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**RULES
OF
ALABAMA STATE BOARD OF HEALTH
ALABAMA DEPARTMENT OF PUBLIC HEALTH**

CHAPTER 420-5-1

ABORTION OR REPRODUCTIVE HEALTH CENTERS



WITH LICENSURE LAW

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**STATE OF ALABAMA
DEPARTMENT OF PUBLIC HEALTH
MONTGOMERY, ALABAMA**

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CHAPTER 420-5-1

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420-5-1-.01 General.

- (1) **Legal Authority for adoption of Rules.** Under and by virtue of authority vested in it by the Legislature of Alabama (*Code of Alabama, 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.
 - (b) "Abortion or Reproductive Health Center" means any health care facility operated substantially for the purpose of performing abortions. Such a facility must be a free-standing 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:
 - 1. The health care facility performs thirty or more abortion procedures per month during any two months of a calendar year;
 - 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.
 - (c) "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. 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.
 - (d) "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 hours in any week to two or more individuals not related by blood or marriage to the owner or administrator of the facility.

- (e) "Abortion Clinic", "Clinic", "Abortion Facility", or "Facility" means Abortion or Reproductive Health Center.
- (f) "Gestational Age" means the time that has elapsed since the first day of the woman's last menstrual period.
- (g) "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.
- (h) "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.
- (i) "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.
- (j) "Physician" means a person currently licensed by the Medical Licensure Commission, State of Alabama, to practice medicine or osteopathy pursuant to *Code of Alabama, 1975*, Section 34-24-50, et seq.
- (k) "Registered Professional Nurse (RN)" means a person currently licensed in the State of Alabama pursuant to *Code of Alabama, 1975*, Section 34-21-21.
- (l) "Qualified person" means an agent of the physician who is a psychologist, licensed social worker, licensed professional counselor, registered professional nurse, or physician.
- (m) "Medical 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.

- (n) "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.

(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 Alabama, 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.** 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

Statutory Authority: *Code of Alabama, 1975, 22-21-20, et seq.*

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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 & 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.

(1) Handling of confidential records.

(3) 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. 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 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

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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. A syphilis test, neisseria gonorrhea culture, 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 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 of 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 videotape 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 physician 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. After such examination, the physician shall enter into the patient's medical record the tests or examinations performed, and his findings regarding viability. 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) 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) 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. 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 must be available to provide care for complications arising from an abortion twenty-four hours a day, seven days a week. 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 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.

(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 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 on such form as the State Board of Health may prescribe. Such forms shall in no event contain the name or the address of the patient whose pregnancy was terminated, nor shall they contain any other information identifying the patient. Individual report forms shall not be available for public inspection, 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 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. 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 polices 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.

Author: Rick Harris, Rick Harris, Rick Harris

Statutory Authority: *Code of Alabama, 1975, 22-21-20*, et seq.

History: Repealed and Replaced: Filed April 17, 2003; effective May 22, 2003.

Amended: 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) Submission of Plans and Specifications.

(a) Scope. Except as provided in Section 420-5-1.03(4)(e), a facility constructed or renovated after the effective date of these rules shall be classified as Business Occupancy. The facility shall comply with the code and standards adopted by the State Board of Health in effect at the time of plan submission.

(b) New Construction, Additions, and Major Alterations. 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, in accordance with Alabama Administrative Code Rule 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.

(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) 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. An attached tag shall bear the initials or name of the inspector and date inspected.

(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 inches in width and not be obstructed.

(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 exit ways remote from each other, leading directly to the outside or to a two-hour fire resistant passage to the outside. 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.

(q) Interior Finish. Interior finish shall meet the following criteria:

1. Interior finish, including combustible, decorative and acoustical material, of exits and of enclosed corridors furnishing access thereto or ways of travel therefrom shall have 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 floors shall be covered wall-to-wall with resilient tile, hard tile, carpet, or the equivalent.

(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) Physically Handicapped. The facility shall comply with ANSI 117.1 making buildings and facilities accessible to, and usable by, the physically handicapped.

(u) 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 video equipment as is compatible with the video format in which the Department of Public Health's abortion educational video program is distributed. All such equipment shall be maintained in good operating condition.

(3) 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) 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, 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) 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) 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

Statutory Authority: *Code of Alabama, 1975, 22-21-20, et seq.*

History: Repealed and Replaced: Filed April 17, 2003; effective May 22, 2003.

Amended: Filed February 21, 2007; effective March 28, 2007.

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

MEDICAL EMERGENCY ABORTION FORM

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

APPENDIX C
CODE OF ALA. 1975, SECTIONS 22-21-20, ET SEQ.

§ 22-21-20. Definitions.

For the purpose of this article, the following terms shall have the meanings respectively ascribed to them by this section:

(1) HOSPITALS. General and specialized hospitals, including ancillary services; independent clinical laboratories; rehabilitation centers; ambulatory surgical treatment facilities for patients not requiring hospitalization; end stage renal disease treatment and transplant centers, including free-standing hemodialysis units; abortion or reproductive health centers; hospices; health maintenance organizations; and other related health care institutions when such institution is primarily engaged in offering to the public generally, facilities and services for the diagnosis and/or treatment of injury, deformity, disease, surgical or obstetrical care. Also included within the term are long term care facilities such as, but not limited to, skilled nursing facilities, intermediate care facilities, assisted living facilities, and specialty care assisted living facilities rising to the level of intermediate care. The term "hospitals" relates to health care institutions and shall not include the private offices of physicians or dentists, whether in individual, group, professional corporation or professional association practice. This section shall not apply to county or district health departments.

(2) PERSON. The term includes individuals, partnerships, corporations and associations. (Acts 1975, 3rd Ex. Sess., No. 140, p. 382, § 1; Acts 1979, No. 79-798, p. 1461; Acts 1991, No. 91-548, p. 1010, § 1; Act 1997, No. 97-632, § 1; Act 2001, No. 1058.)

§ 22-21-21. Purpose of article.

The purpose of this article is to promote the public health, safety and welfare by providing for the development, establishment and enforcement of standards for the treatment and care of individuals in institutions within the purview of this article and the establishment, construction, maintenance and operation of such institutions which will promote safe and adequate treatment and care of individuals in such institutions. (Acts 1949, No. 530, p. 835, § 1; Acts 1962, Ex. Sess., No. 122, p. 157, § 1.)

§ 22-21-22. License -- Required; exceptions.

No person shall establish, conduct or maintain any hospital as defined in Section 22-21-20 without first obtaining the license provided in this article. Hospitals operated by the federal government and mental hospitals under the supervision of the board of trustees of the Alabama State Hospitals shall be exempt from the provisions of this article. (Acts 1949, No. 530, p. 835, § 2; Acts 1962, Ex. Sess., No. 122, p. 157, § 2.)

§ 22-21-23. License -- Application.

Any person desiring licensing under this article shall apply to the State Board of Health therefor. The applicant shall state the name of the applicant and whether an individual, partnership, corporation or other entity, the type of institution for which a license is desired, the location thereof and the name of the person in direct supervision and charge thereof. The person in charge of such hospital must be at least 19 years of age and of reputable and responsible character. The applicant shall submit evidence of ability to comply with the minimum standards

provided in this article or by regulations issued under its authority. (Acts 1949, No. 530, p. 835, § 4; Act 2001, No. 1058.)

§ 22-21-24. License -- Fees; term; form; nontransferable; posting; renewal; hospital licensable when accredited by joint commission.

The application for a license to operate a hospital other than an assisted living facility or a specialty care assisted living facility rising to the level of intermediate care shall be accompanied by a standard fee of two hundred dollars (\$200), plus a fee of five dollars (\$5) per bed for each bed over 10 beds to be licensed in accordance with regulations promulgated under Section 22-21-28. Increase in a hospital's bed capacity during the calendar year is assessed at the standard fee of two hundred dollars (\$200) plus five dollars (\$5) each for the net gain in beds. The initial licensure fee and subsequent annual licensure renewal fee for an assisted living facility and for a specialty care assisted living facility rising to the level of intermediate care shall be two hundred dollars (\$200) plus fifteen dollars (\$15) for each bed. A license renewal application for any hospital, as defined by this chapter, which is not received by the expiration date in a properly completed form and accompanied by the appropriate renewal fee shall be subject to a late penalty equal to two hundred fifty dollars (\$250) or 100 percent of the renewal fee, whichever is greater. No fee shall be refunded. All fees received by the State Board of Health under the provision of this article shall be paid into the State Treasury to the credit of the State Board of Health and shall be used for carrying out the provisions of this article. A license granted under this article shall expire on December 31 of the year in which it was granted. A license certificate shall be on a form prescribed by the department, and shall be posted in a conspicuous place on the licensed premises. Licenses shall not be transferable or assignable and shall be granted only for the premises named in the application. Licenses may be renewed from year to year upon application, investigation, and payment of the required license fee, as in the case of procurement of the original license. All fees collected under this article are hereby appropriated for expenditure by the State Health Department. All hospitals which are accredited by the joint commission on accreditation of hospitals shall be deemed by the State Health Department to be licensable without further inspection or survey by the personnel of the State Department of Health. Further accreditation by the joint commission on accreditation of hospitals shall in no way relieve that hospital of the responsibility of applying for licensure and remitting the appropriate licensure fee as specified in this article. (Acts 1949, No. 530, p. 835, § 5; Acts 1975, 3rd Ex. Sess., No. 140, p. 382, § 2; Acts 1980, No. 80-642, p. 1213; Acts 1988, 1st Ex. Sess., No. 88-902, p. 470; Act 2001, No. 1058.)

§ 22-21-25. License -- Issuance; suspension or revocation; new applications after revocation.

(a) The State Board of Health may grant licenses for the operation of hospitals which are found to comply with the provisions of this article and any regulations lawfully promulgated by the State Board of Health.

(b) The State Board of Health may suspend or revoke a license granted under this article on any of the following grounds:

(1) Violation of any of the provisions of this article or the rules and regulations issued pursuant thereto.

(2) Permitting, aiding or abetting the commission of any illegal act in the institution.

(3) Conduct or practices deemed by the State Board of Health to be detrimental to the welfare of the patients of the institution.

(c) Before any license granted under this article is suspended or revoked, written notice shall be given the licensee, stating the grounds of the complaint, and the date, time, and place set for the hearing of the complaint, which date of hearing shall be not less than 30 days from the date of the notice. The notice shall be sent by registered or certified mail to the licensee at the address where the institution concerned is located. The licensee shall be entitled to be represented by legal counsel at the hearing.

(d) If a license is revoked as provided in this section, a new application for license shall be considered by the State Board of Health if, when, and after the conditions upon which revocation was based have been corrected and evidence of this fact has been furnished. A new license shall then be granted after proper inspection has been made and all provisions of this article and rules and regulations promulgated under this article have been satisfied. (Acts 1949, No. 530, p. 835, § 7; Act 2001, No. 1058.)

§ 22-21-26. License -- Judicial review of suspension or revocation.

Any party aggrieved by a final decision or order of the Board of Health suspending or revoking a license is entitled to a review of such decision or order by taking an appeal to the circuit court of the county in which the hospital is located or is to be located. (Acts 1949, No. 530, p. 835, § 11.)

§ 22-21-27. Advisory board.

(a) There shall be an advisory board of 17 members to assist in the establishment of rules, regulations, and standards necessary to carry out the provisions of this article and to serve as consultants to the State Health Officer. The board shall meet at least twice each year and at the call of the State Health Officer. The members of the board shall annually elect one of its members to serve as chairman.

(b) The advisory board shall be constituted in the following manner:

(1) Four representatives of hospitals, who shall be appointed by the Board of Trustees of the Alabama Hospital Association as follows:

- a. One administrator of a governmental hospital.
- b. One administrator of a nongovernmental nonprofit hospital.
- c. One owner or administrator of a proprietary hospital.
- d. One member of a managing board of a nonprofit hospital.

(2) Three representatives who shall be doctors of medicine appointed by the Board of Censors of the Medical Association of the State of Alabama.

(3) One representative who shall be a registered nurse appointed by the executive board of the Alabama State Nurses Association.

(4) One representative from the State Board of Human Resources who shall be appointed by the board.

(5) One registered pharmacist actively engaged in the practices of pharmacy in the State of Alabama, to be appointed by the executive committee of the Alabama Pharmacy Association.

(6) Three members who shall be appointed by the executive committee of the Alabama Nursing Home Association, each of whom shall be the operator of a duly qualified licensed nursing home.

(7) One member shall be appointed by the Alabama Hospice Association.

(8) Two members shall be appointed by the Assisted Living Association of Alabama, one of whom shall be the operator of a licensed assisted living facility or licensed specialty care assisted living facility rising to the level of intermediate care with 16 or fewer beds, and one of whom shall be the operator of an assisted living facility or licensed specialty care assisted living facility rising to the level of intermediate care with more than 16 beds.

(9) One member who shall be appointed by the Governor to represent the interests of consumers. The consumer representative shall be at least 65 years of age and shall have no financial interest in any facility licensed under this article.

Each new appointee shall serve for five years or until his successor is appointed, whichever is later. Any vacancy caused by a member leaving the position before the expiration of his or her term shall be filled by the organization selecting the original member. The replacement member appointed shall serve for the remainder of the unexpired term.

(c) A member of the advisory board shall not be eligible to succeed himself or herself after serving one full five-year term, but shall be eligible for reappointment if he or she has not served immediately preceding the reappointment.

(d) Members of the advisory board shall serve without compensation, but shall be entitled to reimbursement for expenses incurred in the performance of the duties of the office at the same rate allowed state employees pursuant to general law. (Acts 1949, No. 530, p. 835, § 9; Acts 1959, No. 134, p. 656; Acts 1991, No. 91-548, p. 1010, § 1; Act 2001, No. 1058.)

§ 22-21-28. Rules and regulations.

(a) In the manner provided in this section, the State Board of Health, with the advice and after approval by the advisory board, shall have the power to make and enforce, and may modify, amend and rescind, reasonable rules and regulations governing the operation and conduct of hospitals as defined in Section 22-21-20. All such regulations shall set uniform minimum standards applicable alike to all hospitals of like kind and purpose in view of the type of institutional care being offered there and shall be confined to setting minimum standards of sanitation and equipment found to be necessary and prohibiting conduct and practices inimicable to the public interest and the public health. The board shall not have power to promulgate any regulation in conflict with law nor power to interfere with the internal government and operation of any hospital on matters of policy. The procedure for adopting, amending, or rescinding any rules authorized by this chapter shall conform to the Alabama Administrative Procedure Act. At

any public hearing called for the purpose of soliciting public comment on proposed rules, any interested hospital or any member of the public may be heard.

(b) Any person affected by any regulation, amendment, or rescission thereof may appeal consideration thereof to the circuit court of the county of that person's residence or in which that person does business or to the Circuit Court of Montgomery County, pursuant to the Alabama Administrative Procedure Act. And upon appeal, the question of the reasonableness of such regulation shall be a question of fact for the court to determine, and no presumption shall be indulged that the regulation adopted was and is a reasonable regulation.

(c) Regulations adopted under this section shall become effective as provided in the Alabama Administrative Procedure Act. (Acts 1949, No. 530, p. 835, § 8; Act 2001, No. 1058.)

§ 22-21-29. Inspections.

(a) Every hospital licensed under this article shall be open to inspection to the extent authorized in this section by employees and agents of the State Board of Health, under rules as shall be promulgated by the board with the advice and consent of the advisory board. Employees and agents of the board shall also inspect unlicensed and suspected unlicensed facilities. Nothing in this section shall authorize the board to inspect quarters therein occupied by members of any religious group or nurses engaged in work in any hospital or places of refuge for members of religious orders for whom care is provided, but any inspection shall be limited and confined to the parts and portions of the hospital as are used for the care and treatment of the patients and the general facilities for their care and treatment. No hospital shall, by reason of this section, be relieved from any other types of inspections authorized by law.

(b) All inspections undertaken by the State Board of Health shall be conducted without prior notice to the facility and its staff. Notwithstanding the foregoing, an inspection of a hospital or other health care facility, prior to its licensure, may be scheduled in advance. An employee or contract employee of the state shall not disclose in advance the date or the time of an inspection of a hospital or other health care facility to any person with a financial interest in any licensed health care facility, to any employee or agent of a licensed health care facility, to any consultant or contractor who performs services for or on behalf of licensed health care facilities, or to any person related by blood or marriage to an owner, employee, agent, consultant, or contractor of a licensed health care facility. For purposes of this section, the term inspection shall include periodic and follow-up compliance inspections and surveys on behalf of the State Board of Health, complaint investigations and follow-up investigations conducted by the State Board of Health, and compliance inspections and surveys, complaint investigations, and follow-up visits conducted on behalf of the United States Department of Health and Human Services, Health Care Financing Administration, or its successors. The board may prescribe by rule exceptions to the prohibition where considerations of public health or safety make advance disclosure of inspection dates or times reasonable. Disclosure in advance of inspection dates when such disclosure is required or authorized pursuant to federal law or regulation shall not be a violation of this section. Scheduling inspections of hospitals or other health care facilities by the board at regular, periodic intervals which may be predictable shall not be a violation of this section.

(c) Any employee or contract employee of the state who discloses in advance the date or time of an inspection in violation of subsection (b) shall be guilty of a Class A misdemeanor. Any person who solicits an employee or contract employee of the state to disclose in advance the date or time of an inspection in violation of subsection (b) for the purpose of disclosing the

information to others shall be guilty of a Class A misdemeanor. (Acts 1949, No. 530, p. 835, § 6; Act 1997, No. 97-632, § 1; Act 2001, No. 1058.)

§ 22-21-30. Disclosure of information.

Information received by the State Board of Health through on-site inspections conducted by the State Licensing Agency is subject to public disclosure and may be disclosed upon written request. Information received through means other than inspection will be treated as confidential and shall not be directed publicly except in a proceeding involving the question of licensure or revocation of license. (Acts 1949, No. 530, p. 835, § 10; Acts 1975, 3rd Ex. Sess., No. 140, p. 383, § 3.)

§ 22-21-31. Practice of medicine, etc., not authorized; child-placing.

Nothing in this article shall be construed as authorizing any person to engage in any manner in the practice of medicine or any other profession nor to authorize any person to engage in the business of child-placing. Any child born in any such institution whose mother is unable to care for such child or any child who, for any reason, will be left destitute of parental support shall be reported to the Department of Human Resources or to any agency authorized or licensed by the Department of Human Resources to engage in child placing for such service as the child and the mother may require. In the rendering of service, representatives of the Department of Human Resources and agencies authorized or licensed by the Department of Human Resources shall have free access to visit the child and the mother concerned. (Acts 1949, No. 530, p. 835, § 2; Acts 1962, Ex. Sess., No. 122, p. 157, § 2; Act 2001, No. 1058.)

§ 22-21-32. Repealed by Acts 1977, 1st Ex. Sess., No. 82, p. 1509, § 19, effective June 16, 1977.

§ 22-21-33. Penalty for violation of article, etc.

Any individual, association, corporation, partnership, limited liability company, or other business entity who operates or causes to be operated a hospital of any kind as defined in this chapter or any regulations promulgated thereunder without having been granted a license therefore by the State Board of Health shall be guilty of a Class A misdemeanor upon conviction except that the fine may be up to five thousand dollars (\$5,000) upon conviction of a second or any subsequent offense. The State Board of Health, upon determination that a facility or business is operating as a hospital within the meaning of this statute or any rules promulgated thereunder, and that the facility does not have a current, valid license granted by the State Board of Health, may apply to the circuit court of the county in which the unlicensed facility is located for declaratory and injunctive relief. The proceedings shall be expedited. The sole evidentiary questions before the court in a proceeding shall be whether the facility that is the subject of the action meets the definition of a hospital within the meaning of this chapter and any rules promulgated thereunder, and whether the facility has been granted a current and valid license to operate by the State Board of Health. If the State Board of Health prevails on these questions, then the court shall, upon request of the State Board of Health, forthwith grant declaratory and injunctive relief requiring the operator or operators to close the facility and requiring the operator or operators to move all residents or patients to appropriate placements. Any individual failing to obey an injunction to close a hospital shall be guilty of a Class A misdemeanor except that the fine may be up to five thousand dollars (\$5,000). Any individual, after having once been subject to such an injunction, who shall later operate or cause to be operated a hospital as defined in this chapter or any regulations promulgated thereunder without having been granted a license therefore by the State Board of Health shall be guilty of a Class A misdemeanor except that the

fine may be up to five thousand dollars (\$5,000). The State Board of Health may, upon the advice of the Attorney General, maintain an action in the name of the state for an injunction to restrain any state, county or local governmental unit, or any division, department, board or agency thereof, or any individual, association, corporation, partnership, limited liability company, or other business entity, from operating, conducting or managing a hospital in violation of any provisions of this article, or any regulation promulgated thereunder. No county or municipality shall grant a business license to a hospital as defined in this chapter unless the facility holds a current license to operate granted by the State Board of Health. In any action to collect a fee for services brought against a resident or patient by a hospital as defined in this chapter or regulations promulgated thereunder, it shall be a defense to the action to demonstrate that the operator of the hospital did not have a current, valid license to operate pursuant to this chapter at the time the services in question were rendered. (Acts 1949, No. 530, p. 835, § 12.)

Act 2001, No. 1058. Under the circumstances listed below, an assisted living facility or a specialty care assisted living facility rising to the level of intermediate care may be subject to a civil money penalty imposed by the Board of Health not to exceed ten thousand dollars (\$10,000) per instance. The imposition of the penalty may be appealed pursuant to the provisions of the Alabama Administrative Procedure Act. All money penalties imposed pursuant to this section shall be remitted to the Department of Public Health and shall be deposited in the State General Fund. The penalties shall be deposited in the General Fund and shall not be earmarked for the Department of Public Health. Failure of an assisted living facility or a specialty care assisted living facility rising to the level of intermediate care to pay a civil money penalty within 30 days after its imposition or within 30 days after the final disposition of any appeal shall be grounds for license revocation unless arrangements for payment are made that are satisfactory to the State Board of Health. No assisted living facility or specialty care assisted living facility rising to the level of intermediate care may renew its license to operate if it has any unpaid civil money penalties which were imposed more than 30 days prior to the facility's license expiration date, except for any penalties imposed which are still subject to appeal and except for penalties for which arrangements for payment have been made that are satisfactory to the State Board of Health.

A civil money penalty may be imposed for falsification of any record kept by an assisted living facility or specialty care assisted living facility rising to the level of intermediate care, including a medication administration record or any record or document submitted to the State Board of Health, by an employee or agent of the facility, where such falsification is deliberate and undertaken with intent to mislead the Board of Health, or its agents or employees, or residents, sponsors, family members, another state, county, or municipal government agency, or the public, about any matter of legal compliance, regulatory compliance, compliance with fire or life safety codes, or quality of care.

A civil money penalty may be imposed as a result of a false statement made by an employee or agent of an assisted living facility or a specialty care assisted living facility rising to the level of intermediate care to an employee or agent of the State Board of Health, if the statement is made with intent to deceive or mislead the Board of Health, its agents or employees, about any matter of legal compliance, regulatory compliance, compliance with fire or life safety codes, or quality of care. A civil money penalty shall not be imposed if the facility's employee or agent makes a false statement when he or she has no reason to believe the false statement is authorized by the administrator or operator of the facility and if it is likely that the facility's employee or agent made the statement with the intent to cause damage to the facility.

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