APA-1
6/93

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Department or Agency Alabama Department of Public Health

Rule Number 420-5-1-.03
Rule Title Patient Care

_____ New XXX Amend _____ Repeal _____ Adopt by Reference

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

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

Certification of Authorized Official

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

Signature of Certifying Officer _____ Date 10/20/15

FORM APA2
11/96

STATE BOARD OF HEALTH
NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Public Health

RULE NUMBER AND TITLE: 420-5-1-.03, Patient Care

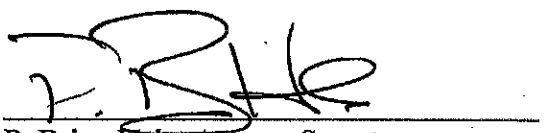
INTENDED ACTION: To amend the current rules

SUBSTANCE OF PROPOSED ACTION: This amendment provides a mechanism for continued operation of a licensed abortion center in the event that there is evidence presented to the Department that no abortion center physician has been able to secure local hospital privileges and that a contract with a qualified covering physician cannot be obtained.

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held on November 24, 2015, at 9:00 a.m., at the RSA Tower, Room 982, 201 Monroe Street, Montgomery, AL 36104.

FINAL DATE FOR COMMENTS AND COMPLETION OF NOTICE: Written or oral comments will be received until the close of the record at 5:00 p.m. on Monday, December 7, 2015. All comments and requests for copies of the proposed amendments should be addressed to the contact person listed below.

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



P. Brian Hale, Agency Secretary

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~~ department physicians, so that all facility nurses and staff cooperate with any physician rendering care for complications arising from an abortion.

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

(3) **Patients' Rights.**

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

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

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

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

(b) Verification of Pregnancy. Pregnancy testing shall be available to the patient and may precede actual registration by the facility. No abortion shall be performed unless the examining physician verifies that the patient is pregnant. Pregnancy test results shall be filed in the patient's medical record.

(c) History and Physical Examination. Prior to the abortion, a medical history shall be obtained and recorded. The patient shall be given an appropriate physical examination, as determined by the physician, which may include testing for sexually transmitted diseases, as indicated below. The facility shall report positive test results for sexually transmitted diseases to the Department of Public Health. Provided that if such results are reported within two business days after receipt to the Department of Public Health, then the Department, and not the abortion clinic, shall be responsible for follow-up and counseling of patients with test results which are positive for sexually transmitted diseases.

(d) Laboratory Tests.

1. The following laboratory tests are required prior to an abortion procedure: hematocrit or hemoglobin, Rh typing, urinalysis as directed by the treating physician, and pregnancy test. Testing for syphilis, gonorrhea, chlamydia, and HIV shall be performed if such 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 testing have been obtained or a waiver of such treatment is signed by the patient. In the case of a medical emergency, as defined in these rules, laboratory tests are not required prior to the procedure.

3. If the above tests are performed by the facility, the facility's laboratory personnel shall meet any requirements which are in effect and which apply to the facility under Rules promulgated by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement ~~Act~~ Amendments of 1988. If the tests are referred, they shall be referred to a hospital, to a pathologist certified, or deemed Board eligible by the American Board of Pathology, who is currently licensed to

practice medicine in Alabama, or who holds an equivalent license in another state, or to an independent clinical laboratory. If the tests are sent to an independent clinical laboratory in Alabama, such laboratory must be licensed by the State to perform clinical and anatomical work. If the tests are referred to a laboratory outside the State, the laboratory must hold an interstate license or letter or exemption under the 1988 Clinical Laboratory Improvement ~~Act~~ Amendments (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 48 hours before the abortion, the physician who is to perform the abortion, the referring physician, or a qualified person has informed and provided the woman in person, or by return receipt certified mail restricted delivery, and if by mail, again in person prior to the abortion, a copy of the printed materials developed by the Department of Public Health which list agencies that offer assistance, adoption agencies, development of the fetus, methods and risks of abortion and childbirth, father's obligations, alternatives to abortion and available methods of birth control. Mailing of the printed materials may be arranged by telephone.

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) Prior to the performance of an abortion, the physician who is to perform the abortion or his or her agent shall receive the signed receipt of the certified mail dated 48 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 the above 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 48 hour waiting period.

8. Consent for Unemancipated and Emancipated Minors. Prior to performing an abortion on a minor, whether unemancipated or emancipated, the physician or his or her agents shall obtain and complete all legally required forms for consent and attach supporting documentation. Forms to be utilized for these purposes are located in Appendix C to these rules and when executed shall, with the supporting documents, be retained as required by these rules as a part of the patient's medical record.

(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 the physician performing the abortion. 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, viability of the fetus and the intrauterine location. After such examination, the physician shall enter into the patient's medical record the tests or examinations performed, and his findings regarding viability and intrauterine location. If the physician determines that the fetus is viable, the pregnancy shall not be terminated at the abortion or reproductive health center except when an immediate abortion is necessary to preserve the life or physical health of the mother.

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

(e) 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.

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

(6) **~~Post-Operative~~ Postoperative Procedures.**

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

care in the event of complications, and the name of the medications given at the abortion clinic.

(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 and must be available to provide care for complications arising from an abortion twenty-four hours a day, seven days a week. Every physician that performs an abortion shall have staff privileges at an acute care hospital within the same standard metropolitan statistical area as the abortion or reproductive health center is located, that permit him or her to perform dilation and curettage, laparotomy procedures, hysterectomy, and any other procedures reasonably necessary to treat abortion-related complications. Please note, ~~E~~enforcement of this requirement is stayed until such time that the restraining order is lifted or there has been a final disposition allowing for enforcement of this requirement in *Planned Parenthood Southeast, et al. v. Strange, et al.*, Civil Action No. 2:13-cv-405-MHT, before the United States District Court for the Middle District of Alabama. Until that time, all licensed abortion or reproductive health centers may comply with these rules if~~, at a minimum,~~ outside covering physician services are obtained through a valid written contract or by maintaining strict compliance with subsection (c) below. 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 he or she will not be available to provide care and he or she does not have another physician who meets ~~neither the outside covering physician nor a substitute physician meeting~~ all the requirements of subsections (b)(1) and (b)(4) ~~will be~~ available to cover for him or her 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~~c) A facility that demonstrates through written documentation its inability to obtain a written contract with an outside covering physician may comply with these rules if, at a minimum, the following criteria are met:

1. The medical director shall ensure that all staff associated with the facility are competent as required by these rules and professional standards of care. There must be documentation maintained in each staff member's personnel file of specific training related to their job description and job duties performed.

2. The training for each staff member shall include training related to the protocol and policy for communication with outside healthcare providers involved in treating patients with post abortion complications. This training shall include notification of the facility medical director or other facility physician of instructions provided to the patient and documented in the patient's medical record.

3. The policy for calls requiring post abortion complication care shall include at least the following:

a. In the event a patient is instructed to present to the nearest emergency department by the facility medical director or other facility physician, the medical director or other facility physician will contact the emergency department and notify its staff of the patient's pending arrival.

b. The medical director or other facility physician shall be available 24/7 to consult with the emergency department physician(s) as necessary during the care of facility patients.

c. A follow-up appointment, with patient consent, will be made with the facility as soon as possible following discharge from the emergency department or hospital.

d. The medical director or other facility physician shall review the complete facility record in detail for all patients that are instructed to present, or who self present, to a hospital emergency department, when such visit is known to the facility, within 24 hours of notification. The purpose of this review is to determine if clinical standards of care were followed by all staff and to identify any information that may aid other healthcare providers in their care of the patient. This review shall be documented in the patient medical record.

e. Documentation of post abortion related care and services provided to a patient of the facility by any outside health care provider shall be included in the facility medical record when such care is known to the facility.

f. The facility policy concerning calls regarding post abortion care must include a list of current working telephone numbers for the medical director and all other facility physicians such that staff are able to reach them 24/7. This list must be readily available to all staff.

g. If the medical director or other facility physician will not be available to consult with emergency department physician(s) or other outside health care provider(s), the facility must be so notified in advance and stop performing abortions no later than 72 hours before the physician's non-availability.

(~~e~~d) Necessity of Physician Availability. A facility may not perform abortions if a facility physician or outside covering physician described in subsection (b) above is not available to provide care for post abortion complications. Alternatively, if the facility has proven an inability to comply with subsection (b), a facility may not perform abortions if the facility's medical director or other facility physician is not available to provide consultation for post abortion complications. If a facility receives notice that no such physician will be available, it must stop performing abortions no later than 72 hours before the physician's non-availability.

(~~d~~e) ~~Post-Operative~~ Postoperative Policies and Procedures. A facility must develop and follow written policies and procedures detailing the sequence of ~~post-operative~~ postoperative 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~~f) 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, date of the procedure, location of the emergency department the patient is presenting to, if known and applicable, 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~~g) ~~Post-Operative~~ Postoperative Instructions. Written instructions shall be issued to all patients upon discharge and shall include at least:

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

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

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

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

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

(~~g~~h) 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 10 days after the last day of the month during which the procedure was performed. A copy of the report shall be kept in the patient's medical record. All reports shall be in a format prescribed by the State Registrar. In no event shall the information reported to the Center for Health Statistics contain the name or the address of the patient whose pregnancy was terminated or any other information identifying the patient. Individual reports shall not be available for public inspection and the information shall be maintained in strict confidence by the Center for Health Statistics. The Center for Health Statistics shall annually make available to the public aggregate data about the number of abortions performed in clinical settings statewide. The Director of the Center for Health Statistics may authorize the release of other aggregate statistical data for official government use. In no event shall the Center release the names of individual physicians or other staff members employed by abortion or reproductive health centers.

(7) **Pharmaceutical Services.**

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

(b) Administering, Dispensing, and Prescribing Drugs and Medicines. Only physicians and properly credentialed nurse practitioners, and physician assistants may prescribe or order medications. Nurse practitioners and physician assistants may prescribe only those medications described in their individual collaborative agreements. Except for standing orders as permitted below, medications shall be prescribed for patients of the facility by patient name after an appropriate medical

evaluation. Oral and telephone orders shall be received only by a physician, nurse practitioner, physician assistant, registered professional nurse, licensed practical nurse, or a pharmacist. Oral and telephone orders shall be immediately documented in writing by the individual receiving the order. Prescribing, dispensing, and administration of medications shall meet all standards required by law and by regulations of the State Board of Medical Examiners and the State Board of Pharmacy. Abortifacient medications shall be prescribed only by a physician. Only a physician may give, sell, dispense, administer, or otherwise prescribe an abortion-inducing drug. The physician giving, selling, dispensing, administering, or otherwise providing or prescribing the abortion-inducing drug shall first examine the pregnant woman in person and document, in the woman's medical chart, the gestational age and intrauterine location of the pregnancy prior to giving, selling, dispensing, administering, or otherwise providing or prescribing the abortion-inducing drug.

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

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

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

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

(g) Emergency Kit or Emergency Drugs.

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

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

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

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

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

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

(8) **Infection Control.**

(a) Infection Control Committee.

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

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

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

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

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

2. Length of time to accomplish sterilization.

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

4. Temperature, time and pressure for steam sterilization.

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

6. Shelf storage time for sterile items.

7. Use of sterilizer indicators.

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

(d) Investigation of Infections.

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

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

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

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

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

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

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

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

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

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

discontinued until approval for continuation of operation is granted by the State Health Department.

3. If the facility wishes to contest such closure, the Health Department shall provide an opportunity for a hearing under the contested case provisions of the Alabama Administrative Procedures Act. Such hearing shall be held not more than two working days after notice of appeal is given to the Health Department, unless the facility agrees otherwise. The facility shall be entitled to full rights of appeal from any adverse decision rendered as a result of the hearing, as set forth by law.

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

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

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

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

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