RULES OF

Department of Health and Senior Services

Division 30—Division of Regulation and Licensure

Chapter 30—Ambulatory Surgical Centers and Abortion Facilities

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TITLE 19 – DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30 – Division of Regulation and Licensure
Chapter 30 – Ambulatory Surgical Centers and Abortion Facilities

19 CSR 30-30.010 Definitions and Procedures for Licensing Ambulatory Surgical Centers

PURPOSE: The Division of Regulation and Licensure, Department of Health and Senior Services has the authority to establish rules for ambulatory surgical centers. This rule defines specific terms and presents procedures to follow in making application for a license.

(1) Definitions.

(A) Administrator means a person who is delegated the responsibility of carrying out the policies and programs established by the governing body.

(B) Ambulatory surgical center. Any public or private establishment operated primarily for the purpose of performing surgical procedures or primarily for the purpose of delivering newborns, and which does not provide services or other accommodations for patients to stay more than twelve (12) hours within the establishment. However, nothing in this definition shall be construed to include the offices of dentists currently licensed under Chapter 332, RSMo.

1. A facility operated primarily for the purpose of performing surgical procedures is one that provides surgical services to fifty-one percent (51%) or more of the patients treated or seen for any health condition, or one that derives fifty-one percent (51%) or more of its revenues from the provision of surgical services or related procedures.

2. The term ambulatory surgical center does not apply to any facility licensed as part of a hospital or any facility used as an office or clinic for the private practice of a physician, dentist or podiatrist.

3. A facility licensed as an ambulatory surgical center shall not use the term hospital in the name of the facility without approval of the Department of Health and Senior Services.

(C) Anesthesiologist. A physician licensed under Chapter 334, RSMo, who has successfully completed a postgraduate medical education program in anesthesiology approved by the Accreditation Council on Graduate Medical Education or the American Osteopathic Association.

(D) Anesthesiologist assistant. A person who meets each of the following conditions:

1. Has graduated from an anesthesiologist assistant program accredited by the American Medical Association's Committee on Allied Health Education and Accreditation or by its successor agency;

2. Has passed the certifying examination administered by the National Commission on Certification of Anesthesiologist Assistants;

3. Has active certification by the National Commission on Certification of Anesthesiologist Assistants;

4. Is currently licensed as an anesthesiologist assistant in the state of Missouri; and

5. Provides health care services delegated by a licensed anesthesiologist.

(E) Certified nurse anesthetist. A registered nurse licensed under Chapter 335, RSMo, who has been graduated from a school of nurse anesthesia accredited by the Council on Accreditation of Educational Programs of Nurse Anesthesia or its predecessor, and is certified or is eligible for certification as a nurse anesthetist by the Council on Certification of Nurse Anesthetists.

(F) Dentist means a person licensed to practice dentistry pursuant to Chapter 332, RSMo.

(G) Department means the Department of Health and Senior Services.

(H) Governing body means an individual owner, partnership, corporation or other legally established authority in whom the ultimate authority and responsibility for management of the ambulatory surgical center is vested.

(I) Governmental unit means any city, county or other political subdivision of this state, or any department, division, board or other agency of any political subdivision of this state.

(J) Infection control officer. An individual who is a licensed physician, licensed registered nurse, has a bachelor's degree in laboratory science, or has similar qualifications and has additional training or educational preparation in infection control, infectious diseases, epidemiology and principles of quality improvement.

(K) Licensed practical nurse (LPN). A person who holds a valid license issued by the State Board of Nursing pursuant to Chapter 335, RSMo.

(L) Medical staff. A formal organization of physicians which may include dentists and podiatrists who are appointed by the governing body to attend patients within the ambulatory surgical center.

(M) Patient. A person admitted to the ambulatory surgical center by and upon the order of a physician, or dentist, or podiatrist in accordance with the orders of a physician.

(N) Person. Any individual, firm, partnership, corporation, company or association, or the legal successors of any of them.

(O) Physician means a person licensed to practice medicine pursuant to Chapter 334, RSMo and who has active or associate staff membership and privileges in a licensed hospital in the community.

(P) Physician with training or experience in the administration of anesthetics. A person licensed to practice medicine under Chapter 334, RSMo whose training and experience (credentials) have been evaluated by the medical staff and privileges granted to direct the anesthesia service or to administer anesthetics or both.

(Q) Podiatrist means a person licensed to practice podiatry pursuant to Chapter 330, RSMo.

(R) Qualified anesthesia personnel. An anesthesiologist who is a physician with training or experience in the administering of anesthetics, a certified registered nurse anesthetist or an anesthesiologist assistant.

(S) Registered nurse (RN). A person who holds a valid license issued by the State Board of Nursing pursuant to Chapter 335, RSMo.

(T) Root cause analysis. A process for identifying the basic or causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event.

(U) Sentinel event. An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a reoccurrence would carry a significant chance of a serious adverse outcome.

(2) Procedure for Licensing.

(A) Application for a license to establish and operate an ambulatory surgical center shall be made in writing to the Department of Health on forms provided by it. Each application

for a license, except applications from a governmental unit, shall be accompanied by an annual license fee of two hundred dollars ($200).

(B) In any facility, except hospitals where surgical procedures may be performed or licensed abortion facilities, a license to establish and operate an ambulatory surgical center shall be required in the absence of evidence demonstrating that the facility does not meet the definition established in subsection (1)(A) and paragraph (1)(A)1. of this rule. The evidence required shall include, but need not be limited to, statistical records of individuals treated, individuals receiving surgical procedures, and financial reports including revenue from surgical and related procedures and total revenues.

(C) The application shall be made by the person(s) or corporation operating the facility.

(D) A license shall not be issued or renewed by the Department of Health until a facility has been surveyed by a representative of the Bureau of Hospital Licensing and Certification and found to be in substantial compliance with the requirements of 19 CSR 30-30.020 and 19 CSR 30-30.030. Ambulatory surgical centers which also provide abortion services shall comply with the social service and counseling required by the Department of Health for the licensure of abortion facilities in 19 CSR 30-30.060(3)(H).

(E) The licensee shall notify the Department of Health in writing of any change of name of the administration.

(F) Separate licenses are required for facilities maintained on separate sites even though operated by the same owner.

(G) The license shall be conspicuously posted in a public area in the facility.

(H) If a facility ceases to provide patient care or to otherwise operate as an ambulatory surgical center within the definition in section 197.200.1, RSMo 1986 for a period in excess of fourteen (14) days without written approval of the Department of Health, the facility shall surrender its license to the Department of Health. The facility shall not operate again as an ambulatory surgical center until an application for an ambulatory surgical center license is submitted with assurance that the facility complies with the requirements of the rules of this chapter and a license is issued.

(I) An ambulatory surgical center which is licensed as part of a hospital does not require a separate license.

AUTHORITY: section 197.225, RSMo 2000 and 197.154, RSMo Supp. 2006. This rule was previously filed as 13 CSR 50-30.010. Original rule filed Dec. 2, 1975, effective Feb. 1, 1976. Amended: Filed Jan. 3, 1990, effective April 12, 1990. Amended: Filed Sept. 20, 2005, effective April 30, 2006. Amended: Filed Jan. 16, 2007, effective Aug. 30, 2007.*

**Original authority: 197.154, RSMo 2004 and 197.225, RSMo 1975, amended 1996.*

19 CSR 30-30.020 Administration Standards for Ambulatory Surgical Centers

PURPOSE: The Division of Regulation and Licensure, Department of Health and Senior Services has the authority to establish standards for the operation of ambulatory surgical centers. This rule provides standards for the administration, medical staff, nursing staff and supporting services to ensure high quality services to users of ambulatory surgical centers.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Organization, Administration, Medical Staff, Nursing Staff and Supporting Services.

(A) Governing Body.

1. The governing body is to establish and adopt bylaws by which it shall abide in conducting all business of the facility. Bylaws so adopted and changes are to be submitted to the Department of Health for its records.

2. Bylaws of the governing body shall provide for the selection and appointment of medical staff members based upon defined criteria and in accordance with an established procedure for processing and evaluating applications for membership. Applications for appointment and reappointment shall be in writing and shall signify agreement of the applicant to conform with bylaws of both the governing body and medical staff and to abide by defined professional ethical standards. Initial appointments to the medical staff shall not exceed twelve (12) months. Reappointments, which may be processed and approved at the discretion of the governing body on a monthly or other cyclical pattern, shall not exceed two (2) years.

3. The governing body shall select and employ an administrator who is a physician licensed in Missouri, a registered nurse (RN) licensed in Missouri or an individual who has at least one (1) year of administrative experience in health care; and shall notify the Department of Health of any change of administration within thirty (30) days after change has been made.

4. The governing body shall require in its bylaws that the ambulatory surgical center and medical staff abide by acceptable professional ethical standards.

5. Representatives of the Department of Health shall have access to inspect the ambulatory surgical center during normal working hours.

6. A written plan shall provide for the evacuation of patients, visitors and personnel in the event of fire or other disaster within the facility and for an alarm system to notify personnel. Personnel are to be acquainted with the evacuation plan to properly perform their duties in the event of a fire or disaster.

7. All fires occurring on the ambulatory surgical center premises shall be reported to the Department of Health within one (1) week giving the cause, location and extent of damage and personal injury, if any.

8. The administrator shall be responsible for the development and enforcement of written policies which prohibit smoking throughout the ambulatory surgical center except specific designated areas where smoking may be permitted. Each designated area shall have one hundred percent (100%) of the air supplied to the room exhausted.

9. Written smoking control policies shall be posted throughout the ambulatory surgical center.

10. Smoking shall be prohibited in any room or compartment where flammable liquids, combustible gases or oxygen are used or stored and in any other hazardous location. Those areas shall be posted with NO SMOKING signs.

11. The administrator shall assure that all patients admitted to the facility are under the care of a physician who is a

member of the staff.

12. The administrator shall develop written procedures for receiving and investigating complaints regarding the facility, its physicians, dentists, podiatrists and employees practicing or working in the facility.

13. The administrator shall designate an individual duly qualified to act in his/her capacity during his/her absence.

14. The administrator shall assure the provision of adequate equipment in good repair within the facility to provide efficient services and protection to the patient and staff.

15. Personnel records shall be maintained on each employee and shall include job application, professional licensing information and health information.

16. If a patient is transferred to another health facility, essential medical information, including diagnosis, is to be transmitted with the patient to insure continuity of care.

(B) Medical Staff.

1. The medical staff of an ambulatory surgical center shall be an organized group which shall initiate and adopt, with approval of the governing body, bylaws, rules and policies governing their professional activities in the facility.

2. Each member of the medical staff shall be a physician, dentist or podiatrist legally licensed to practice in Missouri.

3. Each member of the medical staff shall submit a written application for staff membership on an approved form to the governing body.

4. Surgical procedures shall be performed only by physicians, dentists or podiatrists who at the time are privileged to perform surgical procedures in at least one (1) licensed hospital in the community in which the ambulatory surgical center is located, thus providing assurance to the public that patients treated in the center shall receive continuity of care should the services of a hospital be required. As an alternative, the facility may submit a copy of a current working agreement with at least one (1) licensed hospital in the community in which the ambulatory surgical center is located, guaranteeing the transfer and admittance of patients for emergency treatment whenever necessary.

5. There shall be a chief of staff acceptable to the governing body and other officers and committees as is deemed necessary to meet the goals of the ambulatory surgical center.

6. The medical staff shall develop and utilize appropriate procedures for review and evaluation of surgical practices and techniques at least annually. In those instances when the medical staff membership numbers fewer than three (3), arrangements shall be made with the hospital medical staff where the physicians are privileged or with the medical staff of the hospital guaranteeing the transfer and admittance of patients for emergency treatment for an independent review and evaluation of surgical practices and techniques at least annually. Complete records shall be kept of these reviews and evaluations.

7. The medical staff shall assist in the maintenance of complete records on each patient.

8. The medical staff shall comply with professional ethical standards established, defined and approved by the medical staff.

9. The medical staff of each facility shall develop a policy stipulating which surgically removed tissues shall be sent to the pathologist for review. This policy shall be approved by the governing body.

10. The medical staff shall establish policies for the recommendation of discharge of a member by the governing body.

11. The medical staff bylaws shall require at least one (1) physician member of the medical staff to be on duty in the ambulatory surgical center at all times a patient is receiving or recovering from an anesthetic (local, general or intravenous sedation). Staffing shall be adequate to meet the needs of the patients.

12. The medical staff, as a body or through a committee, shall review and evaluate the quality and appropriateness of all aspects of medical care given at the facility.

13. The administrator shall bring to the attention of the chief of the professional staff any failure by members of that staff to conform with established policies of the facility regarding administrative matters, professional standards and the maintenance of adequate medical records.

(C) Nursing Services.

1. There shall be an organized nursing service under the direction of a professional RN with postgraduate education or experience in surgical nursing.

2. There shall be at least one (1) professional RN on duty in the ambulatory surgical center at all times a patient is in the facility.

3. Written policies and procedures consistent with generally accepted nursing practices are to be developed for the direction and guidance of nursing personnel.

4. All licensed practical nurses and other nursing personnel involved in patient care shall be under the direct supervision of a professional RN.

5. At least one (1) professional RN other than the individual administering anesthesia shall be available in each operating room during surgical procedures.

6. At least one (1) RN shall be in the recovery room during the patients' postanesthetic recovery period at a ratio of no more than four (4) patients to one (1) nurse.

7. Nursing personnel are to be familiar with the location, operation and use of electrocardiogram (EKG or ECG) equipment, pulse oximeter, blood pressure equipment and emergency and resuscitative equipment.

8. There shall be a mechanism for the review and evaluation on a regular basis of the quality and appropriateness of nursing services.

9. Policies shall be developed regarding the use of overtime. The policies shall be based on the following standards:

A. Overtime shall not be mandated for any licensed nursing personnel except when an unexpected nurse staffing shortage arises that involves a substantial risk to patient safety, in which case a reasonable effort must be applied to secure safe staffing before requiring the on-duty licensed nursing personnel to work overtime. Reasonable efforts undertaken shall be verified by the ambulatory surgical center. Reasonable efforts shall include pursuing all of the following:

(I) Reassigning on-duty staff;

(II) Seeking volunteers to work extra time from all available qualified nursing staff who are presently working;

(III) Contacting qualified off-duty employees who have made themselves available to work extra time, per diem staff, float pool and flex team nurses; and

(IV) Seeking personnel from a contracted temporary agency or agencies when such staffing is permitted by law or an applicable collective bargaining agreement and when the employer regularly uses the contracted temporary agency or agencies;

B. In the absence of nurse volunteers, float pool nurses, flex team nurses or contracted temporary agency staff secured by the reasonable efforts as described in (1)(C)9.A. and if qualified reassignments cannot be made, the ambulatory surgical center may require the nurse currently providing

the patient care to fulfill his or her obligations based on the Missouri Nurse Practice Act by performing the patient care which is required;

C. The prohibition of mandatory overtime does not apply to overtime work that occurs because of an unforeseeable emergency or when an ambulatory surgical center and a subsection of nurses commit, in writing, to a set, predetermined staffing schedule or prescheduled on-call time. An unforeseeable emergency is defined as a period of unusual, unpredictable or unforeseeable circumstances such as, but not limited to, an act of terrorism, a disease outbreak, adverse weather conditions, or natural disasters which impact patient care and which prevent replacement staff from reporting for duty;

D. The facility is prohibited from requiring a nurse to work additional consecutive hours and from taking action against a nurse on the grounds that a nurse failed to work the additional hours or when a nurse declines to work additional consecutive hours beyond the nurse's predetermined schedule of hours because doing so may, in the nurse's judgement, jeopardize patient safety;

E. Subparagraph 19 CSR 30-30.020(1)(C)9.D. is not applicable if overtime is permitted under subparagraphs 19 CSR 30-30.020(1)(C)9.A., B., and C; and

F. Nurses required to work more than twelve (12) consecutive hours under subparagraphs 19 CSR 30-30.020(1)(C)9.A., B., or C. shall be provided the option to have at least ten (10) consecutive hours of uninterrupted off-duty time immediately following the worked time.

(D) Emergency Equipment.

1. Equipment shall be provided to handle emergencies resulting from the services rendered in the facility. The following shall be provided as a minimum: portable ECG oscilloscope, portable defibrillator, portable suction equipment, inhalation-resuscitation equipment, emergency tray and equipment for use in airway obstructions.

2. Procedures are to be developed to insure that emergency equipment is kept in good working order.

(E) Anesthesia Service.

1. The anesthesia service shall be under the direction of an anesthesiologist or a physician with training or experience in the administration of anesthetics. The clinical privileges of qualified anesthesia personnel shall be reviewed by the director of anesthesia service and the medical staff and approved by the governing body.

2. An anesthesiologist or physician with training or experience in the administration of anesthetics shall be on the premises and readily accessible during the administration of anesthetics — whether local, general or intravenous sedation — and the postanesthetic recovery period until all patients are alert or medically discharged. Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care and shall continually evaluate the patient's oxygenation, ventilation, circulation and temperature. Oxygen analyzers, pulse oximeter and electrocardiography equipment shall be available.

3. Policies and procedures on the administration of anesthetics and drugs which produce conscious and deep sedation shall be developed by the medical staff in consultation with at least one (1) anesthesiologist and approved by the governing body.

4. Prior to undergoing general anesthesia, patients shall have a history and physical examination by a physician on the patient's record including the results of any necessary laboratory examinations. Each administration of a regional, general or intravenous sedation anesthetic shall be ordered by an anesthesiologist or a physician with training and experience in the administration of anesthetics. The patient records shall contain a preanesthetic evaluation and a postanesthetic note by qualified anesthesia personnel.

5. Periodic inspections shall be made of all areas where flammable anesthetics are administered or stored to insure safeguards are being observed by personnel and equipment meets safety standards. A written record of inspections shall be kept. If the administration of the facility provides written assurance to the Department of Health and Senior Services that no flammable anesthetics will be administered and the area is posted to that effect, safety inspections will not be required.

6. All anesthetics shall be administered by anesthesiologists, physicians with training or experience in the administration of anesthetics, certified registered nurse anesthetists or anesthesiologist assistants supervised by an anesthesiologist, except for local anesthetic agents which may be administered by the attending physician, dentist or podiatrist. Notwithstanding the provisions of sections 334.400 to 334.430, RSMo, or the rules of the Missouri State Board of Registration for the Healing Arts, the governing body of every ambulatory surgical center shall have full authority to limit the functions and activities that an anesthesiologist assistant performs in such ambulatory surgical center. Nothing in this paragraph shall be construed to require any ambulatory surgical center to hire an anesthesiologist who is not already employed as a physician prior to August 28, 2003.

7. Written procedures and criteria for discharge from the recovery service shall be approved by the medical staff.

8. There shall be a mechanism for the review and evaluation on a regular basis of the quality and scope of anesthesia services.

(F) Medical Records.

1. A medical record shall be maintained for every patient cared for in an ambulatory surgical center.

2. Medical records are to be filed for easy accessibility and available for inspection by duly authorized representatives of the Department of Health.

3. The medical record shall support the diagnosis or need for medical services and shall include the following: patient identification; chief complaint, pertinent history and preoperative physician's physical exam, including copies of any laboratory, X-ray, pathology, anesthesia record, preanesthesia and postanesthesia evaluation record and consultation reports; description of surgical procedures, treatments or observations on care provided, including complications, if any; signature or initials of physician on each clinical entry; signature or initials of nursing personnel on notes or observations; condition of patient on discharge; instructions given to patient on release from facility; copy of transfer form if patient is transferred to another health facility; and operative and anesthesia consent forms.

4. The facility shall establish and have approved by the facility governing body a medical record retention policy that meets its needs for clinical, educational, statistical or administrative purposes. All medical records shall be safeguarded against loss and unofficial use.

(G) Sterilizing and Supply.

1. Policies and procedures shall be established in writing for storage, maintenance and distribution of supplies and equipment.

2. Sterile supplies and equipment shall not be mixed with unsterile supplies and shall be stored in dustproof and

moisture-free units. They shall be properly labeled.

3. Sterilizers and autoclaves shall be provided of appropriate type and necessary capacity to adequately sterilize instruments, utensils, dressings, water, operating 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 periodically by an approved method. Adequate surveillance methods for checking sterilization procedures shall be employed. When contractual arrangements for sterile supplies, equipment and instruments have been approved by the Department of Health, on-premises sterilizing equipment is not required other than the required highspeed sterilizer.

4. 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.

(H) Radiological and Pharmaceutical Services.

1. For radiology services performed in the center, the rules authorized by section 192.420, RSMo shall be met. Radiation protection shall be provided in accordance with 19 CSR 20-10.010 – 19 CSR 20-10.200 and the recommendations of the National Council on Radiation Protection and Measurements. There shall be written policies and procedures and records shall be kept of at least annual checks and calibrations of all X-ray and gamma beam therapy equipment. Only qualified personnel shall operate radiological equipment.

2. The use of drugs in the facility shall be under the direction of a designated individual in accordance with accepted standards of practice and applicable state and federal laws. There shall be procedures relating to procuring, storage, security, records, labeling, preparation, orders, administration, adverse reactions and disposal or other disposition of drugs. There shall be specific procedures for controlled drug security and recordkeeping.

3. All radiological services shall be under the direction of a qualified physician.

4. There shall be a mechanism for the review and evaluation on a regular basis of the quality and scope of radiological and pharmaceutical services.

(I) Laboratory Services.

1. Laboratory procedures performed in an ambulatory surgical center shall be limited to routine tests (such as hemoglobin, hematocrit, leucocyte count, glucose, urinalysis and pregnancy tests). Laboratory services obtained under contract shall be from a laboratory located in a hospital licensed under section 197.010, RSMo 1986 or from a laboratory certified as an independent laboratory by the federal Health Care Financing Administration.

2. Procedures performed in the facility shall be appropriate for the services provided and shall be performed according to written or printed instructions. Instructions shall include calibration and control methods that assure the accuracy and precision of each patient test. Equipment shall be calibrated and maintained in conformance with manufacturers' instructions. All instructions shall be available in the facility.

3. The facility shall have access to a blood bank located in a hospital licensed under section 197.010, RSMo 1986 or to a regional blood center licensed by the federal Food and Drug Administration to provide blood for transfusion purposes. The blood bank or blood center shall have crossmatching capability and written procedures for investigating transfusion reactions.

4. Laboratory services shall be under the direction of a physician member of the medical staff.

(J) Supportive Services.

1. Provision shall be made in writing for the laundering and processing of institutional linen and washable goods. Services may be provided by an on-premises laundry operated by the facility or by an outside laundry through contractual agreement.

2. If food services are provided, services shall comply with 19 CSR 20-1.010.

(K) Infection Control.

1. There shall be an active multidisciplinary infection control committee responsible for implementing and monitoring the infection control program. The committee shall include, but not be limited to, the infection control officer, a member of the medical staff, registered professional nursing staff, quality improvement staff and administration. This program shall include measures for preventing, identifying, and investigating health-care-associated infections (HAI) and shall establish procedures for: collecting data, conducting root cause analysis, reporting sentinel events and implementing corrective actions. These measures and procedures shall be applied throughout the ambulatory surgical center, including as part of the employee health program.

2. The ambulatory surgical center shall provide reports to the department as required by 19 CSR 10-33.050.

3. The infection control committee shall conduct an ongoing review and analysis of HAI data and risk factors. Priorities and goals related to preventing the acquisition and transmission of potentially infectious agents will be established based on risks identified.

4. Ambulatory surgical centers shall implement written policies and procedures outlining infection control measures for all patient care and support departments. These measures shall include, but are not limited to, an ambulatory surgical center-wide hand hygiene program that complies with the current Centers for Disease Control and Prevention (CDC) *Guideline for Hand Hygiene in Health-Care Settings*, which is incorporated by reference in this rule. A copy of the CDC *Guideline for Hand Hygiene in Health-Care Settings* may be obtained from the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, DC 20402-9371; telephone: (202) 512-1800. This rule does not incorporate any subsequent amendments or additions. At a minimum, the program shall require every health care worker to properly wash or sanitize his or her hands immediately before and immediately after each and every episode of patient care. Procedures shall include, at a minimum, requirements for the facility's infection control program to conduct surveillance of personnel in accordance with section 197.150, RSMo. Surveillance procedures also may include monitoring the employees' and medical staff's use of hand hygiene products. A mechanism approved by the ambulatory surgical center infection control committee for reporting and monitoring patient and employee infections shall be developed and implemented for all patient care and support departments in the ambulatory surgical center.

5. Orientation and ongoing education shall be provided to all personnel on the cause, effect, transmission and prevention of infections.

6. There shall be a mechanism for the review and evaluation on a regular basis of the quality and effectiveness of infection control throughout the facility.

(L) Any person having a complaint pertaining to the care rendered a patient in an ambulatory surgical center may direct the complaint in writing to the Missouri Department of Health, Bureau of Hospital Licensing and Certification, P.O. Box 570, Jefferson City, MO 65102. The person making the complaint shall be contacted by the Department of Health within five (5) working days of receipt of the complaint and the complaint

shall be investigated by the Department of Health within twenty (20) working days of receipt of the complaint.

(M) Requests for deviations from the requirements of this rule shall be in writing to the Department of Health. Requests and approvals shall be made a part of the permanent Department of Health records for the facility. Licensed ambulatory surgical centers participating in innovative projects may be granted a waiver of exemption from certain requirements. Waivers may be granted by the chief of the Bureau of Hospital Licensing and Certification with the approval of the director of the Division of Health Resources.

AUTHORITY: section 197.225, RSMo 2000 and 197.154, RSMo Supp. 2006. This rule was previously filed as 13 CSR 50-30.020. Original rule filed Dec. 2, 1975, effective Feb. 1, 1976. Amended: Filed June 14, 1988, effective Oct. 13, 1988. Amended: Filed Jan. 3, 1990, effective April 12, 1990. Amended: Filed Sept. 20, 2005, effective April 30, 2006. Amended: Filed Jan. 16, 2007, effective Aug. 30, 2007.*

**Original authority: 197.154, RSMo 2004 and 197.225, RSMo 1975, amended 1996.*

19 CSR 30-30.030 General Design and Construction Standards for Ambulatory Surgical Centers

PURPOSE: The Division of Health Resources, Department of Health has the authority to establish construction standards for ambulatory surgical centers. This rule provides standards for facilities to ensure sanitary and fire-safe facilities.

PUBLISHER'S NOTE: The publication of the full text of the material that the adopting agency has incorporated by reference in this rule would be unduly cumbersome or expensive. Therefore, the full text of that material will be made available to any interested person at both the Office of the Secretary of State and the office of the adopting agency, pursuant to section 536.031.4, RSMo. Such material will be provided at the cost established by state law.

(1) All new ambulatory surgical centers and additions to and remodeling of existing licensed ambulatory surgical centers shall be designed to provide all of the facilities required by this rule and fire-safety standards, arranged to accommodate with maximum convenience all of the functions required by this rule and arranged to provide comfortable, attractive, sanitary, fire-safe, secure and durable facilities for the patients. This rule is applicable to ambulatory surgical centers which began operation or construction or renovation of a building to operate an ambulatory surgical center on any date after April 12, 1990. Existing ambulatory surgical centers licensed by the Department of Health prior to April 12, 1990 shall be maintained in compliance with the rules under which they were initially licensed and are not required to comply with the construction requirements for new ambulatory surgical centers until they are remodeled or expanded. The Department of Health, within its discretion and for good reason, may grant exceptions to this rule. These exceptions shall be in writing and shall be made a part of the Department of Health records for the facility.

(A) General Construction — Related Authorities.

1. Construction of all ambulatory surgical centers and additions to or remodeling of ambulatory surgical centers shall comply with all local and state regulations and codes.

(B) Planning and Construction Procedure.

1. Plans and specifications complying with 19 CSR 30-30.040 shall be prepared for the construction of all ambulatory surgical centers and any additions to and remodeling of ambulatory surgical centers. Plans for ambulatory surgical centers which in addition to other surgical procedures will offer abortion services shall incorporate facilities for patient counseling as required for licensed abortion facilities in 19 CSR 30-30.070(2)(Z). The plans and specifications shall be prepared by an architect or a professional engineer licensed to practice in Missouri. The plans and specifications shall have received written approval of the Department of Health prior to the submission of an application for licensure of the new facility. The license for a new ambulatory surgical center will not be issued prior to the facility being inspected and found in substantial compliance with this rule.

2. The Department of Health shall be notified within five (5) days after construction begins. If construction of the project is not started within one (1) year after the date of approval of the plans and specifications, the plans and specifications shall be amended if necessary to comply with the then current regulations before construction work commences (see 19 CSR 30-30.040 Preparation of Plans and Specifications for Ambulatory Surgical Centers).

(C) Site.

1. Adequate vehicular and pedestrian access shall be provided within the lot lines to the main entrance, ambulance entrance, community activities and services, including loading and unloading space for delivery trucks. Roads, walks, ramps and entrances shall be accessible to the physically handicapped. Details for accommodation of the handicapped shall be consistent with the guidelines contained in *A Guidebook to: The Minimum Federal Guidelines & Requirements for Accessible Design* published January 6, 1981, by the United States Architectural and Transportation Barriers Compliance Board.

2. Adequate off-street parking shall be provided. Space shall be provided at the ratio of two (2) spaces for each patient cart in the recovery room plus parking space to accommodate the maximum number of staff on duty at any one (1) time. A minimum of two (2) handicapped-accessible parking spaces shall be provided for use by the staff and patients.

3. Plans for proposed new ambulatory surgical centers and additions to ambulatory surgical centers should be reviewed by the local fire protection agency assigned to that area. Fire lanes shall be provided and kept clear to provide immediate access for fire-fighting equipment.

(D) General Design — Facilities.

1. The arrangement of the physical plant shall provide for separation of the administrative, business and public areas from patient service areas.

A. Administrative area — at a minimum shall consist of a business office with information center and telephone, administrator's office, medical records storage (may be in patient service area), sufficient to satisfy the requirements of 19 CSR 30-30.020(1)(F)4., lobby and waiting room, telephone available to public, handicapped-accessible public toilets for each sex, handicapped-accessible drinking fountain, and janitor's closet.

B. Patient service areas — at a minimum shall consist of two (2) or more patient change areas per sex with access to toilets; secure storage facilities for each patient's street clothing and belongings; staff lounge with storage for staff's clothing and personal effects, and handwashing facilities; examination room of at least one hundred (100) square feet with handwashing facilities; preoperative holding room sized for at least two (2) patients per operating room with each patient location being at least thirty-five (35) square feet; janitors' closet

with sufficient space for equipment for maintaining the patient service area; laboratory, unless provisions have been made for off-premises laboratory services; postanesthesia recovery room with handwashing facilities, sized to accommodate at least two (2) patient stretchers per operating room with three feet (3') of clear space around the sides and foot of each stretcher; nurses' work station with medication storage and preparation facilities, storage space for emergency equipment; doctors' dressing room, toilet and handwashing facilities arranged to provide a one (1)-way traffic pattern so that personnel entering from outside surgery can change and move directly into the surgical suite corridor; nurses' dressing room, toilet and handwashing facilities; one (1) scrub-up facility for each operating room; materials processing facilities including a decontamination utility room with workcounter, sink, clinic sink with bedpan cleanser and space for holding soiled materials and trash, and a pass-thru window to an adjacent clean workroom with workcounter, sink, high speed sterilizer and space for storing sterilized and packaged clean supplies; and one (1) or more operating rooms.

(I) Operating rooms shall have a floor area of not less than two hundred twenty-five (225) square feet with a minimum dimension of not less than fifteen feet (15').

(II) The administration of general anesthetics in new ambulatory surgical centers is restricted to nonflammable agents. Any new ambulatory surgical center desiring to administer flammable anesthetics shall first receive the written permission of the Missouri Department of Health and will be required to include National Fire Protection Association (NFPA) safety design features for flammable anesthetizing locations into the building.

C. Support facilities – space for mechanical equipment, standby electric generator with automatic transfer switch, medical gas storage, housekeeping supply storage and a general storage room providing at least one hundred (100) square feet per operating room.

(E) General Design – Details.

1. A continuous system of unobstructed corridors and aisles shall extend through the enclosed portion of each story of the facility, connecting all rooms and spaces with each other and with all entrances, exitways and elevators except that mechanical equipment space need not be connected to the corridor system. Corridors providing access to operating rooms and postanesthesia recovery rooms shall be at least eight feet (8') wide, all other corridors shall be at least five feet (5') wide.

2. At least two (2) exits, remote from each other, shall be provided for each floor.

3. Exit doors and doors to operating rooms and recovery rooms shall be at least forty-four inches (44") wide. All other doors through which patients and personnel will pass shall be at least thirty-two inches (32") wide.

4. The width of stairways except stairways, to mechanical spaces, shall not be less than forty-four inches (44").

5. Exit discharge doors shall swing in the direction of exit traffic.

6. Ceilings in operating rooms shall not be less than nine feet (9'). Ceilings in all other rooms shall not be less than eight feet (8'), except that ceilings in corridors and storage rooms may be seven feet six inches (7' 6").

7. Ceilings in operating rooms shall have a smooth washable surface. All other ceilings may be of acoustical material.

8. The floor finish in operating rooms shall be seamless with an integral base covered with the floor and tightly sealed with the wall.

9. Walls shall be smooth and easily cleanable. Walls in operating rooms and recovery rooms shall have waterproof painted, glazed or similar washable surfaces.

10. Floors in the lobby, waiting room and offices shall be easily cleanable. Floors in operating rooms and recovery rooms shall be smooth, slip-resistant and washable.

11. Wall and ceiling surfaces of all required corridors and exitways shall be of a material treated so it does not have a flame-spread classification of more than twenty-five (25) according to the method for the *Fire Hazard Classification of Building Materials* of Underwriters' Laboratories, Inc. Rooms and small office spaces shall have wall and ceiling surfaces with a flame-spread rating of not more than seventy-five (75) when tested according to American Society of Testing and Materials (ASTM) Standard E-84. All floor covering shall have a minimum flame-spread rating of forty-five one hundredths (0.45) watts per square centimeter when tested according to NFPA 253-1978 (Flooring Radiant Panel Test).

12. Paper towel dispensers and soap dispensers shall be provided at all lavatories used for handwashing.

(F) Fire Safety Construction – Specifications and Details.

1. One (1)-story buildings shall be of not less than Type II (111) construction as described in the *Standard on Types Building Construction 1979* published by the NFPA. Fully sprinklered one (1)-story buildings may be of type II (000) construction.

2. Multistory buildings shall be of not less than Type II (222) construction. Fully sprinklered multistory buildings may be of not less than Type II (111) construction.

3. Walls enclosing stairways, elevator shafts, other vertical openings between floors and boiler rooms shall be of construction having a fire rating not less than that required for the structure.

4. The number of stories in any building housing an ambulatory surgical center shall be determine by counting the number of occupiable levels in the structure regardless of their location above or below grade.

5. Ambulatory surgical centers with a floor area of two thousand (2000) square feet or more shall be divided by one (1)-hour rated walls into at least two (2) smoke zones; each zone not exceeding one hundred fifty feet (150') in any dimension. Each smoke zone shall have at least one (1) means of egress which discharges directly to the outside.

6. In a building of multitenant occupancy, the ambulatory surgical center and the entirety of the surgical center's access to exit system shall be separated from other tenants by walls having a fire-resistance rating of at least one (1) hour.

7. Smoke detectors shall be installed in all habitable spaces in the ambulatory surgical center and in the access to exit corridor system at intervals not exceeding seventy-five feet (75') and no more than thirty feet (30') from the ends of corridors.

(G) Elevators.

1. If patient services are located on any floor other than the grade level, at least one (1) elevator is to be provided.

2. Inside dimensions of the elevator shall be at least five feet by seven feet (5' × 7') clear inside to accommodate a wheeled stretcher and attendants. The elevator car door shall have a clear opening of not less than forty-four inches (44").

(H) Electrical Requirements.

1. Every room, including storage rooms, corridors and all other areas shall be sufficiently illuminated to facilitate efficient performance of all necessary work.

2. Operating and recovery rooms shall have general lighting in addition to special lighting units at the surgical tables and for each recovery unit.

3. All sources of light and power in the operating room

shall comply with the *Standard for the use of Inhalation Anesthetics (Flammable and Nonflammable 1978)* published by the NFPA.

4. An approved automatically-operated, electrically-powered fire alarm system which will alert all areas of the facility when activated shall be installed including audible and visual alarm devices located throughout the ambulatory surgical center and its access-to-exit corridor system, manual pull stations near each exit door. The fire alarm system shall be interconnected with all required smoke detectors and extinguishment systems, if provided. The fire alarm system shall be connected directly to the fire department or a dispatch service.

5. An intercom, nurse call system or other means of communication connecting each operating room and the recovery room area to a constantly staffed location shall be installed to summon assistance during emergencies.

6. A generator with on-site fuel storage for at least four (4) hours of operation under load shall be provided as an emergency source of electricity and connected by an automatic transfer switch to certain circuits for lighting and power. The emergency electrical service shall be installed and arranged so that full voltage and frequency is available and supplying power to emergency loads within ten (10) seconds after normal power is interrupted. Emergency electric services shall be provided for the following:

A. Lighting – exitways, including exit signs; all operating room lights; all recovery room lights; minimal task lighting in all clinical areas; generator set location; and elevator if required; and

B. Power – all alarm systems; receptacles in operating and recovery rooms; the operating room communication system; the pump for central suction system, if provided; and elevator, if required.

(I) Heating, Ventilating and Air-Conditioning Equipment.

1. Air-conditioning, heating and ventilating equipment shall be provided, maintained and operated so as to provide an adequate degree of comfort to all occupants.

2. All air delivered to operating rooms shall be delivered at or near the ceiling of the room served and all air returned or exhausted shall be removed near the floor level. At least two (2) return or exhaust outlets shall be used in each operating room and located not closer than three inches (3") to the floor and not more than twelve inches (12") above the floor.

3. The ventilation systems shall be designed and balanced to provide the pressure relationship shown in Table I.

4. For the clinical areas, requirements for outdoor air changes may be deleted or reduced and total air changes per hour supplied may be reduced to twenty-five percent (25%) of the figures listed in Table I when the room is unoccupied and unused, provided that indicated pressure relationships are maintained. An interconnect with the general illumination light switch for each operating room shall be included to insure that the required ventilation rates including outdoor air are automatically resumed upon reoccupancy of the space. This does not apply to certain areas such as toilets and storage which would be considered as in use even though unoccupied.

TABLE I
Pressure Relationships and Ventilation of Certain Areas

Area Designation	Pressure Relationship to Adjacent Areas	Minimum Air Changes of Outdoor Air Per Hour	Minimum Total Air Changes Per Hour	All Air Exhausted Directly to Outdoors	Recirculated Within Room
Operating Room	P	5	15	Optional	No
Recovery	P	2	26	Optional	No
Patient Area Corridor	E	2	24	Optional	No
Treatment Room	E	2	6	Optional	No
Laboratory	N	2	6	Optional	No
Soiled Workroom	N	2	4	Yes	No
Clean Workroom	P	2	4	Optional	Optional
Toilet Room	N		10	Yes	No
Janitor's Closet	N		10	Yes	No

P=Positive N=Negative E=Equal

5. Ventilation systems for the surgical suite which includes the operating rooms, surgical corridor and support areas, and recovery rooms shall have two (2) filter beds. Filter bed no. 1 shall be located upstream of the air-conditioning equipment and have an efficiency rating of not less than twenty-five percent (25%). Filter bed no. 2 shall be located downstream of the air-conditioning equipment and have an efficiency rating of not less than ninety percent (90%). The ventilation systems serving all other areas shall have at least one (1) filter having an efficiency rating of not less than twenty-five percent (25%).

6. Space and access panels shall be provided for the easy maintenance and replacement of all filters installed in the ventilation equipment.

7. Ducts supplying air to the operating suite and recovery rooms shall be externally insulated downstream from the final filter.

8. Variable volume-ventilation systems may be used only in the administrative areas of ambulatory surgical centers.

(J) Plumbing.

1. The requirements of the current edition of the *National Plumbing Code* shall be complied with insofar as they may apply and to the extent they are not superseded by requirements specifically stated in these regulations.

A. Systems shall be designed to supply water to the fixtures and equipment on every floor at a minimum pressure of fifteen pounds per square inch (15 psi) during maximum demand periods.

B. Each water service main, branch main, riser and branch to a group of fixtures should be valved. Stop valves shall be provided at each fixture.

C. Hot, cold and chilled water piping and waste piping on which condensation may occur shall be insulated. Insulation of cold and chilled water lines shall include an exterior vapor barrier.

D. Backflow preventers (vacuum breakers) shall be installed on hose bibbs and on all fixtures to which hoses or tubing can be attached such as janitor's sinks and laboratory fixtures.

E. Hot water distribution systems with recirculating loops and pumps shall be arranged to provide hot water service at each fixture at all times.

F. The hot water-heating equipment shall have sufficient capacity to supply the water at temperatures between one hundred five degrees and one hundred fifteen degrees Fahrenheit (105°F–115°F) at a rate not less than five (5) gallons per hour per recovery stretcher.

G. Lavatories and sinks in patient service areas shall have the water supply spout mounted so that its discharge point is a minimum distance of five inches (5") above the rim of the fixture. All lavatories used by medical and nursing staff and food handlers except those in public toilets shall be trimmed with valves which can be operated without the use of hands.

H. Scrub sinks shall be equipped with faucets which can be operated without the use of hands.

AUTHORITY: section 197.225, RSMo 1986. This rule was previously filed as 13 CSR 50-30.030. Original rule filed Dec. 2, 1975, effective Feb. 1, 1976. Amended: Filed Jan. 3, 1990, effective April 12, 1990.

19 CSR 30-30.040 Preparation of Plans and Specifications for Ambulatory Surgical Centers

PURPOSE: The Division of Health Resources, Department of Health has the authority to establish construction standards for ambulatory surgical centers. This rule provides procedures to follow in the submission of plans and specifications for new construction.

(1) Preliminary Plans and Sketches.

(A) When construction is contemplated, either for new buildings additions to existing buildings or material alterations to existing buildings, the preliminary plans or sketches shall be submitted in duplicate to the Department of Health for review and approval before the preparation of working drawings is undertaken. The preliminary plans may be reviewed by the Department of Health in schematic form, but before they are declared acceptable for procedure with working drawings and specifications, they should also include the following information, stated briefly and not in detailed form required in working drawings and specifications:

1. Site plan showing scale, orientation, street names, topography, walks, drives, fire lanes, parking areas and utilities including fire hydrant location;

2. Plans and elevations of the buildings at a scale of not less than one-eighth inch to one foot no inches (1/8":1' 0");

3. Rooms and corridors, designated by name and number;

4. Windows. Note, wired glass where it is required;

5. Doors, including door swings. Identify fire doors by time rating and Underwriters' Laboratories label;

6. Plumbing fixtures. Show fixtures in proper shape and scale for positive recognition. Identify special types such as service sinks and clinic sinks;

7. Plans of rooms shall indicate principal items of furniture accurately scaled;

8. All other principal items of equipment such as boilers, chiller, cooling tower, electrical substations, tanks, air handlers, fan-coil units, kitchen equipment, laundry equipment, cabinets, counters and any other items which take up space and affect the final layout;

9. Fire and smoke-barrier partition designations;

10. Floor lines, top ceiling line and grade lines, designated and preferably dimensioned, and with basic elevations shown;

11. Ceiling heights of principal rooms and also of each room for which the rules establish a minimum ceiling height. Only one (1) typical room of a group need be so shown;

12. Area of each room for which the rules establish a minimum area. Only one (1) typical room of a group need be so noted; and

13. Brief noted descriptions of the general construction and finish; the structural system; the heating, ventilating and air-conditioning systems, including the fuel supply; the plumbing system including the water supply and sewage disposal; and the electrical system.

(B) In the case of a project which is an addition to an existing building, it will be necessary to give the Department of Health sufficient information about the existing building on which to base a determination of acceptability of the plans for the addition. This information shall cover all items required to be provided in an ambulatory surgical center by the rules of the Department of Health and shall be submitted in the form as required for the particular project by the Department of Health.

(2) Working Drawings and Specifications.

(A) Working drawings and specifications, complete in all respects, shall be submitted in duplicate, covering all phases of the construction project, including site preparation; paving; general construction; mechanical work, including plumbing, heating, ventilating and air conditioning; electrical work and all built-in equipment, including elevators, kitchen equipment, cabinet work, etc.

1. Each sheet of the plans and each set of the specifications shall identify the project by name and location and shall bear the names and addresses of the architect or professional engineer and the owner.

2. Each sheet of the plans and each set of specifications shall bear the official seal and signature of the registered architect or registered professional engineer who prepared it.

3. Each set of the plans and each set of specifications shall bear the date of its completion or its latest revision.

4. The plans shall be on sheets of the same size, securely bound into complete sets, with the sheets in the proper order. The specifications shall be securely bound into complete sets.

(B) The working drawings and specifications shall include the following: the material set out in paragraphs (1)(A)1.–12. of this rule; courses and distances of property lines; dimensions and locations of any building, structures, easements, rights-of-way or encroachments on the site; details of party walls, and walls and foundation adjacent to lot line; detailed information by the city engineer or other official report as to established curbs, buildings lines, streets, alleys, sidewalks; all utilities including size, characteristics and location of these services, piping, mains, sewers, poles, wires, hydrants and manholes upon, over or under the site and location of high pressure gas lines within one thousand two hundred feet (1200') of the building; complete information as to the disposal of sanitary, storm water and subsoil drainage; official datum upon which elevations are based and benchmark established on or adjacent to the site; contours on elevations at two foot (2') intervals over site and elevations at the bottom of excavation; and thickness, consistency, character and estimated safe bearing value of various strata encountered.

AUTHORITY: section 197.225, RSMo 1986. This rule was previously filed 13 CSR 50-30.040. Original rule filed Dec. 2, 1975, effective Feb. 1, 1976.

19 CSR 30-30.050 Definitions and Procedures for Licensing Abortion Facilities

PURPOSE: This rule defines terminology used in 19 CSR 30-30.060 and 19 CSR 30-30.070, and establishes the procedures for applying for an abortion facility license.

(1) The following definitions shall be used in the interpretation and enforcement of 19 CSR 30-30.060 and 19 CSR 30-30.070:

(A) Abortion — The act of using or prescribing any instrument, device, medicine, drug, or any other means or substance with the intent to destroy the life of an embryo or fetus in his or her mother's womb; or, the intentional termination of the pregnancy of a mother by using or prescribing any instrument, device, medicine, drug, or other means or substance with an intention other than to increase the probability of a live birth or to remove a dead or dying unborn child;

(B) Abortion facility — Any clinic, physician's office, or any other place or facility in which abortions are performed or induced other than a hospital;

(C) Administrator — A person who is designated by an abortion facility to provide daily supervision over the abortion facility and who is a physician licensed in Missouri, a registered nurse licensed in Missouri, or an individual who has at least one (1) year of administrative experience in health care;

(D) Complication — Includes, but is not limited to, incomplete abortion, hemorrhage, endometritis, parametritis, pyrexia, pelvic abscess, uterine perforation, failed abortion, cervical lacerations, retained products, or diagnosable psychiatric condition;

(E) Department — The Missouri Department of Health and Senior Services;

(F) Discharge summary — A statement completed by a physician or registered nurse regarding the condition of the patient at the time of discharge;

(G) First trimester — The first thirteen (13) weeks of gestation, based upon gestational age;

(H) Gestational age — The length of pregnancy measured from the onset of the last menstrual period, and except in the case of a medical emergency as defined in section 188.015, RSMo, determined by a physician in a manner consistent with accepted obstetrical and neonatal practices and standards after performing or causing to be performed such medical examinations, imaging studies, and tests as a reasonably prudent physician, knowledgeable about the medical facts and conditions of both the woman and the unborn child involved, would consider necessary to perform and consider in making an accurate diagnosis;

(I) Health assessment — A determination of a patient's physical and mental status;

(J) Licensed practical nurse (LPN) – A person licensed to practice practical nursing pursuant to Chapter 335, RSMo;

(K) OB/GYN – A physician who is board-certified or board-eligible by the American Board of Obstetrics and Gynecology or the American Osteopathic Board of Obstetrics and Gynecology;

(L) Person – Any individual, firm, partnership, corporation, association, or other business entity;

(M) Physician – Any person licensed to practice medicine pursuant to Chapter 334, RSMo;

(N) Registered professional nurse – An individual who is a graduate of an approved school of nursing and who is licensed to practice professional nursing under Chapter 335, RSMo; and

(O) Surgical technologist – An individual who is certified by the National Board of Surgical Technology and Surgical Assisting.

(2) Procedures for Licensing Abortion Facilities.

(A) No abortion shall be performed or induced in any place or facility including a clinic or physician's office, without a license issued by the department, except that abortions may be performed or induced in hospitals without a separate abortion facility license issued by the department.

(B) Application for an abortion facility license shall be made in writing to the department on forms provided by the department by the person who will operate the facility. The forms shall require at least the following information: date of application; name of facility to appear on license; street address, city, county, zip code, telephone number, and email address of facility; facility website address, if any; name of person who will operate facility; organizational chart showing ownership and control of facility; name of chief officer of governing body of facility; name and qualifications of administrator; name and qualifications of OB/GYN consultant; types of abortions that will be performed at the facility (i.e., surgical and/or drug- or chemically-induced); estimated number of each type of abortion that will be performed and/or induced annually at facility; number of facility staff; number of physicians on staff; number of physicians routinely performing or inducing abortions at facility; number of anesthesiologists or CRNAs on staff, if any; usual days and hours of facility operation; usual days and times that abortions are induced or performed at facility; number of procedure rooms; and notarized certification by chief officer of governing body and administrator that application is accurate and facility will follow all applicable laws and regulations.

(C) Each application for an abortion facility license shall be sent to the Missouri Department of Health and Senior Services, Bureau of Ambulatory Care, PO Box 570, Jefferson City, MO 65102, and shall be accompanied by an annual fee of two hundred dollars ($200).

(D) Each license, unless sooner suspended or revoked, shall be issued for a period of one (1) year.

(E) Each license shall be issued only for the persons and premises named in the application.

(F) The facility shall notify the department in writing if the operator of the facility, name of the facility, or premises of the facility changes. The facility shall provide the notification at least thirty (30) days before the change.

(G) Separate licenses are required for abortion facilities maintained on separate sites even if operated by the same person.

(H) The abortion facility license shall be conspicuously posted in a public area in the facility.

(I) No license shall be issued or renewed by the department until the department has inspected the facility and determined that it is in compliance with all requirements of applicable regulations and statutes.

AUTHORITY: section 197.225, RSMo Supp. 2017. Original rule filed July 15, 1987, effective Oct. 25, 1987. Amended: Filed Oct. 24, 2017, effective April 30, 2018.*

**Original authority: 197.225, RSMo 1975, amended 1986, 2017.*

19 CSR 30-30.060 Standards for the Operation of Abortion Facilities

PURPOSE: This regulation establishes standards for the operation of abortion facilities to ensure safe, quality care in accordance with legal requirements.

(1) Governing Body, Administration, and Medical Staff.

(A) The facility shall have a governing body which may be an individual owner or owners, partnership, corporate body, association, or public agency.

1. The governing body shall have full legal responsibility for determining, implementing, and monitoring policies governing a facility's total operation and for ensuring that the policies are administered in a manner to provide acceptable care in a safe environment and in accordance with all legal requirements and standards of care.

2. The governing body shall select and employ an administrator who is a physician licensed in Missouri, a registered nurse licensed in Missouri, or an individual who has at least one (1) year of administrative experience in health care.

3. If there is any change in the designation of the administrator, the governing body shall notify the department within ten (10) calendar days of the change.

4. The governing body shall ensure that, in the absence of the administrator from the facility, a person who meets the qualifications of an administrator as defined in this regulation shall be present at the facility and fulfill the administrator's duties.

5. Bylaws of the governing body shall acknowledge that department surveyors shall be allowed to inspect the facility at any time the facility is in operation. Surveyors shall have due regard for the medical condition and reasonable privacy of the on-site patients.

6. Bylaws of the governing body shall require that the medical staff, facility personnel, and all others providing services relative to the facility shall be directly or indirectly responsible to the governing body through the administrator.

7. The governing body, through the administrator, shall establish criteria for the content of patient records and shall provide for timely completion of those records and disciplinary action for noncompliance.

8. The governing body, through the administrator, shall ensure that the abortion facility abides by all applicable state and federal laws and regulations. This shall include, but not be limited to, compliance with Chapter 188, RSMo, 13 CSR 70-3.030(3), and:

A. Notifying pathology lab of failed abortion within twenty-four (24) hours;

B. Ensuring that the physician providing informed consent to the patient is the physician who performs the procedure;

C. Ensuring that all medical records associated with abortions accurately reflect the date and time the record was created;

D. Ensuring that the physician who performs the abortion performs a pelvic exam at least seventy-two (72) hours before an abortion unless, in the physician's clinical judgment, such pelvic exam is not medically necessary and said physician documents the reason for such determination;

E. Ensuring that any physician, nurse, or other health care provider, or their contracted agents, cooperate with any Department of Health and Senior Services investigator upon written request of the investigator;

F. Ensuring that all employees participate in an annual fire drill;

G. Ensuring that policies are written in accordance with regulatory requirements;

H. Ensuring that endotracheal equipment is maintained and that staff is aware of the location of the equipment;

I. Following all acceptable sterilization standards for surgery instruments and equipment; and

J. Maintaining controlled substance logs in accordance with published regulations.

9. Any violation of law or regulation shall be immediately referred, in writing, with details of said violation or violations, to the Medicaid Audit and Compliance Unit of the Department of Social Services.

10. The governing body, through the administrator, shall be responsible for developing, implementing, and enforcing a policy to ensure protection of facility employees, physicians, and volunteers from retaliation or adverse employer actions by the facility for disclosing information regarding alleged infection control concerns; alleged facility mismanagement or fraudulent activity; or alleged violations of state of federal law or regulations regarding patient care, patient safety, or facility safety.

(B) An administrator shall organize the administrative functions of the facility.

1. The administrator shall be responsible for establishing effective security measures to protect patients, employees, and visitors.

2. The reporting of suspected incidences of child abuse shall be made to the Department of Social Services as required by section 210.115.1, RSMo.

3. The administrator shall be responsible for developing a written plan for evacuation of patients and personnel in the event of fire, explosion, active shooter, or other disaster. The plan shall be kept current and all personnel shall be knowledgeable of the plan. Disaster drills with participation of all staff shall be conducted and documented at least annually.

4. The administrator shall be responsible for reporting all fires, explosions, and disasters affecting the abortion facility and physical actions taken against the facility to the department within twenty-four (24) hours.

5. The administrator shall be responsible for establishing, posting, and enforcing written policies prohibiting smoking throughout the facility.

6. The administrator shall be responsible for establishing, implementing, enforcing, and maintaining comprehensive programs for identifying and preventing infections as further detailed in this regulation and for maintaining a safe environment.

7. The administrator shall develop written personnel policies which contain at least the following:

A. Provisions for orientation of all personnel to the policies and objectives of the facility;

B. Provisions for participation by all personnel in training and orientation periods appropriate to the needs and level of preparation as required by the individual job description;

C. Provision for periodic evaluation of each employee's performance;

D. Provisions for written job descriptions, including job qualifications;

E. Provisions for licensed personnel to have current cardiopulmonary (CPR) training so that at least one (1) licensed and trained personnel is at the facility at all times when patients are present for abortions; and

F. Provisions for criminal background checks and department Employee Disqualification List (EDL) checks for every person within the facility who will have contact with patients within the facility, including physicians, staff, and volunteers. These checks shall be completed before allowing the person to have unsupervised contact with patients within the facility. Provisions shall be made for periodic EDL checks thereafter.

8. The administrator shall be responsible for ensuring that a personnel record is maintained regarding each employee and includes documentation of the employee's job description, qualifications, orientation period, health status, criminal background, EDL status, performance assessment, CPR training, if applicable, education, and training. Each personnel record for a physician, Registered Nurse (RN), or Licensed Practical Nurse (LPN) shall contain verification of current licensure.

(C) The medical staff shall develop and, with the approval of the governing body, shall adopt policies governing physician activities in the abortion facility.

1. Medical staff membership shall be limited to physicians.

2. Each physician requesting staff membership shall submit a written application to the administrator of the facility on a form approved by the governing body. Each application shall be accompanied by evidence of education, training, professional qualifications, licensure, and standards of performance.

3. The governing body, acting upon recommendations of the medical staff, shall approve or disapprove appointments to the medical staff. There shall be written criteria for determining privileges of medical staff. Medical staff shall use a formal method for making recommendations to the governing body regarding delineation of privileges; curtailment, suspension, or revocation of privileges; and appointments and reappointments to the medical staff.

4. Physicians performing abortions at the facility shall have staff privileges at a hospital within fifteen (15) minutes' travel time from the facility or the facility shall show proof there is a working arrangement between the facility and a hospital within fifteen (15) minutes' travel time from the facility granting the admittance of patients for emergency treatment whenever necessary.

5. Each abortion facility shall arrange for at least one (1) OB/GYN to be available either as a staff member or as a consultant for the purpose of providing consultation as needed and advising staff members regarding maintenance of a satisfactory quality of patient treatment.

(2) Direct patient care services.

(A) An abortion shall be performed or induced only by a physician.

(B) Each patient shall be given all the information required by sections 188.027 and 188.039, RSMo, in the formats and timeframes required, by the type of professional required.

(C) The physician who is to perform or induce the abortion shall provide the information required in section 188.027.6, RSMo, orally and in person to the patient at least seventy-two (72) hours before the abortion.

(D) A written medical history shall be obtained for each patient. At least seventy-two (72) hours before the abortion, a health assessment and a pelvic examination shall be performed by the physician who is to perform or induce the abortion, unless in the clinical judgment of that physician such pelvic examination is not medically indicated at such time for that individual patient, in which case such pelvic examination shall be completed on the day of the abortion by the physician performing or inducing the abortion. The basis for the determination to delay the pelvic examination shall be documented in detail in the patient's medical record. Pregnancy shall be confirmed by clinical evidence and laboratory tests. This information shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's medical record.

(E) Ultrasounds at an abortion facility to confirm gestational age and for other imaging purposes such as ultrasounds per section 188.027(4), RSMo, shall be performed by a physician or a person who holds a current certification by the American Registry for Diagnostic Medical Sonography (ARDMS) with advanced training in obstetric/gynecological imaging, or other certified training deemed acceptable by the department.

(F) Nursing services shall be under the direction of an RN. An RN shall be present in the clinical area whenever there is a patient in the procedure room or recovery room. For surgical abortions, an RN, LPN, or a surgical technician shall be present in the procedure room whenever there is a patient in the procedure room. The surgical technician shall be a surgical technologist or shall provide documentation of adequate training in assisting surgical procedures, including surgical abortions.

(G) At facilities performing surgical procedures, an RN or an LPN shall be present in the recovery room when a patient is in the recovery room.

(H) At facilities performing surgical procedures, a physician shall be on the premises and immediately available for any assistance to a patient in the recovery room following a surgical procedure.

(I) No patient shall be discharged from the facility until she is fully reactive and her vital signs are stable.

(J) Written instructions shall be issued to all patients and shall include at least the following:

1. Symptoms of complications;

2. Activities to be avoided; and

3. Abortion facility phone numbers. Numbers provided shall include the number for the OB/GYN or OB/GYN group providing complication care under a complication plan as required by section 188.021, RSMo, and 19 CSR 30-30.061.

(K) The facility shall ensure that each patient is prepared for the abortion in a manner that facilitates her safety and comfort.

(L) The facility shall assist each patient in deciding what method of birth control she will use, if any, after the procedure, respecting her choices.

(M) Facilities performing surgical procedures shall have an emergency tray equipped to treat seizures, bleedings, anaphylactic shock, respiratory arrest, and cardiac arrest immediately available to the procedure room and recovery room of the facility.

(N) Facilities performing surgical procedures shall have emergency drugs, oxygen, and intravenous fluids in the procedure room to stabilize the patient's condition when necessary. A manual breathing bag, suction machine, and endotracheal equipment shall be located in the clinical area for immediate access.

(3) Records and reports.

(A) The facility shall maintain a daily roster of all patients receiving abortion services. The facility shall retain the roster for seven (7) years.

(B) The facility shall maintain a medical record according to professional standards for each patient.

(C) All medical record entries shall be timed, dated, and signed or authenticated by the person making the entry.

(D) The medical record shall contain –

1. Documentation with a unique identifying record number; patient identifying information; name of physician; diagnosis; medical history and physical examination record; laboratory reports; anesthesia administered; allergies/drug reactions; physician's orders; clinical notes; counseling notes; patient consent form; medication administration records; and discharge summary;

2. Documentation establishing that the patient was given all the information required by sections 188.027 and 188.039, RSMo, in the formats and timeframes required, by the type of professional required. If any of the informed consent requirements are performed by a referring physician or qualified professional (where authorized by sections 188.027 or 188.039, RSMo) before the patient presented at the abortion facility, the facility shall obtain documentation from the referring physician or qualified professional establishing such performance in compliance with the law, and shall place the documentation in the patient's medical record;

3. Method used to determine gestational age; gestational age; informed consent checklist required by section 188.027.3, RSMo; copy of abortion report required by section 188.052, RSMo, and 19 CSR 10-15.010; for surgical abortions, copy of tissue report required by section 188.047, RSMo, and 19 CSR 10-15.030; where applicable, copy of complication report required by section 188.052, RSMo, and 19 CSR 10-15.020; and

4. For any patient transferred from the facility due to an emergency or complication, the medical record shall include a report detailing the reason for the transfer. The abortion facility shall attempt to obtain the treatment record of the receiving facility and shall place it in the patient's medical record.

(E) The facility shall retain medical records for adults for seven (7) years from the time of discharge. For minors, the facility shall retain medical records for seven (7) years from the time of discharge or two (2) years past the age the patient reaches majority, whichever is longer.

(F) The facility shall safeguard medical records against loss and unofficial use.

(G) The facility shall ensure that an individual abortion report for each abortion performed or induced via the facility is submitted to the department within forty-five (45) days of the abortion as required by section 188.052, RSMo, and 19 CSR 10-15.010.

(H) The facility shall ensure that an individual complication report for any complication care provided via the facility is submitted to the department within forty-five (45) days of the care as required by section 188.052, RSMo, and 19 CSR 10-15.020.

(4) Infection Control Program. The facility shall establish a comprehensive program for identifying and preventing

infections. The infection control program shall be appropriate for scope and type of abortion procedures performed at the facility.

(A) Infection control standards of the facility must be identified in writing, in compliance with generally-agreed upon national standards such as those of the Centers for Disease Control and Prevention (CDC), Association for Professionals in Infection Control and Epidemiology (APIC), Association of peri-Operative Registered Nurses (AORN), or other standards determined acceptable by the department.

(B) The facility shall have in place procedures for monitoring and enforcing compliance with infection control standards in accordance with section 197.150, RSMo.

(C) The facility shall report healthcare associated infection rates to the department in accordance with section 192.667, RSMo, and 19 CSR 10-33.050.

(D) In accordance with section 192.667, RSMo, the facility shall, in consultation with medical staff, establish an antimicrobial stewardship program for evaluating the judicious use of antimicrobials, especially antibiotics that are the last line of defense against resistant infections.

(E) Infectious and pathological wastes at the facility shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers, or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport.

(F) If kept on-site for more than twelve (12) hours, tissue removed during an abortion shall be refrigerated.

(G) The facility shall ensure that all reportable diseases, disabilities, conditions, and findings regarding facility patients are reported in accordance with 19 CSR 20-20.020.

(H) Upon request, the facility shall provide the department access to data and information related to infection control practices, rates, or treatments of infections as required by section 197.160, RSMo.

(I) The facility shall have policies and procedures for the handling, processing, storing, and transporting of clean and dirty laundry. The facility may provide laundry services at the facility or contract for these services.

(5) Pathology, Laboratory, and Pharmaceutical Services.

(A) All fetal tissue from surgical abortions shall be grossly examined at the time of the procedure by the physician. The results of the tissue examination shall be recorded in the patient's medical record.

(B) Facilities performing surgical abortions shall ensure that all requirements of section 188.047, RSMo, and 19 CSR 10-15.030 are met, including timely submission of tissue reports to the department. If the facility does not perform pathology services internally, the facility shall have a written agreement with a pathology laboratory that shall clearly delineate the laboratory's duties under section 188.047, RSMo, and 19 CSR 10-15.030 regarding tissue reports. The facility shall perform periodic checks to ensure that the laboratory is in compliance with the agreement.

(C) The following laboratory procedures shall be performed on every abortion patient: hemoglobin; urinalysis, including pregnancy test; and Rh typing.

(D) Anti-Rh immune globulin therapy shall be given to all Rh negative patients upon completion of the abortion procedure. If for any reason a patient refuses this therapy, this refusal shall be noted by the physician in the patient's record, and, if possible, documented by the patient's signature on appropriate forms.

(E) The use of drugs in the facility shall be under the direction of a designated individual in accordance with accepted standards of practice and applicable state and federal laws. Drugs must be prepared and administered according to established policies and acceptable standards of practice. The facility shall have procedures regarding procurement, storage, security, records, labeling, preparation, orders, administration, adverse reactions, and disposal or other disposition of drugs.

(F) The facility shall follow all applicable laws and regulations pertaining to controlled substances.

(6) Medical emergencies.

(A) The facility shall develop, implement, and enforce a written protocol for managing medical emergencies including the transfer of any patient requiring further emergency care to a hospital within a reasonable distance from the abortion facility.

(B) The facility shall develop, implement, and enforce a written policy to ensure its compliance with section 574.200, RSMo, regarding the offense of interference with medical assistance.

(7) Complaints.

(A) The facility shall develop, implement, and enforce a policy that provides patients with an efficient means of communicating complaints regarding care provided via the facility.

(B) The facility shall document details of each complaint and the facility's response to each complaint. This documentation shall be available to the department for review upon request.

(C) Anyone with a complaint pertaining to patient care via an abortion facility may send the complaint in writing to the Missouri Department of Health and Senior Services, Bureau of Ambulatory Care, PO Box 570, Jefferson City, MO 65102. The complainant shall provide his or her contact information with the complaint. The department shall contact the complainant within five (5) working days of receipt of the complaint and shall investigate the complaint within twenty (20) working days of receipt of the complaint.

(8) Quality Assessment and Performance Improvement Program.

(A) Each abortion facility shall develop a quality assessment and performance improvement (QAPI) program that includes all health and safety aspects of patient care and shall include a review of appropriateness of care. Results of the QAPI program shall be reviewed at least quarterly by the administrator, director of patient care, a representative of the medical staff, and the governing body.

(B) The facility QAPI program shall include a documented review of at least the following criteria:

1. Completeness of clinical records;

2. Incidence of morbidity and mortality;

3. Complications, including number and percentage of patients affected by the most common types of complications for both surgical and drug- or chemically-induced abortions, as applicable;

4. Specific review of any significant or unusual complications;

5. All cases transferred to a hospital, including a review of assessment and patient risk factors that may have existed before the procedure;

6. All cases that resulted in a length of stay within the

facility of more than eight (8) hours;

7. Errors in diagnosis;

8. Problems in compliance with laws and regulations, including violations cited by the department and reports required by Chapter 188, RSMo;

9. All cases in which the gestational age was determined to be beyond eighteen (18) weeks;

10. For drug- or chemically-induced abortions, the number and percentage of patients who failed to return to the facility for follow-up to confirm the completion of the abortion, and common reasons why the patients failed to return (unless termination of pregnancy was otherwise confirmed); and

11. Periodic evaluation and review of all contracted services, including, but not limited to, pathology services.

(C) The QAPI program shall show evidence of action the facility took regarding problems identified and shall identify opportunities for improvement.

AUTHORITY: section 197.225, RSMo Supp. 2021. Original rule filed July 15, 1987, effective Oct. 25, 1987. Amended: Filed June 14, 1988, effective Oct. 13, 1988. Amended: Filed Oct. 24, 2017, effective April 30, 2018. Emergency amendment filed June 21, 2019, effective July 1, 2019, expired Feb. 27, 2020. Amended: Filed June 21, 2019, effective Feb. 29, 2020. Emergency amendment filed Sept. 28, 2021, effective Oct. 13, 2021, expired April 10, 2022. Amended: Filed Sept. 28, 2021, effective April 30, 2022.*

**Original authority: 197.225, RSMo 1975, amended 1986, 2017.*

19 CSR 30-30.061 Complication Plans for Certain Drug- and Chemically-Induced Abortions Via Abortion Facilities

PURPOSE: This rule establishes the standards governing complication plans required by section 188.021, RSMo, for abortions induced by physicians via abortion facilities. This rule also explains the process for submitting such complication plans to the Department of Health and Senior Services for approval.

(1) For purposes of this rule, the following terms mean:

(A) Abortion – The act of using or prescribing any instrument, device, drug, or any other means or substance resulting in the intentional destruction of an embryo or fetus in a woman's uterus or the intentional termination of a pregnancy of a woman with intent other than to increase the probability of a live birth or to remove a dead or dying embryo or fetus;

(B) Abortion facility – Any clinic, physician's office, or any other place or facility in which abortions are performed or induced other than a hospital;

(C) Complication – Includes, but is not limited to, incomplete abortion, excessive hemorrhage, endometritis, parametritis, pyrexia, pelvic abscess, uterine perforation, failed abortion, retained products, cervical lacerations, or psychiatric issues;

(D) Department – The Missouri Department of Health and Senior Services;

(E) Drug – A drug or chemical used to induce an abortion for which the federal Food and Drug Administration (FDA) label includes any clinical study in which more than one percent (1%) of those administered the drug required surgical intervention after its administration;

(F) OB/GYN –

1. A physician who is board-certified or board-eligible by the American Osteopathic Board of Obstetrics and Gynecology, or who is in a residency approved by that board; or

2. A physician who is board-certified by the American Board of Obstetrics and Gynecology (ABOG); or who is an ABOG Registered Residency Graduate or an ABOG Active Candidate; or who is in an ABOG-approved residency;

(G) Physician – A person licensed to practice medicine pursuant to Chapter 334, RSMo.

(2) Complication plans for certain drug- and chemically-induced abortions.

(A) A physician shall not prescribe or administer a drug without first obtaining written approval from the department of a complication plan applicable to the physician's prescription or administration of the drug.

(B) Each abortion facility shall ensure that no drug is prescribed or administered via its facility until the facility has received written approval from the department of the complication plan of the physician who will prescribe or administer the drug.

(C) To ensure the safety of all patients, a primary objective of complication plans shall be to recognize the importance of the physician-patient relationship by providing for continuity of care and ensuring communication among the physician who induced the abortion and all subsequent health care providers involved in treating the patient's complication.

(D) Every complication plan shall provide that an OB/GYN is on-call and available twenty-four hours a day, seven days a week (24/7) to treat complications related to drugs prescribed or administered via the facility. To ensure this required twenty-four hours a day, seven days a week (24/7) coverage, the complication plan for each physician who will prescribe or administer drugs shall include a written agreement between the physician and an OB/GYN or group of OB/GYNs to treat complications, or in the alternative, a written agreement between the abortion facility and an OB/GYN or group of OB/GYNs to treat complications.

(E) If the physician who will prescribe or administer drugs is an OB/GYN, that physician's complication plan may provide that the physician treats complications, but the physician and/or the abortion facility must have a written agreement with an OB/GYN or group of OB/GYNs to ensure the required twenty-four hours a day, seven days a week (24/7) coverage when the physician is unavailable to treat complications.

(F) An OB/GYN who is a staff member or consultant to the abortion facility as required in 19 CSR 30-30.060 may have a written agreement to treat complications under a complication plan.

(G) Every complication plan shall provide that the OB/GYN with whom there is a written agreement or member of the group of OB/GYNs with which there is a written agreement, or the physician who prescribes or administers drugs if he or she is an OB/GYN, shall:

1. Personally treat all complications, including those requiring surgical intervention, except in any case where doing so would not be in accordance with the standard of care, or in any case where it would be in the patient's best interest for a different physician to treat her; and

2. Assess each patient suffering a complication individually, and shall not, as a matter of course, refer all patients to the emergency room or other facilities or physicians unless the patient is experiencing an immediately life-threatening complication.

3. This regulation does not prohibit screening or triage of patients by a nurse or physician to determine whether or when it is necessary to contact the OB/GYN.

(H) Every complication plan shall provide that, in any case where it would not be in accordance with the standard of care

or would not be in the patient's best interest for the OB/GYN to personally treat the complication (e.g., surgery in a hospital is required, and it is not in the patient's best interest to travel to a hospital where the OB/GYN has privileges), the OB/GYN shall arrange for hand-off of the patient to an appropriately-qualified physician and shall fully brief such physician regarding the patient at the time of hand-off.

(I) Every complication plan shall require that the OB/GYN treating a patient's complication shall prepare a complication report as required by section 188.052, RSMo and ensure that it is submitted to the department.

(J) The abortion facility shall ensure that before discharge, every patient who receives a drug via the facility also receives the phone number, in writing, for the OB/GYN or OB/GYN group providing complication coverage. The phone number given may be for the on-call service rather than the OB/GYN's direct number.

(K) The physician or abortion facility shall submit complication plans to the department for approval in writing using the complication plan submission form provided by the department. The form shall require at least the following information:

1. The full name of each physician whose prescription or administration of drugs via the facility will be covered by the plan;

2. The full name of the OB/GYN who will provide complication coverage, or if an OB/GYN group will provide coverage, the full legal name of the group and the full name of each OB/GYN who is part of the group; and

3. A description of how the complication plan meets each requirement in this regulation, including treating complications requiring surgical intervention.

(L) With the completed complication plan forms, the facility shall also submit:

1. Documents establishing that each OB/GYN who will provide complication coverage under the plan is board-eligible or board-certified by the American Board of Obstetrics and Gynecology or the American Osteopathic Board of Obstetrics and Gynecology; and

2. A copy of the executed written agreement between the physician(s) whose prescription or administration of drugs via the facility will be covered by the plan (and/or the abortion facility) and the OB/GYN or group of OB/GYNs that will provide the complication coverage. The written agreement shall cite this regulation and specify that complication coverage under the written agreement shall be provided in compliance with this regulation.

(M) If any change occurs that prevents full compliance with a complication plan as approved by the department, the facility shall immediately notify the department in writing, providing details regarding the change. If the change results in the facility being unable to provide twenty-four hours a day, seven days a week (24/7) OB/GYN coverage for complications as required by this regulation, the facility shall ensure that no drugs are prescribed or administered via the facility until 1) full compliance with the plan is achieved and the facility has so notified the department in writing, or 2) a new or revised complication plan has been submitted to and approved by the department in writing.

(N) The facility shall ensure that each complication plan approved by the department and currently in use is on file at the facility. The facility shall maintain copies of complication plans no longer in use for seven (7) years following the last use. The facility shall make current and past complication plans available to patients or the department for review upon request.

AUTHORITY: sections 188.021 and 197.225, RSMo Supp. 2017. Emergency rule filed Oct. 24, 2017, effective Nov. 3, 2017, expired May 1, 2018. Original rule filed Oct. 24, 2017, effective April 30, 2018.*

**Original authority: 188.021, RSMo 2013, amended 2017 and 197.225, RSMo 1975, amended 1986, 2017.*

19 CSR 30-30.062 Complication Plans for Certain Drug- and Chemically Induced Abortions

PURPOSE: This rule establishes the standards governing complication plans required by section 188.021, RSMo. This rule also explains the process for submitting such complication plans to the Department of Health and Senior Services for approval.

(1) For purposes of this rule, the following terms mean —

(A) Abortion — The act of using or prescribing any instrument, device, drug, or any other means or substance resulting in the intentional destruction of an embryo or fetus in a woman's uterus or the intentional termination of a pregnancy of a woman with intent other than to increase the probability of a live birth or to remove a dead or dying embryo or fetus;

(B) Abortion facility — Any clinic, physician's office, or any other place or facility in which abortions are performed or induced other than a hospital;

(C) Complication — Includes but is not limited to incomplete abortion, excessive hemorrhage, endometritis, parametritis, pyrexia, pelvic abscess, uterine perforation, failed abortion, retained products, cervical lacerations, or psychiatric issues;

(D) Department — The Missouri Department of Health and Senior Services (DHSS);

(E) Drug — A drug or chemical used to induce an abortion for which the federal Food and Drug Administration (FDA) label includes any clinical study in which more than one percent (1%) of those administered the drug required surgical intervention after its administration;

(F) Local area — The area within a twenty-five- (25-) mile radius of the location where the physician dispenses the abortion producing drug;

(G) OB/GYN —

1. A physician who is board-certified or board-eligible by the American Osteopathic Board of Obstetrics and Gynecology, or who is in a residency approved by that board; or

2. A physician who is board-certified by the American Board of Obstetrics and Gynecology (ABOG), or who is an ABOG Registered Residency Graduate or an ABOG Active Candidate, or who is in an ABOG approved residency; and

(H) Physician — A person licensed to practice medicine pursuant to Chapter 334, RSMo.

(2) Complication plans for certain drug- and chemically induced abortions.

(A) A physician shall not prescribe or administer a drug without first obtaining written approval from the department of a complication plan applicable to the physician's prescription or administration of the drug.

(B) Each abortion facility shall ensure that no drug is prescribed or administered via its facility until the facility has received written approval from the department of the complication plan of the physician who will prescribe or administer the drug.

(C) To ensure the safety of all patients, a primary objective of complication plans shall be to recognize the importance of the physician-patient relationship by providing for continuity of care and ensuring communication among the physician who induced the abortion and all subsequent health care providers involved in treating the patient's complication.

(D) Each abortion facility shall confirm with the patient the location where the patient will complete the drug-induced abortion. Complication plans shall provide for situations when the patient will complete the abortion in the local area as specified in section (3) and situations where the patient will complete the abortion outside the local area as specified in section (4).

(3) Complication plans for facilities that provide drug-induced abortions to ten (10) or more women a month in the local area.

(A) Every complication plan shall provide that an OB/GYN is on call and available twenty-four hours a day, seven days a week (24/7) to treat complications related to drugs prescribed or administered via the facility for patients in the local area. To ensure this required twenty-four hours a day, seven days a week (24/7) coverage, the complication plan for each physician who will prescribe or administer drugs shall include a written agreement between the physician and an OB/GYN or group of OB/GYNs to treat complications or, in the alternative, a written agreement between the abortion facility and an OB/GYN or group of OB/GYNs to treat complications. A facility need not have an on-call OB/GYN available more than seven (7) days after the most recent chemically induced abortion.

(B) If the physician who will prescribe or administer drugs is an OB/GYN, that physician's complication plan may provide that the physician treats complications, but the physician and/or the abortion facility must have a written agreement with an OB/GYN or group of OB/GYNs to ensure the required twenty four hours a day, seven days a week (24/7) coverage when the physician is unavailable to treat complications.

(C) An OB/GYN who is a staff member or consultant to the abortion facility may have a written agreement to treat complications under a complication plan.

(D) Every complication plan shall provide that the OB/GYN with whom there is a written agreement or member of the group of OB/GYNs with which there is a written agreement, or the physician who prescribes or administers drugs if he or she is an OB/GYN, shall –

1. Personally treat all complications, including those requiring surgical intervention, except in any case where doing so would not be in accordance with the standard of care, or in any case where it would be in the patient's best interest for a different physician to treat the patient;

2. Assess each patient suffering a complication individually, and shall not, as a matter of course, refer all patients to the emergency room or other facilities or physicians unless the patient is experiencing an immediately life-threatening complication; and

3. This regulation does not prohibit screening or triage of patients by a nurse or physician to determine whether or when it is necessary to contact the OB/GYN.

(E) Every complication plan shall provide that, in any case where it would not be in accordance with the standard of care or would not be in the patient's best interest for the OB/GYN to personally treat the complication (e.g., surgery in a hospital is required, and it is not in the patient's best interest to travel to a hospital where the OB/GYN has privileges), the OB/GYN shall arrange for hand-off of the patient to an appropriately qualified physician and shall fully brief such physician regarding the patient at the time of hand-off.

(F) Every complication plan shall require that the OB/GYN treating a patient's complication shall prepare a complication report as required by section 188.052, RSMo, and ensure that it is submitted to the department.

(G) The abortion facility shall ensure that before discharge every patient from the local area who receives a drug via the facility also receives the phone number, in writing, for the OB/GYN or OB/GYN group providing complication coverage. The phone number given may be for the on-call service rather than the OB/GYN's direct number.

(H) An abortion facility may request a waiver to the requirement that an OB/GYN or OB/GYN group be on call to treat complications. If an abortion facility cannot contract with an OB/GYN or OB/GYN group to provide treatment for abortion-pill complications, the abortion facility must request to contract with another qualified physician or physician group to fulfill the requirements in section (3) of this rule. The waiver request shall include –

1. An explanation of the abortion facility's recent, unsuccessful efforts to contract with an OB/GYN or OB/GYN group. The explanation shall include the OB/GYN or OB/GYN groups that were contacted and the date they were contacted;

2. The name of the physician or physician group that will provide treatment for complications instead of the OB/GYN or OB/GYN group;

3. An explanation of how the physician or physician group is qualified to address complications to a similar degree as an OB/GYN; and

4. A statement that the physician will comply with all of the requirements in section (3) of this rule that would normally by fulfilled by an OB/GYN or OB/GYN group.

(4) Complication plans for all facilities for drug-induced abortions for patients outside the local area.

(A) Every complication plan shall include provisions for patients who will complete the abortion outside of the abortion facility's local area. When a physician determines that a patient will complete the abortion outside the local area, the complication plan shall require that the physician do the following:

1. Identify the patient's primary care physician or OB/GYN. If the patient does not have a primary care physician or OB/GYN, the physician shall identify an OB/GYN within a reasonable distance of the location where the patient will complete the abortion;

2. Identify the closest emergency room to the location where the patient will complete the abortion and to the patient's home, if that is a different location;

3. Inform the patient about the steps to take in the event the patient has complications from the abortion. The physician shall explain the possible complications from abortion inducing drugs as set out on the United States Food and Drug Administration's approved label for the abortion-inducing drug and explain that the FDA has recognized that up to four and six-tenths percent (4.6%) of women receiving chemically induced abortions have sought treatment at an emergency room;

4. Provide the patient with a letter describing the patient's relevant medical history and prescribed medications, including all medications prescribed to induce the abortion, to present to the patients local OB/GYN practice or emergency room in the event the patient suffers complications. The letter must include the prescribing physician's name and contact information, information about the abortion drugs prescribed,

and an overview of the patient's relevant medical history;

5. If complications occur, the prescribing physician must attempt to contact the treating physician or patient as soon as reasonably possible after learning about the complication in order to fully brief the treating physician on the patient's relevant medical history. If the prescribing physician is unable to contact the treating physician within eight (8) hours, the prescribing physician may leave a message and contact information at the facility where the patient is being treated; and

6. The physician who prescribed the abortion-inducing drugs must take all reasonable measures to follow up with any patient who has suffered complications from an abortion-inducing drug within twenty-four (24) hours of learning of the complication. If the physician is unable to contact the patient within twenty-four (24) hours, he or she must continue to attempt to contact the patient once a day for an additional seventy-two (72) hours. If the physician is unable to contact the patient after ninety-six (96) hours, the physician must document the attempts to contact the patient and the reason for the inability to schedule the follow-up appointment. The follow-up appointment may be in person or via a telehealth visit.

(B) If the prescribing physician does not treat a patient's complications, the prescribing physician shall explain to the physician treating a patient's complication the need to prepare a complication report as required by section 188.052, RSMo, and ensure that it is submitted to the department.

(5) Submission of complication plans to the department.

(A) The physician or abortion facility shall submit complication plans to the department for approval in writing. In addition to the plan, the physician or abortion facility shall provide at least the following information in writing:

1. The full name of each physician whose prescription or administration of drugs via the facility will be covered by the plan;

2. The full name of the OB/GYN or other physician who will provide complication coverage for patients in the local area or, if an OB/GYN or other physician group will provide coverage, the full legal name of the group and the full name of each OB/GYN or other physician who is part of the group;

3. A description of how the complication plan meets each requirement in this regulation, including treating complications requiring surgical intervention;

4. Documents establishing that each OB/GYN who will provide complication coverage for patients in the local area under the plan is board-eligible or board-certified by the American Board of Obstetrics and Gynecology or the American Osteopathic Board of Obstetrics and Gynecology, subject to the exception in the waiver described in subsection (3)(H) of this rule; and

5. A copy of the executed written agreement between the physician(s) whose prescription or administration of drugs via the facility will be covered by the plan (and/or the abortion facility) and the OB/GYN or group of OB/GYNs that will provide the complication coverage for patients in the local area, subject to the waiver in subsection (3)(H) of this rule. The written agreement shall cite this regulation and specify that complication coverage under the written agreement shall be provided in compliance with this regulation.

(B) If any change occurs that prevents full compliance with a complication plan as approved by the department, the facility shall immediately notify the department in writing, providing details regarding the change. If the change results in the facility being unable to provide twenty-four hours a day, seven days a week (24/7) OB/GYN or physician coverage for complications as required by this regulation, the facility shall ensure that no drugs are prescribed or administered via the facility until 1) full compliance with the plan is achieved and the facility has so notified the department in writing, or 2) a new or revised complication plan has been submitted to and approved by the department in writing.

(C) The facility shall ensure that each complication plan approved by the department and currently in use is on file at the facility. The facility shall maintain copies of complication plans no longer in use for seven (7) years following the last use. The facility shall make current and past complication plans available to patients or the department for review upon request.

(6) The department will assess whether to rescind this rule if the preliminary injunction prohibiting enforcement of 19 CSR 30-30.061 is lifted.

AUTHORITY: section 188.021, RSMo Supp. 2024. Emergency rule filed March 13, 2025, effective March 27, 2025, expired Sept. 22, 2025. Original rule filed March 13, 2025, effective Sept. 30, 2025.*

**Original authority: 188.021, RSMo 2013, amended 2017.*

19 CSR 30-30.070 Physical Standards for Abortion Facilities

PURPOSE: Section 197.225, RSMo authorizes the Department of Health and Senior Services to establish physical standards for abortion facilities in order to provide acceptable care in a safe environment. Abortion facilities are defined in section 197.200(1), RSMo and are subject to licensure under section 197.205, RSMo.

PUBLISHER'S NOTE: The publication of the full text of the material that the adopting agency has incorporated by reference in this rule would be unduly cumbersome or expensive. Therefore, the full text of that material will be made available to any interested person at both the Office of the Secretary of State and the office of the adopting agency, pursuant to section 536.031.4, RSMo. Such material will be provided at the cost established by state law.

(1) This regulation does not apply to abortion facilities that do not perform surgical abortions or surgical intervention for abortion complications.

(2) Requests for deviations from requirements on physical facilities shall be in writing to the Department of Health and Senior Services. Approvals for deviations shall be in writing and both requests and approvals shall be made a part of the permanent Department of Health and Senior Services records for the abortion facility.

(3) Any abortion facility constructed or renovated after October 25, 1987 shall have plans prepared by an architect or engineer registered in Missouri. These plans shall be submitted to the department for review and approval prior to construction. New abortion facilities shall have the following:

(A) At least two (2) remote exits shall be provided for each floor directly to the outside or through an enclosed stairway or passageway to the outside;

(B) Corridors serving patients shall be at least six feet (6') wide;

(C) All doors through which patients pass shall be at least

forty-four inches (44") wide and of solid-core construction;

(D) One- (1-) story buildings shall be at least of Type II (111) protected noncombustible construction as described in *Standard on Types of Building Construction 1979* published by the National Fire Protection Association;

(E) Multistory buildings shall be constructed of at least Type II (222) fire-resistive construction as described in *Standard on Types of Building Construction* published by the NFPA, or shall be protected throughout by an approved automatic sprinkler system;

(F) Multistory buildings shall have at least one (1) elevator. The elevator cab shall be at least five feet by seven feet (5' × 7') clear inside. The car door shall have a clear opening of not less than forty-four inches (44");

(G) Trickle-charge battery pack units shall be located to provide emergency lighting in the procedure room, recovery room, exit corridors, and exit stairs to grade;

(H) A manual fire alarm break station shall be located near each exit and connected to a local audible alarm which can be heard throughout the facility;

(I) At least two (2) ABC-type fire extinguishers are to be located in the facility, one (1) in the clinical area;

(J) Illuminated exit signs shall be located above each exit and illuminated directional exit signs shall be located where needed to direct patients and personnel to exits in event of an emergency;

(K) Ceiling, wall, and floor finishes in the clinical area including the procedure rooms, recovery room, personnel change rooms, central sterile and supply, janitor's closet, and laboratory shall be smooth and easily cleanable;

(L) Scrub-up facilities shall be knee- or foot-operated and provided at the rate of one (1) per procedure room. Scrub-up facilities shall be located outside but immediately available to the procedure room;

(M) Procedure rooms shall have the following:

1. A minimum length and width of twelve feet (12');
2. A minimum ceiling height of nine feet (9');
3. A door with a minimum width of forty-four inches (44"); and
4. There shall be no windows in the room except there may be a fixed-view window in the wall between the procedure room and the adjacent corridor;

(N) The recovery room shall be separated from the procedure room and be of sufficient size to accommodate at least four (4) recovery beds or recliners for each procedure room. There shall be three feet (3') of clear space on both sides and at the foot of each recovery bed or recliner;

(O) The procedure room and recovery room shall be provided with a minimum of six (6) air changes per hour. Air supplied to all areas shall be filtered through a filter with at least a twenty-five percent (25%) efficiency rating;

(P) Personnel change rooms shall be provided for each sex and located convenient to the procedure room. Each change room shall be equipped with a toilet and lavatory;

(Q) The laboratory shall be equipped with a counter, sink, and refrigerator;

(R) The procedure room shall be equipped with a ceiling-mounted surgical light, operating table or a conventional gynecological examining table with accessories, closed cabinets for equipment, and sufficient tables to hold an emergency tray and other necessary equipment;

(S) There shall be one (1) electrical outlet in the procedure room for the emergency light and at least one (1) duplex outlet on each wall;

(T) There shall be one (1) electrical outlet in the recovery room for the emergency light and at least one (1) duplex outlet for each two (2) recovery beds or recliners;

(U) Piped-in or portable oxygen and suction equipment shall be located in the recovery room;

(V) The sterilizing room shall be equipped with a steam sterilizer, counter and sink, and storage space for clean supplies. Air pressure in this room shall be positive in relation to adjacent areas;

(W) The soiled/decontamination room shall be equipped with a counter and sink. This room shall be equipped with a constant running exhaust;

(X) A patient toilet with lavatory shall be located convenient to the recovery room. This room shall be equipped with a constant running exhaust;

(Y) At least two (2) patient change rooms with secure storage for personal effects shall be provided; and

(Z) Office space, waiting room, record storage space, and counseling rooms shall be provided. Counseling rooms shall be separate and not smaller than ten feet by ten feet (10' × 10').

(4) Any abortion facility in operation at the time these rules are adopted shall comply with the following:

(A) Smoke detectors shall be located in all rooms and in corridors at thirty-feet (30') intervals unless the building is rated Type II (222) fire-resistive or if it is a one- (1-) story building rated Type II (111) protected-noncombustible as described in *Standard on Types of Building Construction 1979* published by the NFPA. If the building is multistoried and rated combustible, it shall be protected throughout by an approved automatic sprinkler system;

(B) There shall be a system of corridors, passageways, and elevators adequate in size and arrangement to allow a patient on a stretcher to be moved from any point in the abortion facility to a street-level exit;

(C) Space shall be provided for waiting, registration, counseling, medical evaluation, examination, and referral. This space shall be equipped with suitable furnishings and accommodations;

(D) Dressing rooms shall be provided for the privacy, physical comfort, and convenience of patients and personnel;

(E) At least one (1) procedure room shall be adequately equipped, supplied, and staffed to safely perform abortions. The procedure room shall be equipped with an operating table or a conventional gynecologic examining table with accessories, a closed cabinet for equipment, and tables to hold an emergency tray and other necessary equipment. The procedure room shall be well-lighted and maintained at a comfortable temperature;

(F) Personnel change rooms and scrub-up facilities shall be located convenient to the procedure room;

(G) A utility room with facilities for steam sterilization and space for storage of clean and sterilized supplies shall be provided. There shall be sufficient surgical instruments sterilized and available for each patient who presents herself for an abortion. The room shall be arranged to prevent cross traffic of clean and dirty material;

(H) The recovery room shall be separate from the procedure room and be of sufficient size to accommodate at least four (4) recovery beds or recliners for each procedure room. The recovery room shall be well-lighted and maintained at a comfortable temperature. Recovery beds or recliners shall be spaced to permit easy staff access to each patient;

(I) Piped-in or portable oxygen and suction equipment shall be located in the recovery room;

(J) Trickle charge battery pack units shall be located to

provide emergency lighting in the procedure room, recovery room, exit corridors, and exit stairs to grade;

(K) A manual fire alarm break station shall be located near each exit and connected to a local audible alarm which can be heard throughout the facility;

(L) At least two (2) ABC-type fire extinguishers shall be located in the facility, one (1) in the clinical area;

(M) Illuminated exit signs shall be located above each exit door and illuminated directional exit signs shall be located where needed to direct patients and personnel to exits in event of an emergency;

(N) Wall and floor finishes in the procedure room, recovery room, and the sterilization area shall be smooth and easily cleanable;

(O) The laboratory shall be equipped with a counter, sink, and refrigerator; and

(P) At least two (2) remote exits shall be provided for each floor. Each exit shall discharge directly to the outside or through an enclosed stairway or passageway to the outside.

AUTHORITY: section 197.225, RSMo Supp. 2017. Original rule filed July 15, 1987, effective Oct. 25, 1987. Amended: Filed Oct. 24, 2017, effective April 30, 2018.*

**Original authority: 197.225, RSMo 1975, amended 1986, 2017.*

19 CSR 30-30.080 Definitions Relating to Birthing Centers and Procedures for Licensing Birthing Centers

PURPOSE: This rule defines terminology used in this chapter and establishes procedures for licensing birthing centers.

(1) The following definitions shall be used in the interpretation and enforcement of 19 CSR 30-30.090 through 19 CSR 30-30.110:

(A) Administrator — A person who is designated to provide daily supervision and the administration of the birthing center;

(B) Birthing center — A facility, not licensed as part of a hospital, which provides maternity care away from the mother's usual residence and where low risk births are planned to occur following a normal uncomplicated pregnancy;

(C) Certified nurse-midwife (CNM) — A person licensed to practice professional nursing under section 335.046, RSMo and currently certified by examination by the American College of Nurse-Midwives;

(D) Complication — A condition according to written risk criteria of the birthing center that contraindicates continued care in the birthing center;

(E) Department — The Missouri Department of Health;

(F) Discharge plan — A plan for continuing maternal and infant health care following birth;

(G) Health assessment — A determination of a patient's physical and mental status;

(H) Low risk — Normal, uncomplicated prenatal course as determined by adequate prenatal care and prospects for a normal, uncomplicated birth as defined by reasonable and currently accepted criteria of maternal and fetal health;

(I) Person — Any individual, firm, partnership, corporation or association;

(J) Physician — A person licensed to practice medicine under Chapter 334, RSMo who has admitting privileges at a hospital;

(K) Primary care giver — A physician or a certified nurse-midwife who has attended the mother during the prenatal period, will be present at delivery and will be responsible for care during the puerperium period; and

(L) Qualified personnel — A person trained and competent in the services which s/he provides and is licensed or certified as required by statute or professional standard.

(2) The following procedures are required for licensing a birthing center:

(A) A license to establish and operate a birthing center shall be required of any facility other than a hospital or the mother's residence where births are planned to occur and where childbirth deliveries may be performed;

(B) Application for licensure of a birthing center shall be made in writing to the department on forms provided by the department. Each application for a license shall be accompanied by an annual license fee of two hundred dollars ($200);

(C) The application shall be made by the person(s) or corporation operating the facility;

(D) The licensee shall notify the department in writing of any change in the name of the facility or change in the ownership;

(E) Separate licenses are required for facilities maintained on separate sites even though operated by the same owner;

(F) The license shall be conspicuously posted in a public area in the facility; and

(G) A license shall not be issued by the department until a facility is in compliance with all requirements of 19 CSR 30-30.090. In addition, a facility shall be in compliance with 19 CSR 30-30.100 or 19 CSR 30-30.110, depending on the number of birthing rooms in the facility.

MISSOURI DEPARTMENT OF HEALTH
HOSPITAL LICENSING AND CERTIFICATION
APPLICATION FOR BIRTHING CENTER LICENSE

P.O. BOX 570
JEFFERSON CITY, MISSOURI 65102-0570

☐ INITIAL APPLICATION ☐ RENEWAL APPLICATION

In accordance with the requirements of the Missouri Ambulatory Surgical Center Licensing Law (Sections 197.200 through 197.240, RSMo), application is hereby made for a license to conduct and maintain a Birthing Center (see Missouri Ambulatory Surgical Center Licensing Law "Definitions" Section 197.200, subsection (1), RSMo).

DO NOT WRITE IN THIS SPACE
LICENSE NO.
DATE
CERTIFICATE NO.
DATE MAILED

NAME OF FACILITY (NAME TO APPEAR ON LICENSE) TELEPHONE NO.

ADDRESS (STREET AND NUMBER) (CITY) (ZIP CODE)

COUNTY ADMINISTRATOR

MANAGEMENT

NON PROFIT
☐ CORPORATION
☐ OTHER (SPECIFY)

PROPRIETARY
☐ INDIVIDUAL ☐ CORPORATION
☐ PARTNERSHIP ☐ OTHER (EXPLAIN)

CHIEF OFFICER OF GOVERNING BODY LEGAL NAME OF OPERATING CORPORATION

IF OPERATED BY MANAGEMENT CONSULTANT, NAME OF FIRM

STAFFING (numbers):
PERSONNEL PHYSICIANS

OB/GYN CONSULTANT
NAME:
QUALIFICATIONS:

NO. OF ABORTIONS PER YEAR CERTIFIED NURSE MIDWIFE

STATE OF MISSOURI

City of _____

County of _____

_____ (PRESIDENT OF BOARD OF TRUSTEES, OWNER, OR ONE PARTNER OF PARTNERSHIP) and _____ (ADMINISTRATOR) being duly sworn by me on their oath, deposes and says that they have read the foregoing application and that the statements contained therein are correct and true and of their knowledge; and further gives assurance of the ability and intention of the _____ (EXACT LEGAL NAME) Ambulatory Surgical Center to comply with the regulations and codes promulgated under the Missouri Ambulatory Surgical Center Licensing Law (sections 197.200 through 197.240, RSMo), Regulations and Codes.

It is further certified that the _____ (NAME OF FACILITY) will comply with all recommendations for correction and/or improvements as contained in the most recent Licensing Survey Report prepared by the Department of Health and submitted to said Ambulatory Surgical Center.

Signed _____ (PRESIDENT OF BOARD OF TRUSTEES, OWNER OR ONE PARTNER OF PARTNERSHIP)

Signed _____ (ADMINISTRATOR)

Signed and sworn to before me this _____ day of _____, 19____

_____ (NOTARY PUBLIC)

My commission expires _____, 19____

MO 580-0013 (11-86) HL 16 (R1/87)

AUTHORITY: section 197.225, RSMo 1994. Emergency rule filed May 1, 1995, effective May 10, 1995, expired Sept. 7, 1995.* Original rule filed May 1, 1995, effective Nov. 30, 1995. Emergency amendment filed June 19, 1998, effective July 1, 1998, expired Feb. 25, 1999. Amended: Filed June 19, 1998, effective Jan. 30, 1999.*

**Original authority 1975, amended 1986.*

19 CSR 30-30.090 Organization and Management Standards for Birthing Centers

PURPOSE: This rule establishes standards for the operation of birthing centers in order to provide care in a safe environment.

(1) The center shall have a governing body which may be individual owner(s), partnership, corporate body, association or public agency.

(A) The governing body shall have full legal responsibility for determining, implementing and monitoring policies governing the center's total operation and for ensuring that the policies are administered in a manner to provide acceptable care in a safe environment.

(B) The governing body shall select and employ one (1) of the following as an administrator: a physician licensed in Missouri, a certified nurse-midwife (CNM), a registered nurse licensed in Missouri or an individual with a bachelor's degree in a related field and at least one (1) year of administrative experience in health care.

(C) The governing body shall require that an individual who complies with subsection (1)(B) of this rule shall be in charge when the administrator is unavailable in person or by telecommunications.

(D) Governing body bylaws shall acknowledge that duly appointed representatives of the department shall be allowed to inspect the center operation at any time, with consideration for client privacy and confidentiality.

(E) Bylaws of the governing body shall require that the clinical staff, center personnel and all auxiliary organizations directly or indirectly be responsible to the governing body through the administrator.

(F) The governing body, through the administrator, shall establish criteria for the content of patients' records, provision for their timely completion and disciplinary action on occasion of noncompliance.

(G) The governing body shall ensure that the birthing center abides by all applicable state and local laws.

(2) The administrator shall organize the administrative functions of the center and establish a system of authorization, record procedures and internal controls.

(A) The administrator shall be responsible for establishing effective security measures to protect patients, employees and visitors.

(B) The administrator is responsible for assuring that all patients admitted to the center are under the care of a physician or CNM practicing pursuant to a collaborate agreement with a physician who is a member of the clinical staff.

(C) A certificate of live birth shall be filed in accordance with section 193.085, RSMo.

(D) The administrator shall develop procedures and have a written agreement with a licensed ambulance service for emergency transportation. If a written agreement with the ambulance service cannot be achieved due to reasons that are neither regulatory or statutory, the administrator can request a waiver or mediation from the department.

(E) The administrator shall have procedures and a written transfer agreement with a hospital providing emergency, obstetrical and newborn services. If a written agreement with a licensed hospital cannot be achieved due to reasons that are neither regulatory or statutory, the administrator can request a waiver or mediation from the department. Peer review report may be submitted as evidence for mediation.

(F) The administrator shall be responsible for a written plan for evacuation of patients and personnel in the event of fire, explosion or natural disaster. The plan shall be kept current and all personnel shall be knowledgeable of the plan.

(G) The administrator shall be responsible for developing, enforcing and posting written policies which prohibit smoking throughout the birthing center.

(H) Smoking or open flames shall be prohibited in any room or compartment where flammable liquids, combustible gases or oxygen are used or stored and in any other hazardous location. These areas shall be posted with NO SMOKING OR OPEN FLAME signs.

(I) The administrator shall establish a program for identifying and preventing infections and for maintaining a safe environment. The center shall be responsible for identifying infections up to thirty (30) days postpartum in the mother and the infant unless and until they are transferred to another health-care provider prior to thirty (30) days. Infectious and pathological wastes shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport. Infectious waste shall be disposed of in accordance with provisions of 10 CSR 80-7.010.

(J) The administrator shall establish policies and procedures for the handling, processing, storing and transporting of clean and dirty laundry. The facility may provide laundry services on-site or utilize contract services.

(K) The administrator shall develop written personnel policies which contain at least the following:

1. Provision for orientation of all personnel to the policies and objectives of the center and participation by all personnel in appropriate employee training;

2. Provision for periodic evaluation of employees' performance including clinical skills, resuscitation and use of equipment; and

3. Provision for written job descriptions, including job qualifications system for the completion and storage of medical records.

(L) A personnel record shall be maintained on each employee and shall include documentation of each employee's orientation, education, training and health information, as well as verification of current licenses for physicians, registered nurses and licensed practical nurses and documentation of certification for nurse-midwives.

(3) Clinical practice guidelines for the management of routine and emergency care of the mother and her fetus/newborn in pregnancy, birth and postpartum until discharge from care by the center, whether through completion of the program or referral or transfer to other levels of care, shall be drafted by a physician or certified nurse midwife who has clinical staff membership at the birthing center. The guidelines shall be available on-site at all times. Documentation of periodic review and revision are required.

(A) Clinical staff membership shall include physicians or CNMs, or both, but, as defined by the birth center bylaws, may also include other health professionals to provide service at the birth center. A physician or CNM practicing pursuant to a collaborative practice agreement with a physician shall be in attendance and responsible for intrapartum management.

(B) On a form approved by the governing body, each health professional requesting clinical staff membership shall submit a written application to the administrator of the center. Each application shall be accompanied by evidence of education, training, professional qualification, health status certification and licensure.

(C) A written procedure shall be established for recommending to the governing body delineation of privileges; curtailment, suspension or revocation of privileges; and appointments and reappointments to the clinical staff. The governing body, acting upon recommendations of the clinical staff, shall approve or disapprove appointments. Written criteria shall be developed for privileges extended to each member of the clinical staff.

(D) Each birth center shall have at least one (1) physician who is responsible for the following:

1. Sign collaborative practice agreement and meet any other requirements of Missouri law for collaborative practice;

2. Review and sign clinical practice guidelines and risk assessment criteria at least annually; and

3. Be available in person or by telecommunication for consultation.

(4) The center shall maintain a system for the completion and storage of medical records.

(A) The daily patient roster shall be retained for two (2) years.

(B) The medical record shall contain

1. A unique identifying medical record number;
2. Client identifying information;
3. Allergies;
4. Consent;
5. Maternal history;
6. Maternal and newborn physical examinations;
7. Laboratory test results;
8. Initial risk assessment and periodic updates;
9. Interval prenatal evaluations;
10. Problem identification, plan, and follow-up;
11. Labor and birth records, including apgars;
12. Newborn and postpartum recovery records;
13. Medication record, including any drug, and the dose, time, date and person administering;
14. Discharge plan; and
15. Postpartum and infant follow-up visits up to thirty (30) days after the birth or documentation of transfer to another health care provider.

(C) All medical records shall be safeguarded against loss and unofficial use. Medical records for adults and newborns shall be retained as required by the statute of limitations under section 516.105, RSMo.

(D) Medical records are the property of the birthing center and shall not be removed from the center except by court order, subpoena, for microfilming or for off-site storage approved by the governing body. Information provided for statistical purposes shall contain the unique identifying number, not the patient's name.

(5) Patient care services shall be under the direction of a physician or a CNM practicing pursuant to a collaborative practice arrangement with a physician.

(A) Women registering for care at the birthing center and their families shall be informed and shall provide written acknowledgment that they have been informed of the benefits and risks of the services available at the center. They shall be made aware of the risk criteria used for admission and referral.

(B) Birth center clients are limited to those women who are initially determined to be at low maternity risk and who are evaluated regularly throughout pregnancy to assure that they remain at low risk for a pregnancy outcome.

1. Each birth center shall establish a written risk assessment system which shall be a part of the clinical practice guidelines. The individual risk assessment shall be included in the client's medical record.

2. The general health status and risk assessment shall be determined by a physician, CNM or other advanced practice nurse after obtaining a detailed medical history, performing a physical examination and taking into account family circumstances and other social and psychological factors. The client shall be transferred to a hospital if complications occur requiring medical or surgical intervention under the center's written risk criteria.

(C) The center shall provide at least one (1) CNM or physician for each three (3) women in active labor. In addition a qualified staff member shall be available for each client during the entire time the client is in the birth center. All clinical staff shall provide services during labor and delivery in accordance with the policies developed by clinical staff and approved by the governing body.

(D) Qualified personnel and clinical staff of the birth center shall be trained in infant and adult resuscitation and recertified according to standards set by the American Heart Association and the American Pediatric Association.

(E) A primary care giver shall remain on the premises and be immediately available for assistance to the patient during labor, delivery and immediate postpartum stages.

(F) A primary care giver shall be responsible for ensuring and documenting prenatal care, health history, physical examination, and appropriate laboratory studies which shall be placed in the medical record at time of admission in preparation for delivery.

(G) A patient shall meet discharge criteria as defined in the clinical practice guidelines prior to discharge from the facility.

(H) Labor shall not be inhibited, stimulated or augmented with chemical agents during the first or second stage of labor.

(I) General and induction anesthesia shall not be administered. Local and pudendal anesthesia may be administered by a physician or CNM practicing pursuant to a collaborative practice arrangement with a physician if use of the drugs conforms with Missouri law and written clinical practice guidelines of the birth center.

(J) A program for prompt follow-up care and postpartum evaluation after discharge shall be developed and implemented. The follow-up shall include assessment of infant health including physical examination, laboratory screening tests at appropriate times, maternal postpartum status, instruction in child care including immunizations, referral to sources of pediatric care, provision of family planning services, and assessment of mother-child relationship including breast feeding.

(K) The center shall be responsible for detection of Rh incompatibility and administration of RhoGAM as appropriate.

(L) At a minimum, there shall be provision for nutritious liquids and snacks in accordance with 19 CSR 20-1.010.

(M) Prophylactic eye treatment as required in section 210.070, RSMo shall be provided.

(N) Drugs shall be stored and handled under proper security

and environmental conditions and shall be accessible only to authorized persons. Drugs shall be administered and disposed only by licensed practitioners in accordance with applicable state laws and rules. The use of IV's shall be restricted to hydration only or to the establishment of a central line prior to transport to emergency facilities. No IV drugs such as pitocin shall be used for inducement or augmentation of labor.

(O) An emergency drug kit shall be available which includes oxygen, a Deelee suctioning trap or other appropriate equipment for emergency suctioning.

(P) An adequate supply of sterile items shall be available.

(6) The birthing center shall provide a quality assurance program that includes all health and safety aspects of patient care for both mother and newborn and shall include a review of appropriateness of care. Results of the quality assurance program shall be reviewed at least quarterly by the governing body.

(A) The quality assurance program shall include, but not be limited to, the following:

1. A review of the medical record;

2. A determination that every mother-infant pair have an identified source of primary care and have available methods by which to contact that individual after discharge;

3. Incidences of morbidity and mortality of mother and infant;

4. Postpartum infections;

5. A review of all cases transferred to a hospital for delivery, care of the infant or postpartum care of the mother;

6. A review of all cases that resulted in a length of stay of more than twelve (12) hours beyond the birth of the baby;

7. Incidents, problems, and potential problems identified by the staff of the birthing center; and

8. Problems with compliance with state laws and rules.

(B) The quality assurance program shall show evidence of action taken as a result of the identification of a problem, including documented outcome and evaluation.

(7) A birthing center shall provide for essential laboratory services, including, but not limited to, hemoglobin or hematocrit, urinalysis, microscopic analysis and culture, blood type and Rh, syphilis, hepatitis B, rubella, pap smears and pregnancy tests.

(A) Laboratory services may be provided on-site or through a certified laboratory in accordance with federal regulations.

(B) When services are provided by arrangement with an outside provider, the original copy of the signed and dated report shall become part of the mother's permanent record at the birthing center.

(C) Results of tests completed at the birthing center shall be entered, dated and signed in the mother's or child's record by the individual who performed the test. Abnormal test results shall be followed up by the primary provider in accordance with birth center risk criteria and clinical practice guidelines.

AUTHORITY: section 197.225, RSMo 1994. Emergency rule filed May 1, 1995, effective May 10, 1995, expired Sept. 7, 1995. Original rule filed May 1, 1995, effective Nov. 30, 1995. Emergency amendment filed June 19, 1998, effective July 1, 1998, expired Feb. 25, 1999. Amended: Filed June 19, 1998, effective Jan. 30, 1999.*

**Original authority 1975, amended 1986.*

19 CSR 30-30.100 General Design and New Construction Standards for Birthing Centers

PURPOSE: Section 197.225, RSMo authorizes the Department of Health to establish physical standards for birthing centers in order to provide care in a safe environment. Birthing centers are considered ambulatory surgical centers as defined by section 197.200(1), RSMo and are subject to licensure as required by section 197.205, RSMo. This rule establishes up-to-date construction requirements for new birthing center construction to help ensure accessible, functional, fire-safe and sanitary facilities. A new birthing center is one for which plans are submitted to the Department of Health after the adoption of this rule for the construction of a new facility, expansion or renovation of an existing birthing center or the conversion of an existing facility not previously and continuously licensed as a birthing center under Chapter 197, RSMo.

PUBLISHER'S NOTE: The publication of the full text of the material that the adopting agency has incorporated by reference in this rule would be unduly cumbersome or expensive. Therefore, the full text of that material will be made available to any interested person at both the Office of the Secretary of State and the office of the adopting agency, pursuant to section 536.031.4, RSMo. Such material will be provided at the cost established by state law.

(1) Planning and Construction Procedures.

(A) Any birthing center constructed or renovated after the date of the adoption of this rule shall have plans and specifications prepared by an architect registered in Missouri. These plans and specifications shall be submitted to the department for review and approval prior to beginning of construction. The design and construction of birthing centers shall conform to the most stringent requirements of this rule and the local governing building code.

(B) The Department of Health shall be notified in writing within five (5) days after construction begins. If construction of the project is not started within one (1) year after the date of the approval of the plans and specifications, the plans and specifications shall be resubmitted to the Department of Health for its approval and shall be amended, if necessary, to comply with the then current rules before construction work begins.

(C) Requests for variations from requirements on physical facilities shall be requested in writing to the Department of Health and must contain information which demonstrates the providers ability to meet the intent or objectives of the rule through alternative methods. Approvals for deviations shall be requested in writing and both requests and approvals shall be made a part of the permanent Department of Health records for the birthing center.

(D) Where renovation or replacement work is done within an existing facility, all new work or additions, or both, shall comply with the applicable sections of this rule.

(E) Birthing centers which expand their capacity to four (4) or more birthing rooms must comply throughout the facility with the applicable requirements for birthing centers of this size or larger.

(F) References in this rule to, National Fire Protection Association (NFPA), publications are those contained in the twelve (12)- volume 1994 Compilation of NFPA Codes, Standards, Recommended Practices and Guides. Where there are discrepancies between referenced NFPA publication requirements and this rule, the requirements of this rule shall apply.

(2) Design Considerations for the Physically Handicapped. Roads, parking facilities, walks, ramps and entrances shall be accessible and usable by persons who are physically disabled. At least one (1) toilet, telephone and drinking fountain which are accessible for use by handicapped public and clinic patients shall be provided on each floor of a birthing center. Elevator controls and alarms shall be accessible to wheelchair occupants and shall be provided with tactile signage for the visually impaired. Design details for handicapped accessible facilities shall be consistent with the *Guidebook to: The Minimum Federal Guidelines of Requirements for Accessible Design* published January 6, 1981 by the United States Architectural and Transportation Barriers Compliance Board.

(3) Site.

(A) Adequate vehicle and pedestrian access, including loading and unloading space for delivery vehicles, shall be provided within the lot lines to the main entrance, emergency vehicular entrance, community activities and services.

(B) Adequate off-street parking shall be provided. Space shall be provided at the ratio of one (1) space for each of the maximum number of staff persons on duty at any given time plus one (1) parking space for the patient capacity of the birthing and examination rooms in the licensed facility.

(C) Fire lanes shall be provided and kept clear to provide immediate access for fire fighting equipment.

(4) General Birthing Center Design Considerations. The arrangement of the physical plant for a birthing center shall provide for separation of administrative/public, prenatal clinic and birthing suite areas. The birthing suite shall be in a location in the facility that precludes unnecessary traffic through the suite.

(5) Administrative/Public Areas. These areas shall include a business office with a public information center and staff telephone, administrator's enclosed office, medical records storage for at least two (2) years of patient records, public lobby and waiting room, public telephone, public toilet and a drinking fountain.

(6) Staff Areas. An area shall be provided to include secure storage for personal effects, handicapped accessible toilet, shower, change and lounge area sufficient to accommodate staff needs as defined by the program.

(7) Prenatal Clinic and Preadmission Screening Area. This area shall include:

(A) At least one (1) room with a minimum size of two hundred fifty (250) square feet for group education. In birthing centers with fewer than four (4) birthing rooms in response to the program of the facility but in no case shall it be smaller than one hundred twenty (120) square feet;

(B) At least one (1) examination room of not less than ninety (90) square feet and a minimum dimension of nine feet (9'). Each examination room shall be equipped with hand washing facilities. In birthing facilities with only one (1) birthing room, the required examination room shall be equipped to serve as a stand-by birthing room. Examination facilities shall be separate from, but adjacent to, the waiting room and birthing suite; and

(C) A laboratory equipped with a counter, sink and refrigerator which is required if the laboratory performs on-site laboratory work. This requirement may be met by a contractual provision for off-premises laboratory services.

(8) Birthing Suite. The birthing suite shall include at least one (1) birthing room with the following minimum dimensions: length and width of twelve feet (12'), ceiling height of eight feet (8'), and a door three feet (3') in width.

(A) Hand washing facilities shall be located in each birthing room. Lavatories shall be sized for scrubbing and equipped with faucets which are knee, foot or otherwise designed to operate without the use of hands.

(B) Each birthing room shall be equipped with a labor/delivery bed large enough for mother and baby, examination light, capacity to keep the infant warm, storage facilities for supplies and sufficient tables to hold an emergency tray and other necessary equipment.

(C) A toilet with lavatory shall be directly accessible to the birthing room so patients will not be required to enter the corridor. One (1) toilet may serve up to two (2) birthing rooms. No fewer than ten percent (10%) of the birthing rooms shall be served by handicapped accessible toilets. In birthing centers with fewer than four (4) birthing rooms, one (1) handicapped-accessible patient toilet may be provided which is conveniently located to and easily accessible from the birthing rooms without having patients traverse public areas.

(D) A shower shall be conveniently located to and easily accessible from the birthing rooms without requiring patients to traverse public areas. One (1) shower may serve not more than twelve (12) birthing rooms. At least one (1) patient shower shall be handicapped-accessible.

(E) Piped-in oxygen and clinical vacuum shall be provided in each birthing room. Birthing centers with fewer than four (4) birthing rooms may use portable medical gas and vacuum services.

(F) Emergency equipment including intravenous fluids and resuscitation equipment shall be located in near the birthing rooms.

(9) Service and Staff Support Facilities. The birthing suite shall include:

(A) A clean work and sterile storage room equipped with a sterilizer, counter and sink, and storage space for clean supplies;

(B) A separate soiled/decontamination utility room equipped with a clinic sink, counter and sink;

(C) A separate staff-only toilet with a constant running exhaust and a lavatory conveniently located to the birthing suite;

(D) A staff station providing visual supervision of the birthing rooms and support facilities;

(E) A medication storage and preparation station equipped with a sink and refrigerator;

(F) Storage space for emergency equipment; and

(G) Janitor's closet equipped with a mop sink and having sufficient space for the cleaning equipment used to maintain the birthing procedure area. Birthing centers with fewer than four (4) birthing rooms are required to have only one (1) janitor's closet to serve the entire facility. In multi-storied birthing centers at least one (1) janitor's closet shall be provided on each floor.

(10) General Support Facilities. Each birthing center shall include:

(A) Adequate space for the housing and maintenance of mechanical, plumbing and electrical equipment;

(B) Oxygen storage facilities which, if located inside the birthing center, shall be exhausted to prevent the accumulation of quantities of spilled gases. Medical gas storage and

distribution systems shall comply with "NFPA 99, Standard for Health Care Facilities, 1993 Edition" in *1994 National Fire Codes*, Volume 5;

(C) Housekeeping supply and general storage rooms;

(D) A janitor's closet, including a mop sink, to serve the public, business and preadmission clinic areas;

(E) In birthing centers proposing to process laundry on-site, laundry facility design and laundry equipment of a quality to be capable of producing sanitized linen; and

(F) At a minimum, provisions for shelf storage and refrigerated storage of prepackaged nourishments. Provisions shall be made for serving prepackaged nourishments to birthing patients. In birthing centers proposing to prepare food on-site, the design of the dietary facilities must be acceptable to the department and comply with 19 CSR 20-1.010.

(11) Details and Finishes.

(A) A continuous system of unobstructed corridors and aisles shall be provided which connects all rooms and space with each other and all entrances, exits and elevators. Corridors shall be separated from other areas by walls which resist the passage of smoke.

(B) Each exit shall discharge to the outside or through an enclosed stairway or passageway to the outside.

(C) Required exit stairs shall discharge directly to the outside or into a rated fire corridor which extends from the stair discharge to the outside. The fire-resistance rating of fire corridor walls shall be not less than the rating of the stair enclosure requirement located in section (12) of this rule.

(D) Corridors shall be at least six feet (6') wide. All other corridors and aisles shall be at least four feet (4') wide.

(E) Exit doors shall swing in the direction of exit travel.

(F) All doors, procedure rooms and exits shall be at least three feet (3') wide.

(G) All corridor doors shall be of solid wood construction or its equivalent.

(H) Each birthing room shall have an operable window in the outside wall. The window sill shall be not more than three feet (3') above the floor. Easily washable window treatments, such as vertical hanging vinyl blinds, shall be installed to control light and glare. All window treatments shall be inherently flame retardant.

(I) At least one (1) ABC-type fire extinguisher, compliant with "NFPA 10, Standard for Portable Fire Extinguisher," 1990 Edition, 1994 *National Fire Code*, Volume 1, shall be located near each exit on each floor of the birthing center and at the birthing suite's staff station.

(J) A paper towel dispenser and soap dispenser shall be provided at all lavatories used for hand washing.

(K) Finish materials installed on the walls, floors and ceilings in the birthing rooms shall be smooth and washable.

(L) Ceiling, wall and floor finishes shall be smooth and easily cleanable in toilets and bath facilities. Utility and storage rooms used for washing, sterilization and supplies shall have smooth and easily cleanable ceiling, wall and floor finishes.

(M) Floor and wall penetrations by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.

(12) Construction, Including Fire-Resistive Requirements.

(A) Construction of freestanding birthing centers shall comply with "NFPA 101 Section 12-6, New/Ambulatory Health Care Centers, 1994 Edition", 1994 *National Fire Codes*, Volume 5 and this rule.

(B) Multistoried buildings rated combustible Type V shall be protected throughout by an approved automatic sprinkler system. The number of stories in a building housing a birthing center shall be determined by counting all occupiable levels in the building.

(C) Birthing centers shall be separated from other tenants and occupancies by walls having at least a one (1)-hour fire-resistance rating. These walls shall extend from the floor slab below to the floor or roof slab above.

(D) Every stairway, elevator shaft, light and ventilation shaft, chute and other openings between stories shall be enclosed or protected to prevent the spread of fire or smoke from one (1) floor to another. The fire-resistance rating of the enclosure or protection shall be not less than the structural floor separation requirements of "NFPA 220, Standard on Types of Building Construction, 1992 Edition," 1994 *National Fire Code*, Volume 5 for the fire-resistive building type classification required by subsection (12)(A).

(13) Elevators.

(A) Multistoried buildings shall have at least one (1) elevator if birthing room services are located on any floor other than the grade level (main entrance) floor.

(B) The elevator cab shall be at least five feet by seven feet (5' x 7') clear inside. The car door shall have a clear opening of not less than three feet (3').

(C) Elevators shall be equipped with a two (2)-way special service switch to permit cars to bypass all landing button calls and be dispatched directly to any floor.

(D) Elevators shall be equipped with an automatic leveling device of the two (2)-way automatic maintaining type with an accuracy of plus or minus one-half inch (±1/2").

(E) Elevator call buttons, controls and door safety stops shall be of a type that will not be activated by heat or smoke.

(14) Mechanical Requirements.

(A) Heating, ventilating and air conditioning (HVAC) equipment shall be mandated to operate at an ambient temperature of sixty-eight to eighty-five degrees Fahrenheit (68–85°F).

(B) Air supplied to all areas shall be filtered through a filter with at least a twenty-five percent (25%) efficiency rate. Filter efficiencies shall be average atmospheric dust spot efficiencies.

(C) Required exhaust fans shall be nonswitched and constant running. All exhaust fans shall be installed at the discharge end of the duct.

(D) The HVAC systems shall be designed and balanced to provide pressure relationships and air change rates shown in the following table:

Pressure Relationships and Ventilation of Areas in Birthing Centers

Area Designation	Pressure Relationship to Adjacent Areas	Minimum Air Changes of Outside Air Per Hour Supplied to Room	Minimum Total Air Changes Per Hour Supplied to Room	All Air Exhausted Directly to Outdoors	Recirculated Within Room
Birthing Room	P	2	10	Optional	No
Birthing Suite Corridor	E	2	4	Optional	No
Examination Rooms	E	2	6	Optional	No
Soiled/Decontamination Workroom	N	2	10	Yes	No
Clean/Sterile Workroom	P	2	4	Optional	Optional
Laboratory	N	2	6	Optional	No
Toilet Room	N	–	10	Yes	No
Janitor's Closet	N	–	10	Yes	No
Other Area	E	2	4	Optional	No

P=Positive N=Negative E=Equal

(15) Plumbing and Other Piping Systems.

(A) Systems shall be designed to supply water to the fixtures and equipment on every floor at a minimum pressure of fifteen pounds per square inch (15 psi) during maximum demand periods.

(B) Each water service main, branch main, riser and branch to a group of fixtures shall be valved. Stop valves shall be provided at each fixture.

(C) Cold and chilled water piping and waste piping shall be insulated. Insulation of cold and chilled water lines shall include an exterior vapor barrier.

(D) Reduced pressure backflow preventers shall be installed where the water service enters the building and on hose bibbs and on all fixtures to which hoses or tubing can be attached such as janitors' sinks and laboratory fixtures.

(E) Hot water distribution systems shall provide one hundred ten degree Fahrenheit (110°F) water at each fixture at all times.

(F) Sinks in patient service areas shall have the water supply spout mounted so that its discharge point is a minimum distance of five inches (5") above the rim of the fixture. All lavatories used by medical and nursing staff shall have valves which can be operated without the use of hands.

(16) Electrical Requirements.

(A) Every room, including storage rooms, corridor and all other areas shall be sufficiently illuminated.

(B) Trickle charge battery pack units, complying with the standards of "Article 700, Emergency Systems, NFPA 70, *National Electrical Code*, 1994 Edition," in *National Fire Code*, Volume 3, shall be located to provide emergency lighting in the birthing rooms, exit corridors, exit signs, electrical branch panel rooms and exit stairs to point of discharge at grade. These fixtures shall be tested at least quarterly with the tests documented in writing. An emergency stand-by power system is not required in birthing centers.

(C) There shall be one (1) electrical outlet in each birthing room for the trickle charge emergency light and at least one (1) duplex outlet on each wall.

(D) Electrical outlets installed in wet locations, such as the patient toilet areas, shall be ground fault interrupter types.

(E) In birthing center of four (4) or more birthing rooms, an electrically powered fire alarm system shall be installed which will alert all areas of the facility when activated. A fire alarm manual pull station shall be located near each exit and at the staff station. The initiation of this fire alarm system shall be by manual means and by automatic means of any required detection devices.

(F) Birthing centers shall have smoke detectors interconnected with the fire alarm system in all rooms and at thirty-foot (30') intervals in corridors. Birthing centers located in completely sprinklered buildings require only the corridor detectors. In birthing centers of fewer than four (4) birthing rooms, the fire alarm system may consist of the individual required smoke detectors, provided the local alarm may be heard throughout the occupied areas of the birthing center.

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**Original authority 1975, amended 1986.*

19 CSR 30-30.110 General Design and Construction Standards for Existing Birthing Centers

PURPOSE: Section 197.225, RSMo authorizes the Department of Health to establish physical standards for birthing centers in order to provide care in a safe environment. Birthing centers are considered ambulatory surgical centers as defined by section 197.200(1), RSMo and are subject to licensure as required by 197.205, RSMo. This rule establishes physical plant requirements for licensing existing birthing centers. Existing birthing centers are those birthing facilities already in operation at the time these rules are adopted.

PUBLISHER'S NOTE: The publication of the full text of the material that the adopting agency has incorporated by reference in this rule would be unduly cumbersome or expensive. Therefore, the full text of that material will be made available to any interested person at both the Office of the Secretary of State and the office of the adopting agency, pursuant to section 536.031.4, RSMo. Such material will be provided at the cost established by state law.

(1) General Standards.

(A) Any birthing center existing and in continuous operation prior to the date of the adoption of this rule will be inspected by the Department of Health to determine compliance with this rule. Existing birthing centers shall comply with all applicable local regulations and codes and shall hold a certificate of occupancy from the local building authority.

(B) Requests for deviations from requirements on physical facilities shall be requested in writing to the Department of Health and must contain information which determines that the respective intent or objectives of this rule have been met. Approvals for deviations shall be requested in writing and both requests and approvals shall be made a part of the permanent Department of Health records for the birthing center.

(C) References in this rule to, National Fire Protection Association (NFPA), publications are those contained in the twelve (12)-volume 1994 compilation of *National Fire Codes*. Where there are discrepancies between referenced NFPA publication requirements and this rule, the requirements of this rule shall apply.

(2) Access for the Physically Handicapped. Existing birthing centers are required by the United States Department of Justice to currently comply with the federal requirements for accessible design established under the Americans With Disabilities Act. Evidence of compliance as determined by a local authority or other independent third party shall be provided to the department by the owner of the facility.

(3) Site.

(A) Adequate vehicular and pedestrian access shall be provided to the main entrance, emergency vehicular entrance and service entrance.

(B) Adequate parking shall be available in proportion to the number of patients and staff normally occupying the facility.

(C) Means of immediate access to the building for fire fighting and ambulance service personnel and equipment shall be provided.

(4) Administrative/public areas shall include business office with staff telephone and administrator's office, medical records storage for at least two (2) years of active patient records, public lobby and waiting room, telephone, toilet, at least one (1) room for education and training and at least one (1) examination room. In existing birthing centers having only one (1) regular birthing room, one (1) examination room shall be sized and equipped to serve as a stand-by birthing room.

(5) Birthing rooms shall include at least one (1) birthing room sized to accommodate the equipment, personnel and circulation area necessary to accomplish infant delivery; each birthing room door shall be ample in width and conformation to accommodate ambulance stretchers or infant transport warmer.

(A) Hand washing facilities operable without the use of hands shall be accessible within each birthing room and each examination room.

(B) Each birthing room shall be equipped with a bed or delivery chair, storage facilities for supplies, and sufficient tables to hold emergency and other necessary equipment.

(C) A toilet with lavatory and shower shall be easily accessible from the birthing rooms without traversing public areas.

(D) Piped-in or portable oxygen and vacuum service shall be available to each birthing room.

(6) Service and Staff Support Facilities for the Birthing Suite. These facilities shall include:

(A) A clean work and sterile storage area, and storage space for clean supplies;

(B) A separate soiled/decontamination utility area equipped with a counter and sink;

(C) A separate toilet with lavatory for staff;

(D) An area shall be provided for the preparation and storage of medication; and

(E) A staff work area for charting located to permit visual supervision of the birthing suite.

(7) General Support Facilities. These facilities shall include:

(A) Adequate space for the housing and maintenance of mechanical, plumbing and electrical equipment;

(B) Medical gas shall be stored and distributed in accordance with "NFPA 99, Standard for Health Care Facilities, 1993 Edition," in *1994 National Fire Code*, Volume 5; and

(C) Housekeeping supply and general storage areas appropriate to fulfill the needs of the facility.

(8) Details and Finishes.

(A) A continuous system of unobstructed corridors and aisles shall extend through the enclosed portion of each story of the birthing facility, connecting all rooms and spaces with each other and with all entrances, exitways and elevators. Mechanical equipment space need not be connected to the corridor system. Corridors shall be separated from all other areas by partitions constructed to resist the passage of smoke.

(B) At least two (2) remote exits shall be provided for each patient floor. Each exit shall discharge to the outside or through an enclosed stairway or passageway to the outside.

(C) Required exit stairs shall discharge directly to the outside or into an enclosed corridor which extends from the stair discharge to the outside. The fire-resistance rating of the enclosure of a corridor extension of a stair shall be not less than the rating required for the stair enclosure as stated in subsection (9)(D) of this rule.

(D) Corridors serving as a means of access to exit for patients in the birthing suite shall be arranged and of sufficient width to facilitate the movement of patients on stretchers.

(E) Exit doors shall swing in the direction of exit travel.

(F) All doors through which birthing patients pass to access birthing rooms and exits shall be of ample width to accommodate ambulance stretchers and warmers.

(G) Where outside windows exist in the birthing room, washable window treatments shall be installed to control light and glare.

(H) Where outside windows are provided in other areas of the facility, window treatments shall be installed to control light and glare.

(I) At least one (1) ABC-type fire, extinguisher, compliant with "NFPA 10, Standard for Portable Fire Extinguishers, 1990 Edition" *1994 National Fire Code*, Volume 1, shall be located on each floor occupied by the birthing center, including the basement.

(J) A paper towel dispenser and soap dispenser shall be provided at all lavatories used for hand washing.

(K) Ceiling, wall and floor finishes in toilets, bath facilities and utility and storage rooms designed for washing, sterilizing and storage shall be easily cleanable.

(L) Finish materials installed on the walls, floors, and ceilings in the birthing rooms shall be washable. The floors shall not be physically affected by frequent wet cleaning with cleaning and germicidal cleaning agents.

(M) Floor and wall penetrations by pipes, ducts and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.

(9) Construction, Including Fire-Resistive Requirements.

(A) Construction of freestanding birthing centers shall comply with "NFPA 101, Section 13-6, Existing Ambulatory Health Care Centers, 1994 Edition," in *1994 National Fire Codes*, Volume 5 and to the minimum requirements of this rule.

(B) Multistoried buildings rated combustible Type V shall be protected throughout by an approved automatic sprinkler system.

(C) Birthing centers shall be separated from other tenants and occupancies by walls having at least a one (1)-hour fire-resistance rating. These walls shall extend from the floor slab below to the floor or roof slab above.

(D) The number of stories in a building housing a birthing center shall be determined by counting all patient care areas in the building.

(E) Every stairway, elevator shaft, light and ventilation shaft, chute and other openings between stories shall be enclosed or protected to prevent the spread of fire or smoke from one (1) floor to another. The fire-resistance rating of the enclosure or protection shall be not less than the structural floor separation requirements of "NFPA 220, Standard on Types of Building Construction, 1992 Edition," in *1994 National Fire Codes*, Volume 5 for the fire-resistive building type classification required by subsection (9)(A) of this section.

(10) Elevators.

(A) Multistory buildings shall have at least one (1) elevator if patient services are located on any floor other than the grade level (birthing center's main entrance) floor.

(B) The elevator cab and door opening shall be of sufficient size to facilitate the movement of a patient on an ambulance stretcher.

(11) Mechanical Requirements.

(A) Heating, ventilating and cooling equipment shall be provided, maintained and operated to provide ambient temperatures of sixty-eight to eighty-five degrees Fahrenheit (68–85°F).

(B) All toilets and soiled materials holding/workrooms shall be exhausted to the outside by exhaust fans.

(12) Plumbing and Other Piping Systems.

(A) Systems shall be designed to supply water to the fixtures and equipment on every floor at an adequate pressure for their practical use.

(B) Reduced pressure backflow preventers shall be installed where the water service enters the building and on hose bibbs and on all fixtures, such as janitors' sinks and laboratory fixtures, to which hoses or tubing can be attached.

(C) Hot water distribution systems shall be delivered to each fixture at a temperature which precludes the hazard of scalding.

(13) Electrical Requirements.

(A) Every room, including storage rooms, corridor and all other areas shall be sufficiently illuminated to facilitate efficient performance of all necessary tasks.

(B) Trickle charge battery pack units, complying with the standards of "Article 700, NFPA 70, *National Electrical Code*, 1994 Edition," in *National Fire Codes*, Volume 3 shall be located to provide emergency lighting in the birthing rooms, exit corridors, exit signs, electrical branch panel rooms and exit stairs to point of discharge at grade. These fixtures shall be tested at least quarterly with the tests documented in writing. An emergency stand-by power system is not required in birthing centers.

(C) There shall be one (1) electrical outlet for the emergency light and at least two (2) additional duplex outlets in each birthing room.

(D) The fire alarm system in existing birthing rooms may consist of the local alarms from the required smoke detectors provided the alarm from any one (1) of the detectors may be heard throughout the occupied areas of the birthing center. Existing birthing centers with building configurations which preclude a local alarm from alerting all birthing center occupants must have an electrically powered fire alarm system which will alert all areas of the facility when activated.

(E) Existing birthing centers shall have smoke detectors installed at thirty-foot (30') intervals in all rooms and in corridors. All required smoke detectors in existing birthing centers may be battery powered. Battery-powered smoke detectors shall be tested at least quarterly with the tests documented in writing.

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