

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 30-30.050 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.

9. 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 or 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. A health assessment including a pelvic examination shall be performed. 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. 2017. 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.*

**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 30-30.070 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.*