ARKANSAS REGISTER

Transmittal Sheet

Use only for **FINAL** and **EMERGENCY RULES**

Secretary of State
Mark Martin
500 Woodlane, Suite 026
Little Rock, Arkansas 72201-1094
(501) 682-5070
www.sos.arkansas.gov

For Office Use Only:

Effective Date _____ Code Number _____

Name of Agency Arkansas State Medical Board

Department _____

Contact Kevin M. O'Dwyer E-mail kodwyer@htolaw.com Phone 501-372-4144

Statutory Authority for Promulgating Rules ACA §20-16-1501 et seq.

Rule Title: Regulation 36 - Governing Procedures for Abortions

Intended Effective Date (Check One)		Date
☐ Emergency (ACA 25-15-204)	Legal Notice Published	02/02/2016
☑ 10 Days After Filing (ACA 25-15-204)	Final Date for Public Comment	04/07/2016
☐ Other _____ (Must be more than 10 days after filing date.)	Reviewed by Legislatice Council	06/14/2016
	Adopted by State Agency	04/07/2016

Electronic Copy of Rule e-mailed from: (Required under ACA 25-15-218)

Kevin M. O'Dwyer (Contact Person) kodwyer@htolaw.com (E-mail Address) 6/15/16 (Date)

CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted
In Compliance with the Arkansas Administrative Act. (ACA 25-15-201 et. seq.)

Signature

501-296-1802 (Phone Number) support@armedicalboard.org (E-mail Address)

Executive Secretary (Title)

6/15/2016 (Date)

Revised 7/2015 to reflect new legislation passed in the 2015 Regular Session (Act 1258). This act changed the effective date from 30 days to 10 days after filing the rule.

AMENDMENT ADOPTED

REGULATION 36 **ABORTION**

REGULATIONS GOVERNING PROCEDURES FOR ABORTIONS

A. A person authorized to perform abortions under Arkansas law shall not perform an abortion on a pregnant woman before the person tests the pregnant woman to determine whether the fetus that the pregnant woman is carrying possesses a detectible heartbeat.
B. A person authorized to perform abortions under Arkansas law shall perform an abdominal ultrasound test necessary to detect a heartbeat of an unborn human individual according to standard medical practice, including the use of medical devices as determined by standard medical practice.
C. Tests performed pursuant to Ark. Code Ann.§20-16-1303(b)(1) shall be:
    a. Based on standard medical practice for testing for the fetal heartbeat of an unborn human individual which testing includes an abdominal ultrasound test necessary to detect a heartbeat of an unborn human individual according to standard medical practice, including the use of medical devices as determined by standard medical practice;
    b. A test for fetal heartbeat is not required in the case of a medical emergency; and
D. The physician shall obtain, based on available medical evidence, including testing and physical examination, the statistical probability of bringing an unborn human individual to term based on the gestational age of the unborn human individual possessing a detectible heartbeat.
E. If a heartbeat is detected during the test required pursuant to this Rule, the person performing the test shall inform the pregnant woman in writing:
    a. That the unborn human individual that the pregnant woman is carrying possesses a heartbeat;
    b. Of the statistical probability of bringing the unborn human individual to term based on the gestational age of the unborn human individual possessing a detectible heartbeat; and
    c. If a heartbeat has been detected, the pregnant woman shall sign a form acknowledging that she has received the information required under Ark. Code Ann. §20-16-1303(d).
F. DEFINITIONS: As used in this section:
    1) "Abortion" means the use or prescription of any instrument, medicine, drug or any other substance or device or means with the intent to terminate the clinically diagnosable pregnancy of a woman known to be pregnant, with knowledge that the termination by those means will with reasonable likelihood cause the death of the unborn child, other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, or to remove a dead unborn child who died in utero as the result of natural causes, accidental trauma, or a criminal assault on the pregnant woman or her unborn child, and that causes the premature termination of the pregnancy; An act under this section is not an abortion if the act is performed with the intent to:
        i. Save the life or preserve the health of the unborn child;

ii. Remove a dead unborn child caused by spontaneous abortion;
iii. Remove an ectopic pregnancy; or
iv. Treat a maternal disease or illness for which the prescribed drug is indicated;

2) "Abortion-inducing drug" means a medicine, drug, or any other substance prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination will with reasonable likelihood cause the death of the unborn child.
   i. "Abortion-inducing drugs" includes off-label use of drugs known to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion, such as misoprostol, Cytotec, and methotrexate.
   ii. This definition does not apply to drugs that may be known to cause an abortion, but which are prescribed for other medical indicts such as chemotherapeutic agents or diagnostic drugs.
   iii. Use of drugs to induce abortion is also known as a medical, drug-induced, or chemical abortion.
3) "Attempt to perform or induce an abortion" means an act or an omission of a statutorily required act that, under the circumstances as the physician believes them to be, constitutes a substantial step toward the performance or induction of an abortion in violation of this section;
4) "Mifeprex regimen" means the abortion-inducing drug regimen that involves administration of mifepristone or the brand name "Mifeprex" and misoprostol which is the only abortion-inducing drug regimen approved by the United States Food and Drug Administration and is also known as the RU-486 regimen or simply RU-486.
5) "Mifepristone" means the specific abortion-inducing drug regimen known as RU-486 and the first drug used in the Mifeprex regimen;
6) "Mifepristol" means the second drug used in the Mifeprex regimen;
7) "Physician" means any person licensed to practice medicine in the State of Arkansas under the Arkansas Medical Practices Act, §17-95-201 et seq., §17-95-301 et seq., and §17-95-401 et seq., including medical doctors and doctors of osteopathy;
8) "Adverse event" means an undesirable experience associated with the use of a medical product in a patient, including without limitation an event that causes:
   i. Death;
   ii. Threat to life;
   iii. Hospitalization;
   iv. Disability or permanent damage;
   v. Congenital anomaly or birth defect, or both;
   vi. Required intervention to prevent permanent impairment or damage;
   vii. Other serious important medical events, including without limitation:
      1. Allergic bronchospasm requiring treatments in an emergency room;
      2. Serious blood dyscrasias;
      3. Seizures or convulsions that do not result in hospitalization; and
      4. The development of drug dependence or drug abuse;
9) "Final printed labeling" means the United States Food and Drug Administration approved informational document for an abortion-inducing drug which outlines the

protocol authorized by the United States Food and Drug Administration and agreed upon by the drug company applying for United States Food and Drug Administration authorization of that drug.

10) "Conception" means the fusion of a human spermatozoon with a human ovum;
11) "Emancipated minor" means a person under eighteen (18) years of age who is or has been married or who has been legally emancipated;
12) "Facility" means a public or private hospital, clinic, center, medical school, medical training institution, healthcare facility, physician's office, infirmary, dispensary, ambulatory surgical treatment center, or other institution or location where medical care is provided to a person.
13) "First trimester" means the first twelve (12) weeks of gestation;
14) "Gestational age" means the time that has elapsed since the first day of the woman's last menstrual period or as stated in Act 171 of 2013, which prohibits abortions after 20 weeks, which also uses the term "post-fertilization" age;
15) "Hospital" means any institution licensed as a hospital pursuant to the laws of this state;
16) "Medical emergency" means that condition which, on the basis of the physician's good-faith clinical judgment, complicates the medical condition of a pregnant woman and necessitates the immediate termination of her pregnancy to avert her death or for which a delay will create serious risk of substantial and irreversible impairment of a major bodily function;
17) "Pregnant" or "pregnancy" means that female reproductive condition of having an unborn child in the woman's uterus;
18) "Qualified person" means an agent of the physician who is a psychologist, licensed social worker, licensed professional counselor, registered nurse, physician assistant, or physician;
19) "Unborn child" means the offspring of human beings from conception until birth.
20) "Viability" means the state of fetal development when, in the judgment of the physician based on the particular facts of the case before him or here and in light of the most advanced medical technology and information available to him or her, there is a reasonable likelihood of sustained survival of the unborn child outside the body of his or her mother, with or without artificial support.

G. 1. When mifepristone or another drug or chemical regimen is used to induce an abortion, the initial administration of the drug or chemical shall occur in the same room and in the physical presence of the physician who prescribed, dispensed, or otherwise provided the drug or chemical to the patient.

2. The physician who induces the abortion, or a person acting on behalf of the physician who induces the abortion, shall make all reasonable efforts to ensure that the patient returns twelve (12) to eighteen (18) days after the administration or use of mifepristone or another drug or chemical for a follow-up visit so that the physician can confirm that the pregnancy has been terminated and can assess the patient's medical condition.

3. A brief description of the efforts made to comply with this section, including the date, time, and identification by name of the person making the efforts, shall be included in the patient's medical record.

H. This section does not affect telemedicine practice that does not involve the use of mifepristone or another drug or chemical to induce an abortion.

I. 1. If the Arkansas State Medical Board finds that a physician licensed by the board has violated the rules of professional conduct by performing an abortion in violation of Act 139 of 2015, the board shall revoke the physician's license.

2. A penalty shall not be assessed against the woman upon whom the abortion is performed or attempted to be performed.

J. 1. (A) A woman who receives an abortion, the father of the unborn child who was the subject of the abortion if the father was married to the woman who received the abortion at the time the abortion was performed, or a maternal grandparent of the unborn child may maintain an action against the person who performed the abortion in violation of this section for actual and punitive damages.

(B) A woman who attempts to receive an abortion in violation of this section may maintain an action against the person who attempted to perform the abortion for actual and punitive damages.

2. (A) Upon petition by any citizen in the county in which an alleged violation of this section occurred or in which the Defendant resides, a court may enjoin a healthcare professional who has knowingly or recklessly violated this section.

(B) An injunction under subdivision J.2(A) of this section shall prevent the abortion provider from performing further abortions in violation of this section.

K. 1. If a judgment is rendered in favor of the Plaintiff who prevails in an action under subsection J of this section, the court shall award reasonable attorney's fees and costs in favor of the Plaintiff against the Defendant.

2. If a judgment is rendered in favor of the Defendant and the court finds that the Plaintiff's suit was frivolous and brought in bad faith, the court shall order the Plaintiff to pay reasonable attorney's fees to the Defendant.

L. A pregnant woman who obtains or possesses mifepristone or another drug or chemical used for the purpose of inducing an abortion to terminate her pregnancy shall not be subject to an action under subsection J of this section.

M. 1. In a civil proceeding or action brought under this section, the court shall determine if the anonymity of a woman who receives or attempts to receive an abortion shall be preserved from public disclosure without her consent.

2. (A) Upon determining that the woman's anonymity shall be preserved, the court shall issue an order to the parties, witnesses, and counsel and shall direct the sealing of the record and exclusion of individuals from courtrooms or hearing rooms to the extent necessary to safeguard the woman's identity from public disclosure.

2. (B) An order under subdivision M.2.A. of this section shall be accompanied by specific written findings explaining:

i.) Why the anonymity of the woman should be preserved from public disclosure;

ii.) Why the order is essential to that end;

iii) How the order is narrowly tailored to serve that interest; and

iv) Why no reasonable, less restrictive alternative exists.

(C) In the absence of written consent of the woman who receives or attempts to receive an abortion, anyone other than a public official who brings an action under subsection J of this section shall bring the action under a pseudonym.

(D) This subsection does not conceal the identity of the Plaintiff or of a witness from the Defendant.

N. This section does not create or recognize a right to abortion.

Unlawful distribution of abortion-inducing drug.

(a) (1) It shall be unlawful to knowingly give, sell, dispense, administer, or otherwise provide or prescribe an abortion-inducing drug to a pregnant woman to induce an abortion or enabling another person to induce an abortion, unless the person who gives, sells, dispenses, administers, or otherwise provides or prescribes the abortion-inducing drug is a physician and the provision of prescription of the abortion-inducing drug satisfies the protocol authorized by the USFDA as outlined in the final printed labeling for the drug or drug regimen.

(2) In the case of the Mifeprex regimen, the final printed labeling for Mifeprex includes the USFDA-approved dosage and administration instructions for both mifepristone and misoprostol.

(b) Because the failure and complication rates from medical abortion increase with advancing gestational age, because the physical symptoms of medical abortion can be identical to the symptoms of ectopic pregnancy, and because abortion-inducing drugs do not treat ectopic pregnancies but rather are contraindicated in ectopic pregnancies, the physician giving, selling, dispensing, administering, or otherwise providing or prescribing the abortion-inducing drug shall first examine the woman and document in the woman's medical chart prior to giving, selling, dispensing, administering, or otherwise providing or prescribing the abortion-inducing drug the following information without limitation:

(1) Gestational age; and

(2) Intrauterine location of the pregnancy.

(c) Every pregnant woman to whom a physician gives, sells, dispenses, administers, or otherwise provides or prescribes any abortion-inducing drug shall be provided with a copy of the drug's label.

(d) (1) The physician who gives, sells, dispenses administers, or otherwise provides or prescribes any abortion-inducing drug shall have a signed contract with a physician who agrees to handle complications and be able to produce that signed contract on demand by the patient or by the Department of Health.

(2) The physician who contracts to handle emergencies shall have active admitting privileges and gynecological/surgical privileges at a hospital designated to handle any emergencies associated with the use or ingestion of the abortion-inducing drug.

(3) Every pregnant woman to whom a physician gives, sells, dispenses, administers, or otherwise provides or prescribes any abortion-inducing drug shall receive the name and phone number of the contract physician and the hospital at which that physician maintains admitting privileges and which can handle any emergencies.

(e) (1) The physician who gives, sells, dispenses administers, or otherwise provides or prescribes any abortion-inducing drug, or an agent of the physician, shall schedule a follow-up visit for the woman for approximately fourteen (14) days after administration of the abortion-inducing drug to confirm that the pregnancy is completely terminated and to assess the degree of bleeding.

(2) The physician or agent of physician shall make all reasonable efforts to ensure that the woman returns for the scheduled appointment.

(3) A brief description of the efforts made to comply with this subsection, including without limitation the date, time, and identification by name of the person making such efforts, shall be included in the woman's medical record.

Reporting

(a) If a physician provides an abortion –inducing drug to another for the purpose of inducing an abortion as authorized herein, and if the physician knows that the woman who uses the abortion-inducing drug for the purpose of inducing an abortion experiences an adverse event, the physician shall provide a written report of the adverse event within three (3) days of the event to the Arkansas State Medical Board

(b) The Board

a. Shall compile and retain all reports it receives under this section.

b. Shall not release to any person or entity the name or any other personal identifying information regarding a person who:

i. Uses an abortion-inducing drug to induce an abortion; and

ii. Is the subject of a report received by the board under this section.

Informed Consent Requirement

(a) A person shall not perform or induce an abortion without the voluntary and informed consent of the woman upon whom the abortion is to be performed or induced.

(b) Except in the case of a medical emergency, consent to an abortion is voluntary and informed only if:

a. At least forty-eight (48) house before the abortion, the physician who is to perform the abortion or the referring physician has informed the woman, orally and in person, of the following:

i. The name of the physician who will perform the abortion;

ii. Medically accurate information that a reasonable patient would consider material to the decision concerning whether or not to undergo the abortion, including:

1. A description of the proposed abortion method;

2. The immediate and long-term medical risks associated with the proposed abortion method, including without limitation the risks of:

a. Cervical or uterine perforation;

b. Danger to subsequent pregnancies;

c. Hemorrhage; and
d. Infection; and

3. Alternatives to the abortion;

iii. The probable gestational age of the unborn child at the time the abortion is to be performed;

iv. The probable anatomical and physiological characteristics of the unborn child at the time the abortion is to be performed;

v. The medical risks associated with carrying the unborn child to term;

vi. Any need for anti-Rh immune globulin therapy if the woman is Rh negative, the likely consequences of refusing such therapy, and the cost of the therapy; and

vii. Information on reversing the effects of abortion-inducing drugs;

b. At least forty-eight (48) hours before the abortion, the physician who is to perform the abortion, the referring physician, or a qualified person informs the woman, orally and in person, that;

i. Medical assistance benefits may be available for prenatal care, childbirth, and neonatal care, and that more detailed information on the availability of such assistance is contained in the printed materials and informational DVD given to her under §20-16-1504;

ii. The printed materials and information DVD under §20-16-1504 describe the unborn child and list agencies that offer alternatives to abortion;

iii. The father of the unborn child is liable to assist in the support of the child, even in instances where he has offered to pay for the abortion. In a case of rape or incest, the information required under this subsection may be omitted.

iv. The woman is free to withhold or withdraw her consent to the abortion at any time without affecting her right to future care or treatment and without the loss of any state or federally funded benefits to which she otherwise might be entitled; and

v. The information contained in the printed materials and information DVD given to her under §20-16-1504, is also available on a state website;

c. (A) The information required under subdivisions b(a) and (b) of this section is provided to the woman individually and in a private room to protect her privacy to maintain the confidentiality of her decision, to ensure that the information focuses on her individual circumstances, and to ensure that she has an adequate opportunity to ask questions.

(B) Subdivision (c)c.(A) of this section does not preclude the provision of required information through a translator in a language understood by the woman;

d. (A) At least forty-eight (48) hours before the abortion, the woman is given a copy of the printed materials and permitted to view and given a copy of the information DVD under §20-16-1504

(B) If the woman is unable to read the materials, the materials shall be read to her in a language she can understand.

(C) If the woman asks questions concerning any of the information or materials under this subdivision d, the person who provides or reads the information or materials shall answer her questions in a language she can understand.

e. (A) at least forty-eight (48 (hours before an abortion is performed or induced on a woman whose pregnancy has progressed to twenty (20) weeks gestation or more, the physician performing the abortion on the pregnant woman, the referring physician, or a qualified person assisting the physician shall, orally and in person, offer information on fetal pain to the patient

(B) The information required under the previous section and counseling related to that information shall include without limitation the following:

i. that by twenty (20) weeks gestational age, the unborn child possesses all anatomical links in its nervous system, including spinal cord, nerve tracts, thalamus, and cortex, that are necessary in order to feel pain;

ii. That an unborn child at twenty (20) weeks gestation or more is fully capable of experiencing pain;.

iii. A description of the actual steps in the abortion procedure to be performed or induced and at which steps in the abortion procedure the unborn child is capable of feeling pain;

iv. That maternal anesthesia typically offers little pain prevention for the unborn child; and

v. That an anesthetic, analgesic, or both are available so that pain to the unborn child is minimized or alleviated.

f. (A) Before the abortion, the pregnant woman certifies in writing on a checklist form provided or approved by the Department of Health that the information required under this section has been provided.

(B) A physician who performs an abortion shall report monthly to the department the total number of certifications the physician has received.

(C) The department shall make available to the public annually the number of certifications received under this section.

(g) (A) Except in the case of a medical emergency, the physician who is to perform the abortion shall receive and sign a copy of the written certification required under this section before performing the abortion.

(B)The physician shall retain a copy of the checklist certification form in the pregnant woman's medical record; and

(h) At least forty-eight (48) hours before an abortion that is being performed or induced utilizing abortion-inducing drugs, the physician who is to perform the abortion, the referring physician, or a qualified person informs the pregnant woman, orally and in person, that:

(A) It may be possible to reverse the effects of the abortion if the pregnant woman changes her mind, but that time is of the essence; and

(B) Information on reversing the effects of abortion-inducing drugs is available in materials prepared by the department.

AMENDMENT ADOPTED

(c) (1) In the event of a medical emergency requiring an immediate termination of pregnancy, the physician who performed the abortion clearly certifies in writing the nature of the medical emergency and the circumstances that necessitated the waiving of the informed consent requirements under this subchapter.

(2) The certification required under this chapter shall be signed by the physician who performed the emergency abortion and shall be permanently filed in both the records of the physician performing the abortion and the records of the facility where the abortion took place.

(d) A physician shall not require or obtain payment for a service provided in relation to abortion to a patient who has inquired about an abortion or scheduled an abortion until the expiration of the forty-eight (48) hour reflection period required under this section.

(e) All ultrasound images, test results, and forms signed by the patient or legal guardian shall be retained as a part of the patient's medical record and be made available for inspection by the department or other authorized agency.