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IOWA BOARD OF MEDICINE
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IOWA BOARD OF MEDICINE'S STATEMENT ON ADOPTED AND FILED RULE ARC 1034C

On August 30, 2013, the Iowa Board of Medicine voted to adopt and file ARC 1034C (previously ARC 0891C) to establish standards of practice for physicians who prescribe or administer abortion-inducing drugs to terminate a pregnancy – medical abortion. The goal of the new rule is to protect the health and safety of Iowans. The Board believes that all patients, including those in rural Iowa, deserve the highest level of care. The Board believes that a physician must establish an appropriate physician-patient relationship prior to the provision of a medical abortion. The physician's in-person medical interview and physical examination of the patient are essential to establishing that relationship.

Pursuant to Iowa Administrative Code 653 – Chapter 1.8(2)"c"(6), the Board presents this statement of the principal reasons for and against the rule, incorporating therein the reasons either for accepting or overruling considerations urged against the rule. ARC 1034C will be published in the Iowa Administrative Bulletin on October 2, 2013, and will become effective on November 6, 2013.

I. PRINCIPAL REASONS PRESENTED IN SUPPORT OF THE RULE

- 1. To protect the health and safety of patients, standards of practice are needed for physicians who prescribe and administer abortion-inducing drugs to terminate a pregnancy.
- 2. The practices used by physicians who prescribe and administer abortion-inducing drugs using telemedicine are inconsistent with the protocols approved by the U.S. Food and Drug Administration (FDA) and the manufacturer of the drugs.
- 3. Iowa Code Section 707.7(3) only allows physicians to perform abortions in Iowa.
- 4. A physical examination of the patient in telemedicine settings is not being performed by the physician who prescribes and administers the abortion-inducing drugs, but is delegated to non-physician persons who do not have appropriate training to confirm or discover

contraindications or to perform an ultrasound to determine the age and location of the embryo.

5. Physicians who prescribe and administer abortion-inducing drugs using telemedicine may never meet with the patient in person and may never see the patient again for a follow-up appointment.

II. PRINCIPAL REASONS PRESENTED IN OPPOSITION TO THE RULE AND THE BOARD'S REASONS FOR OVERRULING THESE CONSIDERATIONS

- 1. The rule would limit rural Iowa women's access to medical abortions. The new rule does not restrict where medical abortion services may be provided. The emphasis of the rule is on the patient's health and safety and the responsibility of physicians who perform medical abortions. The Board believes that all Iowans are entitled to the same high level of health care, regardless of whether they live in rural or urban areas. The Board believes that the physician's decision that the patient should have a medical or surgical abortion should depend on multiple factors including patient preference, medical and psychological status of the patient, and the patient's access to emergency medical services.
- **2. The rule is politically motivated and is not sound public policy.** While issues such as abortion have been politicized, the Board does not have authority to react politically to any issue. The Board is only authorized to adopt all necessary and proper rules for the licensure and standards of practice for health care providers licensed pursuant to Iowa Code Chapters 148 (physicians) and 148E (acupuncturists). The Board is motivated to adopt this administrative rule by its mandate to protect the health and safety of Iowans.
- 3. The rule is an attempt to ban access to a procedure that is legal. It deprives Iowa women of their constitutionally protected right to obtain a pre-viability abortion. Abortion is legal in Iowa and the goal of the new rule is to protect the health and safety of patients who seek medical abortions. Federal court decisions have set the guidelines for the availability of abortion. Nothing in the rule bans medical abortion. Rather, the rule sets forth the standards of practice that must be followed by physicians who perform medical abortions.
- 4. The Board previously addressed this matter in 2010 when it reviewed Planned Parenthood of the Heartland's medical abortion services using telemedicine and concluded they were safe. The membership of the Board has changed completely over the past three years. The Board has not previously promulgated any rules addressing medical abortion services using telemedicine. This is the first rulemaking proceeding which has given licensed physicians and the public an opportunity to comment on the use of telemedicine in this context. Because there was no rule in place addressing this particular procedure, the Board determined a rule was necessary to protect the health and safety of Iowans.
- 5. The Board promulgated rulemaking without a thorough study or analysis of the matter under regulatory consideration and the Board did not take into consideration the impact the rule may potentially have on expectations and requirements for telemedicine delivery of

other medical services. After accepting a petition on June 28, 2013, to promulgate rulemaking on the standards of practice for physicians who perform medical abortions, Board members studied the matter and reviewed medical research papers and a significant amount of public comments received on a broad spectrum of issues regarding medical abortions. The Board determined that the new rule is narrowly focused on the standards of practice for physicians who perform medical abortions. The Board may determine in the future to more broadly address the standards of practice for other medical services using telemedicine.

6. An appropriate physical examination, including an ultrasound to determine age and location of the embryo, is performed by appropriately trained staff in the telemedicine setting and this information is provided to an off-site physician who remotely prescribes and administers the abortion-inducing drugs. The Board considers a thorough medical history and physical examination to be the cornerstone of good medical care. On this foundation an accurate diagnosis can be made and the most appropriate treatment plan offered to the patient. The Board is concerned about the quality and sufficiency of the physical examination being performed prior to a medical abortion. The first area of concern is the lack of opportunity for a physician to perform a basic physical examination of the patient to screen for conditions that would be contraindications to medical abortion. The drugs used in a medical abortion are mifepristone and misoprostol. As listed in the FDA literature the contraindications to these medications include "confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass; an intrauterine device (IUD) in place; chronic adrenal failure; concurrent long-term corticosteroid therapy; history of allergy to mifepristone, misoprostol, or other prostaglandins; hemorrhagic disorders or concurrent anticoagulant therapy; and inherited porphyrias." As stated in the FDA literature on abortion-inducing drugs, "There are no data on the safety and efficacy of mifepristone in women with chronic medical conditions such as cardiovascular, hypertensive, hepatic, respiratory, or renal disease; insulin-dependent diabetes mellitus; severe anemia or heavy smoking. Women who are more than 35 years of age and who also smoke 10 or more cigarettes per day should be treated with caution because such patients were generally excluded from clinical trials of mifepristone." The Board believes that a basic physical examination of a patient is necessary to exclude this narrower list of contraindications and essential to exclude the list of exclusionary conditions that were not part of the clinical studies. The second area of concern is the quality of the ultrasound that is being performed prior to a medical abortion. Without the option of a clinical pelvic examination of the patient to confirm dating of the embryo, these remote clinics are relying primarily on ultrasound to date the embryo and rule out ectopic pregnancy, which occurs when an embryo implants somewhere other than the uterus. The Board is concerned about the uncertainty of whether clinic staff members providing the ultrasounds are actually qualified to produce useful images to sufficiently rely upon for diagnostic purposes. If an ectopic pregnancy was missed the medications may not expel the embryo and may lead to delayed diagnosis and treatment of this dangerous condition. In the FDA reports of deaths from mifepristone and misoprostol two of the 14 deaths were related to ruptured ectopic pregnancies, and 58 other women suffered morbidity from failed diagnosis of ectopic pregnancy. The Board believes that a basic physical examination for every patient will help to exclude the conditions that are contraindications to the medications. The

Board believes that a pelvic examination may be necessary in some cases to correlate with ultrasound findings and should be available to all women presenting for a medical abortion. The Board believes that adequate ultrasound services and interpretation are necessary if a clinical pelvic examination is not being used to date the embryo. For all these reasons the Board believes that a physician should be present to conduct this physical examination before proceeding with a medical abortion.

- 7. The treatment and consultation recommendations made by the physician in the telemedicine setting are the same standards of appropriate practice as those in face-to-face settings. The physician does not have to be present to perform a medical abortion. Iowa Code section 707.7(3) requires that abortions in Iowa be performed by physicians. The Board believes that the prescribing physician must be physically present with the patient to administer the abortion-inducing drug. This physician-patient relationship is fundamental to the provision of a safe medical abortion. It is the expectation of the Board that physicians recognize the obligations, responsibilities and patient rights associated with establishing and maintaining an appropriate physician-patient relationship in the specific context of prescribing and administering abortion-inducing drugs.
- 8. Patients are already receiving appropriate follow-up care to their medical abortions in remote clinics where a physician is not physically present. The Board believes that follow-up care of the patient is critical after providing a medical abortion. The new rule requires the physician who prescribes and performs a medical abortion to make all reasonable efforts to ensure that the patient is aware of the importance of follow-up care and that she returns for an appointment with the prescribing physician. The Board believes that the physician's in-person interview to collect the patient's medical history and an in-person physical examination will strengthen the physician-patient relationship and result in improved and increased follow-up care of the patient.

III. ADOPTED AND FILED RULE ARC 1034C

653—13.10(147,148,272C) Standards of practice—physicians who prescribe or administer abortion-inducing drugs.

13.10(1) *Definition*. As used in this rule:

"Abortion-inducing drug" means a drug, medicine, mixture, or preparation, when it is prescribed or administered with the intent to terminate the pregnancy of a woman known to be pregnant.

- **13.10(2)** *Physical examination required.* A physician shall not induce an abortion by providing an abortion-inducing drug unless the physician has first performed a physical examination of the woman to determine, and document in the woman's medical record, the gestational age and intrauterine location of the pregnancy.
- **13.10(3)** *Physician's physical presence required.* When inducing an abortion by providing an abortion-inducing drug, a physician must be physically present with the woman at the time the abortion-inducing drug is provided.

13.10(4) Follow-up appointment required. If an abortion is induced by an abortion-inducing drug, the physician inducing the abortion must schedule a follow-up appointment with the woman at the same facility where the abortion-inducing drug was provided, 12 to 18 days after the woman's use of an abortion-inducing drug to confirm the termination of the pregnancy and evaluate the woman's medical condition. The physician shall use all reasonable efforts to ensure that the woman is aware of the follow-up appointment and that she returns for the appointment.

13.10(5) Parental notification regarding pregnant minors. A physician shall not induce an abortion by providing an abortion-inducing drug to a pregnant minor prior to compliance with the requirements of Iowa Code chapter 135L and rules 641—89.12(135L) and 641—89.21(135L) adopted by the public health department.

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