APA-1
6/93

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Department or Agency Alabama Department of Public Health

Rule Number 420-5-1
Rule Title Abortion or Reproductive Health Center Rules

_____ New X Amend _____ Repeal _____ Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare or safety?	Yes
Is there a reasonable relationship between the state's police power and the protection of the public health, safety or welfare?	Yes
Is there another, less restrictive method of regulation available that could adequately protect the public?	No
Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree?	No
Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule?	n/a
Are all facts of the rulemaking process designed solely for the purpose of and so they have as their primary effect, the protection of the public?	Yes
Does the proposed rule have an economic impact?	No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of §41-22-23, Code of Alabama, 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama, 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of Certifying Officer Tahnia Blue Date 9/20/2013

FORM APA2
11/96

STATE BOARD OF HEALTH
NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Public Health

RULE NUMBER AND TITLE: 420-5-1 Abortion or Reproductive Health Centers

INTENDED ACTION: To Amend the current rules

SUBSTANCE OF PROPOSED ACTION: To revise the current rules such that they are compliant with The Women's Health and Safety Act.

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held on October 24, 2013 at the RSA Tower, 201 Monroe Street, Suite 1586, Montgomery, AL 36104. Written comments should be mailed to the agency contact person noted below.

FINAL DATE FOR COMMENTS AND COMPLETION OF NOTICE: Written or oral comments will be received until the close of the record at 5:00 p.m. on November 4, 2013. All comments and requests for copies of the proposed amendments should be addressed to the contact person listed below.

CONTACT PERSON AT AGENCY: Walter T. Geary Jr., M.D., Director, Bureau of Health Provider Standards, Department of Public Health, P.O. Box 303017, Montgomery, Alabama 36130-3017, Telephone number: (334) 206-5366.

Patricia E. Ivie, Agency Secretary

ALABAMA STATE BOARD OF HEALTH
ALABAMA DEPARTMENT OF PUBLIC HEALTH
BUREAU OF HEALTH PROVIDER STANDARDS

CHAPTER 420-5-1
ABORTION OR REPRODUCTIVE HEALTH CENTERS

TABLE OF CONTENTS

420-5-1-.01 General.....2

420-5-1-.02 Administration.....6

420-5-1-.03 Patient Care.....11

420-5-1-.04 Physical Environment.....22

420-5-1-.01 General.

(1) **Legal Authority for ~~a~~Adoption of Rules**. Under and by virtue of authority vested in it by the Legislature of Alabama (Code of Ala. 1975, Section 22-21-20, et seq.~~, Act 2002-419~~), the State Board of Health does hereby adopt and promulgate the following rules governing outpatient abortion or reproductive health centers licensed to operate in the State of Alabama.

(2) **Definitions** (a list of selected terms often used in connection with these Rules):

(a) "AAC Rule" means Alabama Administrative Code Rule.

(~~e~~b) "Abortion" means the use or prescription of any instrument, medicine, drug, or any other substance or device with the intent to terminate the pregnancy of a woman known to be pregnant with knowledge that the termination by those means will with reasonable likelihood cause the death of the unborn child. Such use or prescription is not an abortion if done with the intent to save the life or preserve the health of an unborn child, remove a dead unborn child, or to deliver an unborn child prematurely in order to preserve the health of both the mother (pregnant woman) and her unborn child. The term, abortion, as used in these rules, does not include a procedure or act to terminate the pregnancy of a woman with an ectopic pregnancy, nor does it include the procedure or act to terminate the pregnancy of a woman when the fetus has a lethal anomaly. For purposes of these rules, a lethal fetal anomaly means that the child would die at birth or be still born. For the purpose of this definition, ectopic pregnancy means any pregnancy resulting from a fertilized egg that has implanted or attached outside the uterus. The term also includes a pregnancy resulting from a fertilized egg implanted inside the cornu of the uterus.

(~~e~~c) "Abortion Clinic," "Clinic," "Abortion Facility," or "Facility" means Abortion or Reproductive Health Center.

(d) "Abortion Inducing Drug" means a medicine, drug, or any other substance prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with the knowledge that the termination will with reasonable likelihood cause the death of the unborn child. Use of such drugs to induce abortion is also known as "medical abortion." This includes off-label use of drugs known to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion, such as misoprostol (Cytotec), and methotrexate. This definition does not apply to drugs that may be known to cause an abortion, but which are prescribed for other medical indications, such as chemotherapeutic agents and diagnostic drugs.

(~~b~~e) "Abortion or Reproductive Health Center" means any health care facility, institution, physician's office, or place ~~operated substantially for the purpose of performing~~ where 10 or more abortions are performed during any month, or where 100 or more abortions are performed in any calendar year, or that holds itself out to the public as an abortion provider by advertising by some public means, such as a newspaper, telephone directory, magazine, or electronic media, that it performs abortions. ~~Such a facility must be a freestanding unit and not part of a hospital or other facility licensed for other purposes by the State Board of Health. A health care facility operates substantially for the purpose of performing abortions if any of the following conditions are met~~ This term does not include ~~the following:~~ a health care facility licensed as a hospital pursuant to Chapter 420-5-7, Ala. Admin. Code.

~~1. The health care facility performs thirty or more abortion procedures per month during any two months of a calendar year; or~~

~~2. The health care facility holds itself out to the public as an abortion provider by advertising by some public means, such as a newspaper, telephone directory, magazine, or electronic media, that it performs abortions; or~~

~~3. The health care facility applies to the State Board of Health for licensure as an abortion or reproductive health center.~~

(~~d~~f) "Acute Care Hospital" means a health care facility duly licensed by the State Board of Health to offer to the public not less than fifteen beds and other appropriate facilities for use in diagnosis and treatment of persons in need of acute care for illness, disease, injury, deformity, infirmity, abnormality or pregnancy. A health care facility meets this definition only if the facility is licensed to offer and actually does offer such care or service for not less than twenty-four consecutive hoursin any week to two or more individuals not related by blood or marriage to the owner or administrator of the facility.

(g) "Administer" means to give or apply a pharmacologic or other therapeutic agent to a patient.

(~~g~~h) "Administrator ~~Clinic Director~~" means a natural person who is the governing authority of a health care facility or a natural person who is designated by the governing authority of a health care facility. Such person must have sufficient authority to interpret and implement all policies of the owner or proprietor, and must be qualified to perform those tasks.

Such person shall be the addressee of all correspondence and inquiries from the State Board of Health.

(i) "Dispense" means to sell, distribute, administer, leave with, give away, dispose of, deliver, or supply a drug or medicine to the ultimate user or the user's agent.

(~~f~~j) "Gestational Age" means the time that has elapsed since the first day of the woman's last menstrual period.

(~~hk~~) "Governing Authority" means the owner or proprietor of a health care facility, or the body, such as a board of directors, which exercises control over a health care facility on behalf of its owner or proprietor.

(~~ml~~) Medical ~~e~~Emergency" means a condition which, on the basis of the treating physician's good faith clinical judgment, so complicates the medical condition of a pregnant woman as to necessitate the immediate abortion of her pregnancy to avert her death or in which a delay will create serious risk of substantial and irreversible impairment of a major bodily function. An ectopic pregnancy is per se a medical emergency.

(~~j~~m) "Physician" means a person currently licensed by the Medical Licensure Commission, State of Alabama, to practice medicine or osteopathy pursuant to Code of Ala. 1975, Section 34-24-50, et seq.

(n) "Prescription" means a physician's order for the preparation and administration of a drug or device for a patient.

(~~l~~o) "Qualified ~~p~~Person" means an agent of the physician who is a psychologist, licensed social worker, licensed professional counselor, registered professional nurse, or physician.

(~~k~~p) "Registered Professional Nurse (RN)" means a person currently licensed in the State of Alabama pursuant to Code of Ala. 1975, Section 34-21-21.

(~~n~~q) "These Rules" means Rules 420-5-1-.01 through 420-5-1-.04, Chapter 420-5-1, Abortion or Reproductive Health Centers, Alabama Administrative Code.

(~~i~~r) "Viable" and "Viability" means that stage of fetal development when, the life of the fetus may be continued indefinitely outside the womb by natural or artificial life-supportive systems.

(3) Type of License.

(a) Regular License. A regular license shall be issued by the State Board of Health after the Board has determined that the abortion or reproductive health center is in substantial compliance with the Rules herein adopted.

(b) Probational License. The State Board of Health may issue a probational license when the Board is satisfied that appropriate measures have been taken to minimize any threat to the health and safety of patients and personnel. A probational license may not be granted for more than one year.

(4) **Licensing.**

(a) Application for License. All abortion or reproductive health centers shall apply for licensure on a form designated by the State Board of Health. The application will reflect all data required by Code of Ala. 1975, Section 22-21-20, et seq.

(b) Application Fee. Each application for license shall be accompanied by an application fee as mandated by statute. No application fee shall be refunded. Application fees shall be paid by cash, check or money order made payable to the Alabama Department of Public Health.

(c) Name of Facility. Every abortion or reproductive health center shall be designated by a permanent and distinctive name which shall not be changed once an application has been completed and approved.

(d) Separate License. When more than one facility is operated under the same operating entity, a separate license shall be required for each facility. Separate licenses are not required for separate buildings on the same ground used by the same facility.

(e) Reissuance of License.

1. The following changes in the status of the facility will require issuance of a new license.

(i) Change in facility ownership or operating entity(application fee required).

(ii) Change in facility name (no application fee required).

(iii) Relocation.

2. The governing authority shall file with the State Board of Health an application for license and application fee (if applicable) 30 days before any proposed change requiring a new license in order to permit processing of the application and issuance of the license prior to the desired effective date of the change.

(5) **Right of Appeal.** Any licensee dissatisfied with administrative decision made in the application of these rules may appeal under the procedures of the Alabama Administrative Procedure Act, Code of Ala. 1975, Section 41-22-1, et seq.

(6) **Waivers.** Applications for a waiver to these rules shall be submitted and considered pursuant to the State Board of Health's Rule-Making Procedures, specifically Rule 420-1-2-.09, Waivers or Variances, Ala. Admin. Code. ~~The State Health Officer may approve a waiver to these rules in the following manner:~~

~~(a) The State Health Officer may approve a waiver to any provision of these rules, except for any provision which restates a statutory requirement, or which defines any term.~~

~~(b) To be eligible for a waiver, the licensee must be affected by the provision for which the waiver is requested, and must demonstrate by clear and convincing evidence that:~~

~~1. Local conditions are such that the licensee cannot or need not meet the provision for which the waiver is applied; and~~

~~2. Approval of the waiver will not unreasonably increase the risk of harm that the affected rule provision is intended to protect the public against.~~

~~(c) An application for a waiver shall also contain the name and address of the licensee, a statement of purpose, the period of time for which the waiver is requested and evidence demonstrating that the requirements of subsection (b) above are met.~~

~~(d) An application for a waiver must be presented in writing to the State Health Officer. All supporting evidence referenced in the application must be attached.~~

~~(e) The State Health Officer shall deny any application for a waiver which does not comply with the requirements of this section. Moreover, the Department of Public Health may make periodic evaluations of any waiver that has been granted. The State Health Officer may revoke a waiver if the statements, representations or supporting documentation that are part of the application are discovered to be false or inaccurate, or if local conditions upon which it was based change, or if public health, safety or welfare is adversely affected by a continuation of the waiver.~~

~~(f) Waivers issued by the State Health Officer shall be valid for a finite period of time as specified in the waiver.~~

(7) **Disclosure of Information.** Official reports, such as statements of deficiencies generated by the State Board of Health as a result of on-site inspections, and plans of correction submitted in response to those statements of deficiencies, are subject to public disclosure. Information received through other means and reports, other than statements of deficiencies, shall be deemed to be confidential and shall not be publicly disclosed except in response to a valid subpoena or court order or in proceedings involving the affected facility's license or proceedings involving the license of another facility operated by the same governing authority. Inspection reports will never contain the name or other identification of any patient or client in the inspected facility.

Author: Rick Harris, W.T. Geary, Jr., M.D., Brian Hale
Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.
History: Filed September 1, 1982.
Amended: Filed November 16, 1989; May 22, 1990; August 16, 1990.
Repealed and Replaced: Filed April 17, 2003; effective May 22, 2003.
Amended: Filed January 22, 2004; effective February 26, 2004.

420-5-1-.02 Administration.

(1) **Governing Authority.**

(a) Responsibility. The governing authority is the person or persons responsible for the management, control, and operation of the facility, including the appointment of persons to fill the minimum staffing requirements. The governing authority shall ensure that the facility is

organized, equipped, staffed and administered in a manner to provide adequate care for each patient admitted.

(b) Notification of ~~Clinic~~ Administrator. The State Board of Health shall be advised of the clinic administrator's name within fifteen days of appointment.

(2) **Policies and Procedures.** Policies and procedures for operation of the facility shall be formulated and reviewed annually by the governing authority. They shall include at least the following:

(a) Purpose of the facility, to include scope and quality of services;

(b) Method to ensure compliance with all relevant federal, state, and local laws that govern operations of the facility;

(c) Inservice training requirements;

(d) The person to whom responsibility for operation and maintenance of the facility is assigned and methods established by the licensee for holding such individual accountable;

(e) Provision for annual review and evaluation of the facility's policies, procedures, management and operation;

(f) Provision for a facility-wide quality improvement program;

(g) Patient rights and grievance procedures;

(h) Functional safety and maintenance policies and procedures;

(i) Incident reporting;

(j) Informed Consent;

(k) Patient Care Policies and Procedures;

(l) Handling of confidential records.

(3) **Quality Improvement Program.** There shall be a facility-wide quality improvement program to evaluate patient care and facility services. The program shall be ongoing, have statistical summaries and a written plan of implementation.

(4) **Clinic Schedule.** A schedule listing the days during which the clinic will perform procedures shall be furnished to the Alabama Department of Public Health, Division of Health Care Facilities. Any changes to the schedule or cancellation of procedure days shall be reported to the Division prior to the schedule change taking effect.

(5) **Personnel.**

(a) Each abortion clinic shall utilize personnel to provide services who have appropriate training and qualifications for the services that they provide.

(b) Personnel Files. There shall be a personnel file for each employee which shall include:

1. Job Description. A written job description that describes the duties and responsibilities, position title, authority, and qualifications for each employee.

2. Application. The licensee shall obtain written applications for employment from all employees. The licensee shall obtain and verify information on the application as to education, training, experience, and appropriate licensure, if applicable.

3. Orientation. There shall be a written orientation program to familiarize each new staff member with the facility and its policies and procedures, to include at a minimum, fire and disaster safety, medical emergencies, infection control, and patient confidentiality. There shall be documentation of completion of this orientation maintained in the personnel file.

(c) Medical Director. Each abortion facility shall have a medical director who shall be responsible for supervising all clinical functions and ensuring that the facility meets the requirements of these rules and all professional standards of care. The medical director has ultimate responsibility for the development and implementation of all protocols and policies used by the facility. The medical director shall be board eligible or board certified in obstetrics and gynecology and shall have had at least 12 months experience in treatment of gynecological problems in a surgical environment. The medical director shall ensure that all clinical staff, including both facility and outside covering physicians associated with the facility, are competent as required by these rules and professional standards of care.

(d) Physician Qualifications.

1. Only a physician may perform an abortion. Only a physician may give, sell, dispense, administer, or otherwise prescribe an abortion-inducing drug. All physicians performing abortions at the facility shall be qualified through training and experience in performing abortions and recognizing and managing complications.

2. Before a physician performs any procedure at the facility, the Medical Director shall credential each physician on the basis of his or her qualifications, and a file shall be kept at the facility detailing the qualifications and experience of each physician. This file must, at a minimum, include:

(i) Proof of licensure in Alabama and all other states in which the physician is or has ever been licensed,

(ii) A record of any adverse actions ever taken against the physician's license in Alabama or any other state,

(iii) A current resume,

(iv) A record of staff privileges at any accredited hospital in the United States,

(v) A report from the National Practitioner Databank, and

(vi) Proof of the nature of the physician's training and experience.

This file shall be kept current. The medical director shall review the physician's qualifications at the time the physician is hired and at least yearly thereafter. This review shall include direct observation of the physician's clinical skills, and the results of this review shall be placed in the physician's file. ~~All physicians performing abortions at a facility as of February 1, 2007 shall be credentialed within thirty days of this rule becoming effective.~~

3. For the purposes of this section, acceptable proof of training and experience for a physician performing a procedure at the facility shall consist of at least one of the following:

(i) Certification from an accredited residency or fellowship program in the United States that the physician has been trained to perform abortions and manage and recognize complications;

(ii) Certification from an accredited hospital in the United States that the physician's staff privileges include performing abortions;

(iii) Verification from a properly trained disinterested physician that the disinterested physician has had direct observation of the physician's clinical skill in performing both medical and surgical abortions at a range of gestational ages and finds them to be satisfactory and within the standard of care. For the purposes of this paragraph, a properly trained physician shall meet the requirements of either (i), (ii), or (iii).

4. An outside covering physician shall have staff privileges at a hospital within the same standard metropolitan statistical area that permit him or her to perform dilation and curettage, laparotomy procedures, hysterectomy, and any other procedures reasonably necessary to treat abortion-related complications.

(e) Required Professional Nursing Personnel. Nursing care shall be under the supervision of a registered professional nurse currently licensed in Alabama. At least one registered professional nurse shall be on duty to provide or supervise all nursing care of patients in preparation, during the termination procedure, the recovery period, and initial discharge by the attending physician. Other nursing service personnel shall remain on duty as required to meet the needs of each patient.

(f) Non-Nursing Service Personnel. Non-nursing service personnel; i.e., counselors, housekeeping workers, office workers, etc., shall be assigned in sufficient numbers and shall have sufficient training to meet the needs of all patients.

(g) Cardio-Pulmonary Resuscitation. A person designated to perform cardio-pulmonary resuscitation and at least one other person shall remain on the facility premises from the moment the first patient is sedated until all patients have left the facility premises. Individuals designated to perform cardio- pulmonary resuscitation shall be properly certified and attend a training class in cardio-pulmonary resuscitation at least annually. Each facility shall maintain adequate staffing records to demonstrate that this requirement is met.

(h) Employees who develop signs or symptoms of infectious skin lesions or diseases that would be capable of transmission to patients through normal staff to patient contact shall

not be permitted to have patient contact until free from such signs and symptoms.

(6) **Fire Evacuation Plan.**

(a) Written Evacuation Plan. A written fire control and evacuation plan shall be maintained by each facility. In addition, instructions and fire evacuation routes shall be posted in conspicuous places in the facility and shall be kept current.

(b) Fire Drills. Fire drills shall be conducted at least semi-annually for the staff and written observations of the effectiveness of these rehearsals shall be filed and kept at least three years.

(7) **Communication Facilities.**

(a) Call System. Arrangements shall be provided within the facility to summon additional personnel or help when or if needed in the event of emergency conditions. Requirements will depend on the size of physical configuration of the facility. In general, if all personnel (or occupants) are within hearing distance of any area of the facility, this would be deemed sufficient. Otherwise, there shall be a call system to all portions of the building normally occupied by personnel of the facility.

(b) Telephones. There shall be two or more telephones to summon help in case of fire or other emergency, and these shall be located so as to be accessible from all parts of the building.

(8) **Records and Reports.**

(a) Medical Records to be kept. An abortion facility shall keep adequate records, including procedure schedules, histories, results of examinations, nurses' notes, records of tests performed, copy of report of abortion made to the Center for Health Statistics, and all forms required by law.

(b) Authentication of Records. All records shall be legibly written, dated, and signed in an indelible manner with the identity of the writer indicated.

(c) Filing of Records. All patient medical records shall be filed in a manner which will facilitate easy retrieval of any individual's record.

(d) Storage of Records. Records shall be stored in filing cabinets.

(e) Title to Records. Records of patients are the physical property of the licensee and responsibility for control and maintenance shall rest with the governing authority. Information in the patient's record shall be disclosed to the patient or her designee upon written request within a reasonable amount of time. This may be conditioned upon the payment of a reasonable copying charge.

(f) Disposition of Records. When an abortion or reproductive health center ceases to operate either voluntarily or by revocation of its license, the governing body (licensee) at or prior to such action shall develop a proposed plan for the disposition of its medical records. Such plan shall be submitted to the State Board of Health and shall contain provisions for the

proper storage, safeguarding and confidentiality, transfer or disposal of medical records. Any abortion or reproductive health center that fails to develop a plan of disposition of its records acceptable to the State Board of Health shall dispose of its records as directed by a court of appropriate jurisdiction.

(g) Records shall be Confidential. Records and information regarding patients shall be confidential. Access to these records shall be determined by the governing authority of the facility. Inspectors for licensure shall be permitted to review medical records to determine compliance with these Rules.

(h) Preservation of Records. Medical records shall be preserved either in the original or by microfilm for a period of not less than four years.

(9) **Patient Referral.** Licensee shall maintain a 24-hour answering service. Patients shall receive a return call within a reasonable time.

Author: Rick Harris, W.T. Geary, Jr., M.D., Brian Hale
Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.
History: Filed September 1, 1982.
Amended: Filed August 16, 1990.
Repealed and Replaced: Filed April 17, 2003; effective May 22, 2003.
Amended: Filed February 21, 2007; effective March 28, 2007.
Amended: Filed May 16, 2007; effective June 20, 2007.

420-5-1-.03 Patient Care.

(1) **Patient Care.** All patient care must be rendered in accordance with all applicable federal, state, and local laws, these rules, and current standards of care, including all professional standards of practice. As with any surgical procedure, the physician performing the procedure is responsible for the procedure and for ensuring that adequate follow-up care is provided. In order to facilitate continuity of patient care, the facility physician shall contact and communicate with any physician rendering care for complications arising from the abortion as soon as he [or she] is informed of the existence of such complications. The facility shall develop and follow a policy and procedure for communication with outside physicians, such as emergency room physicians, so that all facility nurses and staff cooperate with any physician rendering care for complications arising from an abortion.

(2) **Policies and Procedures.** The facility shall develop and follow detailed written policies and procedures that are consistent with all applicable federal, state, and local laws, these rules, and current standards of care, including all professional standards of practice. A comprehensive review of these policies and procedures shall be made annually, or whenever it appears that either a comprehensive or limited review is necessary to meet current legal requirements or standards of care. All necessary revisions shall be made and implemented promptly.

(3) **Patients' Rights.**

(a) The facility shall have written policies and procedures to ensure the patient the rights to dignity, privacy, and safety.

(b) The telephone number to register complaints with the Alabama Department of Public Health, Division of Health Care Facilities shall be posted in a prominent location and shall be included in the written material given to the patient upon discharge.

(4) **Admission and Examination Procedures.**

(a) Pre-admission for Abortion. Every woman seeking to have an abortion shall be registered by the facility and shall be seen by a physician or a qualified staff member for a history, physical examination, and laboratory tests.

(b) 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 that the patient is pregnant. Pregnancy test results shall be filed in the patient's medical record.

(c) 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, as indicated below. The facility shall report positive test results for sexually transmitted diseases to the Department of Public Health. Provided that if such results are reported within two business days after receipt to the Department of Public Health, then the Department, and not the abortion clinic, shall be responsible for follow-up and counseling of patients with test results which are positive for sexually transmitted diseases.

(d) Laboratory Tests.

1. The following laboratory tests are required prior to an abortion procedure: hematocrit or hemoglobin, Rh typing, urinalysis as directed by the treating physician, and pregnancy test. Testing for ~~A~~ syphilis ~~test~~, ~~neisseria~~ gonorrhea ~~culture~~, chlamydia, and HIV ~~test~~ shall be performed if such ~~STD~~ tests are properly consented to by the patient.

2. If a prophylactic course of antibiotic medications is not administered or dispensed to a patient in connection with the abortion procedure, then an abortion shall not be performed until the results from the gonorrhea ~~culture~~ testing have been obtained or a waiver of such treatment is signed by the patient. In the case of a medical emergency, as defined in these rules, laboratory tests are not required prior to the procedure.

3. If the above tests are performed by the facility, the facility's laboratory personnel shall meet any requirements which are in effect and which apply to the facility under Rules promulgated by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Act Amendments of 1988. If the tests are referred, they shall be referred to a hospital, to a pathologist certified, or deemed Board eligible by the American Board of Pathology, who is currently licensed to practice medicine in Alabama, or who holds an equivalent license in another state, or to an independent clinical laboratory. If the tests are sent to an independent clinical laboratory in Alabama, such laboratory must be licensed by the State to perform clinical and anatomical work. If the tests are referred to a laboratory outside the

State, the laboratory must hold an interstate license or letter or exemption under the 1988 Clinical Laboratory Improvement Act (CLIA). When specimens are collected on premises, a record must be maintained to reflect the apparent condition of the specimen, time and date collected, and name of the patient. All personnel collecting specimens shall be adequately and appropriately trained and, where otherwise required by law shall be licensed, and their personnel files shall reflect such training and licensure.

4. Each abortion and reproductive health center must develop and retain on file a written quality assurance plan governing the performance of all laboratory procedures performed on-premises. Facilities will be subject to unannounced inspections by the Department of Public Health to determine that on-premises laboratory procedures are being correctly and accurately performed.

(e) Provision for Transfusion. Blood transfusions shall not be administered in an abortion facility.

(f) Informed consent. Except in the case of a medical emergency, as defined in these rules, no abortion shall be performed or induced without the voluntary and informed consent of the woman upon whom the abortion is to be performed or induced. Except in the case of a medical emergency, as defined in these rules, consent to an abortion is voluntary and informed if and only if:

1. At least 24 hours before the abortion, the physician who is to perform the abortion, the referring physician, or a qualified person has informed and provided the woman in person, or by return receipt certified mail restricted delivery, and if by mail, again in person prior to the abortion, a copy of the printed materials developed by the Department of Public Health which list agencies that offer assistance, adoption agencies, development of the fetus, methods and risks of abortion and childbirth, father's obligations, alternatives to abortion and available methods of birth control. Mailing of the printed materials may be arranged by telephone.

2. Prior to an abortion, the physician who is to perform the abortion, the referring physician, or a qualified counselor has informed the woman in person:

(i) The name of the physician who will perform the abortion in writing or a business card.

(ii) The nature of the proposed abortion method and associated risks and alternatives that a reasonable patient would consider material to the decision of whether or not to undergo the abortion.

(iii) The probable gestational age of the embryo or fetus at the time the abortion is to be performed, and the probable anatomical and physiological characteristics of the embryo or fetus at the time the abortion is to be performed. If the fetus is viable or has reached a gestational age, as defined in these rules, of more than 19 weeks, that:

(I) The fetus may be able to survive outside the womb. The person giving this information may advise the patient fully and in good faith of his or her understanding of these terms, and of the nature of any such survival, including that survival may be merely a possibility

or may be of extremely limited duration.

(II) The woman has the right to request the physician to use the method of abortion that is most likely to preserve the life of the child, provided such abortion is not otherwise prohibited by law.

(III) If the child is born alive, the attending physician has the legal obligation to take all reasonable steps necessary to maintain the life and health of the child.

(IV) If at the time of the counseling an ultrasound has been performed and it is the physician's good faith clinical judgment that the fetus is not viable, then the physician need not inform the woman of the information described in (I), (II), and (III).

3. The physician who is to perform the abortion or the referring physician is required to perform an ultrasound before the abortion. The woman has right to view the ultrasound before an abortion. The woman shall complete a required form to acknowledge that she either saw the ultrasound image or that she was offered the opportunity and rejected it.

4. She has the right to view a video~~tape~~ program prepared by the Department of Public Health and the ultrasound.

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

6. She cannot be forced or required by anyone to have an abortion. She is free to withhold or withdraw her consent for an abortion without affecting her right to future care or treatment and without the loss of any state or federally funded benefits to which she might otherwise be entitled.

(i) The patient shall complete and sign the form in Appendix A to these rules.

(ii) Prior to the performance of an abortion, the physician who is to perform the abortion or his or her agent shall receive the signed receipt of the certified mail dated 24 hours before the abortion, if mailed, and the signed forms that she has received the information of subsections (1) and (2) before the abortion, had the opportunity to view the video and the ultrasound, and provided her informed consent for an abortion. The abortion or reproductive health center shall retain the signed receipt, signed forms, and a printed copy of the ultrasound image in the woman's medical file for the time required by law, but not less than four years.

7. When a physician using good faith clinical judgment determines that some specific information required to be given under these informed consent provisions would cause a woman severe non-temporary psychological harm, the physician may forego providing this specific information to the woman. This conclusion does not, however, exempt the physician from otherwise complying with these informed consent provisions or the twenty-four hour waiting period.

(5) **Operative Procedures.**

(a) Medical Services. Only physicians duly licensed in the State of Alabama, shall

order diagnostic work or medications or perform abortions. Pelvic examinations and other medical procedures shall be performed only by ~~a~~ the physician performing the abortion. ~~or by properly trained and licensed physician assistants and nurse practitioners under the direction and supervision of a physician.~~ The governing authority or medical director shall delineate surgical privileges for each physician performing abortions, and shall also establish written criteria setting forth the specific procedures permitted to be performed in the facility, and including general and specific procedures that may not be performed by the various non-physician staff members. Such written criteria shall be placed on file within the facility and shall be available for inspection by the Board of Health.

(b) Patients shall not be admitted for the performance of abortion procedures for which the expected time for surgery and recovery exceeds twelve hours.

(c) Before a physician performs an abortion, the physician shall examine the fetus by use of ultrasound and by such other techniques as to produce a reasonably accurate method of determining the gestational age,~~and~~ viability of the fetus and the intrauterine location. After such examination, the physician shall enter into the patient's medical record the tests or examinations performed, and his findings regarding viability and intrauterine location. If the physician determines that the fetus is viable, the pregnancy shall not be terminated at the abortion or reproductive health center except when an immediate abortion is necessary to preserve the life or physical health of the mother.

(d) Anesthesia. Anesthesia shall be administered to patients only by a Certified Registered Professional Nurse Anesthetist or by a physician deemed qualified by the facility's medical director. The anesthesia must be administered only under the direct physical supervision of a licensed physician. After the administration of an anesthesia, patients shall remain under the physical observation of a Physician, Registered Professional Nurse, or Licensed Practical Nurse (the LPN must be directly supervised by an RN) until the patient is sufficiently alert and able to summon aid.

~~(e) Additional Requirements for Facilities Rendering Patients Incapable of Self Preservation. If the facility treats four or more patients at the same time and meets either subsection 1. or subsection 2. below, then the facility shall be classified as Ambulatory Health Care Occupancy. Flammable anesthetics are prohibited in such facilities except when construction, storage, equipment, and the operating room meet the standards of the National Fire Protection Association (N.F.P.A.) incorporated in Bulletin No. 56A "Standards for the Use of Inhalation Anesthetics."~~

~~1. The facility provides treatment for any patient that would make her incapable of taking action for self-preservation under emergency conditions without assistance from others; or~~

~~2. The facility provides treatment requiring general anesthesia.~~

(~~f~~e) Examination of Tissue Removed. Tissue removed during an abortion shall be examined by a pathologist certified, or deemed Board eligible, by the American Board of Pathology, in anatomical pathology and, if sent to a physician in Alabama, currently licensed to practice medicine and surgery in Alabama, or if sent to a physician in another state, currently licensed to practice medicine in such state. A report of the examination shall be placed in the

patient's medical record. If the examination reveals that no fetal tissue was removed during the abortion, the patient shall be contacted by the facility and she shall be offered or referred for appropriate medical treatment. All medical waste, except such tissue as is sent to a pathologist and not returned to the facility, shall be disposed of in accordance with procedures set forth in the Rules of the Alabama Department of Environmental Management governing medical waste.

(~~g~~f) Anti-Rh immune globulin therapy with required laboratory procedures shall be given to all Rh negative abortion patients within 72 hours of completion of the termination procedure when, in the professional judgment of the physician performing the abortion, lack of such treatment will have an adverse effect on the patient's future childbearing potential. If the treating physician does not consider the treatment necessary, a signed statement to this effect shall be entered in the patient's medical record. Women seeking abortions, if Rh negative, shall be counseled about the necessity or likely necessity of obtaining such therapy, the likely consequences of refusing such therapy, and the cost of such therapy, prior to undergoing the abortion procedure. If for any reason a patient refuses the administration of such treatment when recommended by the physician, the refusal shall be entered in the clinical record, documented and supported by the patient's signature on an appropriate release or waiver form.

(6) **Post Operative Procedures.**

(a) Post Operative Observation. After an abortion procedure, patients shall be observed until a determination can be made whether any immediate post operative complications are present. Patients shall either be discharged within twelve hours of admission in an ambulatory condition without need for further observation or acute care, or shall be offered transportation to a local hospital for further treatment. During and after an abortion procedure performed at an abortion or reproductive health center, a physician shall remain on the premises until all patients are discharged. The discharge order must be signed by the physician. Prior to discharge from the facility, the patient shall be provided with the name and telephone number of the physician who will provide care in the event of complications, and the name of the medications given at the abortion clinic. ~~A physician must remain on the premises until all patients are discharged. The discharge order must be signed by the physician.~~

(b) Responsibility for Continuing Medical Care. The physician who performs an abortion procedure is responsible for ensuring that all patients receive adequate follow-up care. ~~A physician with admitting privileges at a hospital within the same standard metropolitan statistical area as the clinic~~ and must be available to provide care for complications arising from an abortion twenty-four hours a day, seven days a week. Every physician that performs an abortion shall have staff privileges at an acute care hospital within the same standard metropolitan statistical area as the abortion or reproductive health center is located, that permit him or her to perform dilation and curettage, laparotomy procedures, hysterectomy, and any other procedures reasonably necessary to treat abortion-related complications. Enforcement of this requirement is stayed until such time that the restraining order is lifted or there has been a final disposition allowing for enforcement of this requirement in *Planned Parenthood Southeast, et al. v. Strange, et al.*, Civil Action No. 2:13-cv-405-MHT, before the United States District Court for the Middle District of Alabama. Until that time, all licensed abortion or reproductive health centers may comply with these rules if, at a minimum, outside covering physician services are obtained through ~~If no physician performing abortion procedures at the facility can meet this requirement, the facility must have~~ a valid written contract ~~with an outside covering physician~~. The contract with the outside covering physician shall include:

1. a requirement that the outside covering physician shall be available to treat and manage all complications that may reasonably arise as a result of an abortion;

2. the protocol for communication between the facility, the facility physicians, and the outside covering physician so that at least one of the facility physicians shall be available to communicate and consult with the outside covering physician at all times;

3. the outside covering physician's fees;

4. a requirement that the outside covering physician has staff privileges at a hospital within the same standard metropolitan statistical area that permit him or her to perform dilation and curettage, laparotomy procedures, hysterectomy, and any other procedures necessary to treat abortion-related complications; and

5. ~~A~~ a requirement that the outside covering physician notify the facility not less than 72 hours in advance of any absences during which neither the outside covering physician nor a substitute physician meeting all the requirements of subsections (b)(1) and (b)(4) will be available to provide care.

(c) Necessity of Physician with Admitting Privileges. A facility may not perform abortions unless the outside covering physician described in subsection b or a substitute physician with the qualifications described in subsections (b)(1) and (b)(4) is available to provide patient care. If a facility receives notice that no facility physician or outside covering physician will be available, it must stop performing abortions no later than 72 hours before the physician's unavailability.

(d) Post-Operative Policies and Procedures. A facility must develop and follow written policies and procedures detailing the sequence of post-operative care. The facility must have a 24-hour answering service that immediately refers all calls related to post abortion problems to a qualified registered nurse, nurse practitioner, physician assistant, or physician. If a registered nurse, nurse practitioner, or physician assistant will be the initial medical contact, clear protocols must be developed and approved by the medical director, all facility physicians, and any outside covering physicians to establish when a physician will be contacted, which physician will be initially contacted, how the outside covering physician will be contacted if immediate care is needed, and how the patient will be contacted and receive the physician's instructions.

(e) Call Records. In addition to the infection control record required by these rules, a facility must keep a record of all calls taken by the registered nurse, nurse practitioner, physician assistant, or physician. The call record should include the patient's name, time and date of call, a brief description of the reason for the call, and any action taken in response. A full description of any adverse conditions and the instructions or treatment given in response must be noted in the patient's medical record.

(f) Post-Operative Instructions. Written instructions shall be issued to all patients upon discharge and shall include at least:

1. A list of possible complications, the signs and symptoms for each complication, and recommended procedures to be followed in the event of such complication.

2. Activities to be avoided, and the period of time during which the activities should be avoided.

3. A telephone number to call with questions or concerns. If the telephone numbers during and after hours are different, both shall be included, along with the times each will be staffed.

4. Date and time for a follow-up or return visit, with information regarding the importance of keeping the follow- up appointment.

5. The name and telephone number of the physician who will provide care in the event of complications, and the name of the medications given at the abortion clinic.

(g) Reports to the Center for Health Statistics. The administrator of each abortion or reproductive health center shall report each abortion to the Center for Health Statistics no later than ~~ten~~ 10 days after the last day of the month during which the procedure was performed. A copy of the report shall be kept in the patient's medical record. All reports shall be in a format prescribed by the State Registrar ~~on such form as the State Board of Health may prescribe~~. ~~Such forms shall i~~In no event shall the information reported to the Center for Health Statistics contain the name or the address of the patient whose pregnancy was terminated or~~, nor shall they contain~~ any other information identifying the patient. Individual reports ~~forms~~ shall not be available for public inspection~~,~~ and the information shall be maintained in strict confidence by the Center for Health Statistics~~, and shall be destroyed after information from the forms is transferred to the Center's database~~. The Center for Health Statistics shall ~~periodically~~ annually make available to the public aggregate data about the number of abortions performed in clinical settings statewide. The Director of the Center for Health Statistics may authorize the release of other aggregate statistical data for official government use. In no event shall the Center release the names of individual physicians or other staff members employed by abortion or reproductive health centers~~, nor shall the Center release the number of procedures performed at any particular facility~~.

(7) **Pharmaceutical Services.**

(a) Safety. Drug rooms shall be provided with safeguards to prevent entrance of unauthorized persons, including bars on accessible windows and locks on doors. Controlled drugs and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable Federal and State laws.

(b) Administering, Dispensing, and Prescribing Drugs and Medicines. Only physicians and properly credentialed nurse practitioners and physician assistants may prescribe or order medications. Nurse practitioners and physician assistants may prescribe only those medications described in their individual collaborative agreements. Except for standing orders as permitted below, medications shall be prescribed for patients of the facility by patient name after an appropriate medical evaluation. Oral and telephone orders shall be received only by a physician, nurse practitioner, physician assistant, registered professional nurse, licensed practical nurse, or a pharmacist. Oral and telephone orders shall be immediately documented in writing by the individual receiving the order. Prescribing, dispensing, and administration of medications shall meet all standards required by law and by regulations of the State Board of

Medical Examiners and the State Board of Pharmacy. Abortifacient medications shall be prescribed only by a physician. Only a physician may give, sell, dispense, administer, or otherwise prescribe an abortion-inducing drug. The physician giving, selling, dispensing, administering, or otherwise providing or prescribing the abortion-inducing drug shall first examine the pregnant woman in person and document, in the woman's medical chart, the gestational age and intrauterine location of the pregnancy prior to giving, selling, dispensing, administering, or otherwise providing or prescribing the abortion-inducing drug. ~~Abortifacient medications shall be administered only by a physician or by a nurse practitioner, physician assistant, registered professional nurse or licensed practical nurse, under the direct supervision of a physician. For the purposes of this subsection, a physician is directly supervising the administration of an abortifacient medication when he [or she] is in the building and the administration is performed within the physician's sight or pursuant to the physician's written instructions concerning a specific patient given after the examination of the patient.~~

(c) Standing Orders. When permitted by a policy of the facility reduced to writing and approved by the facility's current medical director, limited standing orders may be directed to a nurse practitioner, physician assistant, registered professional nurse or licensed practical nurse. All post- operative complications must be immediately referred to a qualified registered nurse, nurse practitioner, physician assistant, or physician, in accordance with the requirements for post-operative policies and procedures specified in section 420-5-1-.03(6)(d). Standing orders may not be used to prescribe controlled substances or abortifacient medications. Prescriptions or medication orders called or faxed to a pharmacy pursuant to a standing order shall be immediately documented by the nurse practitioner, physician assistant, registered professional nurse or licensed practical nurse, in the same manner required for oral or telephone orders. All oral orders, telephone orders, and records of prescriptions called or faxed pursuant to standing orders shall be verified by the prescribing physician's signature within 48 hours. Such verification may be undertaken by fax. Drugs and medications may not be dispensed except by or under the direct supervision of a physician or pharmacist.

(d) Controlled Substances Permit. Each abortion clinic shall procure a controlled drug permit from the Drug Enforcement Agency if a stock of controlled drugs is to be maintained. The permit shall be displayed in a prominent location.

(e) Records. Records shall be kept of all stock controlled substances giving an account of all items received and administered. Records shall be kept in a manner which allows accurate reconciliation.

(f) Poisonous Substances. All poisonous substances must be plainly labeled and kept in a cabinet or closet separate from medicines and drugs to be prepared for administration.

(g) Emergency Kit or Emergency Drugs.

1. Each abortion clinic shall maintain upon the advice and written approval of the facility's medical director an emergency kit or stock supply of drugs and medicines for treating the emergency needs of patients.

2. The kit or medicine shall be stored in such a manner as to be inaccessible to unauthorized personnel while allowing quick retrieval by authorized personnel.

3. Each emergency kit or stock supply of drugs shall contain a written list of its contents, approved by the medical director, including the name and strength of each drug (with generic equivalents, where appropriate), and amounts to be maintained.

4. At all times, when patients are in the facility, there shall be at least one staff member on the premises who has the knowledge, skills and abilities to operate the emergency equipment. Protocols shall be in place to ensure ongoing training of staff in the use of emergency equipment, the management of emergencies and the indications for emergency transport.

5. Emergency kits and the stock supply of drugs shall be inspected with sufficient frequency to permit the removal of all outdated drugs. Each kit shall contain a log documenting such inspections.

(h) Drug Reference Sources. Each abortion clinic shall maintain reference sources for identifying and describing drugs and medicines.

(8) **Infection Control.**

(a) Infection Control Committee.

1. There shall be an infection control committee composed of a physician and registered professional nurse who shall be responsible for investigating, controlling, and preventing infections in the facility.

2. There shall be procedures to govern the use of sterile and aseptic techniques in all areas of the facility.

3. There shall be continuing education provided to all staff on causes, effects, transmission, prevention, and elimination of infection at least annually.

(b) Sterilization. Definitive written procedures governing sterilization techniques shall be developed. All equipment must be sterilized either by pressurized steam sterilization or gas sterilization. Procedures are to include:

1. Technique to be used for a particular instrument or group of instruments.

2. Length of time to accomplish sterilization.

3. Prohibition against re-use of one-time-use (disposable) items.

4. Temperature, time and pressure for steam sterilization.

5. Proper methods of preparation of items for sterilization (cleaning, wrapping and dating).

6. Shelf storage time for sterile items.

7. Use of sterilizer indicators.

(c) Abortion or reproductive health centers shall adhere to regulations of the United States Occupational Safety and Health Administration for handling medical waste, and regulations of the Alabama Department of Environmental Management and other applicable federal regulations for disposal of medical waste (medical waste includes, but is not limited to, disposable gowns, soiled dressings, sponges, surgical gloves, bacteriological cultures, blood and blood products, excretions, secretions, other bodily fluids, catheters, needles, IV tubing with needles attached, scalpel blades, glassware, and syringes that have been removed from their original sterile containers).

(d) Investigation of Infections.

1. Reports of infections observed during any follow- up or return visit of the patient shall be made and kept as a part of the patient's medical record. Each facility shall maintain a surveillance logbook recording all follow-up visits and telephone inquiries in which infections or other complaints are reported or observed. This logbook shall be reviewed at least quarterly by the facility's medical director. The facility's medical director may specify certain patient complaints, such as mild cramps, which, in his professional opinion and judgment, do not warrant being recorded in the logbook. The logbook shall in all events contain documentation of the following:

(i) Any report by a patient of severe cramps;

(ii) Any report by a patient of passage of a blood clot as large or larger than three centimeters, or one and one fourth inches, in diameter (the approximate size of a fifty cent piece);

(iii) Any report by a patient that she has passed tissue;

(iv) Any report by a patient of foul-smelling discharge;

(v) Any report by a patient that she has soaked two or more sanitary pads in one hour;

(vi) Any report by a patient of a body temperature of 100 degrees Fahrenheit or more;

(vii) Any diagnosis of perforation of the uterus; and

(viii) Any hospitalization of a patient for adverse conditions resulting from a procedure performed at the facility.

2. Efforts shall be made to determine the origin of any infection and if the abortion procedure was found to be related to acquiring the infection, remedial action shall be taken to prevent recurrence. In the event of sustained numbers of infections (three or more patients in one week), the State Health Department shall be immediately notified. Upon order of the Health Department, operation of the facility shall be discontinued until approval for continuation of operation is granted by the State Health Department.

3. If the facility wishes to contest such closure, the Health Department shall provide an opportunity for a hearing under the contested case provisions of the Alabama Administrative Procedures Act. Such hearing shall be held not more than two working days after notice of

appeal is given to the Health Department, unless the facility agrees otherwise. The facility shall be entitled to full rights of appeal from any adverse decision rendered as a result of the hearing, as set forth by law.

(e) Environment. The abortion facility shall provide a safe and sanitary environment, and shall be properly constructed, equipped, and maintained to protect the health and safety of patients and staff.

(9) **Mandatory Reporting.** The abortion facility shall have in place a policy and procedure to obtain the following information:

(a) Any minor child under the age of 16 seeking an abortion from an abortion or reproductive health care facility shall be asked by the physician performing the abortion or his or her agent to state the name and age of the individual who is believed to be the father of the unborn child. While the minor child may refuse to provide the father's name and age, she should be encouraged to do so by the physician or agent consistent with the physician's legal obligation to reduce the incidence of child abuse when there is a reason to suspect that it has occurred.

(b) In addition to any other abuse reporting requirements that may apply to the staff of an abortion or reproductive health center, if the reported age of the father is two or more years greater than the age of the minor child, the facility shall report the names of the pregnant minor child and the father to both local law enforcement and the county Department of Human Resources. If the pregnant minor child is less than 14 years old, the name of the minor child shall be reported to the Department of Human Resources, regardless of whether the father is two or more years older than the minor child. The receipt of reportable information by any member of a facility staff shall trigger the requirement for the facility to report such information.

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Statutory Authority: Code of Ala. 1975, 22-21-20, et seq.
History: Filed September 1, 1982.
Amended: Filed June 2, 1987; November 19, 1987; November 16, 1989; August 16, 1990.
Amended: Filed June 18, 2002; effective July 23, 2002.
Repealed and Replaced: Filed April 17, 2003; effective May 22, 2003.
Amended Appendix only (see Appendix A): Filed September 18, 2003; effective October 23, 2003.
Amended: Filed January 22, 2004; effective February 26, 2004.
Amended: Filed February 21, 2007;effective March 28, 2007.

420-5-1-.04 Physical Environment.

(1) **Existing Facilities.** An existing abortion or reproductive health center shall comply with the requirements for Existing Ambulatory Health Care Occupancy in the currently adopted National Fire Protection Association (NFPA) 101, Life Safety Code.

(2) **Submission of Plans and Specifications.**

(a) Scope. ~~Except as provided in Section 420-5-1.03(4)(e), a~~ A facility constructed or renovated after the effective date of these rules shall be classified as Business Occupancy of the International Building Code, and New Ambulatory Health Care Occupancy of the NFPA Life Safety Code. The facility shall comply with the codes and standards adopted by the State Board of Health in effect at the time of plan submission.

(b) New Facilities ~~Construction~~, Additions, and ~~Major~~ Alterations. Plans and specifications shall be submitted for review and approval to the Alabama Department of Public Health, for any building that is intended to contain an abortion center, and for additions and alterations to existing facilities. ~~When construction is contemplated, either for new buildings, conversions, additions to existing buildings coming within the scope of these Rules, plans and specifications shall be submitted for review by the Alabama Department of Public Health,~~ Submissions shall be in accordance with Alabama Administrative Code ~~Rule~~ Chapter 420-5-22, "Submission of Plans and Specifications for Health Care Facilities."

(c) Minor Alterations and Remodeling. ~~Minor alterations and remodeling which do not affect the structural integrity of the building, which do not change functional operation, which do not affect fire safety, and which do not add beds or facilities over those for which the clinic is licensed, need not be submitted for review.~~ See Alabama Administrative Code Chapter 420-5-22, "Submission of Plans and Specifications for Health Care Facilities," for exceptions to the plan submittal requirements in the case of certain minor alterations or remodeling projects.

(d) Inspections. The State Board of Health and its authorized representatives shall have access to the work for inspection wherever it is in preparation or progress.

(~~2~~3) **General.**

(a) Location. The abortion or reproductive health center shall be located with sufficient parking space provided.

(b) Local Restrictions. The abortion or reproductive health center shall comply with local zoning, building, and fire ordinances in addition to these Rules.

(c) Structural Soundness. The building shall be structurally sound, free from leaks and excessive moisture, in good repair, and painted at intervals to be reasonably attractive inside and out.

(d) Fire Extinguisher. An all-purpose fire extinguisher shall be provided at each exit, special hazard areas and located so that a person will not have to travel more than 75 feet from any point to reach the nearest extinguisher. Fire extinguishers shall be of a type approved by the local fire department or State Fire Marshal and shall be inspected in accordance with the manufacturer's specifications, but not less than ~~annually~~ monthly. An attached tag shall bear the initials or name of the inspector and date inspected. Maintenance on each extinguisher shall be performed by trained personnel at least annually. Maintenance tags showing the year, month, and name of the individual performing maintenance shall be attached to the extinguisher.

(e) Ventilation. The building shall be well ventilated at all times with a comfortable temperature maintained.

(f) Garbage Disposal. Space and facilities shall be provided for the sanitary storage and disposal of waste by incineration, containerization or removal, or by a combination of these techniques. Infectious waste materials shall be rendered non-infectious on the premises by appropriate measures.

(g) Elevators. In multi-story (more than two stories) buildings, at least one elevator for patient use shall be provided.

(h) Doors. Minimum width of doors to all rooms needing access for stretchers shall be 3 feet.

(i) Pest Control. The premises must be free from rodent and insect infestation.

(j) Corridors. Corridors must be of sufficient width to allow stretchers to be maneuvered without impediment. All corridors used as a means of exit shall be a minimum of ~~48~~ 44 inches in width and not be obstructed, or wider when required by code.

(k) Occupancy. No part of an abortion or reproductive health center may be rented, leased, or used for any commercial purpose, or for any purpose not necessary for the operation of the center.

(l) Lighting. All areas of the center shall have sufficient lighting to prevent accidents and promote efficiency of service.

(m) Emergency Lighting. Emergency lighting systems shall be provided to adequately light corridors, procedures rooms, exit signs, stairways and lights at exterior of each exit in case of electrical power failure.

(n) Exits. Each floor of an abortion clinic shall have two or more exits ~~ways~~ remote from each other, leading directly to the outside or to an ~~two-hour fire resistant~~ exit passageway to the outside. Fire resistance ratings of all exit components shall comply with the adopted codes. ~~Exits shall be so located that the maximum distance from any point in a floor area, room or space to an exit doorway shall not exceed 200 feet. If the building is sprinklered, distance may be increased to 300 feet.~~

(o) Exit Doors. Exit doors shall meet the following criteria:

1. Shall be no less than 36 inches wide.

2. Shall swing in the direction of exit and shall not obstruct the travel along any required fire exit.

(p) Exit Signs. Exits~~, except for the front door,~~ shall be equipped with approved illuminated signs. ~~bearing the word "Exit" or "Fire Escape" in letters at least 4½ inches high.~~ Exit signs shall be placed in corridors and passageways to indicate the direction of exit. Exit signs may be omitted at the main exterior exit doors when such is allowed by code.

(q) Interior Finish. ~~Interior finish shall meet the following criteria: 1.~~ Interior wall and ceiling finishes, including combustible, decorative and acoustical material, ~~of exits and of enclosed corridors furnishing access thereto or ways of travel therefrom~~ shall have fire

classification as required by code.~~a flame spread rating of 75 or less or a flame spread rating of 200 or less if facility is sprinklered throughout.~~

~~2. In other areas within facility, the flame spread rating shall be 200 or less.~~

(r) Floors. All interior floors shall be covered wall-to-wall with resilient tile, hard tile, carpet, or the equivalent, and shall have a fire classification as required by code.

~~(s) Carpet. Carpet and/or carpet and pad shall carry a flame spread rating of 75 or less and a smoke density rating of 450 or less in accordance with ASTM E-84.~~

(~~t~~s) Physically Handicapped. The facility shall comply with ANSI A117.1 making buildings and facilities accessible to, and usable by, the physically handicapped.

(~~u~~t) An abortion or reproductive health center shall be equipped with ultrasound equipment~~, a television, and a video cassette player capable of playing VHS video cassettes, or such other~~ and a device ~~video equipment as is compatible with the video format in which~~ capable of displaying the Department of Public Health's abortion educational video program ~~is distributed~~. All such equipment shall be maintained in good operating condition.

(~~3~~4) **Service Facilities.**

(a) Admission Office. There shall be a room designated as the admission office where patients may discuss personal matters in private. The admission office may be combined with the business office and medical records room if privacy can be maintained when confidential matters are being discussed.

(b) Waiting Room. A waiting room in the administrative section shall be provided with sufficient seating for the maximum number of persons that may be waiting at any time. Public toilets, accessible to the physically handicapped, shall be available.

(c) Storage. A janitor's closet and ample storage space shall be provided in the administrative area.

(~~4~~5) **Treatment Facilities.**

(a) Examining Facilities. An examining room of sufficient size to have three feet of clearance at the end and sides of the examining table shall be provided. The examining room will contain a desk suitable for writing, a chair, a lavatory or sink for handwashing, instrument table and shelves or other equipment for storage of equipment as needed. The examining room and procedure room may be the same.

(b) Procedure Room. The procedure room shall have walls and floors covered with a washable surface, a scrub sink with knee, elbow, or foot controls, soap dispenser, and single service towel dispenser.

(c) Recovery Room. One or more recovery rooms containing sufficient beds for recovering patients shall be provided. Reclining type vinyl upholstered chairs may be substituted in lieu of beds. Other items for the patients' comfort may be provided in the room.

(d) Clean Workroom. A clean workroom shall be provided sufficient in size to process and store clean and sterile supply materials and equipment, and must contain a work counter and sink. An autoclave or gas sterilizer must be provided adequate in size to sterilize the equipment in use.

(e) Soiled Workroom. The soiled workroom shall contain a sink, work counter, and waste receptacle. The clean and soiled workroom may be combined if aseptic techniques can be provided.

(f) Toilets. At least one toilet and lavatory with a soap dispenser and towel dispenser shall be provided for each multi-bed recovery room. Toilet facilities shall be provided at no less than one water closet and lavatory per ten recovery beds.

(g) Refrigerator. A refrigerator shall be provided with provisions for safeguarding drugs. The refrigerator shall be capable of maintaining drugs at a temperature of 42 degrees Fahrenheit plus or minus 6 degrees Fahrenheit. If food or beverages are to be stored with drugs, they must be clearly labeled and precautions must be taken to prevent moisture produced by foods and beverages from contaminating drug container contents or defacing labels.

(~~5~~6) **Equipment and Supplies.**

(a) Testing and Diagnostic Equipment. All testing and diagnostic equipment shall be maintained in good working order at all times. If equipment is obsolete or permanently unusable because of irreparable damage or malfunction to the equipment or any other condition that renders its use detrimental to patient care, it shall be immediately separated from the equipment currently in use, clearly tagged as permanently unusable, and properly disposed of as soon as possible. If equipment is temporarily unusable, it shall be immediately separated from equipment currently in use and clearly tagged as being temporarily unusable until it is repaired or otherwise made fit for use. Equipment is temporarily unusable if in need of repair or if not maintained in accordance with manufacturer standards, regardless of whether there is an apparent defect. Tagged equipment shall not be returned to use until repaired and tested to ensure proper operation.

(b) Preventive Maintenance. There shall be a schedule of preventive maintenance developed for all equipment in the facility integral to patient care to assure satisfactory operation thereof. This schedule shall cover at least the following equipment:

1. Ultrasound. All ultrasound machines must be tested and calibrated by a trained, qualified technician in accordance with the manufacturer's recommendations. In no event shall testing and calibration be done less than annually.

2. Autoclave. All autoclaves must be tested and maintained at least annually by a trained, qualified technician in accordance with the manufacturer's recommendations, except that necessary routine weekly cleaning, maintenance, and inspection may be performed by properly trained clinic staff or a trained, qualified technician in accordance with the manufacturer's recommendations. Dated chemical indicators shall be used with every load to ensure sterilization. Biological indicator testing must be performed every 40 service-hours, and the results of the biological indicator testing must be logged.

(c) The facility must maintain a record for all equipment containing the following

information: manufacturer, make, and model of the equipment; date of purchase of the equipment; any dates on which the equipment was removed from service for repair or maintenance and, if applicable, date equipment was returned to service; date and description of all tests, maintenance, or repairs performed on the equipment, including all routine inspection and maintenance performed by clinic personnel; the names and qualifications of the company and technician performing the tests, maintenance, or repairs; and the results of any tests, maintenance, or repairs. In addition, all manufacturer literature and information must be maintained in this record. If any of this information is not available for equipment purchased prior to October 2006, the fact of the missing information shall be noted in the equipment record, and, if there is no record of proper maintenance in the last year, the equipment must be immediately tested and, if necessary, calibrated or repaired.

(d) Medications and supplies which have deteriorated or reached their expiration dates shall not be used for any reason. All expired or deteriorated items shall be disposed of promptly and properly. Each facility shall examine all stored medications and supplies no less frequently than once each month and shall remove from its inventory all deteriorated items and all items for which the expiration date has been reached. The facility shall maintain a log recording each such examination with its date, time, the person conducting the examination, and a description of each item or group of items removed from inventory and the reason for such removal.

(6~~7~~) **Housekeeping Services.**

(a) Personnel. Sufficient personnel are to be employed to maintain the facility clean and orderly.

(b) Techniques. There shall be written procedures outlining techniques to be followed in routine housekeeping and decontamination are to be developed and maintained.

Author: Rick Harris, W.T. Geary, Jr., M.D., Brian Hale, Victor Hunt.
Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.
History: Filed September 1, 1982.
Amended: Filed February 20, 1997; effective March 27, 1997.
Amended: Filed June 18, 2002; effective July 23, 2002.
Repealed and Replaced: Filed April 17, 2003; effective May 22, 2003.
Amended: Filed February 21, 2007; effective March 28, 2007.
Amended: Filed February 21, 2007; effective March 28, 2007.

Appendix A
Attachment to 420-5-1-.03

NOTICE TO ALL PATIENTS

Alabama law provides that abortions may be performed only with the voluntary and informed consent of the patient. This form (front and back) is important to ensure that you have been provided all the information you need to make a fully informed decision. Please complete the form truthfully and accurately.

CERTIFICATION OF RECEIPT OF ABORTION INFORMATION

I certify that I have received the printed materials entitled "Did You Know" and "Alabama's Resource Directory For Women, Children and Families"

by mail on _____ and again in person on _____ .
(date) (date)

OR

only in person on _____
(date)

I understand that Alabama law requires that I be provided these materials at least 24 hours before I undergo an abortion, and I certify that this requirement of the law has been met for me.

_____ _____
Signature of Patient Date

CERTIFICATION OF OPPORTUNITY TO VIEW ULTRASOUND

I certify that Dr. _____, who is the referring physician or the physician who is to perform the abortion, has performed an ultrasound of my unborn child. I certify that I have been offered the opportunity to see this ultrasound and (check only one):

_____ I have reviewed the ultrasound before the abortion.

OR

_____ I rejected the opportunity to view the ultrasound before the abortion.

_____ _____
Signature of Patient Date

CERTIFICATION OF VOLUNTARY AND INFORMED CONSENT FOR ABORTION

On _____, I was informed in person by _____ of
(date) (name of physician or other qualified person)
the following (check all that apply):

____ The abortion will be performed by: _____
(physician's name)

____ The details of the medical or surgical method to be used in performing the abortion, and the medical risks associated with this particular procedure.

____ That I have the right to view an ultrasound of my unborn child, as well as a video entitled "Did You Know," and I have been offered the opportunity to view both.

____ Whether there is a need for me to receive anti-Rh immune globulin therapy, the cost of such therapy, and if I am Rh negative, the likely consequences of refusing such therapy.

____ That I cannot be forced or required by anyone to have an abortion, and that I am free to withhold or withdraw my consent to abortion without affecting my right to any future care or treatment, and without the loss of any state or federally funded benefits to which I might otherwise be entitled.

____ The probable gestational age of my unborn child and the probable anatomical and physiological characteristics of my unborn child as of the date the abortion is to be performed. I have also been advised that (check only one):

____ My unborn child has a gestational age of more than 19 weeks or is viable and that: 1) my child may be able to survive outside the womb; 2) I have the right to request that the physician use the method of abortion that is most likely to preserve the life of my unborn child, provided that method is not prohibited by law; and 3) if my unborn child is born alive, the physician has the legal obligation to take all reasonable steps necessary to maintain the life and health of the child.

OR

____ My unborn child has a gestational age of 19 weeks or less, or an ultrasound has been performed and the physician's good faith clinical judgment is that my unborn child is not viable.

I certify and affirm that I have received the above information, that I have had the opportunity to consider the alternatives available to me, and that I do hereby voluntarily give my fully informed consent to the abortion of my unborn child.

_____ _____
Signature of Patient Date

EMERGENCY MEDICAL ABORTION FORM

Sections 1 and 2 must be completed by the physician performing the emergency medical abortion.

1. It is my good faith clinical judgment that a medical emergency exists that so complicates the medical condition of _____, the patient and a pregnant woman, that an immediate abortion of her pregnancy is necessary. To delay performing this emergency abortion by obtaining informed consent, as otherwise required, would create a serious risk of substantial and irreversible impairment of a major bodily function, or could result in her death. The medical condition(s) that establish this as an emergency is:

_____

_____

_____

_____

_____ _____
Physician MD/DO Date

2. Complete 2A or 2B

A. The patient, _____, was informed prior to the abortion, of the medical conditions which necessitate the performance of an emergency abortion.

_____ _____
Physician MD/DO Date

B. The patient, _____, was not informed prior to the abortion of the medical conditions which necessitate the performance of the emergency abortion, due to the urgency of the situation and the severity of her condition.

_____ _____
Physician MD/DO Date