a local Medicare-certified hospital for clients requiring emergency medical care. The agency must have a written transfer agreement with such a hospital, or all physician members of the agency's medical staff must have admitting privileges at such a hospital.

(h) Backup dialysis services. An agency that supplies home staff-assisted dialysis must have an agreement with a licensed ESRD facility to provide backup outpatient dialysis services.

(i) Coordination of medical and other information. An agency must provide for the exchange of medical and other information necessary or useful in the care and treatment of clients transferred between treating facilities. This provision must also include the transfer of the client care plan, hepatitis B status, and long-term program.

(j) Transplant recipient registry program. An agency must ensure that the names of clients awaiting cadaveric donor transplantation are entered in a recipient registry program.

(k) Testing for hepatitis B. An agency must conduct routine testing of home dialysis clients and agency employees to ensure detection of hepatitis B in employees and clients.

(1) An agency must offer hepatitis B vaccination to previously unvaccinated, susceptible new staff members in accordance with 29 CFR § 1910.1030(f)(1) - (2) (Bloodborne Pathogens).

(A) Staff vaccination records must be maintained in each staff member's personnel file.

(B) New staff members providing home dialysis care must be screened for hepatitis B surface antigen (HBsAg) and the results reviewed prior to the staff providing client care, unless the new staff member provides the agency documentation of positive serologic response to hepatitis B vaccine.

(C) An agency must establish, implement, and enforce a policy for repeated serologic screening of staff. The repeated serologic screening must be based on each staff member's HBsAg/antibody to HBsAg (anti-HBs) and must be congruent with Appendices i and ii of the National Surveillance of Dialysis Associated Disease in the United States, 1993, published by the United States Department of Health and Human Services (USDHHS).

(2) With the advice and consent of a client's nephrologist or attending physician, an agency must make the hepatitis B vaccine available to a client who is susceptible to hepatitis B, provided that the client has coverage or is willing to pay for vaccination.

(A) An agency must make available to clients literature describing the risks and benefits of the hepatitis B vaccination.

(B) Candidates for home dialysis must be screened for HBsAg within one month before or at the time of admission to the agency.

(C) Repeated serologic screening must be based on the antigen or antibody status of the client.

(D) Monthly screening for HBsAg is required for clients whose previous test results are negative for HBsAg.

(E) Screening of HbsAg-positive or anti-HbsAg-positive clients may be performed on a less frequent basis, provided that the agency's policy on this subject remains congruent with Appendices i and ii of the National Surveillance of Dialysis Associated Diseases in the United States, 1993, published by the USDHHS.

(l) CPR certification. All direct client care employees must have current CPR certification.

(m) Initial admission assessment. Assessment of the client's residence must be made to ensure a safe physical environment for the performance of dialysis. The initial admission assessment must be performed by a qualified RN who meets the qualifications under subsection (e)(1)(A) of this section.

(n) Client long-term program. The agency must develop a long-term program for each client admitted to home dialysis. Criteria must be defined in writing and must provide guidance to the agency in the selection of clients suitable for home staff-assisted dialysis and in noting changes in a client's condition that would require discharge from the program. For the purposes of this subsection, Long-term program means the written documentation of the selection of a suitable treatment modality and dialysis setting, which has been selected by the client and the interdisciplinary team.

(o) Client history and physical. The agency must ensure that the history and physical is conducted upon the client's admission, or no more than six months prior to the date of admission, then annually after the date of admission.

(p) Physician orders. If home staff-assisted dialysis is selected, the physician must prepare orders outlining specifics of prescribed treatment.

(1) If these physician's orders are received verbally, they must be confirmed in writing within a reasonable time frame. An agency must adopt and enforce a policy on the time frame for the countersignature of a physician's verbal orders. Medical orders for home staff-assisted dialysis must be revised as necessary but reviewed and updated at least every six months.

(2) The initial orders for home staff-assisted dialysis must be received prior to the first treatment and must cover all pertinent diagnoses, including mental status, prognosis, functional limitations, activities permitted, nutritional requirements, medications and treatments, and any safety measures to protect against injury. Orders for home staff-assisted dialysis must include frequency and length of treatment, target weight, type of dialyzer, dialysate, dialysate flow rate, heparin dosage, and blood flow rate, and must

specify the level of preparation required for the caregiver, such as an LVN or RN.

(q) Client care plan. The client care plan must be developed after consultation with the client and the client's family by the interdisciplinary team. The interdisciplinary team must include the physician, the RN, the dietitian, and the qualified social worker responsible for planning the care delivered to the home staff-assisted dialysis patient.

(1) The initial client care plan must be completed by the interdisciplinary team within 10 calendar days after the first home dialysis treatment.

(2) The client care plan must implement the medical orders and must include services to be rendered, such as the identification of problems, methods of intervention, and the assignment of health care personnel.

(3) The client care plan must be in writing, be personalized for the individual, and reflect the ongoing medical, psychological, social, nutritional, and functional needs of the client, including treatment goals.

(4) The client care plan must include written evidence of coordination with other service providers, such as dialysis facilities or transportation providers, as needed to assure the provision of safe care.

(5) The client care plan must include written evidence of the client's or client's legal representative's input and participation, unless they refuse to participate. At a minimum, the client care plan must demonstrate that the content was shared with the client or the client's legal representative.

(6) For non-stabilized clients, where there is a change in modality, unacceptable laboratory work, uncontrolled weight changes, infections, or a change in family status, the client care plan must be reviewed at least monthly by the interdisciplinary team. Evidence of the review of the client care plan with the client and the interdisciplinary team to evaluate the client's progress or lack of progress toward the goals of the care plan, and interventions taken when progress toward stabilization or the goals are not achieved, must be documented and included in the client record.

(7) For a stable client, the client care plan must be reviewed and updated as indicated by any change in the client's medical, nutritional, or psychosocial condition or at least every six months. The long-term program must be revised as needed and reviewed annually.

Evidence of the review of the client care plan with the client and the interdisciplinary team to evaluate the client's progress or lack of progress toward the goals of the care plan, and interventions taken when the goals are not achieved, must be documented and included in the client record.

(r) Medication administration. Medications must be administered only by licensed personnel.

(s) Client records. In addition to the applicable information described in § 558.301(a)(9) of this chapter (relating to Client Records), records of home staff assisted dialysis clients must include the following:

(1) a medical history and physical;

(2) clinical progress notes by the physician, qualified licensed nurse, qualified dietitian, and qualified social worker;

(3) dialysis treatment records;

- (4) laboratory reports;
 - (5) a client care plan;
 - (6) a long-term program; and
 - (7) documentation of supervisory visits.
- (t) Water treatment.

(1) Water used for dialysis purposes must be analyzed for chemical contaminants every six months. Additional chemical analysis must be conducted if test results exceed the maximum levels of chemical contaminants listed in §3.2.2 (Maximum Level of Chemical Contaminants) of the American National Standards for Hemodialysis Systems, March 1992 Edition, published by the AAMI. Copies of the standards are indexed and filed in the Texas Health and Human Services Commission, 701 W. 51st Street, Austin, Texas 78751, and are available for public inspection during regular working hours.

(2) Water used for dialysis must be treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques.

(3) Water used to prepare dialysate must meet the requirements set forth in §3.2.1 (Hemodialysis Systems) and §3.2.2 (Maximum Level of Chemical Contaminants), March 1992 Edition, published by the AAMI. Copies of the standards are indexed and filed in the Texas Health and Human Services Commission 701 W. 51st Street, Austin, Texas 78751, and are available for public inspection during regular working hours.

(4) Records of test results and equipment maintenance must be maintained at the agency.

(u) Equipment testing. An agency must adopt and enforce a policy to describe how the nurse will check the machine for conductivity, temperature, and pH prior to treatment, and describe the equipment required for these tests. The equipment must be available for use prior to each treatment. This policy must reflect current standards.

(v) Preventive maintenance for equipment. An agency must develop and enforce a written preventive maintenance program to ensure client care related equipment receives electrical safety inspections, if appropriate, and maintenance at least annually or more frequently if recommended by the manufacturer. The preventive maintenance may be provided by agency or contract staff qualified by training or experience in the maintenance of dialysis equipment.

(1) All equipment used by a client in home dialysis must be maintained free of defects, which could be a potential hazard to clients, the client's family, or agency personnel.

(A) Agency staff must be able to identify malfunctioning equipment and report such equipment to the appropriate agency staff. Malfunctioning equipment must be immediately removed from use.

(B) Written evidence of all preventive maintenance and equipment repairs must be maintained.

(C) After repairs or alterations are made to any equipment, the equipment must be thoroughly tested for proper operation before returning to service.

(D) An agency must comply with the federal Food, Drug, and Cosmetic Act, 21 United States Code (USC) §360i(b), concerning reporting when a medical device, as defined in 21 USC § 321(h), has or may have caused or contributed to the injury or death of an agency client.

(2) In the event that the water used for dialysis purposes or home dialysis equipment is

found not to meet safe operating parameters, and corrections cannot be effected to ensure safe care promptly, the client must be transferred to a licensed hospital (if inpatient care is required) or licensed ESRD facility until such time as the water or equipment is found to be operating within safe parameters.

(w) Reuse or reprocessing of medical devices. Reuse or reprocessing of disposable medical devices, including but not limited to, dialyzers, end-caps, and blood lines must be in accordance with this subsection.

(1) An agency's reuse practice must comply with the American National Standard, Reuse of Hemodialyzers, 1993 Edition, published by the AAMI. An agency must adopt and enforce a policy for dialyzer reuse criteria (including any agency-set number of reuses allowed) which is included in client education materials.

(2) A transducer protector must be replaced when wetted during a dialysis treatment and must be used for one treatment only.

(3) Arterial lines may be reused only when the arterial lines are labeled to allow for reuse by the manufacturer and the manufacturer-established protocols for the specific line have been approved by the United States Food and Drug Administration.

(4) An agency must consider and address the health and safety of clients sensitive to disinfectant solution residuals.

(5) An agency must provide each client and the client's family or legal representative with information regarding the reuse practices of the agency, the opportunity to tour the reuse facility used by the agency, and the opportunity to have questions answered.

(6) An agency practicing reuse of dialyzers must:

(A) ensure that dialyzers are reprocessed via automated reprocessing equipment in a licensed ESRD facility or a centralized reprocessing facility;

(B) maintain responsibility and accountability for the entire reuse process;

(C) adopt and enforce policies to ensure that the transfer and transport of used and reprocessed dialyzers to and from the client's home does not increase contamination of the dialyzers, staff, or the environment; and

(D) ensure that HHSC staff has access to the reprocessing facility as part of an agency inspection.

(x) Laboratory services. Provision of laboratory services must be as follows.

(1) All laboratory services ordered for the client by a physician must be performed by a laboratory which meets the applicable requirements of 42 United States Code (USC) §263a, concerning certification and certificates of waiver of a clinical laboratory (CLIA 1988) and in accordance with a written arrangement or agreement with the agency. CLIA 1988 applies to all agencies with laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(2) Copies of all laboratory reports must be maintained in the client's medical record.

(3) Hematocrit and blood glucose tests may be performed at the client's home in accordance with § 558.284 of this chapter (relating to Laboratory Services). Results of these tests must be recorded in the client's medical record and signed by the qualified licensed nurse providing the treatment. Maintenance, calibration, and quality control studies must be

performed according to the equipment manufacturer's suggestions, and the results must be maintained at the agency.

(4) Blood and blood products must only be administered to dialysis clients in their homes by a licensed nurse or physician.

(y) Home dialysis supplies. Supplies for home dialysis must meet the following requirements.

(1) All drugs, biologicals, and legend medical devices must be obtained for each client pursuant to a physician's prescription in accordance with applicable rules of the Texas State Board of Pharmacy.

(2) In conjunction with the client's attending physician, the agency must ensure that there are sufficient supplies maintained in the client's home to perform the scheduled dialysis treatments and to provide a reasonable number of backup items for replacements, if needed, due to breakage, contamination, or defective products. All dialysis supplies, including medications, must be delivered directly to the client's home by a vendor of such products. However, agency personnel may transport prescription items from a vendor's place of business to the client's home for the client's convenience, so long as the item is properly labeled with the client's name and direction for use. Agency personnel may transport medical devices for reuse.

(z) Emergency procedures. The agency must adopt and enforce policies and procedures for medical emergencies and emergencies resulting from a disaster.

(1) Procedures must be individualized for each client to include the appropriate evacuation from the home and emergency telephone numbers. Emergency telephone numbers must be posted at each client's home and must include 911, if available, the number of the physician, the ambulance, the qualified RN on call for home dialysis, and any other phone number deemed as an emergency number.

(2) The agency must ensure that the client and the client's family know the agency's procedures for medical emergencies and emergencies resulting from a disaster.

(3) The agency must ensure that the client and the client's family know the procedure for disconnecting the dialysis equipment.

(4) The agency must ensure that the client and the client's family know emergency call procedures.

(5) A working telephone must be available during the dialysis procedure.

(6) Depending on the kinds of medications administered, an agency must have available emergency drugs as specified by the medical director.

(7) In the event of a medical emergency or an emergency resulting from a disaster requiring transport to a hospital for care, the agency must assure the following:

(A) the receiving hospital is given advance notice of the client's arrival;

(B) the receiving hospital is given a description of the client's health status; and

(C) the selection of personnel, vehicle, and equipment are appropriate to effect a safe transfer.

Notes

26 Tex. Admin. Code § 558.405

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amended to be effective May 1, 2008, 33 TexReg 1136; Transferred from Title 40, Chapter 97 by Texas Register, Volume 44, Number 15, April 12, 2019, TexReg 1893, eff. 5/1/2019; Amended by Texas Register, Volume 46, Number 15, April 9, 2021, TexReg 2431, eff. 4/25/2021