Ambulatory Surgical Centers

Revoked Regulations

28-34-52. (Authorized by K.S.A. 1973 Supp. 65-431; effective Jan. 1, 1974; revoked April 20, 2001.)

28-34-55. (Authorized by K.S.A. 1973 Supp. 65-431; effective Jan. 1, 1974; revoked April 20, 2001.)

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28-34-58. (Authorized by K.S.A. 1973 Supp. 65-431; effective Jan. 1, 1974; revoked April 20, 2001.)

28-34-59. (Authorized by K.S.A. 1973 Supp. 65-431; effective Jan. 1, 1974; revoked April 20, 2001.)

28-34-60. (Authorized by K.S.A. 1973 Supp. 65-431; effective Jan. 1, 1974; revoked April 20, 2001.)

28-34-61. (Authorized by K.S.A. 1973 Supp. 65-431; effective Jan. 1, 1974; revoked April 20, 2001.)

DEFINITIONS

28-34-50. **Definitions.** (a) "Administrator" means an individual appointed by the governing body to act on its behalf in the overall management of the ambulatory surgical center.

(b) "Ambulatory surgical center" means an establishment with the following:

(1) An organized medical staff of one or more physicians;

(2) permanent facilities that are equipped and operated primarily for the purpose of performing surgical procedures and do not provide services or other accommodations for patients to stay more than 24 hours;

(3) continuous physician services during surgical procedures and until the patient has recovered from the obvious effects of anesthesia, and at all other times with continuous physician services available whenever a patient is in the facility; and

(4) continuous registered professional nursing services whenever a patient is in the facility.

Before discharge from an ambulatory surgical center, each patient shall be evaluated by a physician for proper anesthesia recovery. Nothing in this regulation shall be construed to require the office of a physician or physicians to be licensed under this act as an ambulatory surgical center.

(c) "Anesthesiologist" means a physician who is licensed in Kansas to practice medicine and surgery and who has successfully completed a postgraduate medical education program and training program in anesthesiology.

(d) "Change of ownership" means any transaction that results in a change of control over the capital assets of an ambulatory surgical center.

(e) "Clinical laboratory improvement amendments" or "CLIA" is as published in 42 C.F.R. Part 493, as in effect on October 1, 1996 and hereby adopted by reference.

(f) "Dentist" means a person licensed in Kansas to practice dentistry.

(g) "Drug administration" means the direct application of a drug or biological, either by injection, inhalation, ingestion, or any other means, to the body of a patient by one of the following:

(1) A practitioner or individual pursuant to the lawful direction of a practitioner who is acting within the scope of that practitioner's license and who is qualified according to medical staff bylaws; or

(2) the patient at the direction and in the presence of a practitioner.

(h) "Drug dispensing" means delivering prescription medication to the patient pursuant to the lawful order of a practitioner.

(i) "Facilities" means buildings, equipment, and supplies necessary for delivery of ambulatory surgical center services.

(j) "Governing authority " means a board of directors, governing body, or individual in whom the ultimate authority and responsibility for management of the ambulatory surgical center is vested.

(k) "Licensing department" means the Kansas department of health and environment.

(l) "Licensed practical nurse (L.P.N.)" means an individual licensed in Kansas as a

licensed practical nurse.

(m) "Medical staff" means a formal organization of physicians, dentists, and other practitioners who are appointed by the governing authority to attend patients within the ambulatory surgical center. Surgical procedures shall be performed only by practitioners within the scope of their practice who at the time are privileged to perform these procedures in at least one licensed hospital in the community in which the ambulatory surgical center is located, or the ambulatory surgical center shall have a written transfer agreement with the hospital.

(n) "Nursing services" means patient care services pertaining to the curative, restorative, and preventive aspects of nursing that are performed or supervised by a registered nurse pursuant to the medical care plan of the practitioner and the nursing care plan.

(o) "Organized" means administratively and functionally structured.

(p) "Organized medical staff" means a formal organization of physicians, dentists, and practitioners with the responsibility and authority to maintain proper standards of patient care as delegated by the governing authority.

(q) "Patient" means a person admitted to the ambulatory surgical center by and upon the order of a physician, or by a dentist in accordance with the orders of a physician who is a member of the medical staff.

(r) "Physician" means a person holding a valid license from the Kansas state board of healing arts to practice medicine and surgery.

(s) "Podiatrist" means a person holding a valid license from the Kansas state board of healing arts to practice podiatric medicine and surgery.

(t) "Practitioner" means a member of the ambulatory surgical center's medical staff and may include a physician or dentist.

(u) "Qualified nurse anesthetist" means any of the following:

(1) A registered nurse who has been certified as a nurse anesthetist by the council on certification of the American association of nurse anesthetists and has been authorized as a registered nurse anesthetist by the Kansas state board of nursing;

(2) a student enrolled in a program of nurse anesthesia by the council on accreditation of the American association of nurse anesthetists; or

(3) a graduate of an accredited program of nurse anesthesia who is awaiting certification testing or the results of the certification test and has been granted temporary authorization as a registered nurse anesthetist by the Kansas state board of nursing.

(v) "Registered nurse (R.N.)" means a person who is licensed in Kansas as a registered professional nurse.

(w) "Supervision" means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity within that person's sphere of competence. Supervision shall include initial direction and periodic inspection of the actual act of accomplishing the function or activity.

(x) "Survey" means the process of evaluation or reevaluation of an ambulatory surgical center's compliance with this article. (Authorized by and implementing K.S.A. 2000 Supp. 65-429 and K.S.A. 65-43 1; effective Jan. 1, 1974; amended April 20, 2001 .)

LICENSING PROCEDURE

28-34-51. **Licensing procedure.** (a) No construction shall begin until plans and specifications covering the construction of new buildings, additions, or material alterations to existing buildings are submitted to the department, in writing, in accordance with K.A.R. 28-34-62a. A written narrative describing the intended use of the proposed construction shall accompany the plans and specifications.

Ambulatory surgical centers shall be licensed to provide only those services for which they are qualified. The extent of the facility's compliance with this article may be documented by the department in one of the following ways:

(1) The statement of a responsible, authorized administrator or staff member, which shall include one of the following:

(A) Documentary evidence of compliance provided by the facility; or

(B) answers by the facility to detailed questions provided by the licensing department concerning the implementation of any provisions of this article or examples of this implementation that allow a judgement about compliance to be made; or

(2) on-site observations by surveyors.

(c) The application for a license to establish or maintain an ambulatory surgical center shall be submitted to the licensing department. Each application shall be made in writing on forms provided by the department for a license for a new facility or for the renewal of a license for an existing facility. Applications for a license for each new facility shall be submitted at least 90 days before opening.

(d) Upon application for a license from a facility never before licensed, an inspection shall be made by the representative of the licensing department. Every building, institution, or establishment for which a license has been issued shall be periodically surveyed for compliance with the regulations of the licensing department.

(e) A license shall be issued by the department when both the following requirements are met:

(1) Construction is complete.

(2) The facility has completed an application form and is found to be in substantial compliance with K.S.A. 65-425 et seq., and amendments thereto, and K.A.R. 28-34-5 1 through K.A.R. 28-34-62a.

(f) If the facility is found to be in violation of this article, the applicant shall be notified in writing of each violation, and the applicant shall submit a plan of correction to the department. The plan shall state specifically what corrective action will be taken and the date on which it will be accomplished.

(g) Each licensee shall file an annual report on forms prescribed by the department. The license may be suspended or revoked at any time for noncompliance with this article of the licensing department and in accordance with the Kansas administrative procedure act, K.S.A. 77-501 et seq., and amendments thereto.

(h) The licensing department shall be notified within 60 days of any change in ownership or location of an ambulatory surgical center, and a new application form shall be submitted to the licensing department in the event of such a change.

(i) Within 60 days of issuance of an initial license, or following a change of ownership, the administrator shall submit the following information to the licensing department:

(1) Verification of professional liability coverage for the ambulatory surgical center in compliance with K.S.A. 40-340 1 et seq., and amendments thereto; and

(2) a risk management plan in compliance with K.A.R. 28-52-1.

(j) The current license certificate issued by the licensing department shall be framed and conspicuously posted on the premises. The license certificate shall remain the property of the licensing department. (Authorized by and implementing K.S.A. 2000 Supp. 65-429 and K. S.A. 65-431; effective Jan. 1, 1974; amended April 20, 2001.)

PATIENT RIGHTS

28-34-52a. **Patient rights.** (a) The governing authority shall ensure that the facility establishes policies and procedures that support the rights of all patients. At a minimum, each facility shall ensure that each patient has a right to the following:

(1) Receive respectful care given from competent personnel;

(2) receive information of the proposed treatment or procedures to be performed, potential complications, and expected outcomes;

(3) make health care decisions;

(4) access information contained in the patient's medical record, within the limits of state law, by each patient or patient's designated representative;

(5) maintain privacy and security of self and belongings during the delivery of patient care service;

(6) be informed of expected services and financial charges and receive an explanation of the patient's bill; and

(7) be informed of the facility's policies regarding patient rights.

(b) Grievances and complaints. The facility's policies and procedures shall establish a mechanism for responding to patient grievances and complaints.

(c) Reporting of grievances or complaints. Each person having a grievance or complaint pertaining to the provision of any patient services in an ambulatory surgical center may direct the grievance or complaint to the licensing department.

(d) Reporting of abuse, neglect, or exploitation.

(1) Each administrator of an ambulatory surgical center shall be responsible for reporting any incidents of abuse, neglect, or exploitation of any patient, in accordance with K.S.A. 39-1401 et seq., and amendments thereto.

(2) Each administrator of an ambulatory surgical center shall be responsible for reporting any incidents of abuse or neglect of children in accordance with K.S.A. 38-1521 et seq., and amendments thereto. (Authorized by and implementing K. S.A. 65-431; effective April 20, 2001.)

ASSESSMENT AND CARE OF PATIENTS

28-34-52b. **Assessment and care of patients.** (a) Each patient admitted to the ambulatory surgical center shall be under the care of a practitioner who is a member of the medical staff.

(b) Patient care shall meet the needs of the patient and shall be provided by qualified personnel.

(c) An initial assessment of each patient shall be completed by qualified staff. The assessment shall include the following information:

(1) The patient's current physical status;

(2) a history and physical completed within 30 days before any procedure performed at the ambulatory surgical facility;

(3) the results of clinical laboratory tests or diagnostic reports;

(4) a preanesthesia evaluation conducted by a licensed, qualified practitioner granted clinical privileges by the medical staff and governing body; and

(5) the patient's nutritional status.

(d) Each patient's identity shall be verified before the administration of any medication.

(e) Blood and blood products may be administered only by a physician or a registered nurse.

(f) Each patient's status shall be evaluated during anesthesia administration and shall be evaluated by a physician for proper anesthesia recovery before discharge.

(g) The ambulatory surgical center shall have a written transfer agreement with a local hospital for the immediate transfer of any patient requiring medical care beyond the capability of the ambulatory surgical center, or each physician performing surgery at the ambulatory surgical center shall have admitting privileges with a local hospital.

(h) If a patient is transferred to another facility, essential medical information, including the diagnosis, shall be forwarded with the patient to ensure continuity of care.

(i) Each patient shall be discharged in the company of a responsible adult, unless this requirement is specifically waived by the attending physician.

(j) Discharge planning shall include education for each patient and caregiver. The patient education shall be interdisciplinary and include at least the following information:

(1) The patient's medical condition;

(2) the procedure and outcome of procedures performed;

(3) the need and availability of follow-up care; and

(4) the use of prescribed medication and medical equipment. (Authorized by and implementing K.S.A. 65-431; effective April 20, 2001.)

GOVERNING AUTHORITY

28-34-53. **Governing authority.** (a) The governing authority shall be the ultimate authority in the ambulatory surgical center, responsible for its organization and administration, including appointment of the medical staff, employment of an administrator, review and revision of policies and procedures, and maintenance of a physical plant equipped and staffed to adequately meet the needs of the patients.

(b) The governing authority shall be organized in accordance with its approved bylaws, policies, and procedures and shall be in conformance with the Kansas statutes governing ambulatory surgical centers. A copy of the ambulatory surgical center's current bylaws shall be available for review by the licensing department.

(c) Bylaws of the governing authority shall provide for the selection and appointment of medical staff members based on defined criteria and in accordance with an established procedure for processing and evaluating applications for memberships. Each application for appointment and reappointment shall be submitted in writing and shall signify agreement of the applicant to conform with the bylaws of both the governing authority and medical staff and to abide by professional ethical standards.

(d) The governing authority shall demonstrate evidence of a liaison and close working relationship with the medical staff.

(e) The governing authority shall be responsible for the implementation of a risk management program, in accordance with K.S.A. 65-492 1 et seq. and amendments thereto, and K.A.R. 28-52-1 through 28-52-4.

(f) The governing authority shall select and employ an administrator and shall notify the department of any change of administrator within five days after the change has been made.

(g) Each patient admitted to the ambulatory surgical center shall be under the care of a practitioner who is a member of the medical staff.

(h) The governing authority shall ensure that the ambulatory surgical center complies with the following:

(1) Defines, in writing, the scope of services provided;

(2) has an adequate number of qualified personnel; and

(3) maintains effective quality control, quality improvement, and data management activities. (Authorized by and implementing K.S.A. 65-43 1; effective Jan. 1, 1974; amended April 20, 2001.)

MEDICAL STAFF

2 8-34-54. **Medical staff.** (a) The ambulatory surgical center shall have an organized medical staff, responsible to the governing authority of the ambulatory surgical center for the quality of all medical care provided to patients in the ambulatory surgical center and for the ethical and professional practices of its members.

(b) In each ambulatory surgical center, the medical staff, with the approval of and subject to final action by the governing authority, shall formulate and approve medical staff bylaws, policies, and procedures for the proper conduct of its activities and recommend to the governing authority practitioners considered eligible for membership on the medical staff, in accordance with K.A.R. 28-34-50(t).

(c) Each member of the medical staff shall be granted privileges that are commensurate with the member's qualifications, experience, and present capabilities and that are within the practitioner's scope of practice.

(d) Each member of the medical staff shall submit a written application for staff membership on a form prescribed by the governing authority. After considering medical staff recommendations, the governing authority shall affirm, deny, or modify each recommendation for appointment to the medical staff.

(e) Surgical procedures shall be performed only by practitioners who have been granted privileges by the governing authority to perform surgical procedures.

(f) The medical staff of each ambulatory surgical center shall develop a policy stipulating which surgically removed tissues will be sent to a pathologist for review. This policy shall be

approved by the governing authority.

(g) The medical staff bylaws shall require at least one physician member of the medical staff to be available to the ambulatory surgical center at all times that a patient is receiving or recovering from local, general, or intravenous sedation. The staffing shall meet the needs of the patients.

(h) The medical staff shall hold regular meetings for which records of attendance and minutes shall be kept.

(i) Medical staff committee minutes and information shall neither be a part of individual patient records nor be subject to review by other than medical staff members, except as otherwise provided by the governing authority.

(j) The medical staff shall review and analyze at regular intervals the clinical experience of its members and the medical records of patients on a sampling or other basis. All techniques and procedures involving the diagnosis and treatment of patients shall be reviewed periodically and shall be subject to change by the medical staff.

(k) The medical staff shall participate in risk management activities, in accordance with K.S.A. 65-492 1 et seq., and amendments thereto, and K.A.R. 28-52-1 through 28-52-4, and with the ambulatory surgical center's risk management plan. Any ambulatory surgical center having a medical staff with fewer than two physician members shall include provisions for outside peer review in the risk management plan.

(l) All medical orders shall be given by a practitioner and recorded in accordance with

the medical staff policies and procedures. All orders shall be signed or either countersigned or initialed by the attending physician, dentist, or podiatrist.

(m) The medical staff and the governing authority shall review the medical staff privileges at least every two years. (Authorized by and implementing K.S.A. 65-431; effective Jan. 1, 1974; amended April 20, 2001.)

HUMAN RESOURCES

28-34-55a. **Human resources.** (a) The ambulatory surgical center shall provide an adequate number of qualified staff to meet the needs of the patients.

(b) All nursing and ancillary staff employed by or contracted with the ambulatory surgical center shall be qualified and shall provide services consistent with the scope of practice granted by the license, registration, or certification regulations.

(c) One registered nurse shall be on duty at all times whenever a patient is in the ambulatory surgical center.

(d) The ambulatory surgical center shall provide all nursing and ancillary staff services in accordance with written policies and procedures consistent with professional practice standards and reviewed and revised, as necessary.

(e) The governing authority shall ensure that all employees are provided information related to the reporting of reportable incidents in accordance with the ambulatory surgical center's risk management plan.

(f) The governing authority shall ensure that ongoing staff education and training are provided to continually improve patient care services.

(g) The ambulatory surgical center shall maintain personnel records on each employee that shall include the job application, professional and credentialing information, health information, and annual performance evaluations. (Authorized by and implementing K.S.A. 65-431; effective April 20, 2001.)

ANESTHESIA SERVICES

28-34-56a. **Anesthesia services.** (a) If there is a department of anesthesia, it shall be directed by a member of the medical staff with appropriate clinical and administrative experience. The clinical privileges of qualified anesthesia personnel shall be reviewed by the director of anesthesia services and the medical staff and approved by the governing authority.

(b) (1) An anesthesiologist or physician shall be on the premises and readily accessible during the administration of anesthetics, whether local, general, or intravenous, and the postanesthesia recovery period until all patients are alert or medically discharged from the postanesthesia area. Qualified anesthesia personnel shall be present in the room through the administration of all general anesthetics, regional anesthetics, and monitored anesthesia care and shall continuously evaluate the patient's oxygenation, ventilation, circulation, and temperature.

(2) The following equipment shall be available as the scope of practice requires:

(A) Oxygen analyzers;

(B) a pulse oximeter; and

(C) electrocardiography, blood pressure, resuscitation, and suction equipment.

(c) The medical staff, in consultation with qualified anesthesia personnel, shall develop policies and procedures on the administration of anesthetics and drugs that produce conscious and deep sedation and on postanesthesia care . These policies and procedures shall be approved by the governing authority.

(d) Before undergoing general anesthesia, each patient shall have a history and physical examination by a physician entered in the patient's record, including the results of any necessary

laboratory examination. A physician shall examine the patient immediately before surgery and shall evaluate the risk of anesthesia and of the procedure to be performed.

(e) The anesthesiologist or anesthetist shall discuss anesthesia options and risks with the patient or family before surgery.

(f) Qualified anesthesia personnel shall develop a plan of anesthesia care with the physician or dentist. The patient records shall contain a preanesthetic evaluation and a postanesthetic note by qualified anesthesia personnel. Anesthesia services shall write postanesthetic policies and procedures. Follow-up notes shall include postoperative abnormalities or complications.

(g) Flammable anesthetics shall not be used in the ambulatory surgical center.

(h) Anesthesia shall be provided only by a qualified individual licensed to administer anesthesia by the Kansas board of healing arts, the Kansas board of nursing, or the Kansas dental board. Each certified registered nurse anesthetist shall work in an interdependent role as a member of a physician- or dentist-directed health care team.

(i) All anesthetics shall be properly labeled and inventoried according to the facility's policies and procedures.

(j) All equipment for the administration of anesthetics shall be made available, cleaned with a facility-approved disinfectant and clean cloth, and maintained in good working condition.

(k) Written procedures and criteria for discharge from the recovery service shall be approved by the medical staff. Each patient who has received anesthesia shall be discharged in the company of a responsible adult, unless the requirement is specifically waived by the

attending physician.

(l) There shall be a mechanism for the review and evaluation, according to the facility's policies and procedures, of the quality and scope of anesthesia services. (Authorized by and implementing K.S.A. 65-431; effective April 20, 2001.)

MEDICAL RECORDS

28-34-57. **Medical records.** (a) A medical record shall be maintained for each patient cared for in the ambulatory surgical center. The records shall be documented and retrievable by authorized persons.

(b) Each medical record shall be the property of the ambulatory surgical center. Only persons authorized by the governing authority shall have access to medical records. These persons shall include individuals designated by the licensing department for verifying compliance with the state or federal regulations, and for disease control investigations of public health concern.

(c) Each medical record shall be maintained in a retrievable form for 10 years after the date of last discharge of the patient, or one year after the date that the minor patient reaches the age of 18, whichever is greater.

(d) Each medical record shall contain the following information, if applicable:

(1) Patient identification data;

(2) patient consent forms;

(3) patient history and physical;

(4) clinical laboratory reports;

(5) physician's or physicians' orders;

(6) radiological reports;

(7) consultations;

(8) anesthesia records;

(9) surgical reports;

(10) tissue reports;

(11) progress notes;

(12) a description of the care given to that patient based on the type of surgical procedure; (13) the signature or initials of authorized personnel on notes or observations;

(14) the final diagnosis;

(15) the discharge summary;

(16) discharge instructions to the patient;

(17) a copy of transfer form; and

(18) the autopsy findings.

(e) Each record shall be dated and authenticated by the person making the entry. Nursing notes and observations shall be signed and dated by the registered nurse or licensed practical nurse making the entry. Verbal orders by authorized individuals shall be accepted and transcribed only by designated personnel.

(f) The ambulatory surgical center shall furnish, to the appropriate authority, all available information on deceased patients for completion of a death certificate.

(g) The medical record shall be completed within 30 days following the patient's discharge.

(h) Statistical data, administrative records, and records of reportable diseases as required shall be maintained and submitted by the ambulatory surgical center to the licensing department, as requested.

(i) Adequate space, facilities, and equipment shall be provided for completion and storage of medical records.

(j) Nothing in this article shall be construed to prohibit the use of properly automated medical records or use of other automated techniques, if these regulations are met. (Authorized by and implementing K.S.A. 65-43 1; effective Jan. 1, 1974; amended April 20, 2001.)

INFECTION CONTROL

28-34-58a. **Infection control.** (a) Each ambulatory surgical center shall establish and maintain an ongoing infection control program. The program shall be based upon guidelines established by the centers for disease control and the licensing department. The program shall include the following:

(1) Measures for the surveillance, prevention, and control of infections;

(2) the assignment of the primary responsibility for the program, as well as medical staff participation and review of findings, to an individual;

(3) written policies and procedures outlining infection control measures and aseptic techniques;

(4) orientation and ongoing education provided to all personnel on the cause, effect, transmission, and prevention of infections;

(5) policies and procedures that require all employees to adhere to universal precautions to prevent the spread of blood-borne infectious diseases;

(6) policies and procedures related to employee's health;

(7) review and evaluation, according to the facility's policies and procedures, of the quality and effectiveness of infection control throughout the ambulatory surgical center; and

(8) provisions for reporting, to the licensing department, infectious or contagious diseases in accordance with K.A.R. 28-1-2.

(b) Personnel health requirements. Upon employment, each individual shall have a medical examination consisting of examinations appropriate to the duties of the employee,

including a tuberculin skin test. Subsequent medical examinations or health assessments shall be given periodically in accordance with the facility's policies. Each ambulatory surgical center shall develop policies and procedures for the control of communicable diseases, including maintenance of immunization histories and the provision of educational materials for patient care staff. Cases of employees with tuberculin skin test conversion shall be reported to the Kansas department of health and environment.

(c) Any personnel having a condition detrimental to patient well-being, or suspected of having such a condition, shall be excluded from work until the requirements of K.A.R. 28-1-6 are met.

(d) Sanitation and housekeeping. Each ambulatory surgical center shall comply with the following procedures:

(1) Be kept neat, clean, and free of rubbish;

(2) develop written housekeeping procedures;

(3) provide hand-washing facilities; and

(4) develop written procedures for the laundering of linen and washable goods.

(e) Soiled and clean linen shall be handled and stored separately.

(f) All garbage and waste shall be collected, stored, and disposed of in a manner that does not encourage the transmission of contagious disease. Containers shall be washed and sanitized before being returned to work areas, or the containers may be disposable.

(g) Staff shall make periodic checks, according to the facility's policies and procedures, throughout the premises to enforce sanitation procedures.

(h) Sterilizing supplies and equipment. The governing authority shall establish written policies and procedures for the storage, maintenance, and distribution of supplies and equipment.

(1) Sterile supplies and equipment shall not be mixed with unsterile supplies and shall be stored in dustproof and moisture-free units. These sterile units shall be labeled.

(2) Sterilizers and autoclaves shall be provided, of the appropriate type and necessary capacity, to sterilize instruments, utensils, dressings, water, and operating and delivery room materials, as well as laboratory equipment and supplies. The sterilizers shall have approved control and safety features. The accuracy of instruments shall be checked, and surveillance methods, according to the facility's policies and procedures, for checking sterilization procedures shall be employed.

(3) The date of sterilization or date of expiration shall be marked on all sterile supplies, and unused items shall be resterilized in accordance with written policies. (Authorized by and implementing K.S.A. 65-431; effective April 20, 2001.)

ANCILLARY SERVICES

28-34-59a. **Ancillary services.** (a) The ambulatory surgical center shall provide, either directly or through agreement, laboratory, radiology, and pharmacy services to meet the needs of the patients.

(b) Laboratory services. If the ambulatory surgical center provides its own clinical laboratory services, the following criteria shall be met:

(1) The laboratory performing analytical tests within the ambulatory surgical center shall hold a valid CLIA certificate for the type and complexity of all tests performed.

(2) An authorized individual shall, through written or electronic means, request all tests performed by the laboratory. The individual or individuals serving as the laboratory's clinical consultant or consultants shall be as defined in 42 C.F.R. 493.1417 (b), as in effect on October 1, 1996 and hereby adopted by reference.

(3) The original report or duplicate copies of written tests, reports, and supporting records shall be retained in a retrievable form by the laboratory for at least the following periods:

(A) Two years for routine test reports;

(B) five years for blood banking test reports; and

(C) 10 years for histologic or cytologic test reports.

(4) Facilities for procurement, safekeeping, and transfusion of blood, blood products, or both shall be provided or available. If blood products or transfusion services are provided by sources outside the ambulatory surgical center, outside sources shall be provided by a CLIA-certified laboratory. The source shall be certified for the scope of testing performed or products

provided.

(c) If the ambulatory surgical center contracts for laboratory services, the center shall have a written agreement with that CLIA-certified laboratory.

(d) Radiology services. If the ambulatory surgical center provides its own radiology services, the services shall meet the requirements specified in K.S.A. 48-1607, and amendments thereto.

(e) The ambulatory surgical center staff shall meet the following standards:

(1) Allow only trained and qualified individuals to operate radiology equipment;

(2) document annual checks and calibration of all radiology equipment and maintain records of such;

(3) ensure that all radiology and diagnostic services are provided only on the order of a physician; and

(4) document the presence of signed and dated clinical reports of the radiological or diagnostic findings in the patient's record.

(f) If the ambulatory surgical center contracts for radiology services, it shall have a written agreement with a medicare-approved radiology provider or supplier.

(g) Pharmacy services. Each ambulatory surgical center shall provide pharmaceutical services that are appropriate for the services offered by the ambulatory surgical center.

(h) The pharmaceutical service shall be under the direction of an individual designated responsible for the service and shall be provided in accordance with K.A.R. 68-7-11.

(i) Policies and procedures. There shall be policies and procedures developed by a pharmacist, and approved by the governing authority, related to the following:

(1) Storage of drugs;

(2) security of drugs;

(3) labeling and preparation of drugs;

(4) administration of drugs; and

(5) disposal of drugs.

(j) All drugs and biologicals shall be ordered pursuant to a written order issued by a licensed physician.

(k) Each adverse drug reaction shall be reported to the physician responsible for the patient and shall be documented in the patient's record.

(l) Drugs requiring refrigeration shall be stored in a refrigerator that is used only for drug storage.

(m) Quality assurance. There shall be a mechanism for the ongoing review and evaluation of the quality and scope of radiological, laboratory, and pharmacy services. (Authorized by and implementing K.S.A. 65-431; effective April 20, 2001.)

FOOD SERVICES

28-34-60a. **Food services.** (a) Food service and food service policies and procedures shall reflect the level of services offered to meet the needs of the patients.

(b) The food and nutritional needs of patients shall be met in accordance with physician's orders.

(c) There shall be written policies for food storage, preparation, and service. Policies shall meet the following standards:

(1) There shall be a separate storage area above the floor level for food.

(2) Food transportation equipment shall be cleaned and disinfected daily or after each use if uneaten food or unclean dishes are transported.

(3) There shall be separate hand-washing facilities in the food preparation and service area.

(4) The temperature in each food freezer shall be no higher than 0° Fahrenheit.

(5) Dishes and utensils shall be washed in water at 140° Fahrenheit and shall be rinsed at 180° Fahrenheit, or a ware-washing machine and its auxiliary components shall be operated in accordance with the machine's data plate and any other manufacturer's instructions.

(6) Foods being transported shall be protected from contamination and held at required temperatures in clean containers or serving carts.

(7) Except during preparation, cooking, or cooling, potentially hazardous food shall be maintained at or above 140° Fahrenheit or at or below 41° Fahrenheit.

(8) Storage of toxic agents shall be prohibited in food preparation and food serving areas.

(9) Food returned on patients' trays shall not be reused. (Authorized by and implementing K.S.A. 65-431; effective April 20, 2001.)

PHYSICAL ENVIRONMENT

28-34-61a. **Physical environment.** (a) Each ambulatory surgical center shall be designed, constructed, equipped, and maintained to protect the health and safety of patients, staff, and visitors.

(b) Each ambulatory surgical center shall include the following features:

(1) A separate recovery area and waiting area;

(2) business office facilities;

(3) storage areas designated for janitorial supplies and equipment; and

(4) separate toilet facilities designated for patients, staff, and visitors.

(c) Equipment.

(1) Patient resuscitation and suction equipment shall be available in the surgical area at all times.

(2) All equipment shall be clean, functional, and maintained in accordance with the manufacturer's instruction.

(3) Each fire extinguisher shall be the type approved by underwriters laboratories. Extinguishers shall be inspected and tagged annually to assure that nothing has been tampered with or moved from designated areas. All extinguishers shall be functional.

(d) Fire and disaster drills. Each ambulatory surgical center shall meet the following requirements:

(1) Develop a written fire evacuation plan. Drills shall be held according to the facility's policies and procedures to prepare employees for evacuation of patients, staff, and visitors

during a fire emergency. A record of each drill shall be kept on file.

(2) Develop a written plan for addressing the safety of patients, staff, and visitors during disasters. Periodic drills shall be held, and a record of each drill shall be kept on file.

(e) Smoking shall be prohibited in each ambulatory surgical center, and “no smoking” signs shall be posted in accordance with K.S.A. 2 1-4017, and amendments thereto.

(f) Use of space. The physical space licensed as an ambulatory surgical center shall be separate from any physician’s office. (Authorized by and implementing K.S.A. 65-43 1; effective

April 20, 2001.)

CONSTRUCTION STANDARDS

28-34-62a. **Construction standards.** (a) General provisions. All ambulatory surgical center construction, including new buildings and additions or alterations to existing buildings, shall be in accordance with standards set forth in sections 1, 2, 3, 4, 5, 6, and subsections 9.1, 9.2, 9.5, 9.9, 9.10, 9.31, and 9.32 in the American institute of architects academy of architecture for health publication no. ISBN 1-55835-151-5, entitled "1996-97 guidelines for design and construction of hospital and health care facilities," copyrighted in 1996, and hereby adopted by reference.

(b) Provisions for handicapped. All construction shall be in compliance with K.S.A. 58-1301 et seq., and amendments thereto.

(c) Construction plans and specifications.

(1) Plans and specifications for each new ambulatory surgical center and each alteration and addition to any existing ambulatory surgical center, other than minor alterations, shall be prepared by an architect licensed in Kansas and shall be submitted to the licensing department before beginning construction. "Minor alternations" means those projects that do not affect the structural integrity of the building, do not change functional operation, and do not affect fire safety.

(2) Plans shall be submitted at the preliminary plan and outline specification stage.

(3) The preliminary plans shall include the following information:

(A) Sketch plans of the basement, each floor, and the roof indicating the space

assignment, size, and outline of fixed equipment;

(B) all elevations and typical sections;

(C) a plot plan showing roads and parking facilities; and

(D) areas and bed capacities by floors.

(4) Outline specifications shall consist of a general description of the construction, air conditioning, heating, and ventilation systems.

(5) Contract documents and final plans shall be prepared by the architect and consist of working drawings that are complete and adequate for bidding, contract, and construction purposes. Specifications shall supplement the drawings to fully describe the types, sizes, capacities, workmanship, finishes, and other characteristics of all materials and equipment. Contract documents shall be submitted to the licensing department, if requested. The architect shall certify that contract documents and final plans are in compliance with subsections (a) and (b) of this regulation.

(d) Access. Representatives of the licensing department shall, at all reasonable times, have access to work in preparation or progress, and the contractor shall provide proper facilities for this access and inspection. A complete set of plans and specifications shall be available on the job site for use by licensing department personnel. (Authorized by and implementing K.S.A. 65-431; effective May 1, 1986; amended, T-87-51, Dec. 19, 1986; amended May 1, 1987; amended Dec. 29, 1995; amended April 20, 2001.)

GENERAL REQUIREMENTS

28-52-1. General Requirements. (a) Each medical care facility shall establish a written plan for risk management and patient care quality assessment on a facility-wide basis.

(b) The plan shall be approved and reviewed annually by the facility's governing body.

(c) Findings, conclusions, recommendations, actions taken, and results of actions taken shall be documented and reported through procedures established within the risk management plan.

(d) All patient services including those services provided by outside contractors or consultants shall be periodically reviewed and evaluated in accordance with the plan.

(e) Plan format. Each submitted plan shall include the following:

(1) Section I - a description of the system implemented by the facility for investigation and analysis of the frequency and causes of reportable incidents within the facility;

(2) Section II - a description of the measures used by the facility to minimize the occurrence of reportable incidents and the resulting injuries within the facility;

(3) Section III - a description of the facility's implementation of a reporting system based upon the duty of all health care providers staffing the facility and all agents and employees of the facility directly involved in the delivery of health care services to report reportable incidents to the chief of medical staff, chief administrative officer, or risk manager of the facility;

(4) Section IV, organization - a description of the organizational elements of the plan including:

(A) Name and address of the facility;

(B) name and title of the facility's risk manager;

(C) description of involvement and organizational structure of medical staff as related to risk management program, including names and titles of medical staff members involved in investigation and review of reportable incidents;

(D) organizational chart indicating position of the facility's review committee as defined in K.S.A. 65-65-4923 and L. 1986, Ch. 229, new Section 4(a)(2); and

(E) mechanism for ensuring quarterly reporting of incident reports to proper licensing agency;

(5) Section V - a description of the facility's resources allocated to implement the plan; and

(6) Section VI - documentation that the plan as submitted has been approved by the facility's governing body.

(f) Plan submittal. On and after November 1, 1986, each medical care facility shall submit the plan to the department at least 60 days prior to the license renewal date. After an initial plan is approved, any amendments to the plan shall be submitted to the department.

(g) Departmental review. Upon review of the facility's risk management plan or any amendments, the department shall notify the facility in writing if the plan or amendments have been approved or disapproved. The written notification will specify the reason for disapproval.

(h) Revised plan. Within 60 days of the date the facility receives notification the plan has been disapproved, the facility shall submit a revised plan to the department.

(i) Plan publication. The plan shall be disseminated to personnel in accordance with the plan. (Authorized by and implementing L. 1986, Chapter 229, Sec. 4; effective T-87-50, December 19, 1986.)

INCIDENT REPORTING

28-52-2. **Incident reporting.** (a) Each medical care facility shall identify a written form on which employees and health care providers shall report clinical care concerns to the risk manager, chief of staff, or administrator. The original or complete copy of the incident report shall be sent directly to the risk manager, chief of staff, or administrator, as authorized in the facility's risk management plan.

(b) The risk manager, chief of staff, or administrator shall acknowledge the receipt of each incident report in writing. This acknowledgment may be made in the following manner:

(1) file stamping each report;
(2) maintaining a chronological risk management reporting log;
(3) signing or initialing each report in a consistent fashion; or
(4) entering pertinent information into a computer database.

(c) Incident reports, investigational tools, minutes of risk management committees, and other documentation of clinical analysis for each reported incident shall be maintained by the facility for not less than one year following completion of the investigation. (Authorized by and implementing K.S.A. 65-4922; effective February 27, 1998.)

RISK MANAGEMENT COMMITTEE

28-52-3. **Risk management committee.** (a) Each medical care facility shall designate one or more executive committees responsible for making and documenting standard-of-care determinations with respect to each incident report, pursuant to K.A.R. 28-52-2. The jurisdiction of each risk management committee shall be clearly delineated in the facility's risk management plan, as approved by the facility's governing body.

(b) The activities of each risk management committee shall be documented in its minutes at least quarterly, and this documentation shall demonstrate that the committee is exercising overall responsibility for standard- of- care determinations delegated by the committee to individual clinical reviewers and subordinate committees. (Authorized by and implementing K.S.A. 65-4922; effective February 27, 1998.)

STANDARD OF CARE DETERMINATIONS

28-52-4. **Standard-of-care determinations.** (a) Each facility shall assure that analysis of patient care incidents complies with the definition of a "reportable incident" set forth at K.S.A. 65-4921. Each facility shall use categories to record its analysis of each incident, and those categories shall be in substantially the following form:

(1) Standards of care met;

(2) standards of care not met, but with no reasonable probability of causing injury;

(3) standards of care not met, with injury occurring or reasonably probable; or

(4) possible grounds for disciplinary action by the appropriate licensing agency.

(b) Each reported incident shall be assigned an appropriate standard-of-care determination under the jurisdiction of a designated risk management committee. Separate standard-of-care determinations shall be made for each involved provider and each clinical issue reasonably presented by the facts. Any incident determined by the designated risk management committee to meet category (a) (3) or (a) (4) shall be considered a “reportable incident” and reported to the appropriate licensing agency in accordance with KSA 65 -4923.

(c) Each standard-of-care determination shall be dated and signed by an appropriately credentialed clinician authorized to review patient care incidents on behalf of the designated committee. In those cases in which documented primary review by individual clinicians or subordinate committees does not occur, standard-of-care determinations shall be documented in the minutes of the designated committee on a case-specific basis. Standard-of-care determinations made by individual clinicians and subordinate committees shall be approved by the designated risk management committee on at least a statistical basis. (Authorized by and implementing K.S.A. 65-4922; effective February 27, 1998.)