Chapter 44. Abortion Facilities
§4401. Definitions

Abortion—any surgical procedure performed after pregnancy has been medically verified with the intent to cause the termination of the pregnancy other than for the purpose of:

1. producing a live birth;
2. removing an ectopic pregnancy; or
3. removing a dead fetus caused by a spontaneous abortion.

Department—Department of Health and Hospitals, (DHH).

Existing Outpatient Abortion Facility—any outpatient abortion facility, as defined in this §4401, in operation at the time that the licensing standards governing outpatient abortion facilities are promulgated and published.

First Trimester—the time period from 6 to 14 weeks after the first day of the last menstrual period.

General Anesthesia—any drug, element, or other material which, when administered, results in a controlled state of unconsciousness accompanied by a partial or complete loss of protective reflexes, including a loss of ability to independently maintain an airway and respond purposefully to physical stimuli or verbal command.

Gestational Age—the duration of a pregnancy as estimated from the first day of a woman's last menstrual period (LMP) or fertilization date plus two weeks.

Licensed Physicians Assistant—a person who:

1. is a graduate of a program accredited by the Committee on Allied Health Education and Accreditation or its successors; and
2. has successfully passed the national certificate examination administered by the National Commission on the Certification of Physician's Assistants or its predecessors; and
3. is approved and licensed by the Louisiana State Board of Medical Examiners to perform medical services, nursing services, and health-related services provided to patients at an outpatient abortion facility.

Licensee—the person, partnership, corporation, association, organization or professional entity on whom rests the ultimate responsibility and authority for the conduct of the outpatient abortion facility.

Licensing Agency—the Louisiana Department of Health and Hospitals.

Local Anesthesia—those anesthetizing agents administered to affect a very small localized area.

Medical Director—a physician licensed to practice medicine in Louisiana who is responsible for the direction of the medical services, nursing services, and health-related services provided to patients at an outpatient abortion facility.

Outpatient Abortion Facility—any outpatient facility, other than a hospital as defined in R.S. 40:2102 or an ambulatory surgical center as defined in R.S. 40:2133, in which any second trimester or five or more first trimester abortions per month are performed.

Patient—the woman receiving services from an outpatient abortion facility.

Products of Conception—placenta, amniotic sac or membrane, embryo, or fetal elements that result from a human pregnancy.

Second Trimester—the time period from 14 to 23 weeks after the first day of the last menstrual period.

Secretary—the secretary of the Louisiana Department of Health and Hospitals.

Telecommunications—any means of transmitting messages at a distance, including but not limited to telephones, cell phones, pagers, or other similar devices which foster communication.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:705 (May 2003).

§4403. Licensing Requirements

A. An outpatient abortion facility may not be established or operated in this state without an appropriate license issued by the licensing agency.

1. An outpatient abortion facility shall be in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including DHH rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to abortion or abortion procedures.

B. Initial License Application

1. Initial applicants and existing outpatient abortion facilities shall submit a set of architectural plans and specifications to the Office of State Fire Marshal and Division of Engineering and Architectural Services of the department for review and approval.

2. When an architectural requirement on an existing outpatient abortion facility would impose a hardship, financial or otherwise, but would not adversely affect the health and safety of any patient, the existing outpatient abortion facility may submit a request for exception (waiver) to the department, with supporting documentation. The issuance of a waiver by the department does not apply to the Office of State Fire Marshal requirements for approval, which must be addressed exclusively with the Office of State Fire Marshal.

3. An application for license shall be completed and returned to the Health Standards Section by the applicant on forms supplied by the department.

a. Existing outpatient abortion facilities must secure and return a completed licensing application packet to the department within six months from promulgation and
publication of the outpatient abortion facility licensing standards.

b. Existing outpatient abortion facilities shall be allowed to continue to operate without a license until such time as their initial application is acted upon by the department and until any and all appeals processes associated with that initial license have been completed, or the time within which any appeal process may be undertaken and completed has expired, whichever is later.

4. The application must be accompanied with a nonrefundable licensing fee set in accordance with R.S. 40:2006.

5. The department will respond to the applicant within 45 days of submitting the completed application.

6. Announced on-site inspections will be performed and the facility must be in substantial compliance with the requirements of the following offices prior to the issuance of an initial license:
   a. Office of State Fire Marshal
   b. Office of Public Health
   c. DHH Health Standards Section

C. Renewal Application

1. Application for license renewal shall be completed and returned to the Health Standards Section prior to the expiration date of the current license on forms supplied by the department. The application must be accompanied by the annual renewal fee set in accordance with R.S. 40:2006.

2. Inspection and approval by the State Fire Marshal and Office of Public Health are required annually.

3. The licensing agency may perform an unannounced on-site inspection upon annual renewal. If the outpatient abortion facility continues to meet the requirements established in R.S. 40:2175.1 et seq., and the licensing standards adopted in pursuance thereof, a license shall be issued which is valid for one year.

D. Other on-site inspections may be performed to investigate complaints in accordance with R.S. 40:2009.13-2009.20 and perform follow-up surveys as deemed necessary to ensure compliance with these licensing standards.

E. Issuance of License

1. Following receipt of the application and the licensing fee, the department shall issue a license if, after an on-site inspection, it finds that the outpatient abortion facility is in full compliance with the requirements established in accordance with R.S. 40:2175.1 et seq., and the licensing standards adopted in pursuance thereof.

2. A provisional license may be issued in cases where additional time is needed for the outpatient abortion facility to comply fully with the requirements established in accordance with R.S. 40:2175.1 et seq., and the licensing standards adopted in pursuance thereof. The licensing agency may issue a provisional license to an outpatient abortion facility for a period not to exceed six months only if the failure to comply is not detrimental to the health or safety of the women seeking treatment in the outpatient abortion facility. The deficiencies that preclude the outpatient abortion facility from being in full compliance must be cited at the time the provisional license is issued.

3. A license issued to an outpatient abortion facility:
   a. is valid for only one location;
   b. shall be valid for one year from the date of issuance; unless revoked prior to that date;
   c. is not transferable or assignable;
   d. shall be posted in a conspicuous place on the licensed premises.

F. Denial, Suspension or Revocation of License. The procedure for denial, suspension and revocation of a license and appeals resulting from these actions will be the same as provided in the licensing regulations for hospitals, and as contained in R.S. 40:2110.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:705 (May 2003), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:2281 (August 2013).

§4405. Governing Body

A. The abortion facility must have a governing body which meets at least annually. The governing body is the ultimate authority of the facility, and as such, it shall approve and adopt all bylaws, rules, policies, and procedures formulated in accordance with these licensing standards. All bylaws, rules, policies, and procedures formulated in accordance with these licensing standards shall be in writing, revised as necessary, and reviewed annually. If, due to type of ownership or other reasons, it is not possible or practical to establish a governing body, as such, then documents shall reveal the person(s) who are legally responsible for the conduct of the facility and are also responsible for carrying out the functions and obligations contained herein pertaining to the governing body.

B. The responsibilities of the governing body shall include, but not be limited to:

1. organization and administration of the facility;
2. acting upon recommendations from the medical staff relative to medical staff appointments;
3. designation of an administrator who has the responsibility to carry out the day-to-day operations of the facility;
4. designation of a medical director who has responsibility for the direction of medical services, nursing services, and health-related services provided to patients;
5. maintenance of the physical plant;
6. ensuring that the facility is equipped and staffed to meet the needs of the patients in the facility; and

7. establishing a system for periodic evaluation of its operation (quality assurance).

C. The governing body shall establish formal lines of communication with the medical staff through a liaison committee or other acceptable methods. This committee will address problems and programs of mutual concern regarding topics including, but not limited to, patient care, cost containment and improved practice.

D. Minutes of meetings of the governing body shall be maintained to adequately reflect the discharging of its duties and responsibilities.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:706 (May 2003).

§4407. Administration

A. The administrator is the person who has been designated to carry out the day-to-day operations of the facility which include, but are not limited to the following functions:

1. employing qualified staff to provide the medical and clinical services to meet the needs of the patients being served;

2. assigning duties and functions to each employee commensurate with his/her licensure, certification, and experience and competence;

3. retaining a readily accessible written protocol for managing medical emergencies and the transfer of patients requiring further emergency care to a hospital. The written protocol shall identify which emergency equipment and medications the facility will use to provide for basic life support until emergency transportation can arrive and assume care of those in need of service. The facility shall ensure that when a patient is in the facility for an abortion, there is one physician present who has admitting privileges or has a written transfer agreement with a physician(s) who has admitting privileges at a local hospital to facilitate emergency care;

4. developing disaster plans for both internal and external occurrences. Annual drills shall be held in accordance with the plan. Documentation of these drills shall be recorded;

5. ensuring that a CPR-certified staff member who is currently trained in the use of emergency equipment is on the premises at all times when abortion services are being performed in the facility.

B. Personnel Files

1. Personnel folders shall be maintained on each employee. Contents shall include:
   a. application;

b. current license (when required);

c. health screening reports;

d. documentation of areas covered in orientation; and

e. other pertinent information as deemed necessary by the facility.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:706 (May 2003).

§4409. Personnel

A. Medical Staff

1. The medical staff of the facility shall consist of at least one physician who is licensed to practice medicine in Louisiana and is responsible to the governing body of the facility for the quality of all medical care provided to patients in the facility and for the ethical and professional practices of its members.

2. The medical staff shall formulate and adopt bylaws, rules, and policies for the proper conduct of its activities and recommend to the governing body physicians who are considered eligible for membership on the medical staff. Such bylaws, rules, and policies must be in writing and must be approved by the governing body.

3. All applications for membership to the medical staff shall be reviewed by the medical staff and recommendations for appropriate action shall be made to the governing body. The governing body's bylaws shall establish time frames for response to the recommendations of the medical staff.

4. An abortion shall be performed only by a physician who is licensed to practice in Louisiana.

5. A physician must be either present in the facility or immediately available by telecommunications to the staff when there is a patient in the facility.

6. A physician must remain in the facility until all patients are assessed to be stable.

B. Nursing Personnel

1. The outpatient abortion facility shall provide nursing services.

2. The nursing services shall be provided under the direction of a registered nurse.

3. There shall be a plan of administrative authority with delineation of responsibilities and duties for each category of nursing personnel.

4. The number of nursing personnel on duty shall be sufficient to meet the needs of the patient(s) in the facility. An outpatient abortion facility shall have at least one licensed nurse on duty at all times when there is a patient in the facility who is receiving or recovering from an abortion.
5. All nurses employed by the facility shall have a current and valid Louisiana nursing license as a registered nurse (RN) or licensed practical nurse (LPN), as appropriate. The facility shall verify and maintain documentation of the nursing license in the personnel file.

6. All licensed nurses shall have current documentation in their personnel file of successfully completing a basic life support course.

7. Nursing care policies and procedures shall be in writing and be consistent with accepted nursing standards. Policies shall be developed for all nursing service procedures provided at the facility. The procedures shall be reviewed at least annually and revised as necessary.

8. A formalized program of in-service training and evaluation for competency shall be developed for all categories of nursing personnel and for all nursing services provided at the facility. Training related to required job skills shall be provided to nursing personnel. The facility shall maintain documentation of the training provided and evaluation for competency in the personnel file.

C. General Staffing

1. When a patient is in the facility for an abortion, there shall be at least two staff members present, one of which must be either a licensed physician, RN, or LPN.

2. All employees shall be provided orientation and training related to the facility's policies, philosophy, job responsibilities of all staff, and emergency procedures.

D. Health Screening. The facility must have policies governing health screening on personnel in accordance with federal, state and local health laws.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:707 (May 2003), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:2281 (August 2013).

§4413. Post-Operative Care and Procedures

A. The patient's recovery shall be supervised by a licensed physician, a nurse trained in post-operative care, or a licensed physician's assistant. A patient in the post-operative or recovery room shall not be left unattended.

B. The patient shall be given written post-operative instructions for follow-up care. A contact for post-operative care from the facility shall be available to the patient on a 24-hour basis.

C. A licensed physician or nurse shall assess the patient to be awake, alert and medically stable before she is discharged in accordance with policies established by the medical director.

D. Upon completion of an abortion procedure, the physician shall immediately perform a gross examination of the uterine contents and shall document the findings in the patient's chart. If no products of conception are visible, a high-risk protocol for continuing pregnancy or ectopic pregnancy shall be followed.

E. Products of conception shall be disposed in compliance with Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA) and other state and local standards covering the treatment of medical waste.

F. Rh immunoglobulin administration shall be offered to Rh-negative women and documented. If Rh immunoglobulin is not administered in the facility, one of the following is required:

1. informed waiver signed by a patient who refuses RH immunoglobulin; or...
2. documentation of other arrangements for administration.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:708 (May 2003).

§4415. Patient Records and Reports

A. Retention of Patient Records

1. An abortion facility shall establish and maintain a medical record on each patient. The facility shall maintain the record to assure that the care and services provided to each patient is completely and accurately documented, and that records are readily available and systematically organized to facilitate the compilation and retrieval of information. Safeguards shall be established to maintain confidentiality and protection from fire, water, or other sources of damage.

2. The department is entitled to access all books, records, or other documents maintained by or on behalf of the facility on the licensed premises to the extent necessary to ensure compliance with this Chapter 44. Ensuring compliance includes permitting photocopying by the department or providing photocopies to the department of any records or other information by or on behalf of the department as necessary to determine or verify compliance with this Chapter.

3. Patient records shall be under the custody of the facility for a period of seven years from the date of discharge. Patient records shall be maintained on the premises for at least one year and shall not be removed except under court orders or subpoenas. Any patient record maintained off-site after the first year shall be provided to the department for review no later than 24 hours from the time the department requests the medical record.

B. Content of Medical Record

1. The following minimum data shall be kept on all patients:
   a. identification data;
   b. date of procedure;
   c. medical and social history;
   d. physical examination;
   e. chief complaint or diagnosis;
   f. clinical laboratory reports (when appropriate);
   g. pathology report (when appropriate);
   h. physicians orders;
   i. radiological report (when appropriate);
   j. consultation reports (when appropriate);
   k. medical and surgical treatment;
   l. progress notes, discharge notes, and summary;
   m. nurses' records of care given, including medication administration records;
   n. authorizations, consents or releases;
   o. operative report;
   p. anesthesia report, including post-anesthesia report; and
   q. special procedures reports.

2. Signatures. Clinical entries shall be signed by the physician as appropriate, i.e., attending physician, consulting physician, anesthesiologist, pathologist, etc. Nursing notes and observations shall be signed by the nurse.

3. Nurses' Notes. All pertinent observations, treatments and medications given shall be entered in the nurses' notes. All other notes relative to specific instructions from the physician shall be recorded.

4. Completion of the medical record shall be the responsibility of the attending physician.

C. Nothing in this §4415 is intended to preclude the use of automated or centralized computer systems or any other techniques for the storing of medical records, provided the regulations stated herein are met.

D. Other Reports. An abortion facility shall maintain a daily patient roster of all patients receiving abortion services. This daily patient roster shall be retained for a period of three years.

E. Confidentiality

1. If the department, in the course of carrying out its licensing responsibilities under this Chapter 44, obtains any patient identifiable health information regarding a patient from an abortion facility, it shall keep such information strictly confidential and shall not disclose it to any outside person or agency, except as follows:
   a. to the patient who is the subject of the patient identifiable health information;
   b. pursuant to and in compliance with a valid written authorization executed by the patient who is the subject of the patient identifiable health information; or
   c. when required by the secretary of the U.S. Department of Health and Human Services to investigate or determine DHH's compliance with the requirements of the Code of Federal Regulations, Title 45, Part 164, Subpart E.

2. Any person who knowingly discloses such patient identifiable information in violation of Subsection A shall be subject to punishment pursuant to 42 U.S.C. §1320d-6 as follows:
   a. a fine of not more than $50,000, or imprisonment for not more than one year, or both;
   b. if the violation is committed under false pretenses, a fine of not more than $100,000, or imprisonment for not more than five years, or both; and
c. if the violation is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, a fine of not more than $250,000, or imprisonment for not more than 10 years, or both.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:708 (May 2003), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:2281 (August 2013).

§4417. Physical Environment

A. The facility shall have a safe and sanitary environment that is properly constructed, equipped and maintained to protect the health and safety of patients and staff at all times.

1. Abortions shall be performed in a segregated procedure room, removed from general traffic lines with a minimum of 120 square feet, exclusive of vestibule, toilets or closets.

2. There shall be a hand washing fixture within each procedure room.

3. The facility shall have a separate recovery room or area with a minimum clear area of 2 feet, 6 inches around the three sides of each stretcher or lounge chair for work and circulation.

4. The following equipment and supplies shall be maintained to provide emergency medical care for problems that may arise and be immediately available to the procedure and recovery room(s):
   a. surgical or gynecologic table;
   b. surgical instruments for the performance of abortion;
   c. emergency drugs (designated as such by the medical director);
   d. oxygen;
   e. intravenous fluids; and
   f. sterile dressing supplies.

5. All openings to the outside shall be maintained to protect against the entrance of insects and animals.

6. A nurse's station with a countertop, space for supplies, provisions for charting and a communication system shall be provided.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:709 (May 2003).

§4419. Infection Control

A. The facility shall have policies and procedures that address:

1. decontamination;

2. disinfection;

3. sterilization; and

4. storage of sterile supplies.

B. The facility shall make adequate provisions for furnishing properly sterilized supplies, equipment, utensils and solutions.

1. It is expected that some disposable goods shall be utilized; but when sterilizers and autoclaves are used, they shall be of the proper type and necessary capacity to adequately meet the needs of the facility.

2. Procedures for the proper use of equipment and standard procedures for the processing of various materials and supplies shall be in writing and readily available to personnel responsible for sterilizing procedures.

3. Acceptable techniques for handling sterilized and contaminated supplies and equipment shall be established to avoid contamination.

4. Medically necessary surgical instruments used to enter the uterine cavity shall be sterilized for each abortion procedure.

C. There shall be a separate sink for cleaning instruments and disposal of liquid waste.

D. Each facility shall develop, implement, and enforce written policies and procedures for the handling, processing, storing and transporting of clean and dirty laundry.

1. If the facility provides an in-house laundry, the areas shall be designed in accordance with acceptable hospital laundry design in that a soiled laundry area will be provided and separated from the clean laundry area. Dirty and/or contaminated laundry shall not be stored or transported through the clean laundry area.

2. For an in-house laundry, special cleaning and decontaminating processes shall be used for contaminated linens.

E. The facility shall provide housekeeping services that shall assure a safe and clean environment.

1. Housekeeping procedures shall be in writing and followed.

2. Housekeeping supplies shall be provided to adequately maintain the facility.

F. All garbage and waste materials shall be collected, stored and disposed of in a manner designed to prevent the transmission of contagious diseases, and to control flies, insects, and animals.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:709 (May 2003).
§4421. Pharmaceutical Services

A. The facility shall provide pharmacy services and these services shall be commensurate with the needs of the patients and in conformity with state and federal laws.

B. There shall be policies and procedures for the storage, distribution, and handling and administration of drugs and biologicals in the facility.

C. The facility shall provide facilities for proper storage, safeguarding and distribution of drugs.
   1. Drug cabinets must be constructed and organized to assure proper handling and safeguard against access by unauthorized personnel.
   2. Storage areas shall have proper controls for ventilation, lighting and temperature.
   3. Locked areas shall be designed to conform with state and federal laws.

D. In accordance with all applicable laws, records shall be kept on:
   1. all ordering, purchasing, dispensing, and distribution of drugs; and
   2. the disposal of unused drugs.

E. Records for prescription drugs dispensed to each patient shall contain the:
   1. full name of the patient;
   2. name of the prescribing physician;
   3. name and strength of the drug;
   4. quantity dispensed; and
   5. date of issue.

F. Provision shall be made for emergency pharmaceutical service.

G. All outpatient abortion facilities shall have a site-specific Louisiana controlled dangerous substance license and United States Drug Enforcement Administration controlled substance registration for the facility in accordance with the Louisiana Uniform Controlled Dangerous Substance Act and Title 21 of the United States Code.

H. Drugs and biologicals shall be administered in compliance with an order from an individual who has prescriptive authority under the laws of Louisiana. Such orders shall be in writing and signed by the individual with prescriptive authority under the laws of Louisiana.

I. There shall be a supply of drugs for stabilizing and/or treating medical and surgical complications.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:709 (May 2003).

§4423. Anesthesia Services

A. The facility shall have policies and procedures pertaining to the administration of general and local anesthesia that are approved by the medical director.

B. Local anesthesia, nitrous oxide, and intravenous sedation shall be administered by the treating physician or by qualified personnel under the orders and supervision of the treating physician, as allowed by law.

C. General anesthesia, if used, shall be given by an anesthesiologist, certified registered nurse-anesthetist (CRNA), or a physician trained in the administration of general anesthesia.

D. The physician who will perform the abortion shall be present in the facility before anesthesia is administered.

E. A physician shall be present in the facility during the post anesthesia recovery period until the patient is fully reacted and stable.

F. When there is a general anesthesia patient present in the facility, personnel trained in the use of all emergency equipment required shall be present on the premises.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:710 (May 2003).