

902 KAR 20:073. Clinics: ambulatory care.

RELATES TO: KRS 216B.010-216B.131, 216B.990(1), (2)

STATUTORY AUTHORITY: KRS 216B.042, 216B.105

NECESSITY, FUNCTION, AND CONFORMITY: The administrative regulation establishing standards for ambulatory care clinics, 902 KAR 20:072, was found deficient by the Interim Joint Committee on Health and Welfare at its November 25, 1991, meeting. The finding of deficiency resulted from the removal of the requirement for an R.N. to be on site during the hours of the ambulatory care clinic's operation as found in Section 3(3)(a) ("Personnel"). Legislation to establish the deletion of the R.N. requirement in KRS Chapter 216B was not enacted during the 1992 regular session of the General Assembly. Therefore, pursuant to KRS 13A.333(1), 902 KAR 20:072 expired. KRS 216B.042 requires the cabinet to establish standards for health facilities and health services, and authorizes it to promulgate administrative regulations. Without an administrative regulation establishing standards for ambulatory care clinics, the cabinet would be in violation of the legislative mandate expressed in KRS 216B.042. KRS 13A.333(6) prohibits an administrative body from promulgating an administrative regulation that is identical to or substantially the same as an administrative regulation that has expired. This administrative regulation is not identical to or substantially the same as 902 KAR 20:072, because: (1) Only the section relating to R.N. staffing was found deficient; (2) this administrative regulation requires R.N. staffing; and (3) it is required, by legislative mandate, by KRS 216B.042.

Section 1. Definitions. "Clinic" means ambulatory care clinic.

Section 2. Scope of Operations and Services. An ambulatory care clinic is an establishment with organized medical staffs, permanent facilities and medical services to provide diagnosis and treatment for patients who have a variety of medical conditions and do not currently require inpatient care.

Section 3. Administration and Operation. (1) Licensee.

(a) The licensee shall be legally responsible for the clinic and for compliance with federal, state and local laws and regulations pertaining to the operation of the clinic.

(b) The licensee shall establish written policies for the administration and operation of the clinic.

(c) The licensee shall establish lines of authority and designate the person who will be principally responsible for the daily operation of the clinics.

(2) Policies.

(a) Administrative policies. The clinic shall have written administrative policies covering all aspects of the clinic's operation, including:

1. A description of organizational structure, staffing and allocation of responsibility and accountability;

2. A description of referral linkages with inpatient facilities and other providers;

3. Policies and procedures for the guidance and control of personnel performances;

4. A description of services included in the clinic's program;

5. A description of the administrative and patient care records and reports;

6. Procedures to be followed in the storage, handling and administration of drugs and biologicals; and

7. A policy to specify the provision of emergency medical services.

(b) Patient rights policies. The clinic shall adopt written policies regarding the rights and responsibilities of patients. These patients' rights policies shall assure that each patient:

1. Is informed of these rights and of all rules and regulations governing patient conduct and re-

sponsibilities, including a procedure for handling patient grievances.

2. Is informed of services available at the clinic and of related charges including any charges not covered under Medicare, Medicaid, or other third-party payor arrangements.

3. Is informed of his medical condition, unless medically contraindicated (as documented in his medical record), and is afforded the opportunity to participate in the planning of his medical treatment and to refuse to participate in experimental research.

4. Is encouraged and assisted to understand and exercise his patient rights; to this end he may voice grievances and recommend changes in policies and services. Upon the patient's request the grievances and recommendations will be conveyed within a reasonable time to an appropriate decision making level within the organization which has authority to take corrective action.

5. Is assured confidential treatment of his records and is afforded the opportunity to approve or refuse their release to any individual not involved in his care except as required by Kentucky law or third-party payment contract.

6. Is treated with consideration, respect, and full recognition of his dignity and individuality, including privacy in treatment and in the care of his personal health needs.

(3) Personnel.

(a) The clinic shall have at least one (1) licensed physician and at least one (1) registered nurse present during operating hours. A licensed physician shall be designated as medical director.

1. Physician. The physician shall be in active practice, and shall be responsible for all medical aspects of the center, and shall provide direct medical services in accordance with the Medical Practice Act, KRS Chapter 311. Physicians employed by or having an agreement with the clinic to perform direct medical services shall be qualified to practice general medicine (e.g., general practitioners, family practitioners, obstetrician/gynecologists, pediatricians, and internists). Physicians employed by or having an agreement with the clinic to perform direct medical services should be members of the medical staff, or hold at least courtesy staff privileges, at one (1) or more hospitals with which the clinic has a formal linkage agreement.

2. Nurse. The registered nurse(s) shall provide services within their respective scope of practice pursuant to KRS Chapter 314.

(b) In-service training. All clinic personnel shall participate in ongoing in-service training programs relating to their respective job activities. These programs shall include thorough job orientation for new personnel, regular in-service training programs, emphasizing professional competence, and the human relationship necessary for effective health care.

(c) At least one (1) person, in addition to the physician, shall be on duty who has current certification in cardiopulmonary resuscitation.

(4) Medical records.

(a) The clinic shall maintain medical records to contain at least the following:

1. Medical and social history, including data obtainable from other providers;

2. Description of each medical visit or contact, to include condition or reason necessitating visit or contact, assessment, diagnosis, services provided, medications and treatments prescribed, and disposition made;

3. Reports of all physical examinations, laboratory, x-ray, and other test findings; and

4. Documentation of all referrals made, to include reason for referral, to whom patient was referred, and any information obtained from referral source.

(b) Confidentiality of all patient records shall be maintained at all times.

(c) Transfer of records. The clinic shall establish systematic procedures to assist in continuity of care where the patient moves to another source of care, and the clinic shall, upon proper release, transfer medical records or an abstract thereof when requested.

(d) Retention of records. After patient's death or discharge the completed medical record shall be placed in an inactive file and retained for five (5) years or, in case of a minor, three (3) years after

the patient reaches the age of majority under state law, whichever is the longest.

(5) Linkage agreements.

(a) The clinic shall have linkages through written agreements with providers of other levels of care which may be medically indicated to supplement the services available in the clinic. These linkages shall include:

1. Hospitals; and
2. Emergency medical transportation services in the service area.

(b) Linkage agreements with inpatient care facilities shall incorporate provisions for appropriate referral and acceptance of patients from the clinic, provisions for appropriate coordination of discharge planning with clinic staff, and provisions for the clinic to receive a copy of the discharge summary for each patient referred to the clinic.

(6) Utilization review and medical audit. In order to determine the appropriateness of the services delivered there shall be a written plan for utilization review developed by the clinic which specifies the frequency of reviews and composition of the body conducting the review.

(7) Quality assurance program. The clinic shall have a written quality assurance program designed to ensure that there is an ongoing quality assurance program that includes effective mechanisms for reviewing and evaluating patient care, and that provides for appropriate response to findings. The written quality assurance plan shall be approved by the licensee and shall:

- (a) Assign responsibility for the monitoring and evaluation activities;
- (b) Delineate scope of care provided by the clinic;
- (c) Identify the aspects of care that the clinic provides;
- (d) Identify indicators, and appropriate clinical criteria that can be used to monitor these aspects of care;
- (e) Collect and organize data for each indicator;
- (f) Evaluate the care in order to identify problems or opportunities to improve care;
- (g) Take actions to correct identified problems or to improve care;
- (h) Assess the effectiveness of the actions taken and document the improvement in care; and
- (i) Communicate relevant information to other individuals, departments, or services as to the quality assurance program.

Section 4. Provision of Services. (1) Hours of operation and coverage. Scheduled hours of the clinic's operation shall reasonably accommodate the various segments of the population served. Provisions shall be made for scheduled evening hours and/or weekend hours.

(2) Basic services. The clinic shall provide directly (except as noted) at least the following services:

(a) Medical diagnostic and treatment services of sufficiently broad scope to accommodate the basic health needs (including prenatal and postnatal care) of all age groups;

(b) Emergency services.

1. The clinic shall provide emergency medical services during the regularly scheduled hours for treatment of injuries and minor trauma.

2. The clinic shall post in a conspicuous area at the entrance, visible from the outside of the clinic, the hours that emergency medical services will be available in the clinic and where emergency medical services not provided by the clinic can be obtained during and after the clinic's regular scheduled hours of operation.

(c) Preventive health services of sufficiently broad scope to provide for the usual and expected health needs of persons in all age groups;

(d) Education in the appropriate use of health services and in the contribution each individual can make to the maintenance of his own health;

(e) Chronic illness management; and

(f) Laboratory, x-ray and treatment services provided directly or arranged through other providers.

(3) Telephone screening and referral. The clinic shall provide telephone screening and referral services for prospective patients after regularly scheduled hours of operation.

(4)(a) Sharp wastes, including needles, scalpels, razors, or other sharp instruments used for patient care procedures, shall be segregated from other wastes and placed in puncture resistant containers immediately after use.

1. Needles shall not be recapped, purposely bent or broken, or otherwise manipulated by hand, except as permitted by Centers for Disease Control and the Occupational Safety and Health Administration guidelines.

2. The containers of sharp wastes shall either be incinerated on or off site, or be rendered non-hazardous by a technology of equal or superior efficacy, which is approved by the Cabinet for Human Resources and the Natural Resources and Environmental Protection Cabinet.

3. All disposable waste shall be placed in suitable bags or closed containers so as to prevent leakage or spillage, and shall be handled, stored, and disposed of in such a way as to minimize direct exposure of personnel to waste materials.

(b) The ambulatory clinic shall establish specific written policies regarding handling and disposal of all wastes.

1. The following wastes shall be disposed of by incineration, or be autoclaved before disposal, or be carefully poured down a drain connected to a sanitary sewer: blood, blood specimens, used blood tubes, or blood products.

2. Any wastes conveyed to a sanitary sewer shall comply with applicable federal, state, and local pretreatment regulations pursuant to 40 CFR 403 and 401 KAR 5:055, Section 9.

3. Any incinerator used for the disposal of wastes shall be in compliance with 401 KAR 59:020 and 401 KAR 61:010. (19 Ky.R. 2196; eff. 6-16-93.)