

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

EMERGENCY AMENDMENT

19 CSR 30-30.060 Standards for the Operation of Abortion Facilities. The department is amending section (2).

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

EMERGENCY STATEMENT: This emergency amendment allows—under limited circumstances with detailed medical documentation—the physician who is to perform or induce an abortion to delay performing the pelvic examination until the day of the abortion. Without this emergency amendment, this rule and section 188.027, RSMo on informed consent require for every abortion that the physician who is to perform or induce the abortion must conduct the pelvic examination at least seventy-two (72) hours before the abortion. Pelvic examinations are necessary before abortions and can provide information that is necessary for informed consent—including information that informs the proposed abortion method and uterine size and position, which can impact the risks to the woman in light of her medical condition. However, circumstances may exist where the physician who is to perform or induce the abortion determines based on a thorough review of the patient and sound medical judgment that—based on a particular patient’s unique condition—a pelvic examination is not medically indicated. Therefore, this rule should be amended so that pelvic examinations are not required at least seventy-two (72) hours before an abortion for every patient regardless of that particular patient’s unique circumstances, so long as the requirements in this rule are met and a pelvic examination is still performed before every abortion. This rule is necessary to preserve a compelling governmental interest that requires an early effective date because the regular rulemaking process takes several months, and during that time this rule (if not amended) would in conjunction with section 188.027, RSMo require a pelvic examination at least seventy-two (72) hours before an abortion even in those cases where a physician who is to perform or induce the abortion had determined based on a thorough review and sound medical judgment that—based on a particular patient’s unique condition—a pelvic examination was not medically indicated. As a result, the department finds a compelling governmental interest, which requires this emergency action. A proposed amendment, which covers the same material, is published in this issue of the Missouri Register. This emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the Missouri and United States Constitutions. The department believes this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed on June 21, 2019, becomes effective July 1, 2019, and expires February 27, 2020.

(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. **At least seventy-two (72) hours before the abortion, [A] a health assessment [including] 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. [2017] **2018**. * 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 rule filed June 21, 2019, effective July 1, 2019, expires February 27, 2020. A proposed amendment covering this same material is published in this issue of the Missouri Register.*

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