

ALABAMA STATE COMMITTEE OF PUBLIC HEALTH
ALABAMA DEPARTMENT OF PUBLIC HEALTH
BUREAU OF ENVIRONMENTAL AND HEALTH SERVICE STANDARDS
DIVISION OF LICENSURE AND CERTIFICATION
ADMINISTRATIVE CODE

CHAPTER 420-5-5
END STAGE RENAL DISEASE TREATMENT AND TRANSPLANT CENTERS

420-5-5-.03 Patient Care.

(1) General.

(a) Medical Supervision and Emergency Coverage. The facility ensures that the health care of each patient is under the continuing supervision of a physician and that a physician is available 24 hours a day, seven days a week for emergency situations. A roster of physicians providing emergency services is posted at the nurses' station.

(b) Patient Care Policies. The facility shall have written patient care policies relating to all areas of care, and are developed by the physician director or medical staff and approved by the governing body. The patient care policies are reviewed periodically to determine effectiveness, but at least annually.

(c) Patient Long-Term Program and Patient Care Plan.

1. The facility maintains for each patient a written long-term program and patient care plan to ensure that each patient receives the appropriate modality of care and the appropriate care within that modality.

2. The long-term program states that most suitable treatment modality (dialysis or transplantation) and the most suitable dialysis setting (facility or home). The program is developed by a professional team and the patient, is formally reviewed and revised as necessary, and accompanies the patient on inter-facility transfer.

3. The patient care plan is developed by a professional team and the patient, and is based on the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs. The patient care plan is personalized for the individual, reflects the ongoing psychological, social and functional needs of the patient. It is reviewed at least semi-annually.

4. The physician responsible for the patient's medical supervision evaluates the patient's immediate and long-

term needs and prescribes, with input from other professional personnel involved in the care of the patient, a planned regimen of care.

(d) Admission and Discharge Policies and Procedures. Policies and procedures must be developed for admission and discharge of in-facility care, self-care and home-care patients.

(e) Medical History and Physical Examination. A complete patient medical history and physical examination must be obtained and recorded. The physical examination and history must be made prior to or on the date of admission and the patient must be re-examined on an annual basis.

(f) Patient Rights. Policies regarding the rights and responsibilities of patients shall be established. These policies must be made available to patients, any guardians, next-of-kin and sponsoring agencies. The staff of the facility must be trained and involved in the implementation of these policies and procedures. Patients must be fully informed by a physician of their medical condition, unless medically contraindicated (as documented in their medical records).

(g) Patient Transport. If a patient is unable to ride in an upright position or if such patient's condition is such that he or she needs observation or treatment by Emergency Medical Services personnel, or if the patient requires transportation on a stretcher, gurney or cot, the facility shall arrange or request transportation services only from providers who are ambulance service operators licensed by the Alabama State Board of Health. If such patient is being transported to or from a health care facility in another state, transportation services may be arranged with a transport provider licensed as an ambulance service operator in that state. For the purposes of this rule, and upright position means no more than 20 degrees from vertical.

(2) **Emergency Services**

(a) Emergency Supplies and Equipment. Each End Stage Renal Disease Treatment and Transplant Center must, with the advice of the facility's Medical Director, develop policies and procedures relating to the care and treatment of patients experiencing an emergent situation.

(b) Basic Life Support. Each End Stage Renal Disease Treatment and Transplant Center shall be equipped with an Automated External Defibrillator ("AED"). The AED must be maintained and charged at all times according to manufacturer's instructions. A person designated to perform cardio-pulmonary resuscitation ("CPR") and operate the AED and at least one other staff member must be present whenever any patient is in the facility. Individuals designated to perform CPR and operate

the AED must be properly certified and attend a training class on CPR and the operation of an AED at least annually.

(c) Advanced Life Support. Each End Stage Renal Disease Treatment and Transplant Center is responsible for ensuring that patients have timely access to Advanced Cardiac Life Support ("ACLS"). A facility ensures timely access to ACLS if:

1. The facility is located within ten miles of a hospital;
2. The facility is located within ten miles of a rescue squad or ambulance service with ACLS capabilities; or,
3. The facility designates a staff member to perform ACLS. Individuals designated to perform ACLS must be properly certified and trained, and must be present whenever any patient is in the facility. The facility must be equipped with a crash cart that includes all appropriate unexpired ACLS drugs and airway management devices in sizes and quantities appropriate for their patients; and monitor(s); and a manual defibrillator.

(3) Nursing Services.

(a) Director of Nurses. A qualified registered professional nurse must be in charge of nursing services of the facility.

(b) Required Qualified Registered Professional Nurses. At least one qualified registered professional nurse must be on duty at all times while dialysis is in progress to oversee patient care.

(c) Required Supportive Personnel. Supportive personnel (RNs, LPNs, dialysis technicians) shall be assigned to ensure that the needs of the patients are met.

(d) Job Descriptions. The authority, responsibilities, and functions of each category of nursing personnel shall be clearly defined in writing.

(e) Physical Examinations.

1. A pre-employment physical examination and a test for hepatitis, as indicated under Alabama Administrative Code Rule 420-5-5-.02(9)(d) shall be required of all new employees. Provisions shall be made for re-examination at intervals not to exceed twelve months. A re-examination for hepatitis must be in accordance with Alabama Administrative Code Rule 420-5-5-.02(9)(d).

2. The pre-employment physical examination shall include a skin test for tuberculosis. If the skin test is

negative, no further skin testing or examinations are required. If the skin test is positive, a chest x-ray shall be made. If the chest x-ray is essentially negative, INH preventive therapy is highly recommended unless there are contraindications.

(f) Personnel Policies and Procedures. The facility maintains and implements written personnel policies and procedures that support sound patient care and promote good nursing practice.

(g) Training of Personnel. There shall be an effective program of training established for all personnel. A record of this training shall be developed to indicate training given, performance of the individual and acceptable completion of the program. The record shall be maintained in the individual's personnel folder. All trainees shall be under the direct supervision of qualified professional personnel.

(h) Availability of Materials. Personnel manuals, minutes of staff development programs and other pertinent materials shall be updated periodically and made available to all personnel involved in patient care.

(i) Staff Development. An ongoing educational program is planned and conducted at least monthly for the development and improvement of skills of all the facility's clinical personnel, including training related to problems and needs of the renal dialysis patient. Records shall be maintained of programs presented and personnel attending. Each employee receives appropriate and thorough orientation to the facility and its policies and to the employee's position and duties.

(4) Storage, Preparation and Handling of Drugs and Medicines.

(a) Administering Drugs and Medicines. Drugs and medicines shall not be administered to individual patients nor to anyone within or outside the facility unless ordered by a physician, certified registered nurse practitioner or physician assistant duly licensed to prescribe drugs. Such orders shall be in writing and signed by the individual with privileges in the facility, who prescribes the drug or medicine.

(b) Medicine Storage. Medicines and drugs maintained on the nursing unit for daily administration shall be properly stored and safeguarded in enclosures of sufficient size and which are not accessible to unauthorized persons. Only authorized personnel shall have access to storage enclosures. Narcotics and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable State and Federal laws.

(c) Medicine Preparation Area. Medicines and drugs shall be prepared for administration in an area which contains a

counter and a sink. this area shall be located in such a manner to prevent contaminations of medicines being prepared for administration.

(d) Narcotic Permit. Each ESRD and/or Renal Transplant Center shall procure a controlled drug permit from DEA if a stock of controlled drugs is to be maintained. The permit shall be displayed in a prominent location.

(e) Records. Records shall be kept of all stock supplies of controlled substances giving an accounting of all items received and/or administered.

(f) Medication Orders. All oral or telephone orders for medications shall be received by a registered professional nurse, a physician's assistant or a physician and shall be entered on the physician's order sheet with an indication as to the prescribing physician, certified registered nurse practitioner or physician assistant and who wrote the order. Telephone or oral orders shall be signed by the prescribing individual within fifteen days.

(g) Pharmacy. If the facility has a pharmacy, it shall be of sufficient size to permit orderly storage and accurate identification of all drugs and medicines, and avoid overcrowding of preparation and handling areas. The pharmacy shall comply with all State and Federal Regulations governing the operation of a pharmacy. In addition, the pharmacy shall also:

1. Be adequately lighted.
2. Be provided with proper safeguards.
3. Be provided with a counter and sink.
4. Be provided with shelving.
5. Have a refrigerator.
6. Be provided with prescription files.
7. Be provided with books and equipment in accordance with requirements of the Alabama State Board of Pharmacy for compounding and dispensing of drugs.

(h) Poisonous Substances. All poisonous substances must be plainly labeled and kept in a cabinet or closet separate from medicines and drugs to be prepared for administration.

(i) Drug Reference Sources. Each End Stage Renal Treatment and Transplant Center shall maintain reference sources for identifying and prescribing drugs and medicines.

(j) Pharmacist. The facility shall maintain in a prominent location the name and telephone number of registered pharmacist who shall be available to offer advice on the maintenance and use of medicines and drugs, and to offer input into the care planning of the patient.

(k) Safety. If the pharmacies and/or drug rooms are available, they shall be provided with safeguards to prevent entrance of unauthorized persons, including bars on accessible windows and locks on doors.

(5) Dietetic Services.

(a) Qualified Dietitian. There is a qualified dietitian employed by the facility or contracted by the facility who is responsible, in consultation with the attending physician, for assessing the patient's nutritional and dietetic needs, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring patient response.

(b) Self-Care Dialysis Support Service. If the facility furnishes self-care dialysis training after the patient has completed a training program, the facility or center provides the services of a dietitian, either directly or under arrangement.

(6) Social Services.

(a) Social Worker. The facility has a qualified social worker, either employed by the facility, or on a contractual basis, for conducting psychosocial evaluations, participating on professional team review of patient care, providing casework and group work for patients and their families and identifying helpful community resources and assisting patients and their families to use them.

(b) Self-Care Dialysis Support Service. If the facility or center furnishes self-care dialysis training after the patient has completed a training program, the facility or center provides the services of a social worker either directly or under agreement.

(7) Laboratory.

(a) Laboratory Requirements.

1. Patient required laboratory services are available either directly or under arrangements through a hospital laboratory or a licensed independent laboratory.

2. Laboratory work referred to outside sources shall be performed only by facilities which have been licensed by the State Board of Health to perform those laboratory

procedures. In the case of work sent to an out-of-state laboratory, said laboratory shall be licensed, or possess a letter of exemption under the Clinical Laboratory Improvement Act (CLIA).

3. Staff qualified by education and experience may perform hematocrit and clotting time tests within the unit under the direction of a physician as outlined in Rule 420-5-8-.04(4) and (5), Chapter 420-5-8, Independent Clinical Laboratories, Alabama Administrative Code. Evidence of education, training, and experience shall be maintained in the personnel record.

4. If the facility has its own laboratory, it shall be in full compliance with Chapter 420-5-8, Independent Clinical Laboratories, Alabama Administrative Code including all amendments.

(b) Physician Orders. There shall be a written physician's order for laboratory procedures performed.

(c) Laboratory Reports. Completed reports of laboratory tests shall be kept on file with the patient's chart. Such reports shall be signed, initialed or coded to indicate the individual(s) by whom they were performed. There shall be evidence that the results of laboratory reports have been reported to the physician.

(d) Safety Measures. Procedures shall be established and enforced for the safe handling of all potentially infectious specimens and for the disposal or terminal disinfection of such material, supplies or equipment.

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