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ARKANSAS
STATE BOARD OF HEALTH

RULES ~~AND REGULATIONS~~ 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.
Revision effective date: January 1, 2020

ARKANSAS DEPARTMENT OF HEALTH
HEALTH FACILITY SERVICES

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~~DIRECTOR AND STATE~~SECRETARY OF HEALTH
~~OFFICER~~

SECTION 1. PREFACE.

These Rules ~~and Regulations~~ 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 ~~and Regulations~~ for Abortion Facilities in Arkansas are duly adopted and promulgated by the Arkansas State Board of Health pursuant to the authority expressly conferred by ~~the laws of the State of Arkansas in~~ 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 us~~e~~ing or prescri~~ption~~bing ~~of~~ any instrument, medicine, drug, or ~~any~~ other substance~~,~~ ~~or~~ device, or means with the intent to terminate the clinically diagnosable pregnancy of a woman with knowledge that the termination by those means will with reasonable likelihood cause the death of the unborn child.

~~1.~~ 2. ~~To terminate the pregnancy of a woman known to be pregnant with an intention other than to:~~ An act under paragraph (A)(1) above is not an abortion if the act is performed with the intent to:

a. ~~Increase the probability of a live birth~~ save the life or preserve the health of the unborn child;

b. ~~Preserve the life or health of the child after live birth~~ remove a dead unborn child caused by a spontaneous abortion; or

c. remove an ectopic pregnancy. ~~dead unborn child who died as the result of natural causes in utero, accidental trauma, or a criminal assault on the pregnant woman or her unborn child; and~~

~~2. Which causes the premature termination of the 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 known to be pregnant are willfully terminated or aborted ~~each~~ 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. **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.

J. **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.

K. **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 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 a person who has been adjudged 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 abortion** - a non-surgical abortion for which abortifacient pharmaceutical drugs are used to induce the abortion.

AA. **Medical-only abortion facility** - an abortion facility in which no surgical abortions are performed.

BB. **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.

CC. **Minor** means an individual under eighteen (18) years of age.

DD. **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.

EE. **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.

FF. **Patient -** any woman receiving services in the facility and any born-alive infant.

GG. **Physician** – a person licensed to practice medicine in this state, including a medical doctor and a doctor of osteopathy.

HH. **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. **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.

LL. **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; 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) ~~minutes~~ 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. 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 and Regulations 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, ~~Red Cross~~ 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. 1. Signed and witnessed w~~W~~ritten consent for the performance of an induced abortion must be obtained and signed by the patient prior to the abortion and after counseling by a qualified professional.

2. In case of a minor or woman under legal guardianship or custodianship for incompetency, 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.

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.

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;

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 abortion patients 12-18 days, 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 ~~reading~~ 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.

N. Administrative Reports. The Administrator or his/her designee shall report:

1. ~~i~~Infectious or communicable diseases, including sexually transmitted diseases, to the Arkansas Department of Health, as required by:

~~1~~ a. the Rules and Regulations Pertaining to Communicable Disease in Arkansas (Ark. Code Ann. §§ 20-7-109, 110.); and

~~2~~ b. the Rules Pertaining to the Control of Communicable Diseases-Tuberculosis.

2. Induced Terminations of Pregnancy. ~~In accordance with Act 120 of 1981, e~~Each induced termination of pregnancy which occurs in Arkansas shall be reported to

the Division of Health Statistics on a monthly basis. ~~by the person in charge of the Abortion Facility.~~

3. Adverse events associated with abortion-inducing drugs to:
   a. USFDA via Medwatch reporting system; and
   b. Arkansas State Medical Board.

4. 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;
   c. in the form and manner prescribed by the Department;
   d. not identify by any means the physician performing the abortion;
   e. not identify by any means the patient upon whom the abortion was performed nor the patient; and
   f. containing:
      1. the most specific, accurate, and complete reporting for the highest level of specificity;
      2. the date of the abortion that caused or may have caused the abortion complication;
      3. the type of abortion that cause or may have caused the abortion complication;
      4. the gestational age of the fetus at the time that the abortion was performed;
      5. the name and type of healthcare facility in which the abortion was performed;
      6. the date the abortion complication was diagnosed or treated;
      7. the name and type of any healthcare facility other than the reporting healthcare facility in which the abortion complication was diagnosed or treated;
      8. a description of the abortion complication;
      9. the patient's year of birth, race, marital status, state of residence, and county of residence;
      10. 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;
      11. the number of previous live births of the patient; and
      12. the number of previous induced abortions of the patient.
   g. 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.

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).

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.

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 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 abortions.

1. Facility personnel shall schedule a follow-up appointment for the patient to return 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.

~~G~~H. Counseling services. ~~shall be provided for each patient, as follows:~~

1. Seventy two (72)-~~48~~ 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, ~~and~~ 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. D~~d~~ocumentation of counseling shall be included in the patient's medical record~~;~~.

3. ~~if counseling is performed in groups, t~~The patient shall ~~be offered an opportunity to~~ meet ~~privately~~ individually and in a private room with the physician, referring physician, or a qualified ~~counselor~~ person.~~;~~

4. E~~e~~ach patient shall be assessed by a Registered Nurse for counseling needs post-abortion;

5. W~~w~~ritten 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;

(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; and

(e) follow up appointment, if indicated.

6. The patient shall be counseled regarding Rh typing and shall be given Rh immune globulin, if indicated.

I. Drug-induced, 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.

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, ~~which~~ and may include testing for sexually transmitted diseases. ~~The facility shall report positive test results for sexually transmitted diseases to the Department of Health, as required.~~

   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~~. Other testing~~ may also be performed according to facility policy.

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.

~~B. Transfer. The Abortion Facility shall have written procedures for emergency transfer of a patient to an acute care facility.~~

~~C~~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~~D~~. 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~~E~~. Complications.

~~1.~~ 1. General Abortion Facilities shall have emergency drugs, oxygen, ~~and~~ intravenous fluids, and other emergency equipment on site and readily available to stabilize ~~the~~ a patient~~'s condition, when~~if necessary. ~~An ambu bag, suction equipment and endotracheal equipment shall be located in the clinical area for immediate access.~~

~~2. Medical Only Abortion Facilities shall have oxygen, medication, oral airways and supplies available.~~

~~3.~~ 2. All clinical staff shall have documented current competency in cardiopulmonary resuscitation (CPR).

E~~F~~. ~~Report of Induced Termination. In accordance with Act 120 of 1981, each induced termination of pregnancy which occurs in Arkansas shall be reported to the Division of Health Statistics on a monthly basis by the person in charge of the Abortion Facility.~~ 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:

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(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;

(2) or 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;

~~(1)~~(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 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 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 ~~and Regulations~~ Pertaining to The Management of Medical Waste from Generators and Health Care Related Facilities.

~~G. 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 and Regulations 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.~~

G. Manufacturer's Guidelines. Manufacturer's guidelines shall be followed for all equipment and biologicals, including medications, for use within the facility.

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. 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;

   c. Fetal Pain Checklist in cases where woman's pregnancy has progressed to twenty (20) weeks gestation or more (form AS-4010A);

   d. 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

e. 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;

4. a. initial physical examination;

b. evaluation of risk status~~,~~; ~~and~~

c. laboratory test results;

d. gestational age;

e. ultrasound image;

1. opportunity for patient to view ultrasound;

2. 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 abortions, intrauterine location of pregnancy.

5. appropriate referral of patients, as indicated;

6. documentation of each periodic examination, including any follow-up appointment;

7. 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 post-abortion complications, available community resources, and family planning, and most current ADH printed materials and DVD;

8. 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; ~~and~~

9. abortion and post-abortion records~~.~~;

10. 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;

11. a. 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:

i. photocopy of government-issued photo identification card; and

ii. photocopy of written documentation that establishes that the parent or legal guardian is the lawful parent or legal guardian of the pregnant woman;

b. 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

12. 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).

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 ~~nosocomial~~ healthcare associated infections in patients and health care workers.

2. The facility shall follow nationally recognized guidelines ~~standard Center for Disease Control and Prevention (CDC) precautions~~ 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 ~~nosocomial~~ 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 ~~nosocomial~~ 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~~2~~) Scrub technique (applies only to General Abortion Facilities);

   (i~~3~~) Asepsis/sterile technique;

   (j~~4~~) 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~~5~~) 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;

(l~~6~~) Housekeeping;

(m~~7~~) Linen care;

(n~~8~~) Liquid and solid waste disposal of both infectious and regular waste. Disposal of infectious waste shall conform to the latest edition of the Rules ~~and Regulations~~ Pertaining to the Management of Medical Waste from Generators and Health Care Related Facilities;

(o~~9~~) ~~policy for~~ Disposal of ~~products of conception~~ human and fetal tissue;

(p~~10~~) Sharps ~~and needle disposal~~ safety;

(q~~11~~) Separation of clean from dirty processes; and

(r~~12~~) Other means of limiting the spread of contagion;

(s~~h~~) 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 ~~a plan for ensuring that each health care worker has an annual tuberculosis skin test or is evaluated in accordance with current Arkansas Department of Health Rules and Regulations Pertaining to the Control of Communicable Disease - Tuberculosis.~~ 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.

~~C. Reporting. Infectious and communicable diseases shall be reported to the Arkansas Department of Health in accordance with the most current versions of:~~

~~1. Rules and Regulations Pertaining to Communicable Disease in Arkansas; and~~

~~2. Rules Pertaining to the Control of Communicable Diseases-Tuberculosis.~~

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.

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:

1. 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 substance audits;

5. 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.

~~G~~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 hand-wash 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.

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.

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."

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 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 ~~48~~ 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.

_____ _____

Signature of Patient Date_____ Time

Certification of Voluntary and Informed Consent for Abortion

On_____(date) at _____(time), I was informed orally and in person by _____ (name of physician who is to perform the abortion, or the referring physician) of the following:

____ The name of the physician who will perform the abortion

____ A description of the proposed abortion method

____ The immediate and long-term medical risks associated with the particular abortion procedure

____ Alternatives to the abortion

____ The probable gestational age of the unborn child at the time the abortion is to be performed

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

____ The medical risks associated with carrying the unborn child to term

____ Any need for anti-Rh immune globulin therapy if I am Rh negative, the likely consequences of refusing such therapy and the cost of the therapy

____ Information on reversing the effects of abortion-inducing drugs

On_____(date) at _____(time), I was informed orally and in person by _____ (name of physician who is to perform the abortion, the referring physician or a qualified person) of the following:

____ Medical assistance benefits may be available for prenatal care, childbirth, and neonatal care and that more detailed information on the availability of such assistance is contained in the printed materials and informational DVD provided to me

____ The printed informational material and informational DVD describe the unborn child and list agencies that offer alternatives to abortion

____ 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

____ 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 information contained in the printed materials and the DVD, including the Directory of Services, is available on the Arkansas Department of Health website (www.healthy.arkansas.gov)

I certify and affirm that I have received the above information at least ~~48~~ 72 hours before I undergo an abortion, the information was given to me in a private room and I was given the opportunity to ask questions. I do hereby voluntarily give my fully informed consent to the abortion.

_____ _____

Signature of Patient Date_____Time

_____ _____

witness Date_____Time

Fetal Pain Checklist
Twenty (20) Weeks or More Gestational Age
Act 1696 of 2005 and Act 1086 of 2015

On_____(date) at _____, I was informed orally and in person by _____
(name of physician who is performing the abortion or the physician's agent) of the following:

____ By 20 weeks gestational age, the unborn child possesses all anatomical links in its nervous system that are necessary in order to feel pain

____ An unborn child of 20 weeks gestation or more is fully capable of experiencing pain

____ A description of the actual steps of the procedures to be performed or induced and at which steps in the procedure the unborn child is capable of feeling pain

____ Maternal anesthesia typically offers little pain prevention for the unborn child

____ An anesthetic, analgesic or both are available so that pain to the fetus is minimized or alleviated and I have been informed of the medical risks associated with the particular anesthetic or 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 to unborn child pain awareness is contained in the provided printed materials and on the Arkansas Department of Health website (www.healthy.arkansas.gov).

____ I understand the information contained in the printed materials was provided by the State of Arkansas

I certify and affirm that I have received the above information at least ~~48~~ 72 hours before I undergo an abortion and that I do hereby voluntarily give my fully informed consent to the abortion.

_____ _____
Signature of Patient Date_____Time

_____ _____
witness Date_____Time

(AS-4010A)

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

1. Name and birthdate of minor or incompetent woman

20-16-805(b)(1)

_____

Name date of birth

2. Name of parent of minor or legal guardian or custodian of incompetent woman: 20-16-805(b)(2); 20-16-804

_____

Name

3. 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 your abortion;
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 an abortion;
f. know medical assistance benefits may be available for prenatal care and childbirth:
g. know the father is liable to assist in supporting your child, even when the father has offered to pay for an abortion;
h. 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
i. 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.

4. Describe the surgical procedures or medical procedures or both, that are planned to be performed on the pregnant woman (COMPLETED BY PROVIDER): 20-16-810(c)(3)

_____

_____

_____

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

_____

Initials of parent or legal guardian

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;
j. possible continuation of pregnancy;
k. cramping of the uterus or pelvic pain;
l. cervical laceration;
m. incompetent cervix;
n. emergency treatment for any complications; or
o. death.
p. other_____

_____
Initials of pregnant woman

6. Additional information provided by physician to pregnant woman under state law (COMPLETED BY PROVIDER): 20-16-810(c)(5)

_____

_____

_____

7. Pregnant woman's consent statement 20-16-810(b)(4); 20-16-810(c)(6)

a. I understand that the doctor is going to perform an abortion on me that will end my pregnancy and will result in the death of my unborn child. Initial_____
20-16-810(c)(6)(A)

b. I am not being forced to have an abortion. I understand that I may choose not to have the abortion, and that I may withdraw my consent prior to the abortion.
20-16-810(c)(6)(B) Initial_____

c. I give my permission for the procedure. 20-16-810(c)(6)(C) Initial_____

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

_____
Initials of parent or legal guardian

d. I understand that there are risks and hazards that could affect me if I have the planned surgical or medical procedures. 20-16-810(c)(6)(D) Initial_____

e. I have been given the opportunity to ask questions about my condition, alternative forms of treatment, risk of non-treatment, the procedures to be used, and the risks and hazards involved. 20-16-810(c)(6)(E) Initial_____

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) Initial_____

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 and the contents of this form to the pregnant woman and to her parent or legal guardian and have answered all questions. 20-16-810(c)(7)(A)

b. According to my best information and belief, a reasonable person under similar circumstances would rely on the information presented by both the pregnant woman and her parent or legal guardian as sufficient evidence of identity and relationship. 20-16-806(c)

c. To the best of my knowledge, the patient and her parent or legal guardian have been adequately informed and have consented to the procedure. 20-16-810(c)(7)(B)

_____

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 incompetent woman. 20-16-805(b)(3)

b. I am aware that the pregnant minor or pregnant incompetent woman desires an abortion and I consent to the abortion. 20-16-805(b)(3)

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

_____

Initials of parent or legal guardian

c. I understand that the physician who signed the Physician Declaration is going to perform an abortion on the pregnant minor or pregnant incompetent woman, which will end her pregnancy and result in the death of her unborn child. 20-16-810(c)(8)(A)

d. I have had the opportunity to read the Physician Declaration or have had it read to me and have initialed each page. 20-16-810(c)(8)(B)

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 information to give informed consent. 20-16-810(c)(8)(D)

_____ _____

Signature Parent or Legal guardian Date 20-16-810(c)(8)(E)

10. Notarized signatures

20-16-810(b)(2)

_____

Parent or Legal Guardian 20-16-803(3)(A); 20-16-803(3)(B); 20-16-810(b)(2)

Subscribed and sworn to before me

this_____day of_____, 20___

_____

Notary Public

_____

Minor 20-16-803(3)(A)

Subscribed and sworn to before me

this_____day of_____, 20___

_____

Notary Public

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

_____

Initials of parent or legal guardian

SECTION 14. SEVERABILITY.

If any provision of these Rules, or the application thereof to any person or circumstances is held invalid, such provisions or applications of these Rules that can give effect without the invalid provisions or applications will be enforced, and to this end the provisions hereto are declared to be severable.

CERTIFICATION

This will certify that the foregoing revisions to the Rules ~~and Regulations~~ for Abortion Facilities in Arkansas 20~~18~~20 were adopted by the State Board of Health of Arkansas at a regular session of said Board held in Little Rock, Arkansas, on the _____ day of_____ 20~~18~~20.

_____
Nate Smith, M.D., MPH
Secretary of ~~Arkansas State Board of Health~~
~~Director, Arkansas Department of~~ Health

_____
Date

QUESTIONNAIRE
FOR FILING PROPOSED RULES WITH THE
ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY Arkansas Department of Health
DIVISION Health Facility Services
DIVISION DIRECTOR Connie Melton, Branch Chief
CONTACT PERSON Becky Bennett, Section Chief
ADDRESS Freeway Medical Building, 5800 W. 10th Street, Suite 400, Little Rock, AR 72204
PHONE NO. (501) 661-2201 **FAX NO.** (501) 661-2165 **E-MAIL** rebecca.bennett@arkansas.gov
NAME OF PRESENTER AT COMMITTEE MEETING Laura Shue, General Counsel
PRESENTER E-MAIL Laura.shue@arkansas.gov

INSTRUCTIONS

A. Please make copies of this form for future use.
B. Please answer each question completely using layman terms. You may use additional sheets if necessary.
C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this
D. 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

****

1. What is the short title of this rule? Rules for Abortion Facilities

2. What is the subject of the proposed rule? Standards for Abortion Facilities in Arkansas

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 ☐

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

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."

In addition to striking "regulations" throughout, proposed amendments comply with 2019 legislation to amend the rules to add language about reversal of abortion-inducing drugs, right to know, reporting complications, and information about perinatal palliative care.

6. **Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation.**

Ark. Code Ann. §§20-9-302, and Acts 315, 522, 620, 801, and 953 of 2019.

7. **What is the purpose of this proposed rule? Why is it necessary?**

Mandated by 2019 Acts of Arkansas: Act 315 (strike "regulation"); and 522, 620, 801, 953 reversal, right to know, report complications, perinatal palliative care).

8. **Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b).**

www.healthy.arkansas.gov

9. **Will a public hearing be held on this proposed rule? Yes** ☑ **No** ☐ **If yes, please complete the following:**

Date: 09/03/2020

Time: 11:00am

Place: Freeway Medical Tower, Suite 801, 5800 W. 10th St., Little Rock, AR, 72204

10. **When does the public comment period expire for permanent promulgation? (Must provide a date.)**

09/03/2020

11. **What is the proposed effective date of this proposed rule? (Must provide a date.)**

11/01/2020

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.**

Public Hearing and Public Comment period dates TBD upon approval.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas Department of Health
DIVISION Health Facility Services
PERSON COMPLETING THIS STATEMENT Becky Bennett, Section Chief
TELEPHONE NO. (501) 661-2201 **FAX NO.** (501) 661-2165 **EMAIL:** rebecca.bennett@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two (2) copies with the Questionnaire and proposed rules.

SHORT TITLE OF THIS RULE Rules for Abortion Facilities

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 federal rule or regulation?

Current Fiscal Year		Next Fiscal Year	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$ 0.00	Total	$ 0.00

b) What is the additional cost of the state rule?

Current Fiscal Year		Next Fiscal Year	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$ 0.00	Total	$ 0.00

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.

Indexed Summary of Changes – Abortion Facility Rules
090419

Strike "regulations" throughout document	Act 315 of 2019
§3 Definitions	
3(A)(1 & 2) "Abortion" definition – update to most recent legislative definition p. 3-1	Act 953 of 2019, Perinatal Palliative Care Information Act; p. 2, L. 21-25
3(B) add "Abortion Complication" definition p.3-1	Act 620 of 2019, Reporting Abortion Complications p.1, L.31 Proposed as 20-16-605(a)(1)(A-B)
3(C) "Abortion Facility" definition – update ~~Each~~ to "in any" p. 3-1	Act 383 of 2017, p. 2, L. 9 – Various laws 10 in any month; suspension & revocation procedures
3(D) add "Abortion-Inducing Drug" definition p. 3-1	Act 577 of 2015, Drugs Safety Act; 20-16-1503(2)(A-D) Act 1086 of 2015, p. 3, L. 36 & p. 4, L. 1-13 Act to Repeal and Replace Woman's Right to Know Act of 2001 20-16-1702(2)(A-D)
3(G) add "Adverse Event" definition p. 3-2	Act 577 of 2015, p. 5, L. 17-35 Abortion Inducing Drugs Safety Act of 2015 20-16-1503(3) Act 1086 of 2015, p. 4, L. 14-32 Act to Repeal and Replace Woman's Right to Know Act of 2001 20-16-1702(3)
3(H) add "Born-alive infant" definition; p. 3-2	Act 392 of 2017, p. 2, L. 19 Born Alive Infant Protection of 2017 20-16-604(a)(2)
3(H) modified definition of "Consent" p. 3-2,	Act 934 of 2015, p. 7, L. 6-14 Parental Involvement Enhancement Act of 2015 20-16-803(4)

3(O) add "Emancipated minor" definition p. 3-3	Act 934 of 2015, p. 7, L. 15-16 Parental Involvement Enhancement Act of 2015 20-16-803(4)
3(P) add "External member of the human body" definition p. 3-3	Act 535 of 2015 p. 3, L. 3 Amend Laws regarding Disposition of Human and Fetal Tissue 20-17-801(b)(2)(B)
3(Q) add "Fertilization" definition 3-3	Act 171 of 2013 Pain Capable Unborn Child Protection Act of 2013 20-16-1402(3)
3(R) add "Final printed labeling" definition p. 3-3	Act 577 of 2015, p. 5, L. 36, & p. 6, L. 1-4 Abortion Inducing Drugs Safety Act 20-16-1503(4) (FPL administration requirements & K enjoined, appealed, moot) PP v. Jegley; reversed 8th circ. Panel; motion for stay 10.3.17 K. Baker
3(U) "Gestational Age" definition added in 2015 p. 3-4 p. 3-4	Act 577 of 2015, p. 6, L. 5-6 Abortion Inducing Drugs Safety Act 20-16-1503(5);
3(V) add "Human tissue" definition in 2015 p. 3-4	Added in 2015, then updated in 2017 Act 535 of 2015 p. 3, L. 8 added definition of Human Tissue Amend Laws regarding Disposition of Human and Fetal Tissue 20-17-801(b)(2)(C)

3(X) Add definition of "Lethal fetal anomaly"	Act 953 of 2019, Perinatal Palliative Care Information Act p.2, L. 33-35 (term is used in §6(M)(31) p.6-3)
3(CC) add definition of "Minor" in 2015 p. 3-4	Act 934 of 2015, p. 7, L. 24-25 Parental Involvement Enhancement Act 29-16-803
3(EE) added "Parent" definition p. 3-4	Act 934 of 2015, p. 7, L. 26 Parental Involvement Enhancement Act 20-16-803(8)
3(FF) modify definition of "patient" to include born-alive infants p. 3-4	HFS addition – based on Born-alive Patient Act Act 392 of 2017, p. 2, L. 19 Born Alive Infant Protection of 2017 20-16-604(a)(2)
3(HH) add "Post-fertilization age" definition p. 3-4	Act 171 of 2013, p.2, L.36 Pain Capable Unborn Child Protection Act of 2013 20-16-1402(6)
	LRFPS et al v. Rutledge et al. 4:19-cv-449-BRW/4:19-cv-KGB USDC Eastern District, Western Division Complaint for injunction filed 6/26/19 Judge Wilson
3(JJ) add "Probable post-fertilization age of the unborn child" definition p. 3-5	Act 171 of 2013, p. 3, L. 2 Pain Capable Unborn Child Protection Act of 2013 20-16-1402(7)

3(KK) add "Reasonable medical judgment" definition p. 3-5	Act 171 of 2013; p. 3, L. 6 Pain Capable Unborn Child Protection Act of 2013 20-16-1402(8)
3(LL) add "Respectful and proper manner" definition p. 3-5	Act 535 of 2015 p. 3, L. 11 Amend Laws regarding Disposition of Human and Fetal Tissue 20-17-801(b)(2)(D)
p.3-5	
§4 Licensing	
4(K) not new - denial, suspension and revocation paragraph moved here p. 4-2	Moved from §8 Program Requirements, p. 8-3 More appropriate placement in Licensing section
4(C) "within 30 ~~minutes~~ miles (access to hospital with gyn or surgical services)	Act 801 of 2019, p.2, L.14
§5 Governing Body	
§6 General Administration	
6(E) in emergency contacts list, replace ~~red cross~~ with blood services provider p. 6-1	Red Cross no longer provides blood bank services.
6(G) and prevention & control to infection control p. 6-1	ADH suggestion - epidemiology

6(J)(1) add "signed and witnessed" to written consent signature requirement p. 6-1	Public comment and consent forms
6(J)(2) add notarized, written consent for minors and women under legal guardianship p. 6-1	Act 934 of 2015, p. 8, L. 18 Parental Involvement Enhancement Act of 2015 20-16-805(a)(1-2), (b)(1-4)
6(M)(6)(a,b) emergency transfers and medical record forms for emergency transfers p. 6-2	Act 801 of 2019, p. 2, L. 10-13 Multi-titled Proposed as 20-9-302
6(M)(14) infection prevention and control p. 6-1,2	Added underlined language – current industry standard term; eliminated post-abortion surveillance (covered in §10 Infection Prevention and Control)
6(M)(20)(a-b) delineate two categories of patients: woman and born-alive infant p. 6-3	HFS addition – based on Born-alive Patient Act Act 392 of 2017, p. 2, L. 19 Born Alive Infant Protection of 2017 20-16-604(a)(2)
6(M)(23) follow-up appointments for medical abortion patients 12-18 days, or as recommended in the final printed labeling, after abortion services, p. 6-3	Act 139 of 2015, p. 2, L. 24-25 ("12-18 days") To Regulate Certain Abortion Drugs & to Provide for Disciplinary Proceedings 20-16-603(b)(2) Act 577 of 2015, p. 7, L. 30 Abortion Inducing Drugs Safety Act of 2015 ("approximately 14 days") 20-16-1504(e)(1) Final printed labeling: "7-14 days"
6(M)(24)(a) patient receipt of USFDA label for abortion-inducing drugs	Act 577 of 2015, p. 7, L. 10-12 Abortion Inducing Drugs Safety Act of 2015

p. 6-3	20-16-1504(c)
6(M)(24)(b) patient receipt of written notice of reversing abortion-inducing drugs for patients receiving such drugs as required by Act 522 of 2019 p. 6-3	Act 522 of 2019 p.1, L.29-36 Amend Right to Know and Provide Info on Reversing Abortion-Inducing Drugs proposed as amending 20-16-1703(b)
6(M)(25) abdominal ultrasound for heartbeat detection p. 6-3	Act 301 of 2013, p. 2, L.30-36 Arkansas Human Heartbeat Protection Act 20-16-1303(a),(b)(1) Upheld Susan Wright Edwards v. Beck
6(M)(26) consent to include items specified in §9(B)(2)(a-e) [informed consent] p. 6-3	Section 9 – Health information services, ¶B(2)(a-e) "informed consent" p. 9-2
6(M)(27) reporting child maltreatment/abuse p. 6-3	Act 749 of 2009 Child Maltreatment Act 12-18-401 et seq.
6(M)(28) provide printed materials & answer questions in language patient can understand p. 6-3	Act 1086 of 2015, p. 8, L. 24-29 Act to Repeal and Replace Woman's Right to Know Act of 2001 20-16-1703(b)(4)(B) Wording change for clarity
6(M)(31) process for providing perinatal palliative care information for diagnosis of fetal anomaly p. 6-3	Act 953 of 2019, p. 3, L. 20-35 Perinatal Palliative Care Information Act Proposed 20-16-2004

6(N)(1) moved STD reporting to this section p. 6-4	Moved to organize reporting requirements together – previously located in §8(A)(2) on p. 8-1
6(N)(2) moved Induced Terminations of Pregnancy reporting to this section and shortened description for clarity p. 6-4	Moved to organize reporting requirements together - previously located in §8(F) on p. 8-2 Providers use ADH Vital Records Form VR-29 to submit required data. Reports are made for each abortion patient and are submitted monthly to Health Statistics.
6(N)(3) add adverse drug event report re: adverse events associated with abortion-inducing drugs p. 6-4	Act 577 of 2015, p. 8, L. 5-12 Abortion-Inducing Drugs Safety Act 20-16-1505
6(N)(4) add requirement to report abortion complications p. 6-4	Act 620 of 2019, p. 2, L.26 Require Additional Reporting for Abortion Complications Proposed as 20-16-605 Act 801 0f 2019 Born-alive Infant Protection p. 2, L.35
(6)(P) add ~~48~~ 72 hour reflection period within which money may not be collected p. 6-5	Act 383 of 2017, p. 5, L.3 20-16-1703(d) Act 801 of 2019, p.8, L.33-34 Amending Woman's Right-to-Know Act 20-16-1703(d)
§7 Patient Care Services	
	_____
7(F)(1) provide for follow-up appointment 12-18 days, or as recommended in the final printed labeling, following abortion services p. 7-2	Act 139 of 2015, p. 2, L. 24-25 ("12-18 days") To Regulate Certain Abortion Drugs & to Provide for Disciplinary Proceedings 20-16-603(b)(2); and

	Act 577 of 2015, p.7, L. 30 Abortion-Inducing Drugs Safety Act ("approx. 14 days") 20-16-1504(e)(1)
7(F)(2) make reasonable effort to ensure patient returns for follow-up p. 7-2	Act 139 of 2015, p. 2, L. 24-25 ("12-18 days") To Regulate Certain Abortion Drugs & to Provide for Disciplinary Proceedings 20-16-603(b)(2); and Act 577 of 2015, p.7, L. 30 Abortion-Inducing Drugs Safety Act ("approx. 14 days") 20-16-1504(e)(1)
7(H)(1): 72 hour pre-abortion counseling time-frame; ADH printed material and DVD on ADH website; and patient gets copy of most current ADH printed materials and DVD p. 7-2	Act 1086 of 2015, p. 6, L 34; p.7, L. 27; p. 8, L. 21; p. 8, L. 30; p. 9, L.31 Repeal and Replace Right to Know Act of 2001; Provide for Voluntary and Informed Consent 20-16-1703(b) Act 801 of 2019, amending informed consent under Woman's Right to Know Act, 20-16-1703(b) – increased 48 to 72 hours
7(H)(3) Patient shall meet individually and in private room with physician, referring physician, or qualified person p. 7-2	Act 1086 of 2015, p. 8; l 13-17; p. 9, L. 31 20-16-1703(b)(3)(a)
7(I) prohibit abortions by telemedicine p. 7-2,	Act 887 of 2015, p. 3, L. 32-32 Telemedicine Act 17-80-118(b)(3)
7(J) specify that initial administration of abortion-inducing drugs occurs in same room and physical presence of physician who prescribed p. 7-3	Act 139 of 2015, p. 2, L. 17-21 To Regulate Certain Abortion Drugs & to Provide for Disciplinary Proceedings 20-16-603(b)(1)
7(K) add requirement for patient receipt & acknowledgment of USFDA label(s) for abortion-inducing drugs p. 7-3	Act 577 of 2015, p. 7, L. 10-12 Abortion-Inducing Drugs Safety Act 20-16-1504(c)(1,2)
§8 Program requirements	
8(A)(2) move STD reporting requirements to "Administrative Reports" §6(N)(1) p. 6-3	Consolidate and organize
8(A)(2)(a) add requirement to determine gestational age and location of pregnancy prior to medical abortion p. 8-1	Act 577 of 2015, p. 7, L.2-9 Abortion-Inducing Drugs Safety Act 20-16-1504(b)(1,2)

8(A)(3) add requirement for abdominal ultrasound to determine fetal heartbeat p. 8-1	Act 301 of 2013, p. 2, L.35-36 Arkansas Human Heartbeat Protection Act 20-16-1303
8(A)(4) patient to keep most current ADH printed materials & DVD p. 8-1	Act 1086 of 2015, p.7, L. 32,33; p. 8, L. 21-23. 20-16-1703(b)(2)(a-e)
8(B) moved to 6(M)(6), p. 6-2	With other policy and procedure requirements
8(D)(1) change to statutory language	Act 801 of 2019 Born-alive infant protection p.2, L.17-19 20-9-302 Also note: follow manufacturer's guidelines – 8(G), p. 8-3
~~8(E) Report of Induced Termination.~~ Paragraph moved to Administrative Reports, §6 p. 8-2	Moved to more appropriate section "Administrative Reports" §6(N)(2), p. 6-3
~~8(F) Denial, suspension, revocation~~ p.8-2	Moved to §4, LICENSING – more appropriate location p. 4-2
	Added in 2015, then updated in 2017 Act 535 of 2015 p. 3, L. 19-22 Re: disposition of human and fetal tissue 20-17-802(a)
8(F)(3) respectful and proper manner p. 8-3	Act 535 p. 1, L. 32-33 Re: disposition of human and fetal tissue

	20-17-801(a)(1)(A)
~~8(G) Denial, Suspension, etc. p. 802~~	Move to section 4(K), Licensure p. 4-2 – consolidate and organize
8(G) follow MFG Guidelines for facility equipment & biologicals p. 8-3	De-specified emergency equipment requirements in §8(D). Language mirrors CMS facility requirements
§9 Health Information Services	
9(B)(2)(a) Informed Consent Checklist form AS-4010 p. 9-2	Act 1086 of 2015, p. 13, L. 14 Act to Repeal and Replace Woman's Right to Know Act of 2001 20-16-1704 *Informed Consent Checklist*, form ADH AS-4010
9(B)(2)(b) evidence statistical probability of term birth where heartbeat is detected p. 9-2	Act 301 of 2013, p.3, L.20 Human Heartbeat Protection Act 20-16-1303(d)
9(B)(2)(c) fetal pain checklist p. 9-2	Act 1086 of 2015, p. 8, L. 30 & p. 9, L. 1-15 Act to Repeal and Replace Woman's Right to Know Act of 2001 20-16-1703 *Fetal Pain Checklist* form ADH AS-4010-A
9(B)(2)(d) notarized parent/guardian or custodian consent for minors and women under guardianship or custodianship p. 9-2	Act 934 of 2015, p. 8, L. 4-8 Parental Involvement Enhancement Act of 2015 20-16-803(8)(c); 804; 805; 809(b); and 20-16-1704(b)(1)(B)(iv)(b) *Abortion Disclosure and Consent Form for Unemancipated Minors and Women under Legal Guardianship of Custodianship for Incompetency*, fo ADH AS-4011
9(B)(2)(e) medical emergency documentation exceptions p. 9-3	Unborn child pain prevention, Act 1696 of 2005, 20-16-1107 Human Heartbeat Protection, 301 0f 2013, 20-16-1305 Woman's Right to Know, 1086 of 2015, 20-16-1706
9(B)(4)(d) for medical abortions, gestational age p. 9-3	Act 577 of 2015, p. 7, L.2-9 Abortion-Inducing Drugs Safety Act 20-16-1504(b)(1)
9(B)(4)(e) add ultrasound image with: p. 9-3 1. Right to view evidence; and 2. Patient decision to view or not p. 9-3	Act 301 of 2013, p. 2, L.35-36 Arkansas Human Heartbeat Protection Act 20-16-1303 Partially enjoined – Edwards v. Beck

9(B)(4)(f) testing for fetal heartbeat and acknowledgment form if HB detected p. 9-3	Act 301 of 2013, p. 3, L.15-17 Arkansas Human Heartbeat Protection Act 20-16-1303 Partially enjoined (info that abortion is illegal due to heartbeat)
9(B)(4)(g) for medical abortions, intrauterine location of pregnancy p. 9-3	Act 577 of 2015, p. 7, L.2-9 Abortion-Inducing Drugs Safety Act 20-16-1504(b)(2)
9(B)(6) add document any follow-up p. 9-3	577 of 2015, p. 7, L. 36, p. 8, L 3. Drug Safety Act 139 of 2015, p. 2, L.28-30 Drug regulation Act
9(B)(7) add consent for unemancipated minors and women under guardianship or custodianship and most current ADH printed materials and DVD p. 9-3	Act 934 of 2015, p. 8, L. 13-25 Parental Involvement Enhancement Act of 2015 20-16-805
9(B)(10)(a) add description of surgical instruments, techniques, findings, tissues, etc. p. 9-4	Needed for complete reporting - standard
9(B)(10)(b) add identifying info requirement to follow-up appointments for medical abortions p. 9-4	Act 139 of 2015, p. 2, L. 28 To Regulate Certain Abortion Drugs & to Provide for Disciplinary Proceedings 20-16-603(b)(3) 577 of 2015, p. 7, L. 36, p. 8, L 3. Drug Safety Act
9(B)(11)(a)(i-ii) add requirement for and type of proof of relationship for parents and guardians when consent is required p. 9-4	Act 934 of 2015 p. 8, L. 27-35 Parental Involvement Enhancement Act of 2015 20-16-806(a)
9(B)(11)(b) Specify record retention time for items required in 9(B)(11)(a) p. 9-4	Act 934 of 2015, p. 8, L. 36, p. 9, L. 2 Parental Involvement Enhancement Act of 2015 20-16-806(b)
9(12) add physician affidavit when minor or incompetent woman p. 9-4	Act 934 of 2015, p. 9, L. 3-10 Parental Enhancement Involvement Act of 2015 Ark. Code Ann. §20-16-806(c)

	ADH form AS-4011 "Abortion Disclosure and Consent form for Unemancipated Minors and Women under Legal Guardianship or Custodianship for Incompetency"
§10 Infection Prevention and Control	Section title & ¶ 10(4)(d) changed to current terminology
10(A)(1) Change nosocomial to "Healthcare Associated Infections" p. 10-1	change to current terminology Also: 10(A)(4)(a)
10(A)(2) facility to follow national guidelines and manufacturer's instructions. p. 10-1	Remove CDC and replace with "national"; manufacturer's instructions fo chemical cleaners and disinfectants
10(A)(3) add designated infection control and prevention officer p. 10-1	Required for other licensed facilities
10(A)(4) Update infection prevention and control policies and procedures p. 10-1	Fairly comprehensive update and reorganization in infection prevention and control requirements
10(A)(4)(a) change nosocomial to "Healthcare Associated Infections" p. 10-1	change to current terminology
10(A)(4)(b) add "abortion" to maintaining reports of infections in patients p. 10-1 10(A)(4)(c)& (d) same as above (a) and (b); p. 10-1	Patients that do not have abortions are not required to be monitored Change to current terminology and only abortion-receiving patients & health care workers to be assessed for risk of HAI
10(A)(4)(i) add "sterile technique" p. 10-1	Commonly used alternative language
10(A)(4)(j) Sterilization policies – added the following: p. 10-1	Comprehensive update of sterilization policies and procedures
10(A)(4)(j)(1) evaluate effectiveness of sterilization p. 10-1	Assure ongoing sterilization quality
10(A)(4)(j)(2) receiving, decontaminating, cleaning, preparing, disinfecting and sterilizing reusable items p. 10-2	Assure items are properly prepared for sterilization
10(A)(4)(j)(3) specifications for cold-liquid sterilization and gas sterilization (if used) p. 10-2	Process for alternate sterilization outlined
10(A)(4)(j)(4) sterilization techniques other than steam (plasma, ethylene oxide, chemical, etc.) shall follow the manufacturer's directions and meet all state and federal regulations p. 10-2	Ensure proper use of less familiar types of sterilization

10(A)(4)(j)(5) assembling and wrapping of packs (to include the double-wrapped techniques) p. 10-2	Review for proper wrapping of sterile packs/instruments
10(A)(4)(j)(6) autoclaves to include: p. 10-2	Comprehensive update of autoclave (steam) sterilization policies and procedures
10(A)(4)(j)(6)(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 p. 10-2	Promote compliance and create tracking method for HAI epidemiology
10(A)(4)(j)(6)(ii) the efficacy of autoclaves, both for routine and immediate use shall be determined weekly through the use of biological spore monitors p. 10-2	Assure effectiveness of equipment
10(A)(4)(j)(6)(iii) the results of all biological spore monitoring shall be reported to the Infection Prevention Officer p. 10-2	Assure spore monitors results are evaluated
10(A)(4)(j)(6)(iv) failures of the biological spore test shall be brought to the attention of the Infection Prevention Officer or designee immediately so the appropriate surveillance measures can be initiated p. 10-2	Safety measure to identify individual patients at risk of HAI if autoclave fails spore testing
10(A)(4)(j)(6)(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 p. 10-2	Prevents use of equipment with failed sterilization occurrence
10(A)(4)(j)(6)(vi) autoclaves within the facility shall be maintained in accordance with the manufacturer's written directions. Records shall be maintained of all maintenance and repairs for the life of the equipment p. 10-2	Assure staff familiarity and equipment effectiveness
10(A)(4)(j)(6)(vii) chemical indicators for sterility shall be used with each cycle p. 10-2	Safety measure
10(A)(4)(j)(6)(viii) compliance and efficacy of the sterilization policies shall describe the mechanism	Identifies when to re-sterilize unused items

used to determine the shelf life of sterilized packages p. 10-2	
10(A)(4)(j)(6)(ix) products used to contain or wrap instrument sets/pans for sterilization shall follow manufacturers' directions or nationally recognized standards for use in determining the shelf life of the sterilize items(s) p. 10-2	Assure staff familiarity and equipment effectiveness
10(A)(4)(j)(6)(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 p. 10-3	Assure items are properly prepared for sterilization
I10(A)(4)(j)(6)(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 p. 10-3	Assure adequate inventory of instruments
10(A)(4)(j)(6)(xii) procedures for unloading and transporting immediate use sterilized items, which provide for the aseptic transfer within the physical constraints of the facility p. 10-3	Prevent carrying items through unsanitary areas
10(A)(4)(k~~5~~) disinfection to include: p. 10-3	Comprehensive update of disinfection policies and procedures
10(A)(4)(k)(1) cleaning of equipment p. 10-3	Promote systematic cleaning
10(A)(4)(k)(2) evaluating effectiveness of cleaning p. 10-3	Assure quality
10(A)(4)(k)(3) cleaning and disinfecting of surfaces, utensils, and equipment p. 10-3	Comprehensive approach
10(A)(4)(k)(4) receiving, decontaminating, cleaning, preparing, and disinfecting reusable items p. 10-3	System can be reviewed
10(A)(4)(k)(5) a requirement that disinfectants, antiseptics, and germicides are used in accordance with the manufacturer's directions p. 10-3	Safety and effectiveness
10(A)(4)(o~~9~~) policy for disposal of human and fetal tissue p. 10-3	Reviewable
10(A)(4)(p~~10~~) sharps ~~and needle disposal~~ safety	Needles already regarded as sharps

p. 10-3	
10(A)(4)(s)supplies and storage to include: p. 10-4	Comprehensive revision of policies and procedures related to supplies and storage
10(A)(4)(s)(1) storage and distribution of sterile equipment/medical supplies p. 10-4	Assurance of quality
10(A)(4)(s)(2) recalling and disposing of outdated sterile supplies p. 10-4	Assurance of quality
10(A)(4)(s)(3) collection and disposal of supplies recalled by the manufacturer p. 10-4	Method of checking for recalls
10(A)(4)(s)(4) precautions to prevent the mixing of sterile and unsterile supplies and equipment p. 10-4	Assurance of quality
10(A)(4)(s)(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 p. 10-4	Assurance of quality
10(A)(4)(s)(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 p. 10-4	Assurance of quality and allows for cleaning of storage area
10(B)(5) change TB language to ADH standard	Update all TB language in ADH regulated entities
10(C) move to “administrative reports”	Move to 6-4, administrative reports section
§12 Physical Facility requirements	
12(G) Add storage requirement for fetal remains p. 12-8	Act 535 of 2015, p. 2, L. 12 & 17 Act to Amend Laws regarding Disposition of Human and Fetal Tissue 20-17-801(b)(1)
12(I)(1-2) Signs posted to prevent forced abortions in each waiting room, patient consult room, and procedure room. Text specified. p. 12-8, 12-9	Act 1086 of 2015, p.13-14, L.36, 1-19 Woman’s Right to Know Act 20-16-1705
§13 Forms	

Indexed Summary of Changes – Abortion Facility Rules
090419

Added forms to Rules:	
1. Form ADH AS-4010 Informed Consent Checklist changed ~~48~~ to 72 hours and add time of consent pp. 1, 2	20-16-804, 20-16-810(a) Act 801 of 2019, amending Right to Know, p.4, L.31 20-16-1703
2. Form ADH AS-4010-A Fetal Pain Checklist changed ~~48~~ to 72 hours and add time of consent p. 1	Act 801 of 2019, amending Right to Know, p.4, L.31 20-16-1703
3. Abortion Disclosure and Consent for Unemancipated Minors and Women under Legal Guardianship or Custodianship for Incompetency ADH AS-4011	
§14 Add severability clause	