CHAPTER 600. ABORTION FACILITY REGULATIONS

SUBCHAPTER 1. GENERAL PROVISIONS

310:600-1-1. Purpose

The Chapter provides standards for abortions facilities under authority of the following laws: 63 O.S. Supp. 1997, Sections 1-705 and 1-737; and 75 O.S. Supp. 1997, Sections 250.1 through 323, (Administrative Procedures Act).

310:600-1-2. Definitions

The following words or terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise:

"Abortion" *means the purposeful termination of a human pregnancy, by any person with an intention other than to produce a live birth or to remove a dead unborn child {63 O.S. 1991 § 1-730}.*

"Abortion facility" means a specialized hospital that provides abortions on an out-patient basis during the first trimester of pregnancy. The term abortion facility does not include licensed general medical surgical hospitals that provide abortions in addition to other procedures provided in the facility.

"Bed" means each procedure table, gurney, or recovery bed that may be occupied by patients undergoing or recovering from abortions.

"Department" means the Oklahoma State Department of Health.

"First trimester" means a period of a pregnancy measured from the first day of the last normal menses through the end of the fourteenth week or the first twelve (12) weeks of pregnancy as determined by physician examination.

"Governing body" means that person, persons, or legal entity legally responsible for the conduct of the abortion facility that carries out the functions of ownership and governance.

"Licensed practical nurse" means a person currently licensed to practice practical nursing in Oklahoma.

"Registered nurse" means a person currently licensed to practice registered nursing in Oklahoma.

SUBCHAPTER 3. LICENSES

310:600-3-1. Application for license

(a) No person or entity shall operate an abortion facility without first obtaining a license from the Department.

(b) The legal entity responsible for operation of the abortion facility shall be the applicant for the license.

310:600-3-2. Fee for license

(a) The fee for initial license shall be ten dollars ($10.00)

for each bed in the facility. No such fee shall be refunded unless the abortion facility is refused a license. The term of the initial license shall be twelve (12) months.
(b) The fee for a renewal license shall be ten dollars ($10.00) for each bed in the facility. The term of a renewal license shall be twelve (12) months.

310:600-3-3. Deadlines for filing

The license application shall be filed in accordance with the following deadlines:

(1) The application for an initial license of an abortion facility in operation upon the effective date of this Chapter shall be filed within ninety (90) days of the effective date.

(2) The application for an initial license of a new abortion facility shall be filed at least sixty (60) days before the facility begins operations.

(3) The application for a renewal license shall be filed at least thirty (30) days before the expiration date of the current license.

(4) No application shall be considered filed unless it is accompanied by the appropriate fee.

310:600-3-4. Where to file

The application and the license fee shall be delivered or sent to the Department. The effective date shall be the date the application and fee are received.

310:600-3-5. Forms

The applicant for a license shall file application forms as follows:

(1) For an initial license the applicant shall file these forms: Application for License to Operate an Abortion Facility and an Operational Program Narrative.

(2) For renewal of an abortion facility license, the applicant shall file the Application for License to Operate an Abortion Facility and an Operational Program Narrative Update.

310:600-3-6. Description of forms

The forms used to apply for an abortion facility license are the following:

(1) The Application For License to Operate an Abortion Facility requests: The name and address of the facility; name, address, and type of the operating entity; number of beds; the administrator's name; and an affidavit attesting the signature of the applicant.

(2) The Operational Program Narrative requests: A descriptive outlined narrative of facility operations.

(3) The Operational Program Narrative Update requests: An update of the facility operation program narrative

previously filed.

310:600-3-7. Transfer or change of ownership
(a) The license is not transferable or assignable.
(b) If an abortion facility undergoes a change in the legal operating entity, the new entity that will operate the facility shall file an application for initial license sixty (60) days in advance of the change.
(c) A sale of stock in an operating corporation or a sale of membership shares in a limited liability company operating entity shall not be considered a change in ownership if these sales do not result in a change in facility operations.

SUBCHAPTER 5. APPROVAL OR DENIAL OF APPLICATION

310:600-5-1. Eligibility for license
An abortion facility filing an accepted application that has been determined to comply with this Chapter is eligible for a license.

310:600-5-2. Application review
(a) Within thirty (30) days after the application is filed, the Department shall notify the applicant if the abortion facility application is incomplete, accepted or denied.
(b) If the application is incomplete, the applicant shall have thirty (30) days to file the requested clarifying or additional information. If the applicant fails to complete the application within thirty (30) days after notification of an incomplete application, the application shall be summarily dismissed by the Department.
(c) If the application is denied, the applicant shall have thirty (30) days to respond to the Department's decision to deny the application. If the applicant adequately responds to the basis for the Department's denial within thirty (30) days, the Department will reconsider and may approve the application.
(d) If the Department denies an application, the applicant may request a hearing pursuant to the Administrative Procedures Act and OAC 310:002.

SUBCHAPTER 7. ENFORCEMENT

310:600-7-1. Inspections
Each abortion facility is subject to inspection by the Department. These inspections may be routine or conducted as a result of a complaint. Department staff shall have access to any facility or patient record. However, the Department shall not disclose the name of any patient treated in the facility or create a public record that identifies patients. During inspections, Department staff shall respect the privacy of patients and ensure patient confidentiality is maintained.

310:600-7-2. Complaints

The Department shall investigate complaints that allege violations of this Chapter or statutory license provisions. The Department shall accept signed, written complaints from a patient, another treating physician, or an immediate family member.

310:600-7-3. Adverse actions

The State Commissioner of Health may suspend or revoke any abortion facility license based on any of the following:

(1) violation of any provisions of 63 O.S. 1991, § 1-701 et seq. or this Chapter;

(2) permitting, aiding or abetting the commission of any illegal act in the licensed abortion facility; or

(3) conduct or practices deemed by the Commissioner to be detrimental to the welfare of patients of the abortion facility.

310:600-7-4. Hearings

Hearings shall be conducted in compliance with the Administrative Procedures Act and OAC 310:002.

310:600-7-5. Appeals

A final order of the Commissioner of Health may be appealed as provided in the Administrative Procedures Act.

SUBCHAPTER 9. OPERATIONAL PROGRAM NARRATIVE

310:600-9-1. Governance and administration

(a) Each abortion facility shall have an operational program narrative that has been approved by the governing body and accepted by the Department. The facility shall provide services as outlined by the narrative. If facility operations specified in the narrative are modified, the governing body and this Department shall approve the modifications before facility practices are modified.

(b) The narrative shall describe the following:

(1) how the governing body is established by the legal operating entity;

(2) the organizational structure of the body;

(3) how member(s) are appointed and replaced;

(4) the frequency of meetings; and

(5) procedures for the governing body to approve, reapprove, delineate, restrict and deny privileges for physicians and other practitioners providing services in the facility.

(c) The narrative shall describe the process of appointing an administrator who shall be the governing body's on-site designee responsible for the conduct of all affairs of the abortion facility and who is answerable to the governing body

for the day-to-day facility operation.

310:600-9-2. Patient rights

The abortion facility shall protect and promote each patient's rights as specified in this section. Policies describing mechanisms by which patient rights are protected shall be formulated, approved by the governing body and followed by all staff. Policies shall include but not be limited to the following:

(1) The right to receive confidential treatment in a safe environment from considerate professionals;

(2) The right to be informed of the customary charges and acceptable method of payment for the procedure in advance;

(3) The right to be fully advised in understandable terms of the nature of the procedure and possible complications in advance;

(4) The right to receive professional counseling either in the facility or by referral before and after the abortion. Available counseling shall include information on alternatives to abortion and the availability of agencies or services to assist the patient; and

(5) The right to be informed whether or not the attending physician has malpractice insurance coverage.

(6) The right to file a grievance regarding care received and notification of who the patient shall contact at the facility to lodge a complaint.

310:600-9-3. Staffing and personnel

(a) The narrative shall specify facility staffing and stipulate staff approved to assist with procedures and to recover patients. Staffing for services provided shall be based on the volume of procedures performed and acuity level of the patients. Staffing shall ensure desired outcomes of care are achieved and negative outcomes are avoided. Registered nurses and licensed practical nurses providing services shall be identified in the narrative.

(b) Training, continuing education, health examinations, job descriptions and performance appraisal requirements for staff providing patient care shall be stipulated.

(c) The organization of physicians and practitioners with delineated privileges shall be described. The narrative shall explain methods used to recommend appointments and review clinical practice.

(d) Security provisions and practices that ensure patient and staff safety shall be described. The narrative shall stipulate facility protocols and practices for any anticipated external or internal emergency. An evacuation plan and protocol shall be provided or described.

310:600-9-4. Clinical services

(a) The narrative shall describe all abortion procedures

performed, equipment and supplies used for each procedure, and staff required to assist the physician. The narrative shall demonstrate the quantities of supplies, instruments, and equipment available in the facility are sufficient to provide emergency care and support the number of abortions performed on a daily basis.

(b) Drugs and biologicals maintained and administered in the facility shall be specified in the narrative. The narrative shall describe how the facility complies with federal and state laws regarding drug storage, administration and accountability.

(c) If the physician performing the abortion is not certified by the American Board of Obstetrics and Gynecology or the American Osteopathic Board of Obstetrics and Gynecology or an active board eligible candidate for certification in one (1) of the above, the narrative shall stipulate the facility protocols in place to assure consultation from a physician with these qualifications when required.

(d) Anesthesia services provided in the facility shall be fully described. The narrative shall stipulate the qualifications of the staff administering the anesthesia, if these individuals are supervised, and the level of service they are approved to deliver. The narrative shall demonstrate required services are provided by competent individuals in compliance with federal and state law as follows:

(1) An orderly preoperative anesthetic risk evaluation is to be done by the responsible physician and recorded on the chart in all elective cases, and in urgent emergency cases, the anesthetic evaluations will be recorded as soon as feasible.

(2) Every patient receiving general anesthesia, spinal anesthesia, or managed intravenous anesthesia (i.e. local standby, monitored anesthesia or conscious sedation), shall have arterial blood pressure and heart rate measured and recorded at least every five (5) minutes where not clinically impractical, in which case the responsible physician may waive this requirement stating the clinical circumstances and reasons in writing in the patient's chart.

(3) Every patient shall have the electrocardiogram continuously displayed from the induction and during maintenance of general anesthesia. In patients receiving managed intravenous anesthesia, electrocardiographic monitoring should be used in patients with significant cardiovascular disease as well as during procedures where dysrhythmias are anticipated.

(4) During all anesthetics, patient oxygenation will be continuously monitored with a pulse oximeter, and, whenever an endotracheal tube is inserted, correct positioning in the trachea and function will be monitored by end-tidal CO2 analysis (capnography) throughout the time of placement.

(A) Additional monitoring for ventilation will include

palpation or observation of the reservoir breathing bag, and auscultation of breath sounds.

(B) Additional monitoring for circulation will include at least on of the following: Palpation of the pulse, auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, pulse plethysmography, or ultrasound peripheral pulse monitoring.

(5) When ventilation is controlled by an automatic mechanical ventilator, there shall be in continuous use a device that is capable of detecting disconnection of any component of the breathing system. The device must give an audible signal when its alarm threshold is exceeded.

(6) During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient's breathing system will be measured by a functioning oxygen analyzer with low concentration audible limit alarm in use.

(7) During every administration of general anesthesia, there shall be readily available a means to measure the patient's temperature.

(8) Availability of qualified trained personnel dedicated solely to patient monitoring.

(9) These desiderata apply for any administration of anesthesia, including general, spinal, and managed intravenous anesthetics (i.e. local standby, monitored anesthesia or conscious sedation), administered in designated anesthetizing locations and any location where conscious sedation is performed. "Conscious sedation" means a minimally depressed level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command, produced by a pharmacologic or non-pharmacologic method, or a combination thereof.

(10) In emergency circumstances in any situation, immediate life support measures can be started with attention returning to these monitoring criteria as soon as possible and practical.

(e) The maintenance of adequate sterile supplies and linens shall be described. If the facility sterilizes instruments and supplies, the narrative shall indicate how sterilization is achieved, maintained, and documented. The procedure for linen procurement, storage, and processing shall be defined.

(f) The narrative shall describe how informative, timely, confidential, and complete medical records are documented, filed, and maintained for each patient as required by state law. The composition of a complete record shall be described.

(g) The availability of clinical laboratory services required by physicians performing abortions shall be indicated. The narrative shall stipulate clinical laboratory services, including tissue examinations, are provided by laboratories possessing a current certificate appropriate for the extent of

testing required issued by the Department of Health and Human Services.
(h) The narrative shall ensure that patients are informed of birth control methods that may be used after the procedure, advised of diseases that are sexually transmitted, and provided instructions regarding possible complications and activities to be avoided. The instructions shall include information on how to contact the attending physician or abortion facility should a complication arise. The instructions shall also specify when the patient shall return for follow-up care.

310:600-9-5. Quality assessment and performance improvement
(a) The narrative shall indicate the abortion facility has developed a quality assessment and performance improvement program that is effective, data-driven, and implements actions that result in improvements in patient care. The program shall access patient care, staff performance, complaints and grievances, diagnostic and therapeutic services, medication and anesthesia administration, emergencies, safety issues, clinical records, complications, infection control, errors in diagnosis, and problems complying with this Chapter or other federal, state or local laws. The program shall measure, analyze, and track quality indicators or other measures of performance and recommend actions that improve care to the governing body.
(b) Facility infection control shall be an integral part of the quality assessment and performance improvement program described in the narrative. Infection control procedures shall indicate a sanitary environment is maintained, transmission of infections and communicable diseases is avoided, and post procedure infections are tracked.

310:600-9-6. Examinations, tests and procedures
In addition to the provisions specified individually in each facility's operational program narrative, each abortion facility shall comply with the following:
(1) Each patient shall have a medical history and physical including pelvic examination recorded by the physician performing the abortion prior to the procedure. The physician shall determine and document the duration of gestation, identify preexisting medical or other complications, and observe any factors which may influence the choice of the procedure, anesthesia, or care provided.
(2) Not more than seventy-two (72) hours prior to the procedure, each patient shall receive clinical laboratory testing which shall include a hemoglobin and/or hematocrit, Rh type, and pregnancy test.
(3) All tissue removed during the abortion shall be examined by a physician and stored in ten (10) percent formalin for thirty (30) days or until after the follow-up

examination. If the attending physician orders a pathological examination, the tissue shall be examined by a physician who is certified in anatomical pathology by the American Board of Pathology or American Osteopathic Board of Pathology or by a physician who is an active candidate for certification by these boards.
(4) After the follow-up examination or thirty (30) days, tissue not maintained for additional microscopic examination removed during the abortion shall be disposed of in an incinerator designed and approved for the disposal of pathological specimens. The abortion facility may accept a written statement from the pathologist attesting the tissue has been properly incinerated.
(5) Anti-Rh immune globulin therapy shall be given to Rh negative patients that are candidates for the therapy upon completion of the abortion procedure. If the patient refuses this therapy, the physician shall document the refusal in the medical record and if possible obtain the signature of the patient on an appropriate release.
(6) All patients recovering from an abortion shall be released from the facility by order of a physician. A physician or licensed nurse shall remain in the facility until all patients are recovered and released.
(7) Each facility shall maintain supplies and equipment for initial emergency medical care of problems that may arise in the facility (e.g. bleeding, shock, disseminated intravascular coagulations, seizures, and respiratory and cardiac arrest). The equipment and supplies shall be immediately available to the procedure and recovery room.
(8) Emergency drugs, oxygen, and intravenous fluids shall be available in the procedure and recovery room. A manual breathing bag, suction machine, and endotracheal equipment shall be located for immediate access.
(9) Each facility shall establish a written protocol for the transfer of patients requiring emergency treatment that can not be provided on-site. The protocol shall include procedures to contact the local ambulance service and expedite the transfer to the receiving hospital. Appropriate clinical patient information shall be provided to the receiving facility. If the attending physician does not have admitting privileges at a local general hospital, the physician shall attest arrangements have been made with a physician having hospital privileges to receive emergency cases.

SUBCHAPTER 11. PHYSICAL PLANT

310:600-11-1. Facility design and construction

(a) The operational program narrative shall include scaled drawings of facility construction. The drawings shall locate and identify the following:

(1) An entrance, located at grade level, able to accommodate wheelchairs.
(2) A reception and waiting area, and information counter or desk.
(3) Conveniently accessible public toilet.
(4) Conveniently accessible public telephone.
(5) Interview space(s) for private interviews related to social service, credit, and counseling.
(6) Secure general or individual office(s) for business transactions, records, administrative, and professional staff.
(7) Clerical space or rooms separated from public areas for confidentiality.
(8) Storage space for staff personal effects with locking drawers, cabinets or desks near individual work-stations that are staff controlled.
(9) General storage facilities for supplies and equipment needed for continuing operation.
(10) General purpose examination room(s) equipped to perform pelvic and medical examinations. Rooms shall have a minimum floor area of eighty (80) square feet, excluding vestibules, toilets, and closets. Room arrangement shall permit at least two (2) feet and eight (8) inches clearance at each side and at the foot of the examination table. A handwashing fixture and counter or shelf for writing shall be provided.
(11) Nurses station(s) with work counter, communication system, space for supplies, and provisions for charting.
(12) Drug distribution station which may be part of the nurse station but shall include a work counter, sink, refrigerator, and locked storage for biologicals and drugs.
(13) A separate clean storage room or closet for storing clean and sterile supplies. This area shall be in addition to cabinets and shelves.
(14) A soiled holding area for separate collection, storage, and disposal of soiled materials.
(15) A sterilizing room or area if instruments and supplies are sterilized on-site. If sterilizing is accomplished off-site or if disposable sterile supplies are used, the facility shall provide a system for processing and storage.
(16) Wheelchair storage space out of the direct line of traffic.
(17) Procedure room(s) with a minimum area of one hundred forty-four (144) square feet, exclusive of vestibule, toilets, or closets. The minimum room dimension shall be twelve (12) feet. A handwashing fixture and counter or shelf for writing shall be provided. The sink may be within the procedure room or immediately outside. An emergency communication system connected to the nurse station shall be provided.
(18) A designated supervised recovery patient lounge. This

lounge shall contain a control station, space for family members, and provisions for privacy. It shall have convenient patient access to toilets large enough to accommodate a patient and an assistant. Handwashing and nourishment facilities shall be included.

(19) Clothing change areas for staff which shall contain lockers, toilets, lavatories for handwashing.

(20) A housekeeping room containing a floor receptor or service sink and storage space for housekeeping supplies and equipment.

(b) The Department shall review the scaled drawings for compliance and return the drawings to the facility upon licensure.

310:600-11-2. Construction drawings

(a) The construction drawings submitted with the operational program narrative shall indicate the following:

(1) Separation and access to the abortion facility is maintained as described by National Fire Protection Association code 101, 1997 edition, if the facility is part of another building. Building entrances used to reach the abortion facility shall be at grade level, clearly marked, and located so that patients need not go through other activity areas. Lobbies of multi-occupancy buildings may be shared. Design shall preclude unrelated traffic within the abortion facility.

(2) Facility design ensures patient audible and visual privacy and dignity during interviews, examinations, procedures and recovery.

(3) Provisions for convenient access to and use of emergency equipment.

(4) Ceilings and walls in the procedure room are readily washable.

(5) Toilet rooms in recovery areas for patient use are equipped with doors and hardware that permit access from the outside in emergencies. When such rooms have only one opening or are small, the doors shall open outward or be otherwise designed to open without pressing against a patient who may have collapsed within the room.

(6) The building has an elevator with a minimum car inside floor dimension of not less that five (5) feet, if the abortion facility is located above or below the ground floor level of a multi-story building.

(7) Airflow and exhaust are controlled to ensure movement of air from clean to less clean areas to maintain asepsis control.

(b) An abortion facility built after the effective date of this Chapter shall comply with National Fire Protection Association code 101, 1997 edition, Chapter 26, "New Business Occupancies," which is incorporated by reference.

(c) An abortion facility existing at the time of the

effective date of this Chapter shall comply with National Fire Protection Association code 101, 1997 edition, Chapter 27 "Existing Business Occupancies," which is incorporated by reference.
(d) The Department shall return construction drawings to the facility upon licensure.

SUBCHAPTER 13. FEDERAL, STATE AND LOCAL LAWS

310:600-13-1. Licensure or registration of personnel

Staff of the facility shall be licensed or registered in accordance with applicable federal, state and local laws.

310:600-13-2. Conformity with other laws

The facility shall conform with all applicable federal, state, and local laws including but not limited to the following:

(1) fire safety or building codes;
(2) communicable and reportable diseases;
(3) occupational health and safety matters for employees and staff; and
(4) hazardous and infectious waste disposal.

310:600-13-3. Reporting of procedures

Each attending physician performing an abortion shall complete a form documenting all medical facts pertinent to the procedure and other personal facts volunteered by the patient or the physician, pursuant to 63 O.S. Supp. 1997, Section 1-738. The facility shall forward all such reports to the Department monthly. The report shall be confidential and shall not contain the name of the patient.

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