ARKANSAS REGISTER

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Department Center for Health Protection/Health Facilities

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Robert Brech (Contact Person) robert.brech@arkansas.gov (E-mail Address) 11/14/2017 (Date)

CERTIFICATION OF AUTHORIZED OFFICER

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

Robert Brech
Signature

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General Counsel
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11/14/2017
Date

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

Agency # 007.05

RULES AND REGULATIONS FOR ABORTION FACILITIES IN ARKANSAS

ARKANSAS DEPARTMENT OF HEALTH
2017

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.

SECTION 3. DEFINITIONS.

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

A. **Abortion** - the use or prescription of any instrument, medicine, drug, or any other substance or device:

1. To terminate the pregnancy of a woman known to be pregnant with an intention other than to:
   a. Increase the probability of a live birth;
   b. Preserve the life or health of the child after live birth; or
   c. to remove a 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 (20th) week of a woman's pregnancy except as authorized by law. See Ark. Code Ann. § 20-16-1401 et seq.

B. **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 month, including non-surgical abortions.

C. **Act -** Act 509 of 1983 as amended by Act 1176 of 2011.

D. **Administrator -** an individual designated to provide daily supervision and administration of the Abortion Facility.

E. **Consent -** a signed and witnessed voluntary agreement for the performance of an abortion.

F. **Dead fetus or fetal remains** - a product of human conception exclusive of the placenta or connective tissue, which has suffered death prior to the 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.

G. **Department -** the Arkansas Department of Health.

H. **Division -** the Division of Health Facility Services.

I. **Director -** the Chief Administrative Officer in the Division of Health Facility Services.

J. **General Abortion Facility** - an abortion facility that provides surgical abortions or both medical and surgical abortions.

K. **Hospital -** Any acute care facility established for the purpose of providing inpatient diagnostic care and treatment.

L. **Local Anesthesia –** Elimination or reduction of sensation, especially pain, in one part of the body by topical application or local injection of a drug.

M. **Medical abortion** - a non-surgical abortion for which abortifacient pharmaceutical drugs are used to induce the abortion.

N. **Medical-Only Abortion Facility** - an abortion facility in which no surgical abortions are performed.

O. **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.

P. **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.

Q. **Patient -** any woman receiving services in the facility.

R. **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 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.

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, 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 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. Written 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. 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;
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 control, including post- abortion surveillance;
15. fire, safety, and disaster preparedness;
16. housekeeping;
17. laundry;
18. preventive maintenance;
19. processing and/or storage of sterile supplies;
20. patient care;
21. probable post-fertilization age determination; and
22. proper disposition of dead fetuses and fetal remains.

N. Administrative Reports. The Administrator or his/her designee shall report: infectious or communicable diseases to the Arkansas Department of Health, as required by:

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

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

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.

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. A Registered Nurse shall plan, supervise, and evaluate the nursing care of each patient from admission to the facility through discharge.

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

1. prior to the abortion, the patient shall be counseled regarding the abortion procedure, alternatives to abortion, informed consent, medical risks associated with the procedure, potential post-abortion complications, community resources and family planning;

2. documentation of counseling shall be included in the patient's medical record;

3. if counseling is performed in groups, the patient shall be offered an opportunity to meet privately with a qualified counselor;

4. each patient shall be assessed by a Registered Nurse for counseling needs post-abortion;

5. written instructions for post-abortion care shall be given to the patient at discharge, to include at least the following:

   (a) signs and symptoms of possible complications;

   (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.

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 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. 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 onsite proof of pregnancy, such as pregnancy test, copy of a pregnancy test or ultrasound. Other testing may 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 printed materials.

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

C. 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.

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.

E. Complications.

1. General Abortion Facilities shall have emergency drugs, oxygen and intravenous fluids available to stabilize the patient's condition, when 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. All clinical staff shall have documented current competency in cardiopulmonary resuscitation (CPR).

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.

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.

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 or legal guardian 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;

3. complete family, medical, social, reproductive, nutrition, and behavioral history;

4. initial physical examination, evaluation of risk status, and laboratory test results;

5. appropriate referral of patients, as indicated;

6. documentation of each periodic examination;

7. patient counseling regarding the abortion, alternatives to abortion, informed consent, medical risks associated with the abortion, potential post-abortion complications, available community resources, and family planning;

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.

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 infections in patients, and health care workers.

2. The facility shall follow standard Center for Disease Control and Prevention (CDC) precautions.

3. There shall be policies and procedures establishing and defining the Infection Control Program, including:

   (a) definitions of nosocomial infections which conform to the current CDC definitions;

   (b) methods for obtaining reports of infections in patients and health care workers in a manner and time sufficient to limit the spread of infections;

   (c) measures for assessing and identifying patients and health care workers at risk for nosocomial infections and communicable diseases;

   (d) measures for prevention 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 control policies and procedures;

   (g) techniques for:

      (1) hand hygiene including procedures for soap and water as well as alcohol based hand rub if used;

      (2) scrub technique (applies only to General Abortion Facilities);

      (3) asepsis;

      (4) sterilization;

      (5) disinfection;

      (6) housekeeping;

      (7) linen care;

      (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;

(9) policy for disposal of products of conception;

(10) sharps and needle disposal;

(11) separation of clean from dirty processes; and

(12) other means of limiting the spread of contagion;

(h) a requirement that disinfectants, antiseptics, and germicides be used in accordance with the manufacturer's directions;

(i) employee health.

4. 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 Control Program.

5. 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.

B. Employee Health.

1. 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.

2. 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.

3. 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.

4. 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 Comunicable Disease in Arkansas; and

2. the 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 service 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. 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 handwash sink with hands-free controls, soap dispenser and single service towel dispenser.

2. One (1) or more recovery rooms shall be provided. A recovery room shall have a minimum of sixty (60) square feet per patient excluding fixed millwork, vestibule, toilet and closets. The room shall contain a bed or a washable, reclining chair. Multi-patient recovery rooms shall be provided with cubicle curtains for patient privacy.

3. A clean work room shall be provided sufficient in size to process clean and sterilize supply materials and equipment. This room shall contain a handwash sink, work counter and autoclave adequate in size to sterilize the equipment in use.

4. A soiled work room shall be provided. This room shall contain a handwash sink and work counter.

5. At least one (1) barrier free, patient toilet room shall be provided for each recovery room.

SECTION 13. CERTIFICATION.

CERTIFICATION

It is found and determined by the Board of Health that this rule is necessary to clarify mandates placed on abortion facilities in Arkansas as a result of the passage of Act 603 of 2017. Act 603 will become effective on July 31, 2017. The Act is unclear if abortion facilities would be responsible for the disposition of dead fetuses and fetal tissue when the evacuation occurs outside the presence of the inducing physician or away from the facility in which the physician administered the inducing medications. Therefore, an emergency is hereby declared to exist and this Rule, being necessary for the immediate preservation of the public peace, health and safety, shall be in full force and effect from and after July 31, 2017.

This will certify that the foregoing revisions to the Rules and Regulations for Abortion Facilities in Arkansas 2017 were adopted by the State Board of Health of Arkansas at a special session of said Board held in Little Rock, Arkansas, on the 19th day of July, 2017.

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

Nov. 14, 2017
Date

QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL AND JOINT INTERIM COMMITTEE

DEPARTMENT/AGENCY Department of Health

DIVISION Center for Health Protection/Health Facilities Section

DIVISION DIRECTOR Renee Mallory

CONTACT PERSON Robert Brech

ADDRESS 4815 West Markham, St., Slot 31, Little Rock, AR

PHONE NO. 501-661-2297 **FAX NO.** 501-661-2357 **E-MAIL** robert.brech@arkansas.gov

NAME OF PRESENTER AT COMMITTEE MEETING Robert Brech

PRESENTER E-MAIL robert.brech@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 Rule" below.
D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

Donna K. Davis
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? Abortion Facilities in Arkansas

2. What is the subject of the proposed rule? Disposition of fetal tissue

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? 11-14-2017

When does the emergency rule expire? 3-14-2018

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 regulation. _____

Does this repeal an existing rule? Yes ☐ No ☒
If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does. _____

Is this an amendment to an existing rule? Yes ☒ No ☐
If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation. Act 603 of 2017

7. What is the purpose of this proposed rule? Why is it necessary? To clarify that abortion facilities are not responsible for fetal remains expelled away from their facilities.

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).
http://www.healthy.arkansas.gov/aboutADH/Pages/RulesRegulations.aspx

9. Will a public hearing be held on this proposed rule? Yes ☒ No ☐

If yes, please complete the following:

Date: 11/13/2017

Time: 10:00

Place: Suite 801, 5800 West Tenth Street, Little Rock, Arkansas

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

11/13/2017

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

3/15/17

12. Do you expect this rule to be controversial? Yes ☐ No ☒
If yes, please explain. The Department is not aware of any significant controversy at this time regarding this rule.

13. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Department of Health

DIVISION Center for Health Protection/Health Facilities Section

PERSON COMPLETING THIS STATEMENT Robert Brech

TELEPHONE NO. 501-661-2297 **FAX NO.** 501-661-2357 **EMAIL:** robert.brech@arkansas.gov

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

SHORT TITLE OF THIS RULE Abortion Facilities in Arkansas

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;
   N/A

   (b) The reason for adoption of the more costly rule;
   N/A

   (c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and;
   N/A

   (d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.
   N/A

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		Total	

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

Current Fiscal Year		**Next Fiscal Year**	
Genera Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total		Total	

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

Current Fiscal Year	**Next Fiscal Year**
$ 0	$ 0

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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**
$ 0	$ 0

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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.