EXHIBIT I

DEPARTMENT OF HEALTH

SUBJECT: Rules for In Vitro Fertilization, 20 CAR pt. 48

DESCRIPTION: The proposed amendments are to implement changes pursuant to Acts 2025, No. 859, the Reproductive Empowerment and Support Through Optimal Restoration (RESTORE) Act, and to align provisions with current practices and utilization of electronic medical records.

PUBLIC COMMENT: No public hearing was held on this rule. The public comment period expired on August 4, 2026. The agency indicated that it received no comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: The agency indicated that this rule has no financial impact.

LEGAL AUTHORIZATION: The Department of Health may promulgate rules as necessary to accomplish the purposes of Ark. Code Ann. §§ 20-9-201 to -223, regarding health facilities services. Ark. Code Ann. § 20-9-205(b). The Department also has general rulemaking authority for protection of the public health and safety and suppression and prevention of infectious, contagious, and communicable diseases. Ark. Code Ann. § 20-7-109(a)(1)(A), (C). This rule implements Acts 141 and 859 of 2025.

Act 141, sponsored by Senator Justin Boyd, permitted healthcare providers to maintain medical records in an electronic format.

Act 859, sponsored by Representative Alyssa Brown, created the Reproductive Empowerment and Support Through Optimal Restoration (RESTORE) Act.

QUESTIONNAIRE FOR FILING PROPOSED RULES WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT Arkansas Department of Health
BOARD/COMMISSION Division for Health Protection, Health Systems Licensing and Regulation Section
BOARD/COMMISSION DIRECTOR Paula Day, Section Chief
CONTACT PERSON S. Craig Smith, Attorney
ADDRESS 4815 West Markham Street, Slot 31, Little Rock, AR 72205
PHONE NO. (501) 534-6293 **EMAIL** Stephan.Smith@arkansas.gov
NAME OF PRESENTER(S) AT SUBCOMMITTEE MEETING
S. Craig Smith; Paula Day
PRESENTER EMAIL(S) Stephan.Smith@arkansas.gov; Paula.Day@arkansas.gov

INSTRUCTIONS

In order to file a proposed rule for legislative review and approval, please submit this Legislative Questionnaire and Financial Impact Statement, and attach (1) a summary of the rule, describing what the rule does, the rule changes being proposed, and the reason for those changes; (2) both a markup and clean copy of the rule; and (3) all documents required by the Questionnaire.

If the rule is being filed for permanent promulgation, please email these items to the attention of Rebecca Miller-Rice, miller-ricer@blr.arkansas.gov, for submission to the Administrative Rules Subcommittee.

If the rule is being filed for emergency promulgation, please email these items to the attention of Director Marty Garrity, garritym@blr.arkansas.gov, for submission to the Executive Subcommittee.

Please answer each question completely using layman terms.

****

1. What is the official title of this rule?
Rules for In Vitro Fertilization in Arkansas

2. What is the subject of the proposed rule? Rules regarding licensure and administration of the in vitro fertiliza

3. Is this rule being filed under the emergency provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☑

If yes, please attach the statement required by Ark. Code Ann. § 25-15-204(c)(1).

If yes, will this emergency rule be promulgated under the permanent provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☐

4. Is this rule being filed for permanent promulgation? Yes ☑ No ☐

If yes, was this rule previously reviewed and approved under the emergency provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☑

If yes, what was the effective date of the emergency rule? _____

On what date does the emergency rule expire?_____

5. Is this rule required to comply with a *federal* statute, rule, or regulation? Yes ☐ No ☑

If yes, please provide the federal statute, rule, and/or regulation citation.

6. Is this rule required to comply with a *state* statute or rule? Yes ☑ No ☐

If yes, please provide the state statute and/or rule citation.

Ark. Code Ann. §§ 23-85-137; 20-16-2601, et seq.

7. Are two (2) rules being repealed in accord with Executive Order 23-02? Yes ☐ No ☑

If yes, please list the rules being repealed.
If no, please explain.

The proposed amendments are to implement changes pursuant to Acts 2025, No. 859 (the Reproductive Empowerment and Support Through Optimal Restoration (RESTORE) Act), and to align provisions with current practices and utilization of electronic medical records.

8. Is this a new rule? Yes ☐ No ☑

Does this repeal an existing rule? Yes ☐ No ☑
If yes, the proposed repeal should be designated by strikethrough. If it is being replaced with a new rule, please attach both the proposed rule to be repealed and the replacement rule.

Is this an amendment to an existing rule? Yes ☑ No ☐
If yes, all changes should be indicated by strikethrough and underline. In addition, please be sure to label the markup copy clearly as the markup.

9. What is the state law that grants the agency its rulemaking authority for the proposed rule, outside of the Arkansas Administrative Procedure Act? Please provide the specific Arkansas Code citation(s), including subsection(s).

Ark. Code Ann. §§ 23-85-137; 20-16-2601, et seq.

10. Is the proposed rule the result of any recent legislation by the Arkansas General Assembly?
Yes ☑ No ☐

If yes, please provide the year of the act(s) and act number(s).

Acts 2025, No. 859

11. What is the reason for this proposed rule? Why is it necessary?

The proposed amendments are to implement changes pursuant to Acts 2025, No. 859 (the Reproductive Empowerment and Support Through Optimal Restoration (RESTORE) Act, and to align provisions with current practices and utilization of electronic medical records.

12. Please provide the web address by which the proposed rule can be accessed by the public as provided in Ark. Code Ann. § 25-19-108(b)(1).

https://www.healthy.arkansas.gov/proposed-amendment-to-existing-rules

13. Will a public hearing be held on this proposed rule? Yes ☐ No ☑

If yes, please complete the following:

Date: _____

Time: _____

Place: _____

Please be sure to advise Bureau Staff if this information changes for any reason.

14. On what date does the public comment period expire for the permanent promulgation of the rule? Please provide the specific date. 08/04/2026

15. What is the proposed effective date for this rule? 10/1/2026

16. Please attach (1) a copy of the notice required under Ark. Code Ann. § 25-15-204(a)(1) and (2) proof of the publication of that notice.

17. Please attach proof of filing the rule with the Secretary of State, as required by Ark. Code Ann. § 25-15-204(e)(1)(A).

18. Please give the names of persons, groups, or organizations that you anticipate will comment on these rules. Please also provide their position (for or against), if known.

19. Is the rule expected to be controversial? Yes ☐ No ☑

If yes, please explain.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY.

DEPARTMENT Arkansas Department of Health
BOARD/COMMISSION Division of Health Protection, Health Systems Licensing and Regulation Section
PERSON COMPLETING THIS STATEMENT S. Craig Smith, Attorney
TELEPHONE NO. (501) 534-6293 **EMAIL** Stephan.Smith@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the Financial Impact Statement and email it with the questionnaire, summary, markup and clean copy of the rule, and other documents. Please attach additional pages, if necessary.

TITLE OF THIS RULE Rules for In Vitro Fertilization 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 no, please explain:

   (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 reason for adoption of the more costly rule is based on the interests of public health, safety, or welfare, and if so, how; and

   (d) whether the reason for adoption of the more costly rule is within the scope of the agency's statutory authority, and if so, how.

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, private entity, or private business subject to the proposed, amended, or repealed rule? Please identify those subject to the rule, and explain how they are affected.

Current Fiscal Year	**Next Fiscal Year**
$ 0.00	$ 0.00

6. What is the total estimated cost by fiscal year to a state, county, or 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**
$ 0.00	$ 0.00

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.

To: Members, Arkansas State Board of Health

From: Paula Day, Section Chief
Health Systems Licensing and Regulation
Division for Health Protection

Date: March 5, 2026

Subject: To request approval by the State Board of Health of the following proposed amendments to the Rules for In Vitro Fertilization in Arkansas.

Authority: Ark. Code Ann. §§ 23-85-137; 20-16-2601, et seq.

Summary: The proposed amendments are to implement changes pursuant to Acts 2025, No. 859 (the Reproductive Empowerment and Support Through Optimal Restoration (RESTORE) Act), and to align provisions with current practices and utilization of electronic medical records.

Relevant Acts: Acts 859 of 2025

20 CAR § 48-108. Personnel.

- Updated to align with the Rules of Hospitals and Related Institutions in Arkansas regarding Employee Health

20 CAR § 48-109. Medical records.

- Updated to align with the utilization of an electronic medical record.

20 CAR § 48-113. Medications.

- Updated to align with the utilization of an electronic medical record.

20 CAR § 48-114. Surgical services.

- Updated to align with current surgical practice
- Update to define safety, security and integrity of specimens.
- Update to align with the appropriate portions of the Rules of Hospitals and Related Institutions in Arkansas.
- Updated to include Institution of Restorative Reproductive Medicine of America for Act 859

20 CAR § 48-123 Definitions

- Act 859 – Adds the following definitions
  - Assisted reproductive technology
  - Fertility awareness-based methods
  - Fertility education and medical management
  - Infertility
  - Natural procreative technology
  - Reproductive health condition
  - Restorative reproductive health
  - Restorative reproductive medicine

NOTICE OF PUBLIC COMMENT PERIOD

The Arkansas Department of Health (ADH) is accepting public comments on the **Rules for In Vitro Fertilization in Arkansas, 20 CAR Pt. 48** from July 5, 2026 to August 4, 2026. The comment period is provided to allow interested parties and the public to provide any comments. "The proposed changes update the rule to current requirements regarding Definitions from Act 859." The proposed rule revision with a summary of changes can be viewed online at https://www.healthy.arkansas.gov/proposed-amendment-to-existing-rules or you may request a copy from our office at 501-661-2201.

Comments on the proposed changes can also be mailed to Comments, Arkansas Department of Health, Comments, Section of Health Facilities Services, Freeway Medical Tower, 5800 West Tenth Street, Suite 400, Little Rock, Arkansas 72204, or emailed to paula.day@arkansas.gov All comments must be received by 10:00 a.m. on August 4, 2026.

Proposed Rulemaking

~~Title~~Rules for In Vitro Fertilization

Promulgated by:
Department of Health

Title 20. Public Health and Welfare

Chapter I. Generally, Department of Health

Subchapter B. Health Facilities

Part 48. Rules for In Vitro Fertilization

Subpart 1. Generally

20 CAR § 48-101. Purpose.

(a)(1) This part has been prepared for the purpose of establishing criteria for minimum standards for the certification of facilities for in vitro fertilization in Arkansas.

(2) By necessity, they are of regulatory nature, but are considered to be practical minimum design and operation standards for these facilities.

(3) These standards are not static and are subject to periodic revisions in the future as new knowledge and changes in procedure trends become apparent.

(b) However, it is expected that facilities will:

(1) Exceed these minimum requirements; and

(2) Not be dependent upon future revisions in these standards as a necessary prerequisite for improved services.

20 CAR § 48-102. Compliance.

Any authorized representative of the Department of Health shall have the right to enter upon or into the premises of any institution at any time in order to make

whatever inspection is deemed necessary in accordance with the minimum standards and rules prescribed herein.

20 CAR § 48-103. Responsibility.

(a) All facilities for in vitro fertilization shall have an organized governing body or, in its absence, a person who shall be legally responsible for:

(1) Maintaining quality patient care;

(2) Establishing policies for the facility; and

(3) Assuring the conduct of the facility.

(b) The responsible party shall ensure that the facility:

(1) Maintains proper standards of professional work in the facility;

(2) Formulates policies and procedures pertaining to the operation of the facility;

(3) Credentials and appoints members to the medical staff and other authorized staff; and

(4) Develops and maintains an ongoing, comprehensive quality assurance program which will monitor and resolve identified problems.

20 CAR § 48-104. Policy and procedure manual.

(a) The policy and procedure manual shall include at a minimum:

(1) Detailed job descriptions and duties, by job title, of each employee;

(2) Policies and procedures for the general administration of the facility and for each department, section, or service of the facility;

(3) Standards of care;

(4) Procedures provided by the facility with detailed information of each;

(5) Orientation practices for new employees;

(6) Infection control measures;

(7) Cleaning, disinfecting, and sterilizing procedures;

(8) Fire safety and other safety and disaster practices;

(9) Proper routine methods of handling and storing any flammable or explosive agents; and

(10) Documentation of those personnel who may perform procedures and give patient instruction.

(b) All policies and procedures shall be reviewed annually and updated if necessary.

(c) The first page of the manual shall have the current review date and signature of the person conducting the annual review.

20 CAR § 48-105. Credential files.

An individual file shall:

(1) Be maintained for each physician/paraprofessional practicing in the facility; and

(2) Include at least the following:

(A) Specific delineation of privileges, requested and granted;

(B) A signed application with documentation of the applicant's agreement to abide by the facility's bylaws and rules;

(C) Verification of current Arkansas licensure;

(D) Verification of at least three (3) references; and

(E) Documentation of all actions taken concerning the applicant and indicating the types of the privileges granted and other applicable data.

20 CAR § 48-106. Quality assurance.

(a)(1) There shall be an ongoing, comprehensive quality assurance program established for each facility which will monitor and resolve any identified problems.

(2) The program will include a written plan which shall include:

(A) Methods of evaluating all services within the facility;

(B) The evaluation of applicable procedures; and

(C) The evaluation of infection control for the facility.

(b) There must be documented evidence to indicate that the facility has taken appropriate remedial action to address deficiencies identified through the quality assurance program.

(c)(1) There shall also be documented evidence of appropriate action taken regarding each of the problems identified through the quality assurance program.

(2) Monitoring of the problem should continue until the problem is completely resolved with documentation of:

(A) Significant findings;

(B) Conclusions;

(C) Recommended actions; and

(D) Results of actions.

20 CAR § 48-107. Administration.

(a) All medical, surgical laboratory, and procedural care rendered in a facility for in vitro fertilization certified by the Department of Health shall conform to the current standards acceptable to the:

(1) American Medical Association;

(2) American College of Obstetricians and Gynecologists;

(3) American Society for Reproductive Medicine; and

(4) Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), 42 U.S.C. § 263a.

(b) All containers used in the facility shall be:

(1) Legible; and

(2) Accurately labeled as to content.

(c)(1) There shall be a written disaster plan which shall include provisions for complete evacuation of the facility.

(2) The disaster plan should be rehearsed annually with written reports and evaluations of all drills maintained.

(d)(1) Fire extinguishers of the correct type shall be provided in adequate numbers, and shall be properly located and installed.

(2) Personnel shall be trained in the:

(A) Proper use of the equipment; and

(B) Procedures for proper fire containment and evacuation of the facility.

(e) All refrigerated areas, including freezers, shall be provided with reliable thermometers, and records shall be maintained to document the temperatures on a daily basis or at least on each day of operation of the facility.

(f) The facility must have a written plan covering collection, handling, and disposal of all types of waste including:

(1) Toxic;

(2) Infectious; and

(3) Non-infectious.

(g) Ultrasonography services must be available to the facility seven (7) days per week.

20 CAR § 48-108. Personnel.

(a)(1) The facility shall maintain a sufficient number of personnel to provide effective patient care and all other related services to an in vitro fertilization program.

(2) There shall be written personnel policies and procedures which shall be made available to personnel.

(3) Provisions shall be made for orientation and continuing education programs for personnel.

~~(b)(1) Each employee shall have a health file.~~

~~(2) The file shall document at least:~~

~~(A) Annual testing for tuberculosis;~~

~~(B) Documentation of other tests required by the facility; and~~

~~(C) Certification of current training in CPR techniques for all personnel involved in surgical/invasive procedures.~~

(b) **Employee health**.

(1) It shall be the responsibility of administration, with advice and guidance from the medical staff and the Infection Prevention and Control Committee, to establish and enforce policies concerning preemployment physicals and employee health.

(2) The policies shall include but are not limited to:

(A) Requirements for an up-to-date health file for each employee;

(B)(i) Measures for prevention of communicable disease outbreaks, especially Mycrobacterium tuberculosis (TB).

(ii) All plans for the prevention of transmission of TB shall conform to the most current Centers for Disease Control and Prevention Guidelines for the Preventing of the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings; and

(C)(i) Work restrictions placed on personnel who are known to be:

(a) Affected with any disease in a communicable stage;

(b) A carrier of such a disease; or

(c) Afflicted with:

(1) Boils;

(2) Jaundice;

(3) Infected wounds;

(4) Diarrhea; or

(5) Active respiratory infections.

(ii) Such individuals shall not work in any area in any capacity in which there is:

(a) The likelihood of transmitting disease to patients, facility personnel, or other individuals within the facility; or

(b) A potential of contaminating food, food contact surfaces, supplies, or any surface with pathogenic organisms.

(c)(1) Written job descriptions shall:

(A) Be developed for each employee classification; and

(B) Include as a minimum the responsibilities or actual work to be performed in each classification.

(2) In addition, the job descriptions shall include the physical, educational, and licensing or certification requirements for each job classification.

(3) These job descriptions shall be included in the policy and procedure manual for the facility.

(d) Personnel records shall:

(1) Be maintained for each employee; and

(2) Contain no less than:

(A) Current and background information covering qualifications for employment;

(B) Records of all required health examinations; and

(C) Evidence of current registration, verification, or licensure of personnel subject to statutory regulation.

(e)(1) An in vitro fertilization program must include, as a minimum, personnel with the following expertise.

(2) A single individual may fulfill the requirement for expertise in one (1) or more areas:

(A)(i) An individual with training and experience in reproductive endocrinology, particularly in the use of ovulation-inducing agents and the hormonal control of the menstrual cycle.

(ii) The Department of Health would accept an individual who has completed a board-approved fellowship in reproductive endocrinology for fulfillment of this requirement;

(B)(i) An individual with expertise in pelvic reparative (infertility) surgery, as well as experience in laparoscopic and ultrasound-guided oocyte retrieval techniques.

(ii) This combined expertise is necessary not only for the performance of the oocyte retrieval procedures, but also to ensure that the infertile couple is offered the most appropriate treatment modality;

(C)(i) A director of the embryology laboratory.

(ii) See also embryology laboratory personnel section, 20 CAR § 48-115.

(iii) This laboratory director must have personal experience in the organization and maintenance of a basic or clinical embryology laboratory, as well as in tissue culture techniques;

(D) An ultrasonographer (or obstetrician-gynecologist with specialized training and experience in gynecologic sonography) who provides the monitoring of follicular development and supervises ultrasound-directed oocyte retrieval;

(E)(i) Each program must have a designated overall program director.

(ii) If the overall program director is not a licensed physician, there must be a designated medical director who is responsible for the clinical aspects of the treatment program;

(F)(i) An individual experienced in male reproduction (andrology) with special competence in semenology.

(ii) If this individual is not a urologist, then there should be available consultant urologist services with expertise in reproductive surgery.

(iii) This individual should also be involved, when indicated, in recommending the most appropriate treatment options for the couple;

(G)(i) In addition to the laboratory director, there should be a minimum of one (1) other embryology technologist.

(ii) Every embryologist should have a working knowledge of sterile technique and cell tissue culture;

(H) If gamete and/or embryo cryopreservation is offered, there should be an individual with:

(i) Specialized training in cryobiology; and

(ii) Experience in gamete and cryopreservation techniques; and

(I) If oocyte micromanipulation is offered, there should be an individual with specialized training in gamete biology and experience in micromanipulation techniques.

20 CAR § 48-109. Medical records.

(a)(1) A medical record shall be maintained for each patient of the in vitro fertilization facility.

(2) All these records must be kept separate from the other regular records of the facility.

(3) The original or a copy of the original (when the original is not available) of all reports shall be filed in the medical record.

(4) The record shall be:

(A) Permanent; and

(B) Either:

(i) ~~typewritten~~ Typewritten or legibly written in ink; or

(ii) Maintained in an electronic database format.

(5) All dictated reports shall include the date and time of dictation and the date and time of transcription.

(6)(A) Only standard abbreviations, approved by the staff of the facility, shall be used.

(B) This list of abbreviations shall be:

(i) Reviewed annually; and

(ii) Revised if necessary.

(b) **Medical orders.** All medical orders (medication, treatments, tests, and procedures) shall be ~~in writing and shall be signed by the physician~~documented and authenticated by the licensed prescriber.

(c) **Confidentiality.**

(1) Medical records shall be considered confidential.

(2) Only authorized personnel shall have access to the medical records.

(3)~~(A)~~ All medical records shall be secured at all times.

~~(B) If authorized personnel are not present, the records shall be locked.~~

(4) Records shall be available to authorized personnel from the Department of Health.

(d) **Consent for procedures.** A specific consent for procedures shall:

(1) Be documented prior to the procedure to be performed; and

(2) Include the:

(A) Date;

(B) Time; and

(C) Signatures, authentications, or both of:

(i) The patient;

(ii) The physician; and

(iii) A witness.

(e) A history and physical examination shall be documented prior to the procedure.

(f) **Anesthesia.** When anesthesia is utilized, with or without loss of consciousness, a complete anesthesia report, including pre-evaluation and post-follow-up shall be documented by the:

(1) Anesthesiologist and/or the certified registered nurse anesthesiologist (CRNA); or

(2) Physician who administered the anesthesia.

(g) **Procedure report.**

(1) An individualized procedure report shall be:

(A) Written or dictated by the physician immediately following the procedure; and

(B) ~~Signed~~ Authenticated within seventy-two (72) hours.

(2) The report shall describe, in detail:

(A) Techniques;

(B) Findings;

(C) Pre-procedural and post-procedural diagnosis; and

(D) Other pertinent information.

(h) The record of the patient shall also include:

(1) Orders and reports of diagnostic services;

(2) Documentation of any medication administered; and

(3) Progress notes for subsequent clinic visits recorded by applicable disciplines.

20 CAR § 48-110. United States in vitro fertilization registry (U.S. IVF registry) (SART).

(a)(1) In view of the continuing controversy about the success rate of in vitro fertilization, all facilities performing this procedure should participate in the United States In Vitro Fertilization Registry (U.S. IVF Registry) (SART).

(2) Furthermore, it is recommended that each program release (or permit the release from the registry) identifiable clinic-specific success rates in order that patients and physicians may make appropriate choices among programs.

(3) At a minimum, the release data shall include:

(A) The number of stimulation cycles begun;

(B) The number of oocyte retrieval procedures attempted;

(C) The number of women who became pregnant; and

(D) Most importantly, the number of women who deliver live babies.

(4) Annualized statistics should be available within twelve (12) months of the completion of the year's treatment cycles in order that the outcome of all the established pregnancies are available for inclusion.

(b) In vitro fertilization programs that choose not to participate in the U.S. IVF Registry shall prepare similar summaries of their results.

(c)(1) Records shall be kept of all attempts, with both successes and failures documented.

(2) Summaries of all records shall be available for correlation.

(3) The records shall include:

(A) Oocyte recovery;

(B) Fertilization;

(C) Cleavage;

(D) Conceptus transfer;

(E) Biophysical monitoring and fetal growth;

(F) Pregnancy outcome;

(G) All complications; and

(H) Congenital abnormalities.

20 CAR § 48-111. Required reasonable success rate.

There shall be a required reasonable success rate as defined by current American Society for Reproductive Medicine standards.

20 CAR § 48-112. Informed consent.

(a)(1) As with all medical procedures and treatments, the patients must make the final decision on what is appropriate and acceptable treatment in their particular situation.

(2) To comply with this requirement, it is necessary that each prospective patient couple be provided with full disclosure, including at a minimum, the program's own experience with the specific procedure in question, including:

(A) How long the facility has been performing it;

(B) How many times the facility has performed it; and

(C) What the facility's past and current success rates are.

(b) This informed consent requirement shall be met with either the:

(1) Facility's summaries; or

(2) Information for the U.S. IVF Registry.

(c)(1) In addition to the provided information, in vitro fertilization programs shall provide to couples full information concerning alternative procedures available to circumvent their specific infertility problem, including procedures that are not performed by the treating facility.

(2) Attention should also be given to the emotional needs and to the support of these patient couples.

20 CAR § 48-113. Medications.

(a) **Security.** All medications shall be locked when authorized personnel are not present.

(b)(1) Crash carts or emergency medication kits shall be provided.

(2) These carts/kits shall be:

(A) Secured with a breakaway seal; and

(B) Stored in an area observable by licensed personnel.

(3) The cart/kit shall have affixed a listing of the contents.

(c) **Refrigeration.**

(1) Refrigeration shall be provided for the proper storage of biological and other drugs.

(2) An internal thermometer shall be provided and routinely checked to assure temperatures between thirty-six degrees Fahrenheit (36° F) and forty-six degrees Fahrenheit (46° F).

(d) **Controlled substances.**

(1) **Records.**

(A) All controlled substances shall be stored to comply with state and federal regulations.

(B) Records of disposition of controlled substances shall be maintained.

(C) The records shall include:

(i) Actual dosage administered to the patient;

(ii) The patient's name;

(iii) Name of the physician; and

(iv) The date, time, and ~~signature~~ authentication with title of the person administering the medication.

(2) **Breakage or wastage.** When breakage or wastage of a controlled substance occurs, the amount given and the amount wasted must be recorded by the licensed person who wasted the drug and verified by the signature of a licensed person who witnessed the wastage, and how it was wasted.

(3) **Inventory.**

(A) There shall be a count at the opening and closing of the facility of all controlled substances stocked in the facility.

(B) The counts shall be made by two (2) licensed personnel (one (1) to count and one (1) to witness), both of whom shall sign the record with a notation made as to date and time of such count.

(C) Discrepancies in the count are to be noted and reported to appropriate personnel.

(e) **External use only.** Solutions and medications for external use only shall be kept separate from other medication.

(f) **Errors and adverse drug reactions.** Medication errors and adverse drug reactions should be documented and reported to the attending physician.

(g) **Proper maintenance — All drugs.** Drug storage areas should be routinely checked to ensure:

(1) Proper stock levels;

(2) Drugs are in date; and

(3) Containers are properly:

(A) Labeled;

(B) Stored; and

(C) Intact.

20 CAR § 48-114. Surgical services.

(a) Operating room facilities shall be provided for laparoscopic retrieval and ultrasound-guided retrieval.

(b) The operating room shall be ~~availability must be rigidly controlled so patients can be moved in and out seven (7) days a week with a maximum of twenty-four (24) hours' notice~~maintained to preclude unrelated traffic through the suite and to ensure the availability as necessary to meet patients' clinical needs.

(c) Anesthesia must be available seven (7) days a week.

(d) A facility of oocyte and sperm culturing shall be close to the operating room ~~with two-way communication~~with rigid controls to ensure the safety, security, and integrity of the material.

(e)(1) Any in vitro fertilization facility offering services on an outpatient basis that requires the use of general or intravenous anesthetics that render the patient unable to be responsible for his or her actions, and where, in the opinion of the attending physician, hospitalization is not necessary, shall comply with ~~all applicable Sections~~

~~0100 through 1800 (excluding 0900 and 1200 through 1600) of~~ the Rules for Hospitals and Related Institutions in Arkansas ~~of the Department of Health~~, 20 CAR pt. 41, specifically: ~~.~~

(A) 20 CAR §§ 41-101 – 41-107;

(B) 20 CAR § 41-113;

(C) 20 CAR § 41-115;

(D) 20 CAR § 41-117;

(E) 20 CAR § 41-118;

(F) 20 CAR § 41-119;

(G) 20 CAR § 41-133; and

(H) 20 CAR § 41-145.

(2) The most current rules shall apply.

(f) An in vitro fertilization procedure is so complex and highly technical that a large back-up system of laboratory support and specialized personnel should be available seven (7) days a week.

(g)(1) Other assisted reproductive technology (ART) that can include, but not be limited to, in vitro fertilization (IVF), gamete intra-fallopian transfer (GIFT), tubal embryo transfer (TET), zygote intra-fallopian transfer (ZIFT), and others should be considered to be governed by this part.

(2) All facilities licensed or certified by the Department of Health offering these services shall:

(A) Conform to the current guidelines of the American College of Obstetricians and Gynecologists for in vitro fertilization clinics; and either

(B) ~~Also meet~~ Meet the minimal standards of the American Society for Reproductive Medicine for programs of in vitro fertilization; or ~~.~~

(C) Meet the guidelines and standards of the Institute of Restorative Reproductive Medicine of America for programs of restorative reproductive medicine.

20 CAR § 40-115. Embryology laboratory personnel.

(a) **Embryology laboratory director.**

(1) The embryology laboratory director shall be an individual with demonstrated knowledge of all laboratory aspects of assisted reproductive technology (ART).

(2) To be acceptable as an embryology laboratory director, an applicant must fulfill both the following requirements:

(A)(i) Hold an earned doctorate degree (Ph.D.) from an accredited institution in a chemical, physical, or biological science as the major subject or an M.D. degree from an accredited institution.

(ii) The laboratory director should have expertise and/or special training in biochemistry, cell biology, and physiology of reproduction with experience in experimental design, statistics, and problem solving/trouble shooting.

(iii) The laboratory director should:

(a) Be responsible for formulating laboratory policies and protocols; and

(b) Communicate regularly with the medical director regarding patient progress and protocols as they affect the laboratory aspects of treatment; and

(B)(i) Have two (2) years documented pertinent experience in a program performing IVF- or ART-related procedures.

(ii) This experience should include:

(a) Familiarity with laboratory quality control, inspection, and accreditation procedures; and

(b) Detailed knowledge of tissue culture, ART, and andrology procedures performed in mammalian systems.

(b) **Laboratory supervisor.**

(1) **Education.**

(A) If the medical director is also the laboratory director, there should be a qualified, designated laboratory supervisor.

(B) The embryology laboratory supervisor should have a bachelor's or master's degree in a chemical, physical, or biological science.

(2) **Experience.**

(A)(i) The embryology laboratory director or supervisor should have had a period of training of at least six (6) months and at least sixty (60) completed ART procedures in a program that performs at least one hundred (100) IVF procedures per year with a minimum annual ten percent (10%) IVF live birth rate per retrieval cycle.

(ii) A procedure is defined as a combination of the:

(a) Examination of:

(1) Follicular aspirates;

(2) Insemination; and

(3) Documentation of fertilization; and

(b) Preparation for embryo transfer.

(B) Satisfactory completion of this period of training should be documented by a signed letter from the laboratory director of the training program.

(C) In lieu of formalized training, a similar experience with the director's own program is sufficient, provided the program has:

(i) Performed at least one hundred (100) total retrievals; and

(ii) Had at least an annual ten percent (10%) live birth rate per retrieval cycle.

(c) **Laboratory technologists.**

(1) **Education.**

(A) The embryology laboratory technologist should have an earned bachelor's degree from an accredited institution with a physical, chemical, or biological science as the major subject.

(B) Individuals without this educational requirement are acceptable provided they meet all the requirements in the subdivision (c)(2) of this section by January 1, 1992.

(2) **Experience.**

(A) The embryology laboratory technologists should have documented pertinent experience in tissue culture and sterile technique with evidence of completion of thirty (30) complete IVF procedures under continuous supervision of the laboratory director or supervisor.

(B) Experience and documented training in tissue culture, sperm-egg interaction, or related areas of animal reproduction are desirable.

(C) The embryology laboratory technologist works under the supervision of a laboratory director or supervisor.

(D) Programs for the appropriate training of embryology laboratory technologists should be in place for each program with documentation of completion for each employee.

(d) **Laboratory staff.**

(1) **Quantity of procedures**. Each staff embryologist (including the embryology laboratory director or supervisor) should perform at least twenty (20) complete ART procedures a year.

(2) **Expertise.** Among the embryology laboratory staff there should be one (1) or more persons with knowledge and experience in the following fields:

(A) Preimplantation embryology;

(B) Andrology; and

(C) Pre-fertilization and post-fertilization events.

(3) **Knowledge of freeze-thaw.** Before attempting human embryo freezing, at least one (1) member of the embryology laboratory staff should have:

(A) Frozen in excess of two hundred fifty (250) animal embryos; and

(B) Demonstrated the ability to freeze-thaw embryos with a survival/development rate of over fifty percent (50%).

(e) **Consultant visits.**

(1) If the laboratory director is not physically present on a routine basis, consultant visits will be allowed.

(2) These visits are to ensure compliance with all applicable laws and regulations as well as current standards of practice.

(4) The visits should also:

(A) Identify current problems;

(B) Note trends; and

(C) Make recommendations for correction and improvement.

(5) The visits should be bimonthly at the least, while monthly visits are strongly recommended.

(6)(A) Each visit should be documented with a consultant's report.

(B) In addition, relevant in-service educational programs should be provided during each visit.

20 CAR § 48-116. Laboratory services.

(a) **CLIA.**

(1) The laboratory must meet the conditions set forth under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), 42 U.S.C. § 263a, in order to be certified to perform testing on human specimens.

(2) All laboratory services, including andrology and embryology, are subject to CLIA '88.

(3) A referenced laboratory may be used.

(b) Rapid hormonal assays of estradiol and luteinizing hormones must be available seven (7) days per week.

20 CAR § 48-117. Physical environment of oocyte collection/procedure room, embryology laboratory, andrology laboratory.

(a) Size of the oocyte collection/procedure room must meet all of the requirements of a general operating room, with a minimum clear area of two hundred fifty square feet (250 sq. ft.) exclusive of fixed and movable cabinets and shelves.

(b) **Air.**

(1) The air filtration system for the procedure room and for the embryology laboratory must provide twenty (20) air changes per hour.

(2) If the rooms are adjacent, there must be positive pressure from the embryology laboratory room to the procedure room.

(c) **Temperature.** The temperature in the procedure room and in the embryology laboratory must be maintained between sixty-eight degrees Fahrenheit (68° F) and seventy-four degrees Fahrenheit (74° F).

(d) **Humidity.** The humidity in the procedure room and in the embryology laboratory must be maintained between thirty-five percent (35%) and fifty percent (50%).

(e) **Walls and floors.**

(1) Walls and floors must be composed of materials that are:

(A) Easily washed and disinfected; and

(B) Not physically affected by germicidal and cleaning solutions.

(2) Wall bases must be:

(A) Made integral and covered with the floor;

(B) Tightly sealed within the wall; and

(C) Constructed without voids that can harbor insects.

(f) **Ceilings.** Ceilings must have a smooth finish which is washable and waterproof.

(g) **Adequate space and mutual accessibility.**

(1) The laboratory must be constructed and arranged to ensure adequate space for the performance and reporting of tests and for equipment.

(2)(A) The embryology laboratory must be located within one hundred feet (100 ft.) of the oocyte collection/procedure room.

(B) The presence of a general access hallway between the embryology laboratory and the procedure room is not recommended.

(4)(A) As an alternative, oocyte identification and isolation can be performed in the procedure room, using a self-contained, temperature- and environmental-controlled, microscope/incubator unit.

(B) Oocytes can then be transported within this unit (or in a portable incubator) to the embryology laboratory.

(h) **Safety.**

(1) Aerosols and toxic pest control substances must not be used.

(2) Non-toxic (non-powdered) gloves must be worn while handling gametes and embryos.

(3) Toxic fumes that could be harmful to gametes and embryos must be eliminated.

(4) All compressed gas cylinders must be secured to prevent falling.

20 CAR § 48-118. Infection control.

(a) Universal precautions must be observed.

(b) **Medical waste.** The facility must comply with the Rules Pertaining to the Management of Regulated Medical Waste from Health Care Related Facilities, 20 CAR pt. 53, promulgated under the authority of Acts 1913, No. 96 as amended and Acts 1992, No. 41.

(c) **Testing for communicable disease.**

(1) Both partners must be tested for hepatitis B and for the human immunodeficiency virus (HIV) in the three (3) months prior to initiation of the ART treatment cycle.

(2) A full bacteriologic examination must be conducted if the initial semen analysis reveals any sign of infection.

(d) Goggles or glasses and face masks as appropriate must be worn while handling gametes and embryos.

20 CAR § 48-119. Equipment maintenance.

(a) **Maintenance records.**

(1) There must be a documented preventive maintenance program for each piece of equipment, based upon the manufacturer's recommendations.

(2) Maintenance records must be maintained for the life of the instrument.

(3) There must be documentation of remedial action taken when there is equipment failure.

(b) **Individual usage records.** There must be documentation of the following on each day that the facility is open if the particular piece of equipment is in use:

(1) Temperature of each refrigerator, freezer, and incubator;

(2) Adequate humidity of each incubator;

(3) External verification of the gaseous environment in each incubator;

(4) Level of liquid nitrogen in any embryo or gamete storage container; and

(5) Status of gas cylinders and/or liquid nitrogen reservoir supplies.

(c) **Alarm systems.**

(1) Incubators and frozen embryo storage facilities must be equipped with alarms that would sound at a location that is staffed twenty-four (24) hours per day.

(2) Alarms must be tested at least monthly for proper operation.

(d) **Emergency generator.**

(1) There must be an automatic emergency generator in the event of power failure.

(2) The system must be exercised weekly and tested under load monthly.

20 CAR § 48-120. Quality control.

(a) There must be a written quality control program, which includes control bioassays, designed to check for:

(1) Cell culture media and contact materials for toxins;

(2) Inappropriate ionic concentration;

(3) Microbial contamination; or

(4) Other potential hazards to human gametes or embryos.

(b) **Documentation.**

(1) **Quality control procedures.** There must be documentation of all quality control procedures performed.

(2) **Remedial action.** There must be documentation of remedial actions when control procedures do not meet the laboratory's criteria for acceptability.

(3) **Culture medium.** There must be documentation of the following on each batch of culture medium:

(A) Date prepared;

(B) Name of person who prepared the medium;

(C) Osmolarity;

(D) pH;

(E) Method of sterilizations;

(F) Expiration; and

(G) Results of control procedures.

(c) All quality control records must be retained for a period of two (2) years.

20 CAR § 48-121. Embryo cryopreservation.

(a) **Records.**

(1) Duplicate records on frozen embryos must be maintained in the laboratory and with the program director.

(2) Records must contain the following information:

(A) Developmental stage at which frozen;

(B) Freezing protocol used;

(C) Recommended thawing procedures; and

(D) Physical location of each embryo within the storage container.

(b) Embryo containers must be labeled with the following:

(1) Patient's name;

(2) Patient's identification number;

(3) Embryo identification number; and

(4) Date of cryopreservation.

(c) There must be written procedures for the verification of patient identity and the identification of gamete and embryo samples prior to embryo thawing.

20 CAR § 48-122. Required equipment.

(a) **In vitro fertilization.** The following equipment is essential to any in vitro fertilization program:

(1) Incubator;

(2) Centrifuge;

(3) Microscope;

(4) Warming block or isolette; and

(5) Laminar flow hood.

(b) **Cryopreservation.** The following equipment is essential to any in vitro fertilization program which performs cryopreservation:

(1) Controlled-rate freezer; and

(2) Liquid nitrogen storage container.

20 CAR §48-123. Definitions

As used in this part:

(1) "Assisted reproductive technology" means a treatment or procedure involving the handling of a human egg, sperm, or embryo outside of the body with the intent of facilitating a pregnancy including:

(A) Artificial insemination;

(B) Intrauterine insemination;

(C) In vitro fertilization;

(D) Gamete intrafallopian fertilization;

(E) Zygote intrafallopian fertilization;

(F) Egg, embryo, or sperm cryopreservation; and

(G) Egg, sperm, or embryo donation;

(2)(A) "Fertility awareness-based methods" means modern, evidence-based methods of tracking the menstrual cycle of a woman through observable biological signs, including without limitation:

(i) Body temperature;

(ii) Cervical fluid; or

(iii) Hormone production in the reproductive system, including luteinizing hormone and estrogen.

(B) "Fertility awareness-based methods" include without limitation:

(i) Fertility education and medical management;

(ii) The symptothermal method;

(iii) The Creighton Modern Fertility Care System; or

(iv) Billings Ovulation Method.

(3) "Fertility education and medical management" means the program developed in collaboration with the Reproductive Health Research Institute for medical research, protocols, and medical training for healthcare professionals in order to enable

the clinical application of research advances in reproductive endocrinology by providing education for women about their bodies and hormonal health and medical support, as appropriate;

(4) "Infertility" means a symptom of an underlying disease or condition within a person's body that makes successfully conceiving and carrying a child to term difficult or impossible, which is diagnosed after:

(A) Twelve (12) months of sexual intercourse without the use of a chemical, barrier, or other contraceptive method for women under thirty-five (35) years of age; or

(B) Six (6) months of targeted sexual intercourse without the use of a chemical, barrier, or other contraceptive method for women who are thirty-five (35) years of age and older, when contraception should otherwise be possible.

(5) "Natural procreative technology" means an approach to health care that monitors and maintains a woman's reproductive and gynecological health, including laparoscopic gynecological surgery to reconstruct the uterus, fallopian tubes, ovaries, and other organ structures to eliminate endometriosis and other reproductive health conditions.

(6) "Reproduction health condition" means a health condition that makes successfully conceiving a child difficult to impossible when conception should otherwise be possible, including without limitation:

(A) Endometriosis;

(B) Adenomyosis;

(C) Polycystic ovary syndrome;

(D) Uterine fibroids;

(E) Blocked fallopian tubes;

(F) Hormonal imbalances;

(G) Hyperprolactinemia;

(H) Thyroid conditions; and

(I) Ovulation dysfunctions;

(7) "Restorative reproductive health" means a scientific approach to reproductive medicine that seeks to cooperate with or restore normal physiology and anatomy of the human reproductive system, including without limitation:

(A) Body literacy programs that incorporate science-based charting methods;

(B) Teacher-led reproductive health education;

(C) Restorative reproductive medicine;

(D) Natural procreative technology;

(E) Fertility awareness-based methods; and

(F) Fertility education and medical management.

(8)(A) "Restorative reproductive medicine" means a scientific approach to reproductive medicine that seeks to cooperate with or restore the normal physiology and anatomy of the human reproductive system without the use of methods that are inherently suppressive, circumventive, or destructive to natural human functions.

(B) "Restorative reproductive medicine" includes:

(i) Ultrasounds;

(ii) Blood tests;

(iii) Hormone panels test;

(iv) Laparoscopic and exploratory surgeries;

(v) Examination of a patient's overall health and lifestyle;

(vi) Elimination of environmental endocrine disruptors;

(vii) Assessment of the health and fertility of a patient's partner;

(viii) Natural procreative technology;

(ix) Fertility awareness-based methods; and

(x) Fertility education and medical management.