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

EMERGENCY RULE

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.

EMERGENCY STATEMENT: Section 188.021, RSMo, requires physicians who use "any drug or chemical" for "the purpose of inducing an abortion" to "obtain[ ] approval from the department of health and senior services of a complication plan from the physician for administration of the drug or chemical to any patient." The law also gives the Department of Health and Senior Services (DHSS) the authority to "adopt rules, regulations, and standards governing complication plans to ensure that patients undergoing abortions induced by drugs or chemicals have access to safe and reliable care." § 188.021(3). DHSS has issued regulations governing complication plans at 19 CSR 30-30.061. On December 20, 2024, a court preliminarily enjoined enforcement of 19 CSR 30-30.061 as it pertains to complication plans. See Order at 14-15, Comprehensive Health of Planned Parenthood Great Plains v. Missouri, 2416-CV31931 (16th Cir. Ct. Mo. Dec. 20, 2024). The Court found that the regulation might interfere with Missourian's right to reproductive freedom under Article I, § 36 of the Missouri Constitution. But the Court specifically declined to enjoin § 188.021: "The Court finds the language of § 188.021.2 does not necessarily deny, interfere with, delay or otherwise restrict reproductive freedom." Id. at 14. Accordingly, the statutory requirement for a complication plan still exists, but the enabling regulation is enjoined.

No abortion facility or physician submitted a complication plan for DHSS's approval until February 19, 2025. In light of the recent preliminary injunction, DHSS has determined that this emergency regulation is necessary to replace the regulations in 19 CSR 30-30.061. This regulation will protect Missourians' access to "safe and reliable care." § 188.021.3.

Abortion inducing drugs create serious public health risks. The Food and Drug Administration's label for the abortion drug Mifepristone states that up to roughly one in 20 women (4.6%) who take abortion drugs will require emergency room care, with up to seven percent requiring a "surgical procedure because the pregnancy did not completely pass from the uterus or to stop bleeding." FDA-Approved Label for Mifepristone (Mifeprex) (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf (Mifeprex 2023 Label). This means that if an abortion facility performs 10 chemically induced abortions each month, they should expect that six women will be forced to go to the emergency room each year.

Moreover, studies show that the complication rate is much higher for chemical abortions than for surgical abortions. Chemical abortions are "5.96 times as likely to result in a complication as first-trimester aspiration abortions." Ushma D. Upadhyay, et al., Incidence of Emergency Department Visits and Complications After Abortion, 125 Obstetrics & Gynecology 175, 181 (Jan. 2015). Up to 20% of chemical abortions resulted in adverse events such as hemorrhage. "The

overall incidence of adverse events was fourfold higher in the medical compared with surgical abortion cohort (20.0% compared with 5.6%, P<.001)." Niinimaki M., et al., Immediate Complications After Medical Compared With Surgical Termination of Pregnancy. Obstet. Gynecol. 2009 October; 114(4): 795-804. These risks increase with gestational age. The FDA's own label notes that the percentage of surgical interventions due to incomplete chemical abortion is just over ten times higher for women at 64–70 days gestation than for women at less than or equal to 49 days gestation. (Mifeprex 2023 Label Accordingly, continuity of care is especially important for women who obtain chemical abortions.

For those reasons, DHSS finds that the use of abortion inducing drugs without a complication plan poses "an immediate danger to the public health, safety or welfare" and that this "rule is necessary to preserve" the State's "compelling governmental interest" in ensuring that § 188.021, RSMo, is enforced and protecting Missourians from the health and safety risks created by abortion inducing drugs. § 536.025.1(1), RSMo. DHSS has followed procedures "which comply with the protections extended by the Missouri and United States Constitutions." § 536.025.1(2), RSMo.

This emergency rule is also "calculated to assure fairness to all interested persons and parties under the circumstances" and limited in scope to "the circumstances creating an emergency and requiring emergency action." § 536.025.1(3)-(4). The circuit court's preliminary injunction order held that § 188.021, RSMo, "does not necessarily deny, interfere with, delay or otherwise restrict reproductive freedom." See Order at 14, Comp Health, 2416-CV31931. The court found that the statute's implementing regulation could interfere with Article I, § 36 of the Missouri Constitution because the geographic scope of the regulation was not properly tailored to improve or maintain the health of the person seeking care. The court explained, "[A] person who travels three hours to get a medication abortion and then returns home, would not benefit from this requirement. If complications arise after taking the medication, the individual would need to seek emergency care at the nearest hospital emergency room, as with any other medical emergency." Id. at 14-15. The Court took no other issue with the previous regulation. This emergency rule is limited in scope to address the tailoring problem identified by the court's preliminary injunction order—the only problem the preliminary injunction order identified. The rule will ensure that women can quickly and safely receive proper emergency care for abortion-related complications at a convenient location.

This emergency rule is under protective, but the current preliminary injunction prohibits enforcement of a regulation that fully protects women from the heightened complication risks of chemically induced abortions. This regulation thus seeks to protect health as much as possible in light of the recent preliminary injunction. Should that preliminary injunction be lifted, DHSS will assess whether to rescind this emergency rule and enforce the previous, more-protective regulation.

A proposed rule, which covers the same material, is published in this issue of the Missouri Register. The scope of 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 (insert name of agency) believes this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed March 13, 2025, becomes effective March 27, 2025, and expires September 22, 2025.

(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) 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;

(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 subsection (3) and situations where the patient will complete the abortion outside the local area as specified in subsection (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 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.

(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 subsection (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.

4 A statement that the physician will comply with all of the requirements in subsection (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 shall 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 she 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 she 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.

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 waiver (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 emergency rule if the preliminary injunction prohibiting enforcement of 19 CSR 30-30.061 is lifted prior to the expiration date of this emergency rule.

AUTHORITY: sections 188.021, RSMo 2017. Emergency rule filed Mar. 13, 2025, effective Mar. 27, 2025, expires Sep. 22, 2025. A proposed rule covering this same material is published in this issue of the Missouri Register.

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

PRIVATE COST: This emergency rule will cost private entities between zero and one million, twenty-six thousand, five hundred and sixty-two dollars and fifty cents ($0 - $1,026,562.50) in the time the emergency is effective.