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

PROPOSED RULE

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 hour/seven days per 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 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 OB/GYN group 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.

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 as well as placed in the patient's medical record at the abortion facility.

(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.

(K) The physician or hospital 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 OB/GYN group 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 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 2017.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule is estimated to cost private entities $182,500 each per year.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Department of Health and Senior Services, Division of Regulation and Licensure, Dean Linneman, Division Director, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. No public hearing is scheduled.*