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Aspen State Regulation Set: A 4.02 ABORTION CLINIC

ST - A0000 - INITIAL COMMENTS

Title INITIAL COMMENTS

Statute or Rule

Type Memo Tag

Regulation Definition

Interpretive Guideline

These guidelines are meant solely to provide guidance to surveyors in the survey process. This regulation set incorporates recent regulatory changes. Citations for Abortion Clinics (A tags) are not classed.

ST - A0010 - Definitions

Title Definitions

Statute or Rule 390.011 & 390.01114 FS; 59A-9.019, FAC

Type Memo Tag

Regulation Definition

Interpretive Guideline

390.011 Definitions.-As used in this chapter, the term:

- (1) "Abortion" means the termination of human pregnancy with an intention other than to produce a live birth or to remove a dead fetus.
- (2) "Abortion clinic" or "clinic" means any facility in which abortions are performed. The term does not include:
 - (a) A hospital; or
 - (b) A physician's office, provided that the office is not used primarily for the performance of abortions.
- (3) "Agency" means the Agency for Health Care Administration.
- (4) "Born alive" means the complete expulsion or extraction from the mother of a human infant, at any stage of development, who, after such expulsion or extraction, breathes or has a beating heart, or definite and voluntary movement of muscles, regardless of whether the umbilical cord has been cut

First Trimester versus Second Trimester Abortion Clinics:

All regulations in this set apply to clinics which perform second Trimester Abortions, but only some apply to First Trimester Abortion clinics

Verify the type of clinic being surveyed by viewing the license. The License for Abortion Clinics will specify either:
First Trimester Abortions Only or
First & Second Trimester Abortions Only

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and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, caesarean section, induced abortion, or other method.

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

(6) "Gestation" means the development of a human embryo or fetus between fertilization and birth.

(7) "Hospital" means a facility as defined in s. 395.002(12) and licensed under chapter 395 and part II of chapter 408.

(8) "Partial-birth abortion" means a termination of pregnancy in which the physician performing the termination of pregnancy partially vaginally delivers a living fetus before killing the fetus and completing the delivery.

(9) "Physician" means a physician licensed under chapter 458 or chapter 459 or a physician practicing medicine or osteopathic medicine in the employment of the United States.

(10) "Reasonable medical judgment" means a medical judgment that would be made by a reasonably prudent physician, knowledgeable about the case and the treatment possibilities with respect to the medical conditions involved.

(11) "Standard medical measure" means the medical care that a physician would provide based on the particular facts of the pregnancy, the information available to the physician, and the technology reasonably available in a hospital, as defined in s. 395.002, with an obstetrical department, to preserve the life and health of the fetus, with or without temporary artificial life-sustaining support, if the fetus were born at the same stage of fetal development.

(12) "Trimester" means one of the following three distinct periods of time in the duration of a pregnancy:

(a) "First trimester," which is the period of time from fertilization through the end of the 11th week of gestation.

(b) "Second trimester," which is the period of time from the beginning of the 12th week of gestation through the end of the 23rd week of gestation.

(c) "Third trimester," which is the period of time from the

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beginning of the 24th week of gestation through birth.

(13) "Viable" or "viability" means the stage of fetal development when the life of a fetus is sustainable outside the womb through standard medical measures.

390.01114 Parental Notice of Abortion Act.-

(1) SHORT TITLE.-This section may be cited as the "Parental Notice of Abortion Act."

(2) DEFINITIONS.-As used in this section, the term:

(a) "Actual notice" means notice that is given directly, in person or by telephone, to a parent or legal guardian of a minor, by a physician, at least 48 hours before the inducement or performance of a termination of pregnancy, and documented in the minor's files.

(b) "Child abuse" means abandonment, abuse, harm, mental injury, neglect, physical injury, or sexual abuse of a child as those terms are defined in ss. 39.01, 827.04, and 984.03.

(c) "Constructive notice" means notice that is given in writing, signed by the physician, and mailed at least 72 hours before the inducement or performance of the termination of pregnancy, to the last known address of the parent or legal guardian of the minor, by first-class mail and by certified mail, return receipt requested, and delivery restricted to the parent or legal guardian. After the 72 hours have passed, delivery is deemed to have occurred.

(d) "Medical emergency" means a condition that, on the basis of a physician's good faith clinical judgment, so complicates the medical condition of a pregnant woman as to necessitate the immediate termination of her pregnancy to avert her death, or for which a delay in the termination of her pregnancy will create serious risk of substantial and irreversible impairment of a major bodily function.

(e) "Sexual abuse" has the meaning ascribed in s. 39.01.

(f) "Minor" means a person under the age of 18 years.

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59A-9.019 Definitions.

The following definitions shall apply specifically to abortion clinics.

- (1) "Anesthesiologist" means a person currently licensed to practice medicine or osteopathy pursuant to Chapters 458 or 459, F.S., and certified by the American Board of Anesthesiology.
- (2) "Certified Registered Nurse Anesthetist, (CRNA)" means a person currently licensed pursuant to Chapter 464, F.S., and certified by the Council on Certification of Nurse Anesthetists.
- (3) "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.
- (4) "F.A.C." means the Florida Administrative Code.
- (5) "Facility" means those objects, including physical plant, equipment, and supplies necessary for providing required services.
- (6) "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.
- (7) "Licensure" means the process of obtaining official or legal permission to operate an abortion clinic.
- (8) "Medical Director" means a physician licensed under Chapters 458 or 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.
- (9) "Patient" means any woman receiving services in an abortion clinic.
- (10) "Person" means any individual, firm, partnership, corporation, or association.

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(11) "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.

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

(13) "Registered Professional Nurse, (R.N.)" means a person currently licensed as a R.N. pursuant to Chapter 464, F.S.

(14) "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.

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

ST - A0050 - Licensure Procedures

Title Licensure Procedures

Statute or Rule 390.014(2) FS

Type Rule

Regulation Definition

390.014 Licenses; fees.-

(2) A separate license shall be required for each clinic maintained on separate premises, even though it is operated by the same management as another clinic; but a separate license shall not be required for separate buildings on the same premises.

Interpretive Guideline

Applies to all abortion clinics

The License for Abortion Clinics will specify either:

First Trimester Abortions Only or

First & Second Trimester Abortions Only

Is the license posted in a readily visible location to patients?

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Does the address on the license match the clinics physical location?

ST - A0100 - Physical Plant Req.-2nd Trimester

Title Physical Plant Req.-2nd Trimester

Statute or Rule 59A-9.022, FAC

Type Rule

Regulation Definition

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

Interpretive Guideline

Applies only to clinics that perform 2nd Trimester Abortions

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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.

ST - A0150 - Clinic Supplies/Equip. Stand.-2nd Trimester

Title Clinic Supplies/Equip. Stand.-2nd Trimester

Statute or Rule 59A-9.0225(1), FAC

Type Rule

Regulation Definition

Interpretive Guideline

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

Applies only to clinics that perform 2nd Trimester Abortions

(1) Each abortion clinic providing second trimester abortions shall provide essential clinic supplies and equipment as required in subsections (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.

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ST - A0151 - Clinic Supplies/eqpt.-2nd Trimest-Emerg eqpt

Title Clinic Supplies/eqpt.-2nd Trimest-Emerg eqpt

Statute or Rule 59A-9.0225(2), FAC

Type Rule

Regulation Definition

Interpretive Guideline

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

Applies only to clinics that perform 2nd Trimester Abortions

(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.

ST - A0152 - Clinic Supplies/eqpt.-2nd Trimest--Anesthesia

Title Clinic Supplies/eqpt.-2nd Trimest--Anesthesia

Statute or Rule 59A-9.0225(3), FAC

Type Rule

Regulation Definition

Interpretive Guideline

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

Applies only to clinics that perform 2nd Trimester Abortions

(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.

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(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.

ST - A0153 - Clinic Suppl/eqt-2d Trimes-Resuscitative Meds

Title Clinic Suppl/eqt-2d Trimes-Resuscitative Meds

Statute or Rule 59A-9.0225(4), FAC

Type Rule

Regulation Definition

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

Interpretive Guideline

Applies only to clinics that perform 2nd Trimester Abortions

(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.

ST - A0154 - Clinic Suppl/eqt-2nd Trimest-Sterilization Eq

Title Clinic Suppl/eqt-2nd Trimest-Sterilization Eq

Statute or Rule 59A-9.0225(5), FAC

Type Rule

Regulation Definition

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

(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

Interpretive Guideline

Applies only to clinics that perform 2nd Trimester Abortions

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control and safety features.

ST - A0155 - Clinic Suppl/eqpt-2nd Trimester-Ultrasound Eqpt

Title Clinic Suppl/eqpt-2nd Trimester-Ultrasound Eqpt

Statute or Rule 59A-9.0225(6), FAC

Type Rule

Regulation Definition

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

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

Interpretive Guideline

Applies only to clinics that perform 2nd Trimester Abortions

ST - A0156 - Clinic Suppl/eqp-2nd Trimester-Eqpt Maintenance

Title Clinic Suppl/eqp-2nd Trimester-Eqpt Maintenance

Statute or Rule 59A-9.0225(7), FAC

Type Rule

Regulation Definition

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

(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

Interpretive Guideline

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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.

ST - A0200 - Clinic Personnel-Licensed Physician

Title Clinic Personnel-Licensed Physician

Statute or Rule 309.0111(2) FS; 59A-9.023, FAC

Type Rule

Regulation Definition

309.0111, F.S.

(2) PERFORMANCE BY PHYSICIAN REQUIRED.-No termination of pregnancy shall be performed at any time except by a physician as defined in s. 390.011.

59A-9.023, FAC

Abortions shall be performed only by a licensed physician.

Interpretive Guideline

Applies to all abortion clinics

See tag A0010 above. Physician means a person currently licensed to practice medicine or osteopathy pursuant to Chapter 458 or 459, F.S.

ST - A0201 - Clinic Personnel-2nd Trimester

Title Clinic Personnel-2nd Trimester

Statute or Rule 59A-9.023(1-3), FAC

Type Rule

Regulation Definition

Each abortion clinic providing second trimester abortions shall

Interpretive Guideline

Applies only to clinics that perform 2nd Trimester Abortions

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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.

ST - A0202 - Clinic Personnel-2nd Tri-Orientation/Training

Title Clinic Personnel-2nd Tri-Orientation/Training

Statute or Rule 59A-9.023(4-5), FAC

Type Rule

Regulation Definition

(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,

Interpretive Guideline

Applies only to clinics that perform 2nd Trimester Abortions

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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.

ST - A0250 - Clinic Policies/Procedures-2nd Trimester

Title Clinic Policies/Procedures-2nd Trimester

Statute or Rule 59A-9.024, FAC

Type Rule

Regulation Definition

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

Interpretive Guideline

Applies only to clinics that perform 2nd Trimester Abortions

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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.

ST - A0300 - Medical Screening/Eval.-2nd Trimester

Title Medical Screening/Eval.-2nd Trimester

Statute or Rule 59A-9.025(1), FAC

Type Rule

Regulation Definition

(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

Interpretive Guideline

Applies only to clinics that perform 2nd Trimester Abortions

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and shall maintain a medical record for each such patient that records history, care and services. Any abortion clinic that performs second trimester abortions shall 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 past surgeries, 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. Urine or blood tests for pregnancy shall be performed before the abortion procedure.

ST - A0301 - Medical Screening/eval.-2nd Trimester-Lab Svc

Title Medical Screening/eval.-2nd Trimester-Lab Svc

Statute or Rule 59A-9.025(2) and (4-8), FAC

Type Rule

Regulation Definition

59A-9.025 Medical Screening and Evaluation of Patients Receiving Second Trimester Abortions.
(2) Laboratory Services.

Interpretive Guideline

Applies only to clinics that perform 2nd Trimester Abortions

Review the clinic's personnel records and a sample of patient records to ensure that all required documentation has

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- (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, F.S.
- (b) All laboratory services provided on-site shall be performed in compliance with state of Florida clinical laboratory licensure and federal CLIA provisions.
- (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.
- (8) A test for anemia shall be performed.

been made.

If patient specimens (blood or urine) are tested on site:

A CLIA Certificate of Waiver is required if on site testing is limited to tests categorized as waived, such as a waived pregnancy/HCG tests.

A CLIA Certificate of Compliance or CLIA Certificate of Accreditation and a State of Florida Clinical Laboratory License is required for on site nonwaived testing such as Rh testing or nonwaived HCG testing.

For Rh testing performed on site, the laboratory must:

- a. Have testing reagents that are not expired and stored at the proper temperature as indicated on the manufacturer's instructions or label.
- b. Be enrolled in proficiency testing (CLIA approved proficiency testing includes, but is not limited to, enrollment in American Proficiency Institute, American Association of Bioanalysts, or College of American Pathologists)
- c. Perform and document quality control of the kit or reagents (positive and negative controls).
- d. Document patient test results.

ST - A0302 - Medical Screening/eval.-2nd Tri-Lab Eq/Suppl

Title Medical Screening/eval.-2nd Tri-Lab Eq/Suppl

Statute or Rule 59A-9.025(3), FAC

Type Rule

Regulation Definition

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

(3) Laboratory Equipment and Supplies.

(a) All equipment and supplies for the collection, storage, and testing of specimens shall meet the provisions of Chapter 59A-7, F.A.C., and shall be maintained according to

Interpretive Guideline

Applies only to clinics that perform 2nd Trimester Abortions

59A-7 F.A.C. is the chapter for Clinical Laboratories. (see excerpt below)

59A-7.023(5) Food, drink, items used for patient care or treatment, or medication shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where biomedical waste or other potentially infectious materials or laboratory testing supplies, including reagents, are present.

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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.

(a) If clinical specimens are collected, have on its premises a refrigerator equipped with an accurate thermometer and capable of maintaining a temperature range of 2-8 degrees centigrade.

(c) Record daily temperature of the refrigerator when in use.

ST - A0350 - Abortion Procedure-2nd Trimester

Title Abortion Procedure-2nd Trimester

Statute or Rule 59A-9.026, FAC

Type Rule

Regulation Definition

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.

Interpretive Guideline

Applies only to clinics that perform 2nd Trimester Abortions

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(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.

ST - A0360 - Termination/3rd Trimester, When Allowed

Title Termination/3rd Trimester, When Allowed

Statute or Rule 390.0111(1), FS

Type Rule

Regulation Definition

(1) TERMINATION IN THIRD TRIMESTER; WHEN ALLOWED.-No termination of pregnancy shall be performed on any human being in the third trimester of pregnancy unless one of the following conditions is met:

(a) Two physicians certify in writing that, in reasonable medical judgment, the termination of the pregnancy is necessary to save the pregnant woman's life or avert a serious risk of substantial and irreversible physical impairment of a major bodily function of the pregnant woman other than a psychological condition.

(b) The physician certifies in writing that, in reasonable medical judgment, there is a medical necessity for legitimate emergency medical procedures for termination of the pregnancy to save the pregnant woman's life or avert a serious risk of imminent substantial and irreversible physical

Interpretive Guideline

Applies to all abortion clinics

Has the clinic performed any 3rd trimester abortions? Was necessity certified in writing?

See related third trimester abortion regulations in tag A0366, A0370 and A0380.

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impairment of a major bodily function of the pregnant woman other than a psychological condition, and another physician is not available for consultation.

ST - A0362 - Termination/Consents Required

Title Termination/Consents Required

Statute or Rule 390.0111(3)(a), FS

Type Rule

Regulation Definition

(3) CONSENTS REQUIRED.-A termination of pregnancy may not be performed or induced except with the voluntary and informed written consent of the pregnant woman or, in the case of a mental incompetent, the voluntary and informed written consent of her court-appointed guardian.

(a) Except in the case of a medical emergency, consent to a termination of pregnancy is voluntary and informed only if:

1. The physician who is to perform the procedure, or the referring physician, has, at a minimum, orally, in person, informed the woman of:

a. The nature and risks of undergoing or not undergoing the proposed procedure that a reasonable patient would consider material to making a knowing and willful decision of whether to terminate a pregnancy.

b. The probable gestational age of the fetus, verified by an ultrasound, at the time the termination of pregnancy is to be performed.

(I) The ultrasound must be performed by the physician who is to perform the abortion or by a person having documented evidence that he or she has completed a course in the operation of ultrasound equipment as prescribed by rule and who is working in conjunction with the physician.

Interpretive Guideline

Applies to all abortion clinics

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(II) The person performing the ultrasound must offer the woman the opportunity to view the live ultrasound images and hear an explanation of them. If the woman accepts the opportunity to view the images and hear the explanation, a physician or a registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant working in conjunction with the physician must contemporaneously review and explain the images to the woman before the woman gives informed consent to having an abortion procedure performed.

(III) The woman has a right to decline to view and hear the explanation of the live ultrasound images after she is informed of her right and offered an opportunity to view the images and hear the explanation. If the woman declines, the woman shall complete a form acknowledging that she was offered an opportunity to view and hear the explanation of the images but that she declined that opportunity. The form must also indicate that the woman's decision was not based on any undue influence from any person to discourage her from viewing the images or hearing the explanation and that she declined of her own free will.

(IV) Unless requested by the woman, the person performing the ultrasound may not offer the opportunity to view the images and hear the explanation and the explanation may not be given if, at the time the woman schedules or arrives for her appointment to obtain an abortion, a copy of a restraining order, police report, medical record, or other court order or documentation is presented which provides evidence that the woman is obtaining the abortion because the woman is a victim of rape, incest, domestic violence, or human trafficking or that the woman has been diagnosed as having a condition that, on the basis of a physician's good faith clinical judgment, would create a serious risk of substantial and irreversible impairment of a major bodily function if the woman delayed terminating her pregnancy.

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c. The medical risks to the woman and fetus of carrying the pregnancy to term.

2. Printed materials prepared and provided by the department have been provided to the pregnant woman, if she chooses to view these materials, including:

- a. A description of the fetus, including a description of the various stages of development.
- b. A list of entities that offer alternatives to terminating the pregnancy.
- c. Detailed information on the availability of medical assistance benefits for prenatal care, childbirth, and neonatal care.

3. The woman acknowledges in writing, before the termination of pregnancy, that the information required to be provided under this subsection has been provided.

Nothing in this paragraph is intended to prohibit a physician from providing any additional information which the physician deems material to the woman's informed decision to terminate her pregnancy.

ST - A0365 - Termination/Consents & Medical Emergency

Title Termination/Consents & Medical Emergency

Statute or Rule 390.0111(3)(b) FS

Type Rule

Regulation Definition

(b) If a medical emergency exists and a physician cannot comply with the requirements for informed consent, a physician may terminate a pregnancy if he or she has obtained at least one corroborative medical opinion attesting to the medical necessity for emergency medical procedures and to the fact that to a reasonable degree of medical certainty the

Interpretive Guideline

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continuation of the pregnancy would threaten the life of the pregnant woman. If a second physician is not available for a corroborating opinion, the physician may proceed but shall document reasons for the medical necessity in the patient's medical records.

ST - A0366 - Termination/Std of Medical Care 3rd Trimester

Title Termination/Std of Medical Care 3rd Trimester

Statute or Rule 390.0111(4) FS

Type Rule

Regulation Definition

(4) STANDARD OF MEDICAL CARE TO BE USED IN THIRD TRIMESTER.-If a termination of pregnancy is performed in the third trimester, the physician performing the termination of pregnancy must exercise the same degree of professional skill, care, and diligence to preserve the life and health of the fetus which the physician would be required to exercise in order to preserve the life and health of a fetus intended to be born and not aborted. However, if preserving the life and health of the fetus conflicts with preserving the life and health of the pregnant woman, the physician must consider preserving the woman's life and health the overriding and superior concern.

Interpretive Guideline

Applies to all abortion clinics

See related regulation at A0370

ST - A0367 - Termination/Partial-Birth

Title Termination/Partial-Birth

Statute or Rule 390.0111(5) FS

Type Rule

Regulation Definition

(5) PARTIAL-BIRTH ABORTION PROHIBITED;

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EXCEPTION.-

- (a) No physician shall knowingly perform a partial-birth abortion.
- (b) A woman upon whom a partial-birth abortion is performed may not be prosecuted under this section for a conspiracy to violate the provisions of this section.
- (c) This subsection shall not apply to a partial-birth abortion that is necessary to save the life of a mother whose life is endangered by a physical disorder, illness, or injury, provided that no other medical procedure would suffice for that purpose.

(7) "Partial-birth abortion" means a termination of pregnancy in which the physician performing the termination of pregnancy partially vaginally delivers a living fetus before killing the fetus and completing the delivery. 390.011(7)

Interview clinic staff and physician regarding any Partial Birth abortions conducted. Review those records.

ST - A0368 - Termination/Experimentation on Fetus

Title Termination/Experimentation on Fetus

Statute or Rule 390.0111(6) FS

Type Rule

Regulation Definition

(6) EXPERIMENTATION ON FETUS PROHIBITED;
EXCEPTION.-No person shall use any live fetus or live, premature infant for any type of scientific, research, laboratory, or other kind of experimentation either prior to or subsequent to any termination of pregnancy procedure except as necessary to protect or preserve the life and health of such fetus or premature infant.

Interpretive Guideline

Applies to all abortion clinics

ST - A0370 - Termination/Infants Born Alive

Title Termination/Infants Born Alive

Statute or Rule 390.0111(12)(a-d) FS

Type Rule

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Regulation Definition

(12) INFANTS BORN ALIVE.-

(a) An infant born alive during or immediately after an attempted abortion is entitled to the same rights, powers, and privileges as are granted by the laws of this state to any other child born alive in the course of natural birth.

(b) If an infant is born alive during or immediately after an attempted abortion, any health care practitioner present at the time shall humanely exercise the same degree of professional skill, care, and diligence to preserve the life and health of the infant as a reasonably diligent and conscientious health care practitioner would render to an infant born alive at the same gestational age in the course of natural birth.

(c) An infant born alive during or immediately after an attempted abortion must be immediately transported and admitted to a hospital pursuant to s. 390.012(3)(c) or rules adopted thereunder.

(d) A health care practitioner or any employee of a hospital, a physician's office, or an abortion clinic who has knowledge of a violation of this subsection must report the violation to the department.

Interpretive Guideline

Applies to all abortion clinics

ST - A0380 - Termination of Pregnancy During Viability

Title Termination of Pregnancy During Viability

Statute or Rule 390.01112 FS

Type Rule

Regulation Definition

(1) No termination of pregnancy shall be performed on any human being if the physician determines that, in reasonable medical judgment, the fetus has achieved viability, unless:

(a) Two physicians certify in writing that, in reasonable medical judgment, the termination of the pregnancy is

Interpretive Guideline

Applies to all abortion clinics

(12) "Viable" or "viability" means the stage of fetal development when the life of a fetus is sustainable outside the womb through standard medical measures.

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necessary to save the pregnant woman's life or avert a serious risk of substantial and irreversible physical impairment of a major bodily function of the pregnant woman other than a psychological condition; or

(b) The physician certifies in writing that, in reasonable medical judgment, there is a medical necessity for legitimate emergency medical procedures for termination of the pregnancy to save the pregnant woman's life or avert a serious risk of imminent substantial and irreversible physical impairment of a major bodily function of the pregnant woman other than a psychological condition, and another physician is not available for consultation.

(2) Before performing a termination of pregnancy, a physician must determine if the fetus is viable by, at a minimum, performing a medical examination of the pregnant woman and, to the maximum extent possible through reasonably available tests and the ultrasound required under s. 390.0111(3), an examination of the fetus. The physician must document in the pregnant woman's medical file the physician's determination and the method, equipment, fetal measurements, and any other information used to determine the viability of the fetus.

(3) If a termination of pregnancy is performed during viability, the physician performing the termination of pregnancy must exercise the same degree of professional skill, care, and diligence to preserve the life and health of the fetus that the physician would be required to exercise in order to preserve the life and health of a fetus intended to be born and not aborted. However, if preserving the life and health of the fetus conflicts with preserving the life and health of the woman, the physician must consider preserving the woman's life and health the overriding and superior concern.

Ask clinic staff if there have been any live births. Sample those records. Was there all due diligence to preserve life?

Before abortion, physician must determine viability by at least an Ultrasound, physical exam and reasonably available tests (examples: bimanual examination (pelvic exam) and HCG testing)

See related A0366 and A0370

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ST - A0385 - Parental Notification

Title Parental Notification

Statute or Rule 390.01114(3) FS

Type Rule

Regulation Definition

(3) NOTIFICATION REQUIRED.-
(a) Actual notice shall be provided by the physician performing or inducing the termination of pregnancy before the performance or inducement of the termination of the pregnancy of a minor. The notice may be given by a referring physician. The physician who performs or induces the termination of pregnancy must receive the written statement of the referring physician certifying that the referring physician has given notice. If actual notice is not possible after a reasonable effort has been made, the physician performing or inducing the termination of pregnancy or the referring physician must give constructive notice. Notice given under this subsection by the physician performing or inducing the termination of pregnancy must include the name and address of the facility providing the termination of pregnancy and the name of the physician providing notice. Notice given under this subsection by a referring physician must include the name and address of the facility where he or she is referring the minor and the name of the physician providing notice. If actual notice is provided by telephone, the physician must actually speak with the parent or guardian, and must record in the minor's medical file the name of the parent or guardian provided notice, the phone number dialed, and the date and time of the call. If constructive notice is given, the physician must document that notice by placing copies of any document related to the constructive notice, including, but not limited to, a copy of the letter and the return receipt, in the minor's medical file. Actual notice given by telephone shall be

Interpretive Guideline

Applies to all abortion clinics

Refer to Definitions applicable under the Parental Notice of Abortion Act in A0010, Definitions

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confirmed in writing, signed by the physician, and mailed to the last known address of the parent or legal guardian of the minor, by first-class mail and by certified mail, return receipt requested, with delivery restricted to the parent or legal guardian.

(b) Notice is not required if:

1. In the physician's good faith clinical judgment, a medical emergency exists and there is insufficient time for the attending physician to comply with the notification requirements. If a medical emergency exists, the physician shall make reasonable attempts, whenever possible, without endangering the minor, to contact the parent or legal guardian, and may proceed, but must document reasons for the medical necessity in the patient's medical records. The physician shall provide notice directly, in person or by telephone, to the parent or legal guardian, including details of the medical emergency and any additional risks to the minor. If the parent or legal guardian has not been notified within 24 hours after the termination of the pregnancy, the physician shall provide notice in writing, including details of the medical emergency and any additional risks to the minor, signed by the physician, to the last known address of the parent or legal guardian of the minor, by first-class mail and by certified mail, return receipt requested, with delivery restricted to the parent or legal guardian;
2. Notice is waived in writing by the person who is entitled to notice and such waiver is notarized, dated not more than 30 days before the termination of pregnancy, and contains a specific waiver of the right of the parent or legal guardian to notice of the minor's termination of pregnancy;
3. Notice is waived by the minor who is or has been married or has had the disability of nonage removed under s. 743.015 or a similar statute of another state;
4. Notice is waived by the patient because the patient has a minor child dependent on her; or

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5. Notice is waived under subsection (4).
(c) Violation of this subsection by a physician constitutes grounds for disciplinary action under s. 458.331 or s. 459.015.

ST - A0400 - Recovery Rm Stand.-2nd Trimester

Title Recovery Rm Stand.-2nd Trimester

Statute or Rule 59A-9.027, FAC

Type Rule

Regulation Definition

Each abortion clinic which is providing second trimester abortions shall comply with the following recovery room standards when providing second trimester abortions.

(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

Interpretive Guideline

Applies only to clinics that perform 2nd Trimester Abortions

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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/MCHQ/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.

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ST - A0450 - Post Proc. F/up Care-2nd Trimester

Title Post Proc. F/up Care-2nd Trimester

Statute or Rule 59A-9.028, FAC

Type Rule

Regulation Definition

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.

Interpretive Guideline

Applies only to clinics that perform 2nd Trimester Abortions

ST - A0500 - Incident Reporting-2nd Trimester

Title Incident Reporting-2nd Trimester

Statute or Rule 59A-9.029, FAC

Type Rule

Regulation Definition

This section shall apply to incidents involving patients

Interpretive Guideline

Applies only to clinics that perform 2nd Trimester Abortions

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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 Section 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.

Section 390.012(3)(h)1., F.S. defines serious injury as: 1 ... For the purposes of this paragraph, "serious injury" means an injury that occurs at an abortion clinic and that creates a serious risk of substantial impairment of a major bodily organ.

ST - A0550 - Disposal of Fetal Remains

Title Disposal of Fetal Remains

Statute or Rule 390.0111(7) FS; 59A-9.030, FAC

Type Rule

Regulation Definition

390.0111

(7) FETAL REMAINS.-Fetal remains shall be disposed of in a sanitary manner pursuant to s. 381.0098 and rules adopted thereunder. Failure to dispose of fetal remains in accordance with this subsection is a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

59A-9.030, FAC

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

Interpretive Guideline

Applies to all abortion clinics

Chapter 64E-16 addresses Biomedical waste. Some excerpts from the chapter:

64E-16.004(1)

(a) Storage of biomedical waste at the generating facility shall not exceed 30 days.

(c) Indoor storage areas shall have restricted access and be designated in the written operating plan. They shall be located away from pedestrian traffic, be vermin and insect free, and shall be maintained in a sanitary condition. They shall be constructed of smooth, easily cleanable materials that are impervious to liquids.

(d) Outdoor storage areas, including containers and trailers, shall, in addition to the above criteria, be conspicuously marked with the international biological hazard symbol... and shall be secured against vandalism and unauthorized entry.

(b) All packages containing biomedical waste shall be visibly identifiable with the international biological hazard

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symbol and one of the following phrases: "BIOMEDICAL WASTE", "BIOHAZARDOUS WASTE", "BIOHAZARD", "INFECTIOUS WASTE", or "INFECTIOUS SUBSTANCE".

64E-16.004 (2)(c)(1). Biomedical waste, except sharps, shall be packaged and sealed at the point of origin in impermeable, red plastic bags or, at the discretion of the generator, into sharps containers.

64E-16.004 (2)(d)(1). Sharps shall be discarded at the point of origin into single use or reusable sharps containers. Sharps containers must be sealed when full. A sharps container is considered full when materials placed into it reach the designated fill line, or, if a fill line is not indicated, when additional materials cannot be placed into the container without cramming ...

64E-16.006(1) A biomedical waste generator (facility that produces biomedical waste) shall not negotiate for the transport of biomedical waste with a person who is not registered with the department as a biomedical waste transporter.

ST - A0600 - Clinical Records

Title Clinical Records

Statute or Rule 59A-9.031(1), FAC

Type Rule

Regulation Definition

(1) A permanent individual clinical record shall be kept on each clinic patient. Clinical records shall be complete, accurately documented, and systematically organized to facilitate storage and retrieval.

(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.

Interpretive Guideline

Applies to all abortion clinics - (1) and (a)

Parts (b) and (c) apply only to 2nd trimester clinics.

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ST - A0601 - Clinical Records - Retention

Title Clinical Records - Retention

Statute or Rule 59A-9.031(2), FAC

Type Rule

Regulation Definition

Interpretive Guideline

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

Applies to all abortion clinics

ST - A0650 - Reports

Title Reports

Statute or Rule 390.0112(1,3-5) FS; 59A-9.034, FAC

Type Rule

Regulation Definition

Interpretive Guideline

390.0112

Termination of pregnancies; reporting.-

(1) The director of any medical facility in which abortions are performed, including a physician's office, shall submit a report each month to the agency. The report may be submitted electronically, may not include personal identifying information, and must include:

- (a) Until the agency begins collecting data under paragraph (e), the number of abortions performed.
- (b) The reasons such abortions were performed.
- (c) For each abortion, the period of gestation at the time the abortion was performed.
- (d) The number of infants born alive or alive immediately after an attempted abortion.
- (e) Beginning no later than January 1, 2017, information consistent with the United States Standard Report of Induced

Applies to all abortion clinics

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Termination of Pregnancy adopted by the Centers for Disease Control and Prevention.

(3) If the termination of pregnancy is not performed in a medical facility, the physician performing the procedure shall be responsible for reporting such information as required in subsection (1).

(4) Reports submitted pursuant to this section shall be confidential and exempt from the provisions of s. 119.07(1) and shall not be revealed except upon the order of a court of competent jurisdiction in a civil or criminal proceeding.

(5) Any person required under this section to file a report or keep any records who willfully fails to file such report or keep such records may be subject to a \$200 fine for each violation. The agency shall be required to impose such fines when reports or records required under this section have not been timely received. For purposes of this section, timely received is defined as 30 days following the preceding month.

59A-9.034, FAC

Pursuant to Section 390.0112, F.S., an abortion clinic must submit a report each month to the Agency, regardless of the number of terminations of pregnancy. Monthly reports must be received by the Agency within 30 days following the preceding month. Monthly reports must be submitted on the Monthly Report of Induced Terminations of Pregnancy, AHCA Form 3130-1010 OL, February 2016, which is hereby incorporated by reference. This form is only accepted electronically and is available at:

<<http://ahca.myflorida.com/ITOP>>. A copy of the form can also be found at:

<<http://www.flrules.org/Gateway/reference.asp?No=Ref-06701>>. Failure to submit this report so that it is timely received by the Agency will result in an administrative fine being imposed pursuant to Section 390.0112(4), F.S.