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AGENCY HEALTH CARE ADMIN

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JEB BUSH, GOVERNOR

CHRISTA CALAMAS, SECRETARY

August 24, 2006

Brian T. Moore
 Chief Attorney
 Joint Administrative Procedures Committee
 120 Holland Building
 600 South Calhoun Street
 Tallahassee, Florida 32399-1300

RECEIVED
 2006 AUG 24 PM 1:40
 JOINT ADMINISTRATIVE
 PROCEDURES COMMITTEE

Dear Mr. Moore:

This letter is in response to your letter of August 22, 2006, wherein you commented on and had questions about portions of the proposed changes to Chapter 59A-9, F.A.C. The Agency responds to each point as follows:

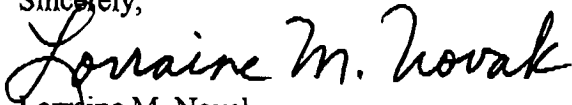
- 9.019(25)** In the definition of "first trimester," the parenthetical "(the first 14 completed weeks from the last normal menstrual period)" is equivalent to "the first 12 weeks of pregnancy." As we discussed, the conclusion that the parenthetical is the equivalent of "the first 12 weeks of pregnancy" was reached after consultation with Agency physicians as well as after review of written comments and letters the Agency received from other medical professionals during the rulemaking process. It was clear from the medical professionals that the term "first twelve weeks of pregnancy" and "first 14 completed weeks from the last normal menstrual period" are used interchangeably by physicians, and in fact describe the same time period with the same ending point.
- 9.020(1)** The Agency has added the mailing address and complete website address for this form. A copy of the revised rule was provided to you in our meeting today. I am attaching another copy to this letter for your convenience.
- 9.020(5)** See 9.020(1).
- 9.023(4)** The Agency has corrected this typographical error. Please see the attached revised rule.
- 9.027(3)** The form's title, effective date, and complete address where it can be obtained are included in the attached revised rule.
- 9.034** A copy of the Department of Health form was provided to you at today's meeting; another copy is attached for your convenience. Also, the complete mailing address for obtaining the form has been added to the attached revised rule.



Having responded to these concerns and made the necessary corrections and additions, it is my understanding that your office would certify the rule for the Department of State. The Agency intends to file this rule for final adoption on September 5, 2006. Please let me know if there is any further information I can provide to you as you prepare to certify this rule.

Finally, I want to thank you again for meeting at our office today. Your comments and questions were very helpful, as we continue in the rulemaking process.

Sincerely,



Lorraine M. Novak
Assistant General Counsel

Attachments

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PROCEDURES COMMITTEE

CHAPTER 59A-9 ABORTION CLINICS

- 59A-9.018 Purpose.
- 59A-9.019 Definitions.
- 59A-9.020 Licensure Procedures.
- 59A-9.021 Investigations and License and Validation Inspections.
- 59A-9.022 Physical Plant Requirements for Abortion Clinics When Providing Second Trimester Abortions.
- 59A-9.0225 Clinic Supplies and Equipment Standards for Second Trimester Abortions.
- 59A-9.023 Clinic Personnel. ~~Clinic Staff and Consultants~~
- 59A-9.024 Clinic Policies and Procedures for Second Trimester Abortions.
- 59A-9.025 Medical Screening and Evaluation of Patients Receiving Second Trimester Abortions.
- 59A-9.026 Second Trimester Abortion Procedure.
- 59A-9.027 Recovery Room Standards for Second Trimester Abortions.
- 59A-9.028 Post Procedure Follow-up Care for Patients Receiving Second Trimester Abortions.
- 59A-9.029 Abortion Clinic Incident Reporting for Second Trimester Abortions.
- 59A-9.030 Disposal of Fetal Remains.
- 59A-9.031 Clinical Records.
- 59A-9.034 Reports.

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59A-9.018 Purpose.

The agency adopts the following minimum rules and standards governing services in the first and second trimesters provided in an abortion clinic to comply with the requirements of Chapters 381 and 390, F.S.

Specific Authority 390.012 F.S. Law Implemented 381.0012, 382, 390.011, 390.012, 390.013 FS. History—New 6-13-90, Formerly 10D-72.018.

59A-9.019 Definitions.

The following definitions shall apply specifically to abortion clinics.

- (1) "Abortion" means the termination of human pregnancy with the intention other than to produce a live birth or to remove a dead fetus.
- (2) "Abortion Clinic" or "Clinic" means a facility, institution, or place in which abortions are performed other than a hospital or a physician's office that is not used primarily for the performance of abortions.
- (3) "Anesthesiologist" means a person currently licensed to practice medicine or osteopathy pursuant to Chapter 458 or 459, Florida Statutes, and certified by the American Board of Anesthesiology.
- (3) "~~Consultant~~" means ~~an individual who provides professional services either upon request or on the basis of a prearranged schedule, usually on a contract basis, who is neither a member of the employed staff of the facility, nor whose services are provided within the terms of an affiliation agreement.~~

(4) "Advanced Registered Nurse Practitioner, (ARNP)" means a person currently licensed pursuant to Chapter 464, Florida Statutes.

(5) (4) "Agency" "AHCA" means the Agency for Health Care Administration.

(6) "Certified Registered Nurse Anesthetist, (CRNA)" means a person currently licensed pursuant to Chapter 464, Florida Statutes, and certified by the Council on Certification of Nurse Anesthetists.

(7) (12) "Clinical staff" means the individuals employed full or part time by an abortion clinic who are licensed or certified to provide care prior to, during, or after an abortion.

(8) "Department" means the Department of Health.

(9) (5) "F.A.C." means the Florida Administrative Code.

(10) (6) "Facility" means those objects, including physical plant, equipment, and supplies necessary for providing required services.

(11) (7) "Hospital" means a facility licensed under Chapter 395, F.S.

(12) (8) "License" means the certificate issued by the agency for the operation of the facility. This document constitutes the authority to receive patients and to perform the services included within the scope of this rule and as specified on the license.

(13) (9) "Licensed" means that person or facility to which the term is applied has a current or valid license, certificate or registration issued by the State of Florida to follow his profession or vocation within the State of Florida, and when applied to a health care facility means that the facility has a current license issued by the agency AHCA.

(14) (10) "Licensee" means the person who has been granted a license to operate an abortion clinic and who has ultimate authority and responsibility for the operation, management, control, conduct, and functioning of the abortion clinic.

(15) (11) "Licensure" means the process of obtaining official or legal permission to operate an abortion clinic.

(16) "Licensed Practical Nurse, (L.P.N.)" means a person currently licensed as an L.P.N. pursuant to Chapter 464, Florida Statutes.

(17) "Medical Director" means a physician licensed under Chapter 458 or Chapter 459, F.S., and who has admitting privileges at a licensed hospital in this state or has a transfer agreement with a licensed hospital within reasonable proximity of the abortion clinic.

(18) (13) "Patient" means any woman receiving services in an abortion clinic.

(19) (14) "Person" means any individual, firm, partnership, corporation, or association.

(20) "Physician Assistant, (P.A.)" means a person currently licensed as a P.A. pursuant to Chapter 458 or 459, Florida Statutes.

(21) (15) "Physician" means a ~~person physician~~ currently licensed to practice medicine or osteopathy pursuant to Chapter 458 or 459, F.S. ~~under Chapter 458 or Chapter 459, F.S., or a physician practicing medicine or osteopathy in the employment of the United States or this state.~~

(22) (16) "Premises" means those buildings, beds, and facilities of the clinic and all other buildings, beds, and facilities for the performance of abortions located in such reasonable proximity to the main address of the licensee and appear to the public to be under the domain and the control of the licensee.

(23) "Reasonable proximity" means a distance not to exceed thirty (30) minutes transport time by emergency vehicle.

(24) "Registered Professional Nurse, (R.N.)" means a person currently licensed as a R.N. pursuant to Chapter 464, Florida Statutes.

(25) "Trimester" means a 12-week period of pregnancy.

- (a) First Trimester. The first 12 weeks of pregnancy (the first 14 completed weeks from the last normal menstrual period).
- (b) Second Trimester. That portion of a pregnancy following the 12th week and extending through the 24th week of gestation.
- (c) Third Trimester. That portion of pregnancy beginning with the 25th week of gestation.

(26) "Volunteer" means a person who is not employed by the facility who interacts with patients on behalf of the abortion clinic.

Specific Authority 390.012 F.S. Law Implemented 390.011, 390.012, 390.013 FS.

History--New

6-13-90, Amended 4-17-91, Formerly 10D-72.019, Amended 8-24-94, _____.

59A-9.020 Licensure Procedures.

(1) All persons ~~planning~~ ~~contemplating~~ the operation of an abortion clinic under the provisions of Chapter 390, F.S., shall make application for a license to the Agency for Health Care Administration, Office of Health Facility Regulation, Tallahassee, Florida, on Agency Form 3130-1000-revised July, 2005 ~~MAR-94~~, "Abortion Clinic Licensure Application", hereby incorporated by reference, which can be obtained from the Agency for Health Care Administration, Hospital and Outpatient Services Unit, Mail Stop 31, 2727 Mahan Drive, Office of Health Facility Regulation, Tallahassee, Florida, 32308 or on the agency website at:

http://ahca.myflorida.com/MCHO/Health_Facility_Regulation/Hospital_Outpatient/abort

ion.shtml, and ~~must shall~~ receive a license prior to the acceptance of patients for care and treatment. The application shall be made under oath and shall contain such information as the agency AHCA reasonably requires, which may include evidence of the applicant's ability to comply with applicable laws and rules.

(2) A license fee of \$250 shall accompany the application for a license or a license renewal. The license fee shall be made payable to the agency and is not refundable.

(3) Each license shall be valid only for the persons to whom it is issued and shall not be subject to sale, assignment, or other transfer, voluntary or involuntary, nor shall a license be valid for any premises other than for which it was originally issued.

(4) A current license shall be posted in a conspicuous place within ~~on~~ the licensed premises where it can be viewed by patients.

(5) A license, unless sooner suspended or revoked, shall automatically expire one year from the date of issuance, and shall be renewable annually upon application for renewal and payment of the fee prescribed by these rules, provided that the applicant and abortion clinic meet the requirements established under Chapter 390, F.S., and Chapter 59A-9, F.A.C. Application for renewal of a license shall be made not less than 60 days prior to expiration of a license on agency Form 3130-1000-revised July 2005 ~~MAR 94~~, available from ~~provided by~~ the Agency for Health Care Administration, Hospital and Outpatient Services Unit, Mail Stop 31, 2727 Mahan Drive, AHCA Office of Health Facility Regulation, Tallahassee, Florida 32308. The application is also available on-line at the agency website at:
http://ahca.myflorida.com/MCHO/Health_Facility_Regulation/Hospital_Outpatient/abortion.shtml.

(6) Where the agency finds that there has been a failure to comply with the requirements established under this part or in rules promulgated hereunder, the agency is authorized to deny, modify, suspend, or revoke a license.

Specific Authority 390.012, F.S. Law Implemented 20.42(2)(a), 390.011, 390.012, 390.014, 390.015, 390.016, 390.017, 390.018, 390.019, 390.021 FS. History—New 6-13-90, Amended 4-17-91, 10-9-91, Formerly 10D-72.020, Amended 8-24-94, _____.

59A-9.021 Investigations and License and Validation Inspections.

(1) The agency AHCA has the right to enter an abortion clinic to make or cause to be made such inspections and investigations as are necessary to:

(a) Assure compliance with the licensure requirements; and standards as specified in statute and rule;

(b) Respond to complaints; and

(c) Protect the public health and safety.

(2) The agency shall conduct an annual unannounced licensure inspection of all abortion clinics facilities.

(3) The fee for the renewal license shall be \$250.

(4) Representatives of the agency shall have the right to enter upon the premises of any facility licensed or applying for license, pursuant to this Chapter, at any reasonable time in order to determine the state of compliance with the provisions of Chapter 390, F.S., and these rules, providing that such entry and inspection shall be made with the least possible disruption to clinic activities and in a manner considerate of the privacy and

confidentiality of any patient who is present therein. All inspections shall be unannounced.

Specific Authority 390.012 F.S. Law Implemented 381.0012, 382, 390.011, 390.012, 390.014, 390.019 FS. History—New 6-13-90, Amended 4-17-91, 10-9-91, Formerly 10D-72.021, Amended _____.

59A-9.022 Physical Plant Requirements for Abortion Clinics When Providing

Second Trimester Abortions.

The following are minimum standards of construction and specified minimum essential physical plant requirements which must be met when providing second trimester abortions. These requirements shall apply to all new abortion clinic construction and shall apply to any abortion clinics receiving an initial license after the effective date of these rules when the abortion clinic provides second trimester abortions. Any abortion clinic which provides second trimester abortions and is in operation at the time of adoption of this rule shall be given one year within which to comply with the physical plant requirements.

- (1) Consultation room(s) with adequate private space specifically designated for interviewing, counseling, and medical evaluations;
- (2) Dressing rooms designated for staff and patients;
- (3) Handwashing station(s) equipped with a mixing valve and wrist blades and located in each patient exam/procedure room or area;
- (4) Private procedure room(s) with adequate light and ventilation for abortion procedures;

- (5) Post procedure recovery room(s) equipped to meet the patient's needs;
- (6) Emergency exits wide enough to accommodate a standard stretcher or gurney;
- (7) Cleaning and sterilizing area(s) adequate for the cleaning and sterilizing of instruments;
- (8) Adequate and secure storage area(s) for the storage of medical records and necessary equipment and supplies; and
- (9) If not otherwise required by the Florida Building Code, at least one general use toilet room equipped with a hand washing station.

Specific Authority: 390.012(1), F.S. Law Implemented 390.012(3)(a), 390.013 F.S.

History-New _____

59A-9.0225 Clinic Supplies and Equipment Standards for Second Trimester

Abortions.

- (1) Each abortion clinic providing second trimester abortions shall provide essential clinic supplies and equipment as required in (1) through (7) when performing second trimester abortions. Any such abortion clinic which is in operation at the time of adoption of this rule and providing second trimester abortions shall be given one year within which to meet these standards as follows:
 - (a) A surgical or gynecological examination table(s);
 - (b) A bed or recliner(s) suitable for recovery;
 - (c) Oxygen with flow meters and masks or equivalent;
 - (d) Mechanical suction;

(e) Resuscitation equipment to include, at a minimum, resuscitation bags and oral airways;

(f) Emergency medications, intravenous fluids, and related supplies and equipment;

(g) Sterile suturing equipment and supplies;

(h) Adjustable examination light;

(i) Containers for soiled linen and waste materials with covers; and

(j) Appropriate equipment for the administering of general anesthesia, if applicable.

(2) Emergency equipment shall be provided for immediate use, maintained in functional condition, and capable of providing at least the following services:

(a) Inhalation therapy;

(b) Defibrillation;

(c) Cardiac monitoring;

(d) Suctioning; and

(e) Maintenance of patient airway.

(3) Anesthesia.

(a) The clinic shall have anesthesia equipment maintained in proper working order for the appropriate administering of general and local anesthesia, analgesia, and sedation if ordered by the physician.

(b) All reusable anesthesia equipment in direct contact with the patient shall be cleaned or sterilized as appropriate after each use and such cleaning and sterilization shall be documented.

(4) Resuscitative Medications Required.

The clinic shall have a crash cart at the location the anesthetizing is being carried out.

The crash cart must include, at a minimum, those emergency medications to support the procedures performed as determined by the medical director.

(5) Sterilization Equipment.

Sterilizing equipment of appropriate type shall be available and of adequate capacity to properly sterilize instruments and materials. The sterilizing equipment shall have approved control and safety features.

(6) Ultrasound equipment shall be located in the clinic.

(7) Equipment Maintenance.

(a) When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to insure proper operation, and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper calibration before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.

(b) All anesthesia and surgical equipment shall have a written preventive maintenance program developed and implemented. Equipment shall be checked and tested in accordance with the manufacturer's specifications at designated intervals, not less than annually, to ensure proper operation and a state of good repair.

(c) All surgical instruments shall have a written preventive maintenance program developed and implemented. Surgical instruments shall be cleaned and checked for function after use to ensure proper operation and a state of good repair.

Specific Authority: 390.012(1), F.S. Law Implemented 390.012(3)(b), 390.013F.S.

History_____.

59A-9.023 Clinic Personnel ~~Clinic Staff and Consultants~~

Abortions shall be performed only by a licensed physician. Each abortion clinic providing second trimester abortions shall have a staff that is adequately trained and capable of providing appropriate service and supervision to the patients. The clinic will have a position description for each position delineating duties and responsibilities and maintain personnel records for all employees performing or monitoring patients receiving a second trimester abortion. Any abortion clinic which is in operation at the time of adoption of this rule and performing second trimester abortions shall be given six months within which to comply with these clinical staff requirements as follows:

(1) Physicians.

The clinic shall designate a licensed physician to serve as a medical director.

(2) Nursing Personnel.

Nursing personnel in the clinic shall be governed by written policies and procedures relating to patient care, establishment of standards for nursing care and mechanisms for evaluating such care, and nursing services.

(3) Allied health professionals, working under appropriate direction and supervision, may be employed to work only within areas where their competency has been established.

(4) Orientation. Each facility shall have and execute a written orientation program to familiarize each new staff member, including volunteers, with the facility and its policies

and procedures, to include, at a minimum, fire safety and other safety measures, medical emergencies, and infection control.

(5) In-service Training. In-service training programs shall be planned and provided for all employees including full time, part time and contract employees, at the beginning of employment and at least annually thereafter and will also apply to all volunteers to insure and maintain their understanding of their duties and responsibilities. Records shall be maintained to reflect program content and individual attendance. The following training shall be provided at least annually, and for surgical assistants and volunteers, must include training in counseling, patient advocacy and specific responsibilities associated with the services they provide:

(a) Infection control, to include at a minimum, universal precautions against blood-borne diseases, general sanitation, personal hygiene such as hand washing, use of masks and gloves, and instruction to staff if there is a likelihood of transmitting a disease to patients or other staff members.

(b) Fire protection, to include evacuating patients, proper use of fire extinguishers, and procedures for reporting fires;

(c) Confidentiality of patient information and records, and protecting patient rights;

(d) Licensing regulations; and

(e) Incident reporting.

Specific Authority: 390.012, F.S. Law Implemented 381.0012, 382, 390.011, 390.012,

390.013F.S. History—New 6-13-90, Amended 4-17-91, Formerly 10D-72.023,

Amended _____.

59A-9.024 Clinic Policies and Procedures for Second Trimester Abortions.

An abortion clinic providing second trimester abortions shall have written policies and procedures to implement policies and to assure that quality patient care shall relate specifically to the functional activities of clinic services. These written procedures shall apply to second trimester abortions and shall be available and accessible to clinic personnel and shall be reviewed and approved annually by the clinic's medical director. Any abortion clinic which is in operation at the time of adoption of this rule and providing second trimester abortions shall be given six months within which to comply with these clinic policies and procedure requirements which shall include but not be limited to the following:

1. Patient admission;
2. Pre- and post-operative care;
3. Physician's orders;
4. Standing orders with required signatures;
5. Medications, storage and administration;
6. Treatments;
7. Surgical asepsis;
8. Medial asepsis;
9. Sterilization and disinfection;
10. Documentation: Medical records and facility records;
11. Patient discharge;
12. Patient transfer;
13. Emergency measures;

14. Incident reports;

15. Personnel orientation;

16. Inservice education record;

17. Anesthesia;

18. Equipment and supplies: availability and maintenance;

19. Volunteers; and

20. Visitors.

Specific Authority: 390.012(1), F.S. Law Implemented 390.012(3)(c), 390.013F.S.

History--New _____

59A-9.025 Medical Screening and Evaluation of Patients Receiving Second

Trimester Abortions.

(1) Each abortion clinic that provides second trimester abortions shall formulate and adhere to written patient care policies and procedures designed to ensure professional and safe care for patients undergoing second trimester abortions and shall maintain a medical record for each such patient that records history, care and services. Any abortion clinic that performs second trimester abortions which is in operation at the time of adoption of this rule shall be given six months within which to comply with these patient care policies and procedures for patients undergoing second trimester abortions, to include but not limited to the following:

(a) Admission criteria and procedures;

(b) Identification in the medical record of physician(s) and nurse(s) involved in providing the services offered for patients undergoing second trimester abortions;

(c) Specific details regarding the pre-operative procedures performed, to include:

1. History and physical examination, to include verification of pregnancy, estimation of gestational age, identification of any preexisting conditions or complications; including allergies to medications, antiseptic solutions, or latex; and a complete obstetric and gynecological history.

2. Special examinations, lab procedures, and/or consultations required, to include ultrasonography to confirm gestational age and a physical examination including a bimanual examination estimating uterine size and palpation of the adnexa. The physician shall keep original prints of each ultrasound examination of a patient in the patient's medical history file. For an abortion in which an ultrasound examination is not performed before the abortion procedure, urine or blood tests for pregnancy shall be performed before the abortion procedure.

(2) Laboratory Services.

(a) Laboratory services shall be provided on-site or through arrangement with a laboratory that holds the appropriate federal Clinical Laboratory Improvement Amendments (CLIA) certificate and state of Florida clinical laboratory license issued pursuant to Chapter 483, Part I, Florida Statutes.

(b) All laboratory services provided on-site shall be performed in compliance with state of Florida clinical laboratory licensure and federal CLIA provisions.

(3) Laboratory Equipment and Supplies.

(a) All equipment and supplies for the collection, storage, and testing of specimens shall meet the provisions of Rule 59A-7 F.A.C. and shall be maintained according to manufacturer's instructions and in a manner that ensures accurate test results.

(b) Temperature controlled spaces for the storage of specimens or testing supplies shall be monitored and recorded to ensure that the proper storage temperature is maintained.

(c) All dated supplies and materials shall not be used beyond their expiration date.

(d) Adequate facilities and supplies for the collection, storage and transportation of laboratory specimens shall be available on site.

(4) Rh factor. Rh testing for Rh negative patients shall be conducted, unless reliable written documentation of blood type is available.

(5) All laboratory test reports shall be placed in the patient's medical record.

(6) All laboratory test and storage areas, records and reports shall be available for inspection by the agency.

(7) If a person who is not a physician performs an ultrasound examination, that person shall have documented evidence that he or she has completed a course in the operation of ultrasound equipment. The physician, registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant shall, at the request of the patient and before the abortion procedure is performed, review the ultrasound evaluation results with the patient, including an estimate of the probable gestational age of the fetus.

(8) A test for anemia shall be performed.

Specific Authority: 390.012(1), F.S. Law Implemented 390.012(3)(d), 390.013F.S.

History—New _____.

59A-9.026 Second Trimester Abortion Procedure .

Any abortion clinic which is providing second trimester abortions must be in compliance with the following standards relative to second trimester abortion procedures. Any

abortion clinic in operation at the time of adoption of this rule, when performing second trimester abortions, shall be given six months within which to comply.

(1) A physician, registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant shall be available to all patients throughout the abortion procedure.

(2) The abortion procedure will be performed in accordance with obstetric standards and in keeping with established standards of care regarding the estimation of gestational age of the fetus.

(3) Anesthesia service shall be organized under written policies and procedures relating to anesthesia staff privileges, the administration of anesthesia, and the maintenance of strict safety controls.

(4) Prior to the administration of anesthesia, patients shall have a history and physical examination by the individual administering anesthesia, including laboratory analysis when indicated.

(5) Appropriate precautions, such as the establishment of intravenous access at least for patients undergoing post-first trimester abortions.

(6) Appropriate monitoring of the patient's vital signs by professionals licensed and qualified to assess the patient's condition will occur throughout the abortion procedure and during the recovery period until the patient's condition as specified by the type of abortion procedure performed, is deemed to be stable in the recovery room.

Specific Authority: 390.012(1), F.S. Law Implemented 390.012(3)(e), 390.013 F.S.

History--New ..

59A-9.027 Recovery Room Standards for Second Trimester Abortions.

Each abortion clinic which is providing second trimester abortions shall comply with the following recovery room standards when providing second trimester abortions. Any abortion clinic providing second trimester abortions and in operation at the time of adoption of this rule shall be given one year within which to comply with these standards.

(1) Following the procedure, post procedure recovery rooms will be supervised and staffed to meet the patient's needs. A physician or physician assistant, a licensed registered nurse, a licensed practical nurse or an advanced registered nurse practitioner who is trained in the management of the recovery area shall be available to monitor the patient in the recovery room until the patient is discharged. The individual must be certified in basic cardiopulmonary resuscitation. A patient in the post-operative or recovery room shall be observed for as long as the patient's condition warrants.

(2) The clinic shall arrange hospitalization if any complication beyond the medical capability of the staff occurs or is suspected. The clinic shall ensure that all appropriate equipment and services are readily accessible to provide appropriate emergency resuscitative and life support procedures pending the transfer of the patient or a viable fetus to the hospital. A physician shall sign the discharge order and be readily accessible and available until the last patient is discharged to facilitate the transfer of emergency cases if hospitalization of the patient or viable fetus is necessary. The clinic medical records documenting care provided shall accompany the patient. These records will include the contact information for the physician who performed the procedure at the clinic.

(3) A physician shall discuss Rho (D) immune globulin with each patient for whom it is indicated and will ensure that it is offered to the patient in the immediate postoperative period or that it will be available to the patient within 72 hours following completion of the abortion procedure. If the patient refuses the Rho (D) immune globulin, refusal Form 3130-1002, January 2006, "Refusal to Permit Administration of Rh(D) Immunoglobulin", herein incorporated by reference, shall be signed by the patient and a witness, and shall be included in the patient's medical record. The form can be obtained by written request from the Agency for Health Care Administration, Hospital and Outpatient Services Unit, Mail Stop 31, 2727 Mahan Drive, Tallahassee, Florida, 32308, or from the agency website at:

http://ahca.myflorida.com/MCHO/Health_Facility_Regulation/Hospital_Outpatient/abortion.shtml.

(4) Written instructions with regard to post abortion coitus, signs of possible medical complications, and general aftercare shall be given to each patient. Each patient shall have specific written instructions regarding access to medical care for complications, including a telephone number to call for medical emergencies. The physician will ensure that either a registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant from the abortion clinic makes a good faith effort to contact the patient by telephone, with the patient's consent, within 24 hours after surgery to assess the patient's recovery. A contact for post-operative care from the facility shall be available to the patient on a 24-hour basis.

(5) Facility procedures must specify the minimum length of time for recovery as warranted by the procedure type and gestation period.

Specific Authority: 390.012(1), F.S. Law Implemented 390.012(3)(f), 390.013 F.S.

History-New _____.

59A-9.028 Post Procedure Follow-up Care for Patients Receiving Second Trimester Abortions.

Each abortion clinic which is providing second trimester abortions shall comply with the following post procedure follow-up care requirements when providing a second trimester abortion. Any abortion clinic operating at the time of adoption of this rule shall be given six months within which to comply.

(1) The clinic shall offer a post abortion medical visit that includes a medical examination and a review of the results of all laboratory tests.

(2) A urine pregnancy test will be obtained at the time of the follow-up visit to rule out continuing pregnancy. If a continuing pregnancy is suspected, the patient shall be evaluated and a physician who performs abortions shall be consulted.

(3) The clinic shall provide for the education of the patient in post-procedure care, including specific instructions in case of emergency.

Specific Authority: 390.012(1), F.S. Law Implemented 390.012(3)(g), 390.013 F.S.

History-New _____.

59A-9.029 Abortion Clinic Incident Reporting for Second Trimester Abortions.

This section shall apply to incidents involving patients receiving second trimester abortions in any abortion clinic providing second trimester abortions. Those abortion clinics providing second trimester abortions which are in operation at the time of

adoption of this rule shall be given six months within which to comply with the following clinic incident reporting requirements.

(1) At a minimum an abortion clinic shall record each incident that results in serious injury to a patient as defined in s. 390.012(3)(h)1, F.S. or a viable fetus at an abortion clinic and shall report an incident in writing to the agency within 10 days after the incident occurs.

(2) If a patient death occurs the abortion clinic shall report the death to the department and the appropriate regulatory board not later than the next workday. The report to the department shall be filed as required by Rule 64V-1.0061, F.A.C.

Specific Authority: 390.012(1), F.S. Law Implemented 390.012(3)(h), 390.013 F.S.

History-New _____.

59A-9.030 Disposal of Fetal Remains.

Fetal remains shall be disposed of in a sanitary and appropriate manner and in accordance with standard health practices and Chapters 381, 390, F.S., and ~~64E-16 10D-104~~, F.A.C.

Specific Authority 390.012 FS. Law Implemented 381.0012, 382, 390.011, 390.012 F.S.

History-New 6-13-90, Amended 4-17-91, Formerly 10D-72.030, Amended _____.

59A-9.031 Clinical Records.

(1) A permanent individual clinical record shall be kept on each clinic patient.

(a) Clinical records shall be complete, accurately documented, and systematically organized to facilitate storage and retrieval.

(b) Clinical records involving second trimester abortion procedures shall be kept confidential and secure.

(c) Operative reports signed by the physician performing the second trimester abortion shall be recorded in the clinical record immediately following the procedure or that an operative progress note is entered in the clinical record to provide pertinent information.

(2) Clinical records shall be kept on file for a minimum of five years from the date of the last entry.

Specific Authority 390.012 FS. Law Implemented 381.0012, 382, 390.011, 390.012, 390.013 FS. History--New 6-13-90, Amended 4-17-91, Formerly 10D-72.031, Amended _____.

59A-9.034 Reports.

Pursuant to Chapters 382 and 390, F.S., an abortion clinic must submit a report each month to the Office of Vital Statistics of the Department of Health and Rehabilitative Services, regardless of the number of terminations of pregnancy. Monthly reports must be received by the department within 30 days following the preceding month using DOH HRS-Form 1578, May 2004 May-94, "Monthly Report of Induced Terminations of Pregnancy", hereby incorporated by reference, and which can be obtained by written request from the Department of Health and Rehabilitative Services, Office of Vital Statistics, Public Health Statistics, P.O. Box 210, Jacksonville, Florida 32231-0042, or by telephone request at (904) 359-6900, extension 1049.

Specific Authority 390.012 FS. Law Implemented 20.42(2)(a), 382.002, 390.002, 390.011, 390.012 FS. History--New 6-13-90, Formerly 10D-72.034,

Amended 8-24-94. _____.

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JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE



STATE OF FLORIDA
Department of Health

MONTHLY REPORT OF INDUCED TERMINATIONS OF PREGNANCY

THIS REPORT IS FOR THE MONTH AND YEAR OF: _____

1. FACILITY NAME		2. FACILITY ADDRESS (Street Address):	
3. CITY OF FACILITY:	4. COUNTY:	5. ZIP CODE:	6. TELEPHONE NUMBER AND AREA CODE:
7. DIRECTOR, PHYSICIAN OR AUTHORIZED REPRESENTATIVE:		8. TITLE	
9. SIGNATURE		10. DATE SIGNED	

<input type="checkbox"/> PERSONAL CHOICE				
<input type="checkbox"/> PHYSICAL CONDITION				
<input type="checkbox"/> MENTAL CONDITION				
<input type="checkbox"/> ABNORMAL FETUS				
<input type="checkbox"/> OTHER (Specify):				

PLEASE SEND THIS REPORT TO:

**DEPARTMENT OF HEALTH
OFFICE OF VITAL STATISTICS
PUBLIC HEALTH STATISTICS
P.O. Box 210
JACKSONVILLE, FL 32231-0042**

FLORIDA LAW REQUIRES THE DIRECTOR OF ANY MEDICAL FACILITY IN WHICH ANY PREGNANCY IS TERMINATED, OR PHYSICIAN PERFORMING THE PROCEDURE, TO SUBMIT A MONTHLY REPORT TO THE DEPARTMENT OF HEALTH, OFFICE OF VITAL STATISTICS, FOR RECEIPT WITHIN 30 DAYS FOLLOWING THE PRECEDING MONTH. ANY PERSON REQUIRED TO FILE A REPORT WHO WILLFULLY FAILS TO FILE SUCH, MAY BE SUBJECT TO A \$200 FINE FOR EACH VIOLATION (SECTION 390.002(1) AND (4)), FLORIDA STATUTES, AND CHAPTER 59-A-9.034, (FLORIDA ADMINISTRATIVE CODE).

DH Form 1578, May 04. (Replaces Nov 99, which may not be used)

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ATTACHMENT 2