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Proposed Rule Cover Sheet

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ARKANSAS STATE BOARD OF HEALTH

RULES FOR ABORTION FACILITIES IN ARKANSAS



Promulgated under the Authority of Acts 509 of 1983 and 1176 of 2011, as amended, and other laws of the State of Arkansas.

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ARKANSAS DEPARTMENT OF HEALTH HEALTH FACILITY SERVICES

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SECTION 1. PREFACE.

These Rules have been prepared for the purpose of establishing criteria for minimum standards for licensure, operation and maintenance of Abortion Facilities. By necessity they are of a regulatory nature but are considered to be practical minimum design and operational standards for their facility type. These standards are not static and are subject to periodic revisions. It is expected Abortion Facilities will exceed these minimum requirements and will not be dependent upon future revisions as a necessary prerequisite for improved services.

SECTION 2. AUTHORITY.

These Rules for Abortion Facilities in Arkansas are duly adopted and promulgated by the Arkansas State Board of Health pursuant to the authority expressly conferred by Acts 509 of 1983 and 1176 of 2011; Ark. Code Ann. § 20-9-302 as amended, and other laws of the State of Arkansas.

SECTION 3. DEFINITIONS.

Note: see Section 12 for additional definitions for Physical Facilities requirements

- A. **1. Abortion** the act of using or prescribing any instrument, medicine, drug, or other substance, device, or means with the intent to terminate the clinically diagnosable pregnancy of a woman with knowledge that the termination by those means will with reasonable likelihood cause the death of the unborn child.
 - 1. An act under paragraph (A)(1) above is not an abortion if the act is performed with the intent to:
 - a. save the life or preserve the health of the unborn child;
 - b. remove a dead unborn child caused by a spontaneous abortion; or

c.

remove an ectopic pregnancy.

Note: Abortions are prohibited during and after the twentieth (20) week of a woman's pregnancy except as authorized by law. See Ark. Code Ann. § 20-16-1405;

- B. **Abortion Complication** any harmful event or adverse outcome with respect to a patient related to an abortion that is performed on the patient and that is diagnosed or treated by a physician or at a healthcare facility, including but not limited to shock, uterine perforation, cervical laceration, hemorrhage, aspiration or allergic response, infection, sepsis, death, incomplete abortion, damage to the uterus, and an infant born alive after an abortion.
- C. Abortion facility A clinic, health center, or other facility in which the pregnancies of ten (10) or more women pregnancy of a woman known to be pregnant are is willfully terminated or aborted in any month, including nonsurgical abortions.
- D. **Abortion-inducing drug** 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.
 - 1. "Abortion-inducing drugs" include 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.
 - 2. This definition does not apply to drugs that may be known to cause an abortion, but which are prescribed for other medical indications such as chemotherapeutic agents or diagnostic drugs.
 - 3. Use of drugs to induce abortion is also known as a medical, drug-induced, or chemical abortion.
- E. **Act -** Act 509 of 1983 as amended by Act 1176 of 2011.

- F. **Administrator -** an individual designated to provide daily supervision and administration of the Abortion Facility.
- G. **Adverse event** an undesirable experience associated with the use of a medical product in a patient, including without limitation an event that causes:
 - 1. death;
 - 2. threat to life;
 - 3. hospitalization;
 - 4. disability or permanent damage;
 - 5. congenital anomaly or birth defect, or both;
 - 6. required intervention to prevent permanent impairment or damage;
 - 7. other serious important medical events, including without limitation:
 - a. allergic bronchospasm requiring treatment in an emergency room;
 - b. serious blood dyscrasias;
 - c. seizures or convulsions that do not result in hospitalization; and
 - d. the development of drug dependence or drug abuse.
- H. **Born-alive infant** the complete expulsion or extraction of an infant from a mother, regardless of the state of gestational development, who shows any evidence of life, including without limitation:
 - 1. breathing;
 - 2. heartbeat;
 - 3. umbilical cord pulsation; or
 - 4. definite movement of voluntary muscles.
- I. Chemical Abortion
 - 1. Means the use, provision, prescription, or dispensation of a medication, drug, or any other substance used, provided, prescribed, or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman.
 - 2. Includes the off-label use of drugs know to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion and does not apply to drugs that may be known to cause an abortion but which are prescribed for other medical indications.
 - 3. Chemical abortion is also known as a medical abortion.

- J. **Consent -** a signed and witnessed voluntary agreement for the performance of an abortion; or
 - 1. in the case of a pregnant woman who is less than eighteen (18) years of age, a notarized written statement signed by the pregnant woman and her mother, father, or legal guardian declaring that the pregnant woman intends to seek an abortion and that her mother, father, or legal guardian consents to the abortion; or
 - 2. in the case of a pregnant woman who is an incompetent person, a notarized written statement signed by the pregnant woman's guardian declaring that the guardian consents to the performance of an abortion upon the pregnant woman.
- K. **Dead fetus or fetal remains** a product of human conception exclusive of its placenta or connective tissue, which has suffered death prior to its complete expulsion or extraction from the mother as established by the fact that, after the expulsion or extraction the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.
- L. **Department -** the Arkansas Department of Health.
- M. **Division -** the Division of Health Facility Services.
- N. **Director -** the Chief Administrative Officer in the Division of Health Facility Services.
- O. **Emancipated minor** means a person less than eighteen (18) years of age who is or has been married or who has been legally emancipated.
- P. **External member of the human body** means an arm or one (1) or more joints of the arm, a hand, a finger or one (1) or more joints of the finger, a leg or one (1) or more joints of the leg, a foot, a toe or one (1) or more joints of the toe, an ear or the greater part of the ear, or the nose or the greater part of the nose.
- Q. **Fertilization** the fusion of a human spermatozoon with a human ovum.
- R. **Final printed labeling** the United States Food and Drug Administration ("USFDA")- approved informational document for an abortion-inducing drug which outlines the protocol authorized by the USFDA and agreed upon by the drug company applying for USFDA authorization of that drug.
- S. **General abortion facility** an abortion facility that provides surgical abortions or both medical and surgical abortions.

- T. **Hospital -** Any <u>licensed</u> acute care facility established for the purpose of providing inpatient diagnostic care and treatment.
- U. **Gestational age** the time that has elapsed since the first day of the woman's last menstrual period.
- V. **Human tissue** means any tissue of the human body, including without limitation an external member of the human body, placenta, or fetal connective tissue.
- W. **Incompetent person** means <u>a person</u> who has been adjudged a disabled person and has had a guardian appointed for her.
- X. **Lethal fetal anomaly** means a fetal condition diagnosed before birth that will result in the death of the unborn child with reasonable certainty within three (3) months of the birth.
- Y. **Local anesthesia** Elimination or reduction of sensation, especially pain, in one part of the body by topical application or local injection of a drug.
- Z. Medical/<u>Chemical</u> abortion a non-surgical abortion for which abortifacient pharmaceutical drugs are used to induce the abortion. <u>Medical abortion is also known as a Chemical abortion</u>.

AA. Medical Emergency –

- 1. A condition that, on the basis of the physician's good-faith clinical judgement or reasonable medical judgement, complicates the medical condition of a pregnant woman and necessitates the immediate termination of her pregnancy to advert her death or for which a delay will create serious risk of substantial and irreversible impairment of a major body function.
- 2. A medical emergency does not include a condition based on a claim or diagnosis that a pregnant woman will engage in conduct that she intends to result in her death or in substantial and irreversible impairment of a major body function.
- 3. Upon determination by the physician that a medical emergency exist with respect to the pregnant woman, the physician shall certify the specific medical conditions that constitutes the medical emergency.
- BB. BB. Medical-only abortion facility an abortion facility in which no surgical abortions are performed. Medical abortion is also known as a Chemical abortion.
- CC. **Minimal sedation (anoxiolysis)** a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilator and cardiovascular functions are unaffected.
- DD. **Minor** means an individual under eighteen (18) years of age.

EE. **Moderate sedation/analgesia ("Conscious Sedation")** – a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate.

FF. **Parent** means:

- 1. Either parent of the pregnant woman if both parents are living;
- 2. One (1) parent of the pregnant woman if only one (1) is living or if the second parent cannot be located through reasonably diligent effort; or
- 3. The court-appointed guardian or custodian if the pregnant woman has one.
- GG. **Patient -** any woman receiving services in the facility and any born-alive infant.
- HH. **Physician** a person licensed to practice medicine in this state, including a medical doctor and a doctor of osteopathy.
- II. **Post-fertilization age** the age of the unborn child as calculated from the fertilization of the human ovum.
- JJ. **Probable post-fertilization age of the unborn child** what, in reasonable medical judgment, will, with reasonable probability, be the post-fertilization age of the unborn child at the time the abortion is planned to be performed or induced.
- KK. Qualified Technician means a) a registered diagnostic medical sonographer who is certified in obstetrics and gynecology by the American Registry of Diagnostic Medical Sonography; or b) a certified nurse midwife or advanced practice registered nurse with certification in obstetrical ultrasonography.
- LL. **Reasonable medical judgment** a medical judgment that would be made by a reasonably prudent physician knowledgeable about the case and treatment possibilities with respect to the medical conditions involved.
- MM. **Respectful and proper manner** means either releasing the human tissue to the patient or authorized person, incineration, burial, or cremation.
- NN. **Surgical abortion** means a pregnancy is ended by surgically removing the contents of the uterus through use of suction device or other instrument(s).

SECTION 4. LICENSING.

- A. Application for License. Application for a license or renewal of a license shall be made on forms provided by the Arkansas Department of Health. The application shall set forth:
 - 1. The complete name and address of the Abortion Facility
 - 2. The facility type:
 - a) General Abortion Facility; or
 - b) Medical-Only Abortion Facility; or
 - c) Any clinic, health center, or other facility in which a pregnancy of a woman know to be pregnant is willfully terminated or aborted in any month, including nonsurgical abortions; and
 - 3. Additional information as required by the Arkansas Department of Health.
- B. Grandfather provisions.
 - 1. A facility, in existence on January 1, 2012 and in substantial compliance with the physical facility requirements in Section 12, submitting initial application for licensure by July 1, 2012 is exempted from the physical facility requirements in Section 12 of these Rules for its existing physical structure. Notwithstanding this provision, a facility must be in compliance with these rules after January 1, 2014, unless the modifications would be impracticable.
 - 2. Except as otherwise provided in Section (4)(B)(1), Abortion Facilities shall comply with all requirements set forth in these Rules and Regulations. The Rules and Regulations shall become effective on January 1, 2012.
- C. Availability of Emergency Services. A General Abortion Facility shall be within thirty (30) miles of a hospital which provides gynecological or surgical services.
- D. Fee. Each application for initial licensure of an Abortion Facility shall be accompanied by a fee of five hundred dollars (\$500). The fee shall be payable to the Arkansas Department of Health.
- E. Renewal of License. A license, unless revoked, shall be renewable annually upon payment of a fee of five hundred dollars (\$500) to the Arkansas Department of Health accompanied by an application for re-licensure. The application for annual license renewal along with the fee shall be postmarked no later than January 2 of the year for which the license is issued.

- F. Issuance of License. A license shall be issued only for the premises, services, and person or persons reflected in the application. The license shall be posted in a conspicuous place in the Abortion Facility. The license shall be effective on a calendar year basis and shall expire on December 31 of each calendar year. The license shall not be transferrable and shall expire if a change of ownership occurs.
- G. Change of Ownership. It shall be the responsibility of the Abortion Facility to notify the Division of Health Facility Services in writing at least thirty (30) days prior to the effective date of a change of ownership. The following information shall be submitted for review and approval:
 - 1. license application;
 - 2. five hundred dollars (\$500) change of ownership fee; and
 - 3. legal documents, ownership agreements, and other information to support re- licensure requirements.
- H. Management Contract. It shall be the responsibility of the Abortion Facility to notify the Division of Health Facility Services in writing at least thirty (30) days prior to entering into a management contract or agreement with an organization or firm. A copy of the contract or agreement shall be submitted for review to assure the arrangement does not affect the license status.
- I. Closure. Once an Abortion Facility closes, it shall no longer be considered licensed. The license issued to the Abortion Facility shall be returned to the Division of Health Facility Services. To be eligible for re-licensure, the Abortion Facility shall meet requirements for new construction and all the current life safety and health regulations.
- J. Inspection. Any authorized representative of the Arkansas Department of Health shall have the right to enter upon or into the premises of any Abortion Facility at any time in order to make whatever inspection it deems necessary in order to assure minimum standards and regulations are met.
- K. A person who knowingly conceals or removes information that is relevant to an inspection of an abortion facility shall be guilty upon conviction of a Class A misdemeanor.
- L. Denial, Suspension or Revocation. The Department may deny, suspend or revoke the license of any Abortion Facility on the following grounds: violation of any of the provisions of the Act or Rules lawfully promulgated hereunder; and/or conduct or practices detrimental to the health or safety of patients and employees of any such facilities. This provision shall not be construed to have any reference to healing practices authorized by law.

SECTION 5. GOVERNING BODY.

An Abortion Facility shall have an organized Governing Body, consisting of at least one (1) member, which may be the Medical Director, with local representation which shall be legally responsible for maintaining patient care and establishing policies for the facility and shall be legally responsible for the conduct of the facility.

- A. The Governing Body Bylaws. The Governing Body shall adopt written bylaws which shall ensure the following:
 - 1. Maintenance of professional standards of practice;
 - 2. Terms, responsibilities and methods of selecting members and officers;
 - 3. Methods by which Quality Improvement is established; and
 - 4. Compliance with federal, state and local laws.
- B. Governing Body Minutes. The Governing Body minutes shall include at least the following information:
 - 1. Review, approval and revision of the Governing Body bylaws, rules, regulations and protocols;
 - 2. Review and approval of the Quality Improvement Plan for the facility at least annually, and review of Quality Improvement summaries at least quarterly.
- C. Quality Improvement (QI) Program.
 - 1. The Abortion Facility shall develop, implement, and maintain a QI program to include:
 - a) Collection of data on the functional activities identified as priorities in QI and benchmark against past performance and national or local standards; and
 - b) Development and implementation of improvement plans for identified issues, with monitoring, evaluation and documentation of effectiveness.
 - 2. The scope of the QI Program shall include, but not be limited to, activities regarding the following:
 - a) Assessment of processes and outcomes utilizing facility-specific clinical data;

- b) Evaluation of patient satisfaction;
- c) Evaluation of staff performance according to facility protocols; and
- d) Complaint resolution.
- 3. The facility shall evaluate the effectiveness of the QI Program annually and establish priorities for the QI Program.

SECTION 6. GENERAL ADMINISTRATION.

- A. Each facility shall have an Administrator responsible for the management of the facility. The Medical Director may also function as facility administrator.
- B. Policies and procedures shall be provided for the general administration of the facility and for each service. All policies and procedures shall have evidence of ongoing review and/or revision. The first page of each manual shall have the annual review date and signatures of the person(s) conducting the review.
- C. Provisions shall be made for safe storage of patients' valuables.
- D. Each facility shall develop and maintain a written disaster plan which includes provisions for complete evacuation of the facility. The plan shall provide for widespread disasters as well as for a disaster occurring within the local community or the facility. The disaster plan shall be rehearsed at least twice a year. One (1) drill shall simulate a disaster of internal nature and the other external. Written reports and evaluation of all drills shall be maintained.
- E. There shall be posted a list of names, telephone numbers, and addresses available for emergency use. The list shall include the key facility personnel and staff, the local police department, the fire department, ambulance service, blood services vendor, and other available emergency units. The list shall be reviewed and updated at least every six (6) months.
- F. There shall be current reference material available onsite to meet the professional and technical needs of Abortion Facility personnel including current books, periodicals, and other pertinent materials.
- G. All employees shall be required to have annual in-services on safety, fire safety, back safety, infection prevention and control, universal precautions, disaster preparedness and confidential information.
- H. Procedures shall be developed for the retention and accessibility of the patients' medical records if the Abortion Facility closes.
- I. Any Abortion Facility that closes shall meet the requirements for new construction in order to be eligible for re-licensure. Once a facility closes, it is no longer licensed. The license shall be immediately returned to Health Facility Services. To be eligible for licensure, all the referenced National Fire Codes (NFPA) and health regulations shall be met.

J. Informed consent

1. Signed and witnessed written consent for the performance of an induced abortion (chemical, medical, or surgical) must be obtained and signed by the patient prior to the

<u>administration of any medication or anesthesia</u>, prior to the abortion and after counseling by a qualified professional.

- 2. a. In case of a minor, notarized written consent for the performance of an induced abortion must be obtained and signed by both the patient and the parent or legal guardian or custodian.
 - b. In case of a woman under legal guardianship or custodianship for incompetency, notarized written consent for the performance of an induced abortion must be obtained and signed by the parent or legal guardian or custodian.
- 3. Written or verbal consent shall not release the facility or its personnel from upholding the rights of patients including, but not limited to, the right to privacy, dignity, security, confidentiality, and freedom from abuse or neglect.
- 4. Medical/Chemical abortion shall not be performed or induced without the voluntary and informed consent of the pregnant woman upon whom the medical/chemical abortion is to be performed or induced.
- K. Each facility shall have a Medical Director who shall be a physician currently licensed to practice medicine in Arkansas, and who shall be responsible for the direct coordination of all medical aspects of the facility program.
- L. There shall be written policies and procedures developed and approved by the Medical Director and Administrator which define the care provided at the facility.
- M. Policies and procedures shall include, but not be limited to the following:
 - 1. personnel policies;
 - 2. provision of medical and clinical services;
 - 3. provision of laboratory services;
 - 4. examination of fetal tissue;
 - 5. disposition of medical waste;
 - 6. emergency services, including but not limited to:
 - a. written procedure for emergency transfer to an acute care facility; and
 - b. a medical record form that contains information required for an emergency transfer to an acute care facility;
 - c. <u>written agreements with hospital and transport services (See Section</u> 6.Q).

- 7. criteria for discharge;
- 8. health information systems (including electronic records);
- 9. provision of pharmacy services;
- 10. medication administration;
- 11. anesthesia/analgesia/sedation administration as applicable;
- 12. counseling services;
- 13. patient education;
- 14. infection prevention and control;
- 15. fire, safety, and disaster preparedness;
- 16. housekeeping;
- 17. laundry;
- 18. preventive maintenance;
- 19. processing and/or storage of sterile supplies;
- 20. patient care;
 - a. pregnant and post-abortion women clients; and
 - b. born-alive infants;
- 21. probable post-fertilization age determination;
- 22. proper disposition of dead fetuses and fetal remains;
- 23. follow-up appointments for medical/chemical abortion patients at approximately seven (7) to fourteen (14) 12-18 days after the administration of the abortion-inducing drug., or as recommended in the final printed labeling, following abortion services, including administration of abortion inducing drugs
- 24. patient receipt of:
 - a. USFDA label(s) for abortion-inducing drugs;
 - b. written notice on reversing the effects of abortion-inducing drugs for patients receiving such drugs as required by Act 522 of 2019;
- 25. ultrasound (abdominal) heartbeat detection;
- 26. consent including but not limited to items specified in §9 (B)(2);

- 27. child maltreatment and/or abuse reporting; and
- 28. providing printed materials and answering the woman's questions in a language that she can understand;
- 29 pre-procedure; and
- 30. process to insure that perinatal palliative care information is provided to the mother of unborn child diagnosed with lethal fetal anomaly 72 hours before the abortion as required by Act 953 of 2019, the Perinatal Palliative Care Information Act.
- 31. Report crimes to law enforcement. Reportable crimes include but not limited to rape, incest, and child maltreatment.
- N. Administrative Reports. The Administrator or his/her designee shall report:
 - 1. Infectious or communicable diseases, including sexually transmitted diseases, to the Arkansas Department of Health, as required by:
 - a. the <u>Rules and Regulations</u> Pertaining to <u>Communicable Reportable</u> <u>Disease in Arkansas (Ark. Code Ann. §§ 20-7-109, 110.);</u> and
 - b. the <u>Rules Pertaining to the Control of Communicable Diseases-Tuberculosis.</u>
 - 2. Induced Terminations of Pregnancy. Each induced termination of pregnancy, whether chemical, medical, or surgical, which occurs in Arkansas shall be reported to the Division of Health Statistics on a monthly basis.
 - 3. <u>Medical/Chemical Abortion Reporting. Each healthcare provider shall report chemical abortion data to the Arkansas Department of Health, Division of Vital Statistics in the form and manner prescribed by the Department.</u>
 - 4. Adverse events associated with abortion-inducing drugs to:
 - a. USFDA via Medwatch reporting system; and
 - b. Arkansas State Medical Board.
 - 5. Abortion complications. Each abortion facility shall report each abortion complication (including live birth) diagnosed or treated by the facility. Reports shall be submitted to the Arkansas Department of Health, Division of Vital Statistics.
 - a. not later than the 30th day after the date on which the abortion complication was diagnosed or treated;

- b. in the form and manner prescribed by the Department;
- c. not identify by any means the physician performing the abortion;
- d. not identify by any means the patient upon whom the abortion was performed nor the patient; and
- e. containing:
 - a. the most specific, accurate, and complete reporting for the highest level of specificity;
 - b. the date of the abortion that caused or may have caused the abortion complication;
 - c. the type of abortion that cause or may have caused the abortion

complication;

- d. the gestational age of the fetus at the time that the abortion was performed;
- e. the name and type of healthcare facility in which the abortion was performed;
- f. the date the abortion complication was diagnosed or treated;
- g. the name and type of any healthcare facility other than the reporting healthcare facility in which the abortion complication was diagnosed or treated;
- h. a description of the abortion complication;
- i. the patient's year of birth, race, marital status, state of residence, and county of residence;
- j. the date of the first day of the patient's last menstrual period that occurred before the date of the abortion that caused or may have caused the abortion complication, if known;
- k. the number of previous live births of the patient; and
- 1. the number of previous induced abortions of the patient.
- f. An event associated with a medical procedure performed after a natural

miscarriage, spontaneous abortion, or fetal death is not subject to reporting under this rule.

- 6. Abortion due to Criminal Act Reporting. Each healthcare provider shall report abortions performed due to rape or incest to the Arkansas Department of Health, Division of Vital Statistics in the form and manner prescribed by the Department.
- O. Each facility shall ensure that each dead fetus or fetal remains are disposed of in accordance with the provisions of Ark. Code. Ann. § 20-17-102.
 - 1. The requirements of this subsection shall not apply to abortions induced by the administration of medications when the evacuation of any human remains occurs at a later time and not in the presence of the inducing physician nor at the facility in which the physician administered the inducing medications.
- P. Seventy-two (72) Hour Reflection Period. A physician, facility, employee or volunteer of a facility, or any other person or entity 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 72-hour reflection period required by Act 383 of 2017 as amended by Act 801 of 2019, Ark. Code Ann. § 20-16-1703(d).
- Q. Written Agreements. Abortion facilities shall have a written agreement that is a legally binding contractual document with a licensed acute care hospital and a licensed local ambulance service.
 - 1. The abortion facility shall file the written agreements with the Arkansas Department of Health; Health Facility Services within 10 days of the finalization of the agreement.
 - 2. <u>An abortion facility shall have ninety (90) days after January 1, 2022 to come into compliance.</u>
 - a. If applying for an extension of time to comply with the written agreement requirements shall submit a request to the Department in writing which contains a certification under oath that the abortion facility has exhausted all reasonable efforts to obtain a written agreement and include a detailed description of the efforts taken.

¹Section 6(O) was promulgated in 2017. At the time of filing this Rule Section 6(O) is enjoined by <u>Hopkins v.</u> Jegley, No. 4:17-cv-00404-KGB, 2021 U.S. Dist. LEXIS 1602 (E.D. Ark. Jan. 5, 2021).

3. <u>Hospital</u>

- a. Agreement shall include the hospital's agreement to accept, evaluate, and treat patients with complications related to procedures performed at an abortion facility and
 - <u>Direct charges to the patient or third-party payor and</u>
 - Acknowledge receipt of patient's personal effects.
- b. The agreement shall be with a hospital in the same county and not further than thirty (30) miles of the abortion facility.
- c. <u>Identify responsibilities of the abortion facility:</u>
 - Notify the hospital of the impending transfer and
 - Provide complete and accurate information to include copies of relevant portions of the patient's medical record, demographics, and insurance information and
 - Transfer the patient with the patient's personal effects along with a listing the effects.

4. Ambulance Service

- a. Agreement shall include the licensed local ambulance service's agreement to transport patients:
 - From the abortion facility to the hospital the facility has a written agreement or
 - As otherwise directed by the patient and
 - Be located in the same county as the abortion facility and no further than 5 miles or 10 minutes from the abortion facility and
 - Provides services in accordance with all federal and state laws and regulations and
 - Employ sufficient staff to provide care and operate vehicles and equipment and
 - Responding medical staff to be familiarized with the floor plan of the abortion facility and knowledgeable with the terms of the written agreement.

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SECTION 7. PATIENT CARE SERVICES.

An Abortion Facility shall have an adequate number of personnel qualified under this section available to provide direct patient care as needed.

A. Qualifications.

- 1. Only physicians who are currently licensed to practice medicine in Arkansas may perform abortions.
- 2. All facility personnel, medical and others, shall be licensed to perform the services they render when such services require licensure under the laws of the State of Arkansas. Documentation of current licensure shall be maintained in the personnel file for each employee.
- 3. Providers of patient counseling shall, at a minimum, possess current licensure as a nurse, Social Worker, or documented experience and training in a related field. Special training in counseling which is deemed acceptable by the Department shall be required.
- 4. All clinical staff of the facility shall be required to provide documentation of training and continued competence in cardiopulmonary resuscitation (CPR) or its equivalent.

B. Staffing Requirements.

- 1. There shall be a sufficient number of Registered Nurses in the facility at all times when patients are present.
- 2. Registered Nurses shall be on duty to supply or supervise all nursing care of patients.
- 3. There shall be sufficient staff, qualified technician or physician, to complete ultrasonography as required prior to the performance of an abortion.
- C. Authority and responsibilities of all patient care staff shall be clearly defined in written policies, including periodic monitoring and assessment of patients.
- D. Services shall be organized to ensure management functions are effectively conducted. These functions shall include, but are not limited to:
 - 1. review of policies and procedures at least annually to reflect current standards of care:
 - 2. establishment of a mechanism for review and evaluation of care and

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services provided at the facility;

- 3. orientation and maintenance of qualified staff for provision of patient care;
- 4. annual in-service education programs for professional staff; and
- 5. provision of current nursing literature and reference materials.
- E. Patients shall have access to twenty-four (24) hour telephone consultation with either a Registered Nurse or physician associated with the facility.
- F. Follow-up appointments medical/chemical abortions.
 - 1. Facility personnel shall schedule a follow-up appointment for the patient to return 7-14 12-18 days, or as recommended in the final printed labeling, after a medical abortion.
 - 2. Facility personnel shall make reasonable efforts to ensure that the patient returns for the follow-up appointment.
- G. A Registered Nurse shall plan, supervise, and evaluate the nursing care of each patient from admission to the facility through discharge.
- H. Counseling services.
 - 1. Seventy two (72)- hours prior to the abortion, the patient shall be counseled regarding the abortion procedure, alternatives to abortion, informed consent (including consent for unemancipated minors and women under legal guardianship or custodianship), medical risks associated with the procedure, potential post-abortion complications, community resources, family planning, and ADH printed materials and DVD available on the ADH website at: www.healthy.arkansas.gov. and patient shall be given a copy of the most current ADH printed materials and DVD.
 - 2. Documentation of counseling shall be included in the patient's medical record.
 - 3. The patient shall meet individually and in a private room with the physician, referring physician, or a qualified person.
 - 4. Each patient shall be assessed by a Registered Nurse for counseling needs post-abortion;
 - 5. Written instructions for post-abortion care shall be given to the patient at discharge, to include at least the following:
 - a) signs and symptoms of possible complications;

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- b) activities allowed and to be avoided;
- c) hygienic and other post-discharge procedures to be followed;
- d) abortion Facility emergency telephone numbers available on a twenty-four (24) hour basis;
- e) follow up appointment, if indicated; and
- f) <u>Human Trafficking literature also known as "Laura's Card". See</u> Appendix 3.
- 6. The patient shall be counseled regarding Rh typing and shall be given Rh immune globulin, if indicated.
- 7. Medical/Chemical Abortion
 - a) Detailed description to include risk and complications;
 - b) <u>Information regarding Rh incompatibility;</u>
 - c) Risk increase with advancing gestational age;
 - d) Reversing the effects if the woman changes her mind;
 - e) Post abortion care;
 - f) Follow-up visit.
- I. Drug-induced, <u>medical</u>, chemical and surgical abortions shall not be performed by telemedicine.
- J. Initial administration of abortion-inducing drugs shall occur in the same room and physical presence of the physician who prescribed, dispensed, or otherwise provided the drug(s) to the patient.
- K. Patient shall receive and acknowledge a copy of the USFDA label(s) for any abortion- inducing drugs(s) she receives.
- L. A healthcare professional shall not perform a pelvic exam on unconscious or anesthetized patient unless the following conditions exist and the patient is informed:
 - 1. Obtains written consent
 - 2. Court order for collection of evidence
 - 3. <u>Is within the scope and practice of the healthcare provider</u>
 - 4. <u>Medical emergency exist and the pelvic exam is immediately necessary for diagnosis or treatment.</u>

SECTION 8. PROGRAM REQUIREMENTS.

- A. Admission Evaluation. Every woman seeking to have an abortion shall be registered by the facility and evaluated by means of a history, physical examination, counseling, and laboratory tests.
 - 1. Verification of Pregnancy. Pregnancy testing shall be available to the patient and may precede actual registration by the facility. No abortion shall be performed unless the examining physician verifies the patient is pregnant. Pregnancy test results shall be filed in the patient's medical record.
 - 2. History and Physical Examination. Prior to the abortion, a medical history shall be obtained and recorded. The patient shall be given an appropriate physical examination, as determined by the physician, and may include testing for sexually transmitted diseases.
 - a. Physical examinations preceding medical abortions shall include a determination of gestational age and location of pregnancy.
 - b. Pelvic examinations shall be performed only by qualified personnel, as defined by their Practice Acts.
 - 3. Pre-abortion Tests. The following are required prior to an abortion: hematocrit or hemoglobin, Rh typing, and abdominal ultrasound for fetal heartbeat detection. Other onsite proof of pregnancy, such as pregnancy test, copy of a pregnancy test or ultrasound. may also be performed according to facility policy.
 - <u>Ultrasound requirements shall be performed prior to the pregnant woman</u> giving consent, performed by a physician or qualified technician, and shall:
 - Provide a simultaneous verbal explanation of the ultrasound to include the presence and location of the unborn child, the number of children, the dimensions of the unborn child and the presence of external members and internal organs if present and viewable and
 - <u>Inform the pregnant woman if the ultrasound image indicated that the</u> unborn child has died and
 - Display so that the pregnant woman may view them and documented in the medical record that the images were displayed to the pregnant woman and
 - Retain the ultrasound image with the date performed in the medical record;

NOTE:

- <u>Current law does not prevent a pregnant woman from averting her eyes</u> or looking away from the ultrasound image and
- Does not apply in the case of a medical emergency in which the physician has certified the specific medical condition that constitutes the medical emergency and

- Physician or pregnant woman is not subject to a penalty if the pregnant woman declines to looked at the presented ultrasound image.
- 4. Counseling. Patient counseling services shall be offered prior to initiation of any abortion and if indicated following the abortion. In addition to verbal counseling, patients shall be given and allowed to keep the most current ADH printed materials and DVD.
- 5. Consent. See Informed Consent Section 6.J.
- B. Anesthetic agents.
 - 1. Anesthesia, analgesia and anoxiolysis shall be administered only by a qualified professional acting within the scope of his or her Arkansas license.
 - 2. Anesthesia administration in Abortion Facilities shall be limited to local anesthesia, minimal sedation, and moderate sedation.
- C. Discharge criteria, developed by the clinical staff and approved by the Governing Body, may be utilized to evaluate patients' medical stability for discharge. Patients may be discharged only on the order of a physician. Patients receiving sedation shall be discharged in the company of a responsible adult.
- D. Complications.
 - 1. General Abortion Facilities shall have emergency drugs, oxygen, intravenous fluids, and other emergency equipment on site and readily available to stabilize a patient if necessary.
 - 2. All clinical staff shall have documented current competency in cardiopulmonary resuscitation (CPR).
- E. Human/Fetal Tissue Disposal.
- 1. A physician or facility that performs an abortion shall ensure that fetal remains and all parts are disposed of in a fashion similar to that in which other tissue is disposed

NOTE: Act 535 of 2015, Ark. Code Ann. §20-17-802 provides:

- (b) A person shall not perform any biomedical or behavioral research on:
 - (1) a fetus born alive as the result of a legal abortion unless the research is for the exclusive benefit of the fetus so born; or
 - (2) a fetus born dead as the result of a legal abortion or any

fetal tissue produced by the abortion.

- (c) a person shall not buy, sell, give, exchange, or barter or offer to buy, sell, give, exchange, or barter any fetus born dead as a result of a legal abortion or any organ, member, or tissue of fetal material resulting from a legal abortion.
- (d) a person shall not possess either a fetus born dead as a result of a legal abortion or any organ, member, or tissue of fetal material resulting from a legal abortion.
- (e) This section does not apply to:
 - (1) a physician performing a legal abortion or a pathologist performing a pathological examination as the result of a legal abortion;
 - (2) an employee, agent, or servant of a physician performing a legal abortion or pathologist performing a pathological exam as the result of a legal abortion;
 - (3) the staff, faculty, students, or governing body of any institution of higher learning or institution of secondary education to the extent of courses of instruction taught and research conducted at the institutions;
 - (4) licensed physicians or their employees, agents, and servants while in the conduct of medical research;
 - (5) any licensed physician when performing a standard autopsy examination; or

- 2. An external member of the human body shall not be disposed of within forty-eight (48) hours of its removal or acquisition unless consent is obtained in writing from the patient or the person authorizing the medical/chemical or surgical treatment of the patient.
- 3. All human tissue shall be disposed of in a respectful and proper manner in compliance with the Arkansas Department of Health Rules Pertaining to The Management of Medical Waste from Generators and Health Care Related Facilities.



SECTION 9. HEALTH INFORMATION SERVICES.

The Abortion Facility shall maintain a system for the completion and storage of the medical record. The record shall provide a format for continuity and documentation of legible, uniform, complete, and accurate patient information readily accessible and maintained in a system that ensures confidentiality.

A. General Requirements.

- 1. The Abortion Facility shall adopt a record form for use that contains information required for transfer to an acute care facility.
- 2. Record reviews with criteria for identification of problems and follow up shall be reported to the Medical Director at least quarterly.
- 3. Responsibility for the processing of records is assigned to an individual employed by the Abortion Facility.
- 4. All medical records shall be retained in either the original, microfilm, or other acceptable methods for ten (10) years after the last discharge.
- 5. The original or a copy of the original (when the original is not available) of all reports shall be filed in the medical record.
- 6. The record shall be permanent and shall be either typewritten or legibly written in blue or black ink.
- 7. All typewritten reports shall include the date of dictation and the date of transcription.
- 8. All dictated records shall be transcribed within forty-eight (48) hours.
- 9. Errors shall be corrected by drawing a single line through the incorrect data, labeling it as "error", initialing, and dating the entry.
- 10. Policies and procedures for Health Information Services shall be developed. The manual shall have evidence of ongoing review and/or revision. The first page of the manual(s) shall have the annual review date and signatures of the person(s) conducting the review.
- 11. Medical records shall be protected to ensure confidentiality, prevent loss, and ensure reasonable availability.
- 12. All medical records, whether stored within the facility or away from the facility shall be protected from destruction by fire, water, vermin, dust, etc.

- 13. Medical records shall be considered confidential. All medical records (including those filed outside the facility) shall be secured at all times. Records shall be available to authorized personnel from the Arkansas Department of Health.
- 14. Written consent of the patient and/or parent, legal guardian or custodian shall be presented as authority for release of medical information. There shall be policies and procedures developed concerning all phases of release of information.
- 15. Original medical records shall not be removed from the facility except upon receipt of a subpoena duces tecum by a court having authority for issuing such an order.
- 16. Medical records shall be complete and contain all required signed documentation no later than thirty (30) days following the patient's discharge.
- 17. After the required retention period, medical records may be destroyed by burning or shredding. Medical records shall not be disposed of in landfills or other refuse collection sites.
- 18. Each entry into the medical record shall be authenticated by the individual who is the source of the information. Entries shall include all observations, notes, and any other information included in the record.
- 19. Signatures shall be, at least, the first initial, last name, and title. Computerized signatures may be either by code, number, initials, or the method developed by the facility.
- 20. There shall be policies and procedures for use of electronic medical records. The policies and procedures shall provide for the use, exchange, security, and privacy of electronic health information. The policies and procedures shall provide for standardized and authorized availability of electronic health information for patient care and administrative purposes. The policies and procedures will be in compliance with current guidelines and standards as established in federal and state statutes.
- B. Record Content. Each record shall include but not be limited to documentation of:
 - 1. demographic and patient information;
 - 2. informed consent:
 - a. Informed Consent Checklist form AS-4010:
 - b. See Medical/Chemical Abortion Section 6.J.4.
 - c. Documented evidence statistical probability of bringing unborn human individual to term based on gestational age of the unborn individual

possessing a detectable heartbeat was reviewed and signed by the pregnant woman;

- d. Fetal Pain Checklist in cases where woman's pregnancy has progressed to twenty (20) weeks gestation or more (form AS-4010A);
- e. For unemancipated minors and women under legal guardianship or custodianship for incompetence, Abortion Disclosure and Consent Form for Minors and Women under Legal Guardianship or Custodianship for Incompetency form AS-4011; and
- f. In cases of medical emergency where informed consent is not obtained, physician's written certification of:
 - 1) nature of the emergency;
 - 2) waiver of consent; and
 - 3) circumstances that necessitated the waiver;
- 3. complete family, medical, social, reproductive, nutrition, and behavioral history;
 - a. initial physical examination;
 - b. evaluation of risk status;
 - c. laboratory test results;
 - d. gestational age;
 - e. ultrasound image;
 - 1) opportunity for patient to view ultrasound;
 - 2) Verbal explanation of ultrasound
 - 3) patient acceptance or rejection of viewing ultrasound;
 - f. testing for fetal heartbeat and if heartbeat detected, an acknowledgment form as required by Ark. Code Ann. § 20-16-1303(e); and
 - g. for medical/<u>chemical</u> abortions, intrauterine location of pregnancy.
- 4. appropriate referral of patients, as indicated;

- 5. documentation of each periodic examination, including any follow-up appointment;
- 6. patient counseling regarding the abortion, alternatives to abortion, informed consent (including consent for unemancipated minors and women under legal guardianship or custodianship), medical risks associated with the abortion, potential postabortion complications, available community resources, and family planning, and most current ADH printed materials and DVD;
- 7. patient education regarding post-abortion signs and symptoms of possible complications, activities allowed and to be avoided, hygienic and other post-discharge procedures to be followed, telephone numbers to access emergency care, and follow-up appointments;
- 8. abortion and post-abortion records;
 - a. for surgical abortions, a written report describing surgical instruments used, surgical techniques, findings and tissues removed or altered;
 - b. for medical abortions, documentation of date, time, name of individual(s), and description of efforts made regarding patient follow-up appointment;
- 9. copies of proof of parent or guardian identification and relationship in cases where pregnant woman is an unemancipated minor or an incompetent woman under legal guardianship or custodianship, including:
 - a. photocopy of government-issued photo identification card; and
 - b. photocopy of written documentation that establishes that the parent or legal guardian is the lawful parent or legal guardian of the pregnant woman;
 - c. documentation required by (9)(B)(11)(a) shall be maintained for five (5) years past the patient's age of majority and no less than seven (7) years; and
- 10. physician affidavit when abortion is performed after receiving parental or legal guardian or custodian consent ("Abortion Disclosure and Consent form for Unemancipated Minors and Women under Legal Guardianship or Custodianship for Incompetency" ADH form AS4011).
- 11. A brief description of all efforts made to comply with Section 6.M.23. including the date, time, and identification by name of the person making such efforts shall be included in the medical record or chart.
- 12. <u>Documentation of the law enforcement reporting of a crime committed against a patient.</u>

SECTION 10. INFECTION CONTROL FOR ABORTION FACILITIES.

A. General.

- 1. The facility shall develop and use a coordinated process that effectively reduces the risk of endemic and epidemic healthcare associated infections in patients and health care workers.
- 2. The facility shall follow nationally recognized guidelines and manufacturer's instructions.
- 3. There shall be a designated infection prevention and control officer for the facility.
- 4. There shall be policies and procedures establishing and defining the Infection Prevention and Control Program including:
 - a. Definitions of healthcare associated infections which conform to the current CDC definitions;
 - b. Methods for obtaining reports of infections in abortion patients and health care workers in a manner and time sufficient to limit the spread of infections;
 - c. Measures for assessing and identifying abortion patients and health care workers at risk for healthcare associated infections and communicable diseases;
 - d. Measures for prevention and control of infections;
 - e. Provisions for education of patients and family concerning infections and communicable diseases including hand hygiene and isolation precautions;
 - f. Plans for monitoring and evaluating all infection prevention and control policies and procedures;
 - g. Techniques for hand hygiene including procedures for soap and water as well as alcohol based hand rub if used;
 - h. Scrub technique (applies only to General Abortion Facilities);
 - i. Asepsis/sterile technique;
 - j. Sterilization to include;
 - 1) Evaluating effectiveness of sterilization;

- 2) Receiving, decontaminating, cleaning, preparing, disinfecting and sterilizing reusable items;
- 3) Specifications for cold-liquid sterilization, steam sterilization, and gas sterilization (if used);
- 4) Sterilization techniques (steam, plasma, ethylene oxide, chemical, etc.) shall follow the manufacturer's directions and meet all state and federal regulations;
- 5) Assembling and wrapping of packs (to include the double-wrapped techniques);
- 6) Autoclaves to include:
 - i. Records shall be maintained of all autoclave loads, both routine and immediate use which shall include the date, time, lot number (on routine loads), the time at temperature (where a recorder is not available), item(s) sterilized and shall identify the person performing the task;
 - ii. The efficacy of autoclaves, both for routine and immediate use shall be determined weekly through the use of biological spore monitors;
- iii. The results of all biological spore monitoring shall be reported to the infection prevention and control officer;
- iv. Failures of the biological spore test shall be brought to the attention of the infection prevention and control officer or designee immediately so the appropriate surveillance measures can be initiated;
- v. All materials sterilized from the date of the biological spore monitor failure to the last successful biological spore monitor shall be re-sterilized before use;
- vi. Autoclaves within the facility shall be maintained in accordance with manufacturer's written directions. Records shall be maintained of all maintenance and repairs for the life of the equipment;
- vii. Chemical indicators for sterility shall be used with each cycle;

- viii. Compliance and efficacy of the sterilization policies shall describe the mechanism used to determine the shelf life of sterilized packages;
 - ix. Products used to contain or wrap instrument sets/pans for sterilization shall follow the manufacturers' directions or nationally recognized standards (such as CDC or AORN) in determining the shelf life of the sterilized items(s);
 - x. All items which are to be sterilized, whether for immediate use or to be stored, shall be cleaned and decontaminated before the sterilization process;
 - xi. Immediate use (autoclaving) shall be restricted to unplanned or emergency situations and never used as a convenience to compensate for inadequate inventories of instruments; and
- xii. Procedures for unloading and transporting immediate use sterilized items, which provide for the aseptic transfer within the physical constraints of the facility.
- k. Disinfection to include;
 - 1) Cleaning of equipment;
 - 2) Evaluating effectiveness of cleaning;
 - 3) Cleaning and disinfecting of surfaces, utensils, and equipment;
 - 4) Receiving, decontaminating, cleaning, preparing, disinfecting and sterilizing reusable items; and
 - 5) A requirement that disinfectants, antiseptics, and germicides be used in accordance with the manufacturer's directions;
- 1. Housekeeping;
- m. Linen care;
- n. Liquid and solid waste disposal of both infectious and regular waste.

 Disposal of infectious waste shall conform to the latest edition of the

 Rules Pertaining to the Management of Medical Waste from Generators
 and Health Care Related Facilities;
- o. Disposal of human and fetal tissue;

- p. Sharps safety;
- q. Separation of clean from dirty processes; and
- r. Other means of limiting the spread of contagion;
- s. Supplies and storage to include:
 - 1) Storage and distribution of sterile equipment/medical supplies;
 - 2) Recalling and disposing/reprocessing of outdated sterile supplies;
 - 3) Collection and disposal of supplies recalled by the manufacturer;
 - 4) Precautions to prevent the mixing of sterile and unsterile supplies and equipment;
 - 5) Items previously packaged, sterilized and issued but not used may be returned to the sterile storage area if the integrity of the packaging has not been compromised and there is no evidence of contamination; and
 - 6) Sterile materials shall be stored eight to ten inches from the floor and at least 18 inches from the ceiling and at least two inches from outside walls. Items shall be positioned so that packages are not crushed, bent, compressed or punctured and sterility is not compromised.

B. Employee Health.

- 1. There shall be an orientation program for all new health care workers concerning the importance of infection control and each health care worker's responsibility in the facility's Infection Prevention and Control Program.
- 2. There shall be a plan for each employee to receive annual in-services and educational programs, as indicated, based upon assessment of the infection control process.
- 3. The facility shall develop policies and procedures for screening health care workers for communicable diseases and monitoring health care workers exposed to patients with any communicable diseases.
- 4. There shall be policies regarding health care workers with infectious diseases or carrier states. The policies shall clearly state when health care workers shall not render direct patient care.

NOTE: Health care workers employed by the facility who are afflicted with any disease in a communicable stage, or while afflicted with boils, jaundice, infected

wounds, diarrhea, or acute respiratory infections, shall not work in any area in any capacity in which there is a likelihood of such person contaminating food, food contact surfaces, supplies, or any surface with pathogenic organisms or transmitting disease to patients, facility personnel or other individuals within the facility.

- 5. There shall be Measures for prevention of communicable disease outbreaks, especially mycobacterium tuberculosis (TB). All plans for the prevention of transmission of TB shall conform to the most current CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Facilities.
- 6. There shall be a plan for ensuring that all health care workers who are frequently exposed to blood and other potentially infectious body fluids are offered immunizations for hepatitis B.

SECTION 11. PHARMACEUTICAL SERVICES.

A. Organization.

- 1. Abortion Facilities shall have provisions for pharmaceutical services regarding the procurement, storage, distribution and control of all medications. The Abortion Facility shall be in compliance with all state and federal regulations.
- 2. Pharmaceutical services shall be under the direction of a licensed pharmacist if required by State law. In case the Abortion Facility does not require a licensed pharmacist, the Medical Director shall assume the responsibility of directing Pharmaceutical Services. A licensed pharmacist means any person licensed to practice pharmacy by the Arkansas State Board of Pharmacy who provides pharmaceutical services as defined in the Pharmacy Practice Act. The pharmacist or Medical Director shall make provisions that shall include, but not be limited to:
 - a. development and implementation of pharmacy policies and procedures;
 - b. annual review and revisions of pharmacy policies and procedures, with documentation of dates of review;
 - c. maintenance of medications in the Abortion Facility to meet the needs of the population served;
 - d. maintenance of medications in the Abortion Facility to ensure accountability; and
 - e. proper storage of medications.
- B. Staffing. Pharmaceutical services shall be provided by a licensed pharmacist or Medical Director as required by State law. If the service is provided by a consulting pharmacist, it may be done so on a consulting basis. Onsite consultation by the pharmacist shall be required at least monthly. Documentation of each consultation visit shall be recorded and maintained at the Abortion Facility. Documentation of each visit shall include compliance with, but not be limited to:
 - 1. proper storage of drugs;
 - 2. disposal of medications no longer needed, discontinued, or outdated;
 - 3. proof of receipt and administration of controlled substances and proper

- storage of such medications;
- 4. verification that medications in stock conform to the specified quantities on posted lists;
- 5. proper labeling; and
- 6. maintenance of emergency carts or kits.
- 7. If the service is under the direction of the Medical Director, he/she may designate the above required monthly documentation to a licensed nurse.
- C. Policies and Procedures. There shall be pharmacy policies and procedures to include, but not be limited to:
 - detailed job description of the licensed pharmacist and/or Medical Director;
 - 2. procurement of medications;
 - 3. distribution and storage of medications;
 - 4. a listing of stock medications with minimum and maximum quantities to be maintained in the Abortion Facility;
 - 5. a listing of medications with exact quantities to be maintained in emergency kits;
 - 6. destruction of deteriorated, non-sterile, unlabeled, or damaged medications;
 - 7. listing controlled substances to be destroyed on the proper forms and either sending a copy of the form with the medications to the Arkansas Department of Health by registered mail or delivering the form and medications in person;
 - 8. maintenance of all drug records for a minimum of two (2) years;
 - 9. maintenance of medications brought to the Abortion Facility;
 - 10. drug recalls;

- 11. reporting of adverse drug reactions and medication errors to the attending physician and the Governing Body;
- 12. accountability of controlled substances;
- 13. reporting of suspected drug loss, misuse, or diversion, according to state law;
- 14. use of Automatic Medication Dispensing Devices, if applicable.
- D. Drug storage and security. Medications maintained at the Abortion Facility shall be properly stored and safeguarded to ensure:
 - 1. locked storage of all medications;
 - 2. proper lighting and ventilation, as required by the manufacturer;
 - 3. proper temperature controls with daily temperature documentation of medication refrigerators to ensure storage between thirty-six (36) and forty-six (46) degrees Fahrenheit, or two (2) to eight (8) degrees Centigrade;
 - 4. separate storage of biologicals and medications from food;
 - 5. accessibility to licensed personnel only; and
 - 6. proper use of any Automatic Medication Dispensing Devices.
- E. Controlled Substances.
 - 1. Controlled drugs shall be double locked.
 - 2. A record of the procurement and disposition of each controlled substance shall be maintained in the Abortion Facility and be readily retrievable. Each entry on the disposition record shall reflect the actual dosage administered to the patient, the patient's name, date, time, and signature of the licensed person administering the medication. The signature shall consist of a first initial, last name, and title. (Licensed personnel who may legally administer controlled substances shall include only those personnel authorized by their current Practice Act and licensed by the Arkansas State Medical Board or Arkansas State Board of Nursing.) Any error of entry on the disposition record shall follow a policy for correction of errors and accurate accountability. If

the licensed person who procures medication from the double locked security is not the licensed person who administers the medication, then both persons shall sign the disposition record;

- 3. When breakage or wastage of a controlled substance occurs, the amount given and amount wasted shall be recorded by the licensed person who wasted the medication and verified by the signature of a licensed person who witnessed the wastage. Documentation shall include how the medication was wasted. In addition to the above referenced licensed personnel, licensed pharmacists shall be allowed to witness wastage of controlled substances. When a licensed person is not available to witness wastage, the partial dose shall be sent to the Arkansas Department of Health, Division of Pharmacy Services and Drug Control for destruction;
- 4. There shall be an audit each shift change of all controlled substances stocked in the Abortion Facility which shall be recorded by an oncoming nurse and witnessed by an off-going nurse. If only one (1) shift exists, an audit shall be conducted at the opening and closing of the abortion facility daily. If discrepancies are noted, the Director of Nursing, Pharmacy Consultant and/or Medical Director shall be notified. As with the witnessing of wastage, licensed pharmacists shall be allowed to witness controlled
- 5. substance audits;
- 6. Records generated by Automatic Dispensing Devices shall comply with these requirements.

F. Medications.

- 1. All verbal or telephone orders for medications shall be received by a licensed nurse or Registered Pharmacist and reduced to writing into the patient's medical record. Verbal or telephone orders shall be countersigned by the practitioner within twenty-four (24) hours. Signed facsimile orders are acceptable, provided the facsimile paper is of a permanent nature.
- 2. The Abortion Facility may procure medications for its patients through community pharmacists, or medications may be procured through the facility's physician.

SECTION 12. PHYSICAL FACILITIES, ABORTION FACILITIES.

A. Definitions.

- 1. **Accessible** barrier free; approachable by all peoples including those with physical disabilities.
- 2. **Addition** an extension or increase in floor area and/or height of an existing building, or structure.
- 3. **Alter or Alteration** any change(s) and modification in construction, occupancy, installation, or assembly of any new structural components, and any change(s) to the existing structural component, in a system, building, and structure.
- 4. **And/Or** (in a choice of two (2) code provisions) signifies use of both provisions shall satisfy the code requirements and use of either provision is acceptable, also. The most restrictive provision shall govern. Where there is a conflict between a general requirement and a specific requirement, the specific or restrictive requirement shall be applicable.
- 5. **Architect** a duly registered professional licensed by the Arkansas State Board of Architects to use the title "architect."
- 6. **Corridor** a passage way into which compartments or rooms open and which is enclosed by partitions and/or walls and a ceiling, or a floor/roof deck above.
- 7. **Engineer** duly registered professional licensed by the Arkansas Board of Registration for Professional Engineers and Land Surveyors to use the title "engineer."
- 8. **New construction** the assembly of a new free standing structure.
- 9. **Renovation** construction performed within an existing facility.
- 10. **Room** a separate, enclosed space, with doorway(s), for the one (1) named function.
- 11. **Toilet** a room designed exclusively for a water closet and lavatory.
- B. Plan Review. Plans for all new construction and/or alterations shall include site requirements, preliminary drawings, submission of plan review fee, final construction documents, letter of approval for construction documents, site observation and final site observation.
 - 1. No new mechanical, electrical, plumbing, fire protection, or medical gas system shall be installed, nor any such existing system materially altered or extended,

until complete drawings and specifications for installation, alteration, or extensions have been submitted to the Division for review and approval.

2. Site Requirements.

- a. The site location shall be easily accessible to the community and to ser vice vehicles such as fire protection apparatus.
- b. The Abortion Facility shall have security measures for patients, personnel, and the public consistent with the conditions and risks inherent in the location of the facility.
- c. Site utilities shall be reliable (water, natural gas, sewer, electricity and communication). The water supply shall have the capacity to provide normal usage plus fire-fighting requirements. The electricity shall be of stable voltage and frequency.
- d. The site shall afford good drainage and shall not be subject to flooding.
- e. Soil bearing capacity shall be sufficient to support the building and paved areas.
- f. Paved access roads and walks shall be provided within the boundary of the property to public service and emergency entrances.
- g. Paved parking spaces shall be provided to satisfy the needs of patients, employees, staff, and visitors. In the absence of a formal parking study, each facility shall provide not less than one (1) space for each day shift staff member and employee plus one (1) space for each patient bed/recliner. Parking spaces shall be provided for emergency and delivery vehicles.
- 3. Preliminary Drawings. Schematic drawings for the Abortion Facility shall be submitted to the Division. These drawings shall illustrate a basic understanding of the architectural, mechanical, electrical and plumbing systems. Schematic drawings shall include schematic plans, building sections, exterior elevations (all sides), preliminary finish schedule, and general notes. Code criteria shall be submitted that is specific to the proposed facility and exhibits knowledge of the building and fire code requirements including but not limited to construction type, fire protection ratings, means of egress and smoke compartmentalization. Drawings shall be at a scale to clearly represent the intent. A graphic and/or written scale and directional arrow shall be on each drawing.
- 4. Submission of Plan Review Fee. A plan review fee in the amount of one (1) percent of the total cost of construction or five hundred dollars (\$500.00), whichever is less, shall be paid for the review of drawings and specifications. The

plan review fee check is to be made payable to the Division of Accounting, Arkansas Department of Health. A detailed estimate must accompany the plans unless the maximum fee of five-hundred dollars (\$500.00) is paid. The Division will coordinate review of plans for all Arkansas Department of Health offices.

- 5. Final Construction Documents.
 - a. Plans and specifications shall be prepared by an architect and/or engineer licensed by the State of Arkansas. The architect and engineer shall prepare and submit construction documents with the respective seals for each professional discipline. Architectural construction documents shall be prepared by an architect, and engineering (mechanical, electrical, civil and structural) construction documents shall be prepared by an (mechanical, electrical, civil and structural) engineer. Periodic observations of construction shall be provided and documented by each design professional to assure that the plans and specifications are followed by the contractor, and that "as build" prints are kept current. The interval for periodic observation shall be determined and approved by the Division prior to beginning construction.
 - b. Working drawings and specifications shall be prepared in a manner that clearly defines the scope of the work and is consistent with the professional standard of practice for architects and engineers. Working drawings and specifications shall be complete for contract purposes.
 - c. Final construction documents shall be reviewed and approved by the Division prior to the beginning of construction. The Division shall have a minimum of six (6) weeks to review final construction documents after which time an approval letter shall be issued. Plan review with other Health Department Divisions shall be coordinated by the Division.
- 6. Site Observation During Construction. The Abortion Facility shall be observed during construction and before occupancy.
 - a. The Division shall be notified when construction begins and a construction schedule shall be submitted to determine inspection dates.
 - b. Representatives from the Division shall have access to the construction premises and the construction project for purposes of making whatever inspections deemed necessary throughout the course of construction.
 - c. Any deviation from the approved construction documents shall not be permitted until a written construction addenda or change order is approved by the Division.
- 7. Final Site Observation.

- a. Upon completion of construction and prior to occupancy approval by the Division, the owner shall be furnished one (1) complete set of contract documents, plans and specifications showing all construction, fixed equipment, and mechanical and electrical systems as installed or built. In addition, the owner shall be furnished a complete set of installation, operation, and maintenance manuals and parts lists for the installed equipment.
- b. No Abortion Facility shall occupy any new construction, addition, renovation and/or alteration until approval has been granted from all city, county, and other state regulatory agencies in addition to the Division.

C. General Considerations.

- 1. The requirements set forth herein have been established as minimum requirements for new construction, addition(s), renovation(s) and alteration(s) in Abortion Facilities requiring licensure under these regulations.
- 2. Abortion Facilities undertaking new construction, an addition, renovation, and/or alteration shall minimize disruption of existing functions. Access, exits and fire protection shall be maintained for occupancy safety.
- 3. The building and equipment shall be maintained in a state of good repair at all times.
- 4. The premises shall be kept clean, neat, free of litter and rubbish.

D. Codes and Standards.

- 1. Nothing stated herein shall relieve the owner from compliance with building, fire, subdivision and zoning codes, ordinances, and regulations of city, county and other state agencies.
- 2. Compliance with referenced codes and standards shall be that of the latest edition(s).
- 3. Accessibility requirements shall be those set forth by the Arkansas State Building Services, Minimum Standards and Criteria Accessibility for the Physically Disabled Standards.
- 4. Electrical Systems. Electrical devices shall be installed in accordance with NFPA 70, National Electrical Code.
- 5. Mechanical Systems.

- a. HVAC systems shall be installed in accordance with the Arkansas State Mechanical Code.
- b. Air ventilation and filtering requirements shall be in accordance with ASHRAE Standard 62, Ventilation for Acceptable Indoor Air Quality and ASHRAE 52, Filter Efficiencies.
- 6. Plumbing and Gas Systems.
 - a. Plumbing systems shall be installed in accordance with the Arkansas State Plumbing Code.
 - b. Gas systems shall be installed in accordance with the Arkansas State Gas Code.
- 7. New Abortion Facilities shall meet the criteria of NFPA 101, Life Safety Code, Chapter 26, New Business Occupancies. Existing buildings proposed for use as Abortion Facilities shall meet the criteria of NFPA 101, Life Safety Code, Chapter 27, Existing Business Occupancies. Both new Abortion Facilities and existing buildings proposed for use as Abortion Facilities shall meet the following additional requirements:
 - a. Emergency lighting shall be connected to rechargeable back-up (ninety (90) minute minimum duration) batteries as a means of emergency illumination for procedure rooms, corridors, stairways, exit signs and at the exterior of each exit.
 - b. A protected premises fire alarm system as defined in NFPA 72, National Fire Alarm Code, Chapter 3 shall be required.
 - c. Fire extinguisher(s) shall be easily accessible and shall be provided, located, and inspected as defined in NFPA 10, Standard for Portable Fire Extinguishers.
 - d. At least two (2) separate exits that are remote from each other shall be provided on every story of Abortion Facility use.
 - e. The minimum clear door opening for patient use shall be two (2) feet eight (8) inches.
 - f. Gas fired equipment rooms shall be separated with one (1) hour fire resistance partitions.
 - g. No operable fireplace shall be permitted. Inoperable fireplace(s) shall be sealed at the upper and lower portions of the flue.

- h. Cabinets or casework in patient use areas shall be furred to the ceiling above or provided with sloping tops to facilitate cleaning.
- i. A panic bar releasing device shall be provided for all required exit doors subject to patient traffic.
- j. Medical gas, air and vacuum systems, if provided, shall meet installation, testing, maintenance and certification criteria of NFPA 99, Standard for Health Care Facilities.

E. Design Considerations

- 1. Each Abortion Facility design shall ensure patient acoustic and visual privacy during interview, examination, treatment and recovery.
- 2. The premises shall be kept free from insect and vermin infestation.
- 3. The building shall be well ventilated at all times with a comfortable temperature maintained.
- 4. Space and facilities shall be provided for the sanitary storage and disposal of waste by incineration, containment or removal, or by a combination of these techniques.
- 5. Waiting/Reception area(s) shall be provided with sufficient seating for the maximum number of people that may be waiting at any one (1) time. A reception and information counter or desk shall be provided.
- 6. A barrier free public toilet rooms shall be provided. This room may be conveniently located outside the Abortion Facility as part of shared tenant spaces in the same building.
- 7. Public telephone(s) shall be provided.
- 8. A housekeeping room with mop sink shall be provided.
- 9. Storage space shall be provided for both administrative and clinical needs.
- 10. A business office room shall be provided.
- 11. A medical records storage room shall be provided. This room shall protect records against undue destruction from dust, vermin, water, smoke and fire. It shall be constructed as a one (1) hour fire resistance rated enclosure and protected by a smoke detection system connected to the fire alarm. Storage for records shall be accessible and at least six (6) inches above the floor.

- 12. A consultation room shall be provided.
- 13. An examination room shall be provided. The examination room shall have a minimum floor area of eighty (80) square feet excluding fixed millwork, vestibule, toilet and closets. The room shall contain an examination table and chair, charting counter or desk, instrument table and shelves, hand-washing sink and equipment storage as needed. Room arrangement shall permit at least three (3) feet clearance at each side and at the foot of the examination table. Entry door swing and view angles shall maximize patient privacy. This room may be combined with the procedure room.

F. Interior Finishes.

- 1. Interior finishes shall meet the flame spread and smoke development requirements of NFPA 101, Life Safety code.
- 2. Finished floors, ceilings and walls shall be provided for all rooms and spaces except mechanical and electrical rooms.
- 3. Procedure rooms and soiled work rooms shall have a monolithic finish floor and base, stain resistant for its intended use and integral with each other (i.e., sheet vinyl floor with continuous sheet vinyl base). Seams in the monolithic floor and base shall be chemically welded.
- 4. Toilet rooms, clean work rooms, housekeeping rooms and examination rooms (when combined with the procedure room) shall not have a carpeted floor finish.
- 5. Procedure rooms, soiled work rooms and clean work rooms shall have smooth, washable, moisture resistant, ceilings of gypsum board, plaster or mylar faced lay-in ceiling tiles.
- 6. Wall finishes for all rooms shall be smooth, moisture resistant and washable.
- G. Storage of fetal remains. Each facility shall have refrigerated storage for holding fetal bodies for 48 (forty-eight) hours.
- H. General Abortion Facilities: additional requirements. In addition to the preceding requirements, General Abortion Facilities shall also meet the requirements below.
 - 1. A procedure room shall be provided. The procedure room shall have a minimum floor area of one-hundred-twenty (120) square feet excluding fixed millwork, vestibule, toilet and closets. The minimum room dimension shall be ten (10) feet. The room shall contain a hand-wash sink with hands-free controls, soap dispenser and single service towel dispenser.

- 2. One (1) or more recovery rooms shall be provided. A recovery room shall have a minimum of sixty (60) square feet per patient excluding fixed millwork, vestibule, toilet and closets. The room shall contain a bed or a washable, reclining chair. Multi-patient recovery rooms shall be provided with cubicle curtains for patient privacy.
- 3. A clean work room shall be provided sufficient in size to process clean and sterilize supply materials and equipment. This room shall contain a handwash sink, work counter and autoclave adequate in size to sterilize the equipment in use.
- 4. A soiled work room shall be provided. This room shall contain a hand-wash sink and work counter.
- 5. At least one (1) barrier free, patient toilet room shall be provided for each recovery room.
- I. Signage: Text of Signs. Abortion Facilities shall display signs 1. A sign shall be conspicuously posted in each waiting room, patient consultation room, and procedure room used by patients for whom abortions are performed, induced, prescribed or for whom the means for an abortion are provided.
 - 1. <u>Prevention of Forced Abortion Signage. See Appendix 1.</u>
 ADH makes these signs available.
 - 2. The signs shall display the following text:

 "It is against the law for anyone, regardless of his or her relationship to you, to force you to have an abortion. You have the right to contact any local or state law enforcement or any social service agency to receive protection from any actual or threatened physical, emotional, or psychological abuse. It is against the law to perform, induce, prescribe for, or provide you with the means for an abortion without your voluntary consent."
 - 2. National Human Trafficking Signage. See Appendix 2.

SECTION 13. FORMS

- 1. Form AS-4010 Informed Consent Checklist
- 2. Form AS-4010A Fetal Pain Checklist
- 3. Form AS-4011 Abortion Disclosure and Consent Form for Unemancipated Minors and Women under Legal Guardianship or Custodianship for Incompetency

Informed Consent Checklist

NOTICE TO ALL PATIENTS

Arkansas law provides that abortions may be performed only with the voluntary and informed consent of the patient. In compliance with <u>Act 560 of 2021</u>, Act 1086 of 2015 and Act 1696 of 2005, this form is important to ensure that you have been provided all of the information you need to make a fully informed decision.

Certification of Receipt of Abortion Information

I certify that I have received the printed materials entitled "Abortion – Making a Decision" and "Arkansas Directory of Services" and a copy of the DVD entitled "Abortion – Making a Decision".

I understand that Arkansas law requires that I am provided these materials at least 72 hours before I undergo an abortion. I also understand that if I am unable to read the materials, the materials must be read to me in a language I can understand. I certify that this requirement of the law has been met for me.

Signat	ture of Patient	Date	Time
Cert	ification of Voluntary and Infor	med Consent for Abor	tion
On	(date) at(time), I was in	formed orally and in person b	oy
(name	e of physician who is to perform the abo	rtion, or the referring physici	an) of the following:
	The name of the physician who will po	erform the abortion	
	A description of the proposed abortio	n method <u>whether it be surg</u> i	ical or medical/chemical.
	The immediate and long-term medica	I risks associated with the par	ticular abortion procedu
	The risk if complications from a medic	cal/chemical abortion with ac	dvancing gestational age.
	Alternatives to the abortion		
	The probable gestational age of the u	nborn child at the time the a	bortion is to be performe
	The probable anatomical and physioloultrasound images and verbally review	_	
	The medical risks associated with carr	ying the unborn child to term	
	Any need for anti-Rh immune globulir of refusing such therapy and the cost	• • • • • • • • • • • • • • • • • • • •	the likely consequences
	Information on reversing the effects o	f abortion-inducing (medical/	chemical abortion)drugs

Signat	tare or rations		rime	
	ture of Patient	Date	Time	
abort	ify and affirm that I have received th ion, the information was given to mo ions. I do hereby voluntarily give my	e in a private room and I was giv	en the opportunity to ask	
	Information on Human Traffickin	g, also known as "Laura's Card"		
	The information contained in the Services, is available on the Arkan (www.healthy.arkansas.gov)		-	
	I am free to withhold or withdraw my consent to the abortion at any time without affecting my right to future care or treatment and without the loss of any state or federally funded benefits to which I might be entitled			
	The father of the unborn child is liable to assist in support of the child, even in instances in which the father has offered to pay for the abortion			
—	The printed informational materia agencies that offer alternatives to		e the unborn child and list	
	Medical assistance benefits may be that more detailed information or materials and informational DVD	n the availability of such assistan		
(name	e of physician who is to perform the ving:	abortion, the referring physician	n or a qualified person) of the	
	(date) at(time), I was	•	•	

Fetal Pain Checklist Twenty (20) Weeks or More Gestational Age

Act 1696 of 2005 and Act 1086 of 2015

On	, I was informed o	orally and in person by	
(name	of physician who is performing the abortion	on or the physician's ago	ent) of the following:
	By 20 weeks gestational age, the unborn nervous system that are necessary in ord	•	omical links in its
	An unborn child of 20 weeks gestation or	more is fully capable o	f experiencing pain
	A description of the actual steps of the pr which steps in the procedure the unborn		
	Maternal anesthesia typically offers little	pain prevention for the	unborn child
	An anesthetic, analgesic or both are availa and I have been informed of the medical analgesic that is available	-	
	I have a right to view the printed materials related to unborn child pain awareness		
	I understand that the information related provided printed materials and on the Ar (www.healthy.arkansas.gov).		
	I understand the information contained in of Arkansas	n the printed materials	was provided by the State
	y and affirm that I have received the above on and that I do hereby voluntarily give my		
Signat	ure of Patient	Date	Time
 <u>W</u> witr	ness	 Date	Time

Abortion Disclosure and Consent Form for Unemancipated Minors and Women under Legal Guardianship or Custodianship for Incompetency

Source: Act 934 of 2015, Parental Involvement Enhancement Act, Ark. Code Ann. §20-16-810(a); 20-16-804

Name <u>D</u> date of <u>B</u> birth
Name of parent of minor or legal guardian or custodian of ncompetent woman: 20-16-805(b)(2); 20-16-804
Name
Pregnant woman's list of rights 20-16-810(b)(3)&(c)(1-2); 20-16-808,809; 20-16-1701 You have the right to: a. know the name of the doctor who will perform yourabortion; b. know medical risks associated with the procedure; c. know medical risks of carrying the fetus to term; d. know the probable age of your fetus; e. know a spouse, boyfriend, parent, friend or other person cannot force you to have abortion; know medical assistance benefits may be available for prenatal care and childbirth; know the father is liable to assist in supporting your child, even when the father had offered to pay for an abortion; know that printed and/or electronic materials describing the fetus are available for you to view, along with a list of agencies that offer alternatives to abortion; the printed materials can be mailed to you or you can view them on the internet; and petition a circuit court in the county of your residence for a waiver of the consent requirement and you may participate in the proceedings on your own behalf.
Describe the surgical procedures or medical procedures or both hat are planned to be performed on the pregnant woman COMPLETED BY PROVIDER): 20-16-810(c)(3)

Initials of pParent or Llegal Gguardian

5.	List of risks and hazards 20-16-810(c)(4)						
	a. infection;						
	 b. blood clots; c. hemorrhage; d. allergic reactions; e. a hole in the uterus or other damage to the uterus; f. sterility; 						
						g. injury to the bowel or bladder;	
						h. possible hysterectomy as a result of complication or injury during the	procedure;
	i. failure to remove all products of conception;						
	possible continuation of pregnancy; cramping of the uterus or pelvicpain;						
	I. cervical laceration;						
	m. incompetent cervix;						
	n. emergency treatment for any complications; or						
	o. death.						
	p. other						
	Initials of	pregnant woman					
_	Additional information provided by physician to preg						
	woman under state law (COMPLETED BY PROVIDER						
	Pregnant woman's consent statement 20-16-810(b)(4); 20-16-810 I understand that the doctor is going to perform an abortion on me my pregnancy and will result in the death of myunborn child. 20-16-810(c)(6)(A)	that will end					
		Initial					
	20-10-010(C)(O)(A)	muai					
b.	I am not being forced to have an abortion. I understand that I may have the abortion, and that I may withdraw my consent prior to the 20-16-810(c)(6)(B)	choose not to					
	I am not being forced to have an abortion. I understand that I may have the abortion, and that I may withdraw my consent prior to the 20-16-810(c)(6)(B)	choose not to abortion. Initial					
b. c.	I am not being forced to have an abortion. I understand that I may have the abortion, and that I may withdraw my consent prior to the	choose not to abortion.					
	I am not being forced to have an abortion. I understand that I may have the abortion, and that I may withdraw my consent prior to the 20-16-810(c)(6)(B)	choose not to abortion. Initial					

d.	I understand that there are risks and hazards that could affect me if planned surgical or medical procedures. 20-16-810(c)(6)(D)	I have the Initial
e.	I have been given the opportunity to ask questions about my condit alternative forms of treatment, risk of non-treatment, the procedures and the risks and hazards involved. 20-16-810(c)(6)(E)	
f.	I have been given information required by statute; 20-16-810(c)(6)(F)	Initial
g.	I have sufficient information to give informed consent. 20-16-810(c)(6)(F)I	nitial
8.	Physician Declaration Ark. Code Ann. 20-16-810(b)(5); 20-16-810(c)(7)	
a.	Either I or my assistant has, as required, explained the procedure a contents of this form to the pregnant woman and to her parent or le and have answered all questions. 20-16-810(c)(7)(A)	
b.	According to my best information and belief, a reasonable person u circumstances would rely on the information presented by both the woman and her parent or legal guardian as sufficient evidence of id relationship. 20-16-806(c)	pregnant
C.	To the best of my knowledge, the patient and her parent or legal gubeen adequately informed and have consented to the procedure. 20-	
	Signature of Physician 20-16-810(c)(7)	
9.	Parental Consent Statement Ark. Code Ann. 20-16-805 (b)(3); 20-16-810(c)(8)	
a.	I am the parent or legal guardian of the pregnant minor or pregnant woman. 20-16-805(b)(3)	incompetent
b.	I am aware that the pregnant minor or pregnant incompetent woma abortion and I consent to the abortion. 20-16-805(b)(3)	n desires an
	I have read and I understand the information inc	luded on this page:
	Initials of p Parent or Llegal	<u>G</u> guardian

C.	I understand that the physicial is going to perform an abortion incompetent woman, which wideath of her unborn child. 20-16-810(c)(8)(A)	n on the pregnant minor or	pregnant
d.	I have had the opportunity to r had it read to me and have init	•	
e.	e. I have had the opportunity to ask questions of the physician or the physician's assistant about the information in the Physician Declaration and the surgical and medical procedures to be performed on the pregnant minor or pregnant incompetent woman.20-16-810(c)(8)(C)		
f.	I believe that I have sufficient i	nformation to give informed	d consent. 20-16-810(c)(8)(D)
	Signature Parent or Legal guardi	an Da	ate 20-16-810(c)(8)(E)
10	D. Notarized signatures		
Pa	rent or Legal Guardian 20-16-803(3)(A); 20-16-803(3)(B); 20-16-810(b)(2)	<u> </u>
Subsc	ribed and sworn to before me		
		thisday of	, 20
		Notary Publ	ic
Mi	nor 20-16-803(3)(A)		

this_____day of_______, 20____

Notary Public

I have read and I understand the information included on this page

Subscribed and sworn to before me

SECTION 14. APPENDICES

- 1. Appendix 1 Prevention of Forced Abortion Signage
- 2. Appendix 2 Human Trafficking Signage
- 3. Appendix 3 Laura's Card



CERTIFICATION

This will certify that the foregoing revisions to the Rules for Abortion Facilities in Arkansas 2021 were adopted by the State Board of Health of Arkansas at a regular session of said Board held in Little Rock, Arkansas, on the 28th day of January 2021.

José R. Romero, MD, FAAP, FIDSA, FPIDS, FAAAS Secretary of Health Arkansas Board of Health

5/27/21 Date

QUESTIONNAIRE FOR FILING PROPOSED RULES WITH THE ARKANSAS LEGISLATIVE COUNCIL

DF	EPARTMENT/AGENCY		
	VISION		
DI	VISION DIRECTOR		
CO	ONTACT PERSON		
ΑI	DDRESS		
PE	IONE NO FAX NO E-MAIL		
NA	DDRESS E-MAIL E-MAIL		
PR	RESENTER E-MAIL		
	INSTRUCTIONS		
Α.	Please make copies of this form for future use.		
В.	Please answer each question completely using layman terms. You may use additional sheets if necessary.		
	If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.		
E.	Submit two (2) copies of the Questionnaire and Financial Impact Statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:		
	Jessica C. Sutton		
	Administrative Rules Review Section		
	Arkansas Legislative Council		
	Bureau of Legislative Research One Capitol Mall, 5th Floor		
	Little Rock, AR 72201		
**	LITTIC NOCK, AN 72201 ***********************************		
1.	What is the short title of this rule?		
2.	What is the subject of the proposed rule?		
3.	Is this rule required to comply with a federal statute, rule, or regulation? Yes No		
	If yes, please provide the federal rule, regulation, and/or statute citation.		
4.	Was this rule filed under the emergency provisions of the Administrative Procedure Act?		
	Yes No		
	If yes, what is the effective date of the emergency rule?		
	When does the emergency rule expire?		
	Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure		
	Act? Yes No		

	Does this repeal an existing rule? Yes No If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does.
	Is this an amendment to an existing rule? Yes No If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."
6.	Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation.
7.	What is the purpose of this proposed rule? Why is it necessary?

5. Is this a new rule? Yes No If yes, please provide a brief summary explaining the rule.

8.	by Arkansas Code § 25-19-108(b).
9.	Will a public hearing be held on this proposed rule? Yes No If yes, please complete the following:
	Date:
	Time:
	Place:
10.	When does the public comment period expire for permanent promulgation? (Must provide a date.)
11.	What is the proposed effective date of this proposed rule? (Must provide a date.)
12.	Please provide a copy of the notice required under Ark. Code Ann. § 25-15-204(a), and proof of the publication of said notice.
13.	Please provide proof of filing the rule with the Secretary of State as required pursuant to Ark. Code Ann. § 25-15-204(e).
14.	Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DE	EPARTMENT
DI	VISION
PE	CRSON COMPLETING THIS STATEMENTEMAIL:
ΓE	CLEPHONE NO FAX NO EMAIL:
	comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file o (2) copies with the Questionnaire and proposed rules.
SH	IORT TITLE OF THIS RULE
1.	Does this proposed, amended, or repealed rule have a financial impact? Yes No
2.	Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and
	information available concerning the need for, consequences of, and alternatives to the rule?
	Yes No
3.	In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly
	rule considered? Yes No
	If an agency is proposing a more costly rule, please state the following:
	a) How the additional benefits of the more costly rule justify its additional cost;
	b) The reason for adoption of the more costly rule;
	c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and
	d) Whether the reason is within the scope of the agency's statutory authority, and if so, please explain.

4.	If the purpose of this rule is to implement a federal rule or regulation, please state the following:				
	a) What is the cost to implement the fede <u>Current Fiscal Year</u>	eral rule or regulation? <u>Next Fiscal Year</u>			
	General Revenue Federal Funds	Federal Funds			
	Cash Funds Special Revenue Other (Identify)	Cash Funds Special Revenue Other (Identify)			
	Total	Total			
	b) What is the additional cost of the state				
	<u>Current Fiscal Year</u>	Next Fiscal Year			
	General Revenue Federal Funds	General Revenue Federal Funds			
	Cash Funds Special Revenue	Cash Funds Special Revenue			
	Other (Identify)	Other (Identify)			
	Total	Total			
5.	What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.				
	Current Fiscal Year	Next Fiscal Year			
	\$	\$			
6.	What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.				
	Current Fiscal Year	Next Fiscal Year			
	\$	\$			

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars (\$100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes No

If YES, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

- (1) a statement of the rule's basis and purpose;
- (2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;
- (3) a description of the factual evidence that:
 - (a) justifies the agency's need for the proposed rule; and
 - (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;
- (4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and
- (7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
 - (a) the rule is achieving the statutory objectives;
 - (b) the benefits of the rule continue to justify its costs; and
- (c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.



Arkansas Department of Health

4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000 Governor Asa Hutchinson José R. Romero, MD, Secretary of Health

PROPOSED REVISIONS TO RULES FOR ABORTION FACILITIES IN ARKANSAS

November 23, 2021

PURPOSE

The Arkansas Department of Health (Department) is seeking Governor Hutchinson's review of proposed amendments to the Rules for Abortion Facilities in Arkansas.

BACKGROUND

Pursuant to A.C.A. § 20-9-302 et seq., the Department has authority to promulgate the Rules for Abortion Facilities in Arkansas. These rules establish minimum standards for licensure, operation and maintenance of Abortion Facilities.. These standards are not static and are subject to periodic revisions.

KEY POINTS

The proposed rule:

- Adds definitions.
- o Makes Changes to comply with Acts 346, 498, 560, 562, 740, 787, and 949 of 2021.

DISCUSSION

The Rules for Abortion Facilities in Arkansas are duly adopted and promulgated by the Arkansas State Board of Health pursuant to the authority expressly conferred by Acts 509 of 1983 and 1176 of 2011; Ark. Code Ann. § 20-9-302 as amended, and other laws of the State of Arkansas.

There were seven legislative acts – Act 346, Act 498, Act 560, Act 562, Act 740, Act 787, and Act 949– which required modification to the Rules for Abortion Facilities in Arkansas

The following changes are proposed:

Section 3: Definitions revised or added as listed below

- 3.J. Chemical Abortion (Act 560)
- 3.T. Hospital (Act 740)
- 3.AA. Medical Emergencies (Act 498 and 560)

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3.KK. Qualified Technician (Act 498)
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Section 6: General Administration

6.J.1. - Added all abortion types (Act 560)

6.J.4. – Chemical abortion requirements; Added "medical" (Act 560)

6.M.6.c. – Added reference to written agreements abortion facilities (Act 740)

6.M.23. – Change timeframe for follow-up visit after performance of an abortion and clarifying reason for the follow-up visit. (Act 562)

6.N.2. - Added all abortion types (Act 560)

6.N.3. – Chemical Abortion reporting requirement. Added "medical" (Act 560)

6.Q. – Written Agreement requirement. (Act 740)

Section 7: Patient Care Services

7.B.3. – Staffing requirements for ultrasound (Act 498)

7.F.1. – Change timeframe for follow-up visit (Act 562)

7.H.7. – Add counseling requirement for chemical abortion. Added "medical" (Act 560)

7.L. – Add Pelvic examination on unconscious or anesthetized patient requirement (Act 346)

Section 8: Program Requirements

8.A.3 – Ultrasound viewing requirement (Act 498)

8.A.5. – Consent requirement with reference to 6.J.4. (Act 560)

Section 9: Health Information Services

9.B.2.b. – Documentation regarding Chemical abortion. Added "medical" (Act 560)

9.B.3.e. – Ultrasound right to view requirement changes. (Act 498)

9.B.11. – Documentation of efforts utilized to ensure follow-up visit. (Act 562)

Section 12: Physical Facilities; Abortion Facilities

12.I.2. National Human Trafficking Posting requirement (Act 740)

Section 13: Forms

Informed consent – update to include 1) chemical abortion description and risk, 2) information on chemical abortion, 3) Laura's card, and 4) new ADH logo. Added" medical" (Act 560)

Abortion Disclosure and consent – Capitalization errors corrected and new ADH logo.

Section 14: Appendices (New Section)

Appendix 1 – Prevention of Forced Abortions

Appendix 2 - Human Trafficking Poster

Appendix 3 – Laura's Card

Section 15: Severability

Changed Section # from 14 to 15

RECOMMENDATION

We recommend that the proposed amendments to the Rules for Abortion Facilities in Arkansas be approved as proposed by the Department.