

TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Emergency Rule LSA Document

DIGEST

Temporarily amends 410 IAC 26 to make the rule applicable only to abortion clinics providing surgical abortions, to update and add definitions, and to update license application and license renewal requirements, plan of correction requirements, license survey requirements, the content of medical records, employee training requirements, anesthesia service requirements, patient care requirements, other service requirements, and physical plant requirements. Temporarily adds informed consent brochure requirements. Temporarily removes outdated references and makes technical corrections. Statutory authority: IC 16-19-3-5; IC 16-21-2-2.5.

SECTION 1. This document applies to abortion clinics that perform surgical abortion procedures. An abortion clinic that provides an abortion inducing drug for the purpose of inducing an abortion must comply with LSA Document # X.

SECTION 2. (a) This SECTION supersedes 410 IAC 26-1-3.

(b) "Abortion clinic" means the following:

(1) a health care provider (as defined in IC 16-18-2-163(d)(1)) that performs surgical abortion procedures.

(2) The term does not include the following:

(A) A hospital that is licensed as a hospital under IC 16-21-2.

(B) An ambulatory outpatient surgical center that is licensed as an ambulatory outpatient surgical center under IC 16-21-2.

(C) A health care provider that provides, prescribes, administers, or dispenses an abortion inducing drug to fewer than five (5) patients per year for the purposes of inducing an abortion.

SECTION 3. "Affiliate" has the meaning set forth in IC 16-18-2-9.4.

SECTION 4. "Minimal sedation" means a drug-induced state during which patients respond normally to verbal commands although cognitive function and coordination may be impaired. Ventilatory and cardiovascular functions are unaffected.

SECTION 5. "Moderate sedation" means a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

SECTION 6. (a) This SECTION supersedes 410 IAC 26-2-1.

(b) A license must be obtained from the state health commissioner under IC 4-21.5-3-5 before:

(1) establishing;

(2) conducting;

(3) operating; or

(4) maintaining;
an abortion clinic. An abortion clinic may not operate without a license issued by the commissioner.

(c) A license to operate an abortion clinic:

(1) expires one (1) year after the date of issuance;

(2) is not assignable or transferable;

(3) is issued only for the premises named in the application; and

(4) is issued only for the scope of procedures to be performed as indicated by the applicant on the application.

(d) A license is valid for only one (1) location. Multiple clinics may not be operated under one (1) license.

(e) Upon closure of the clinic, the license shall be returned to the division.

SECTION 7. (a) This SECTION supersedes 410 IAC 26-2-3.

(b) To obtain a license to operate an abortion clinic, an application for a license to operate an abortion clinic must be submitted to the division. At the latest, however, the application must be received by the department at least forty-five (45) days before the anticipated opening of the clinic. At least forty-five (45) days before the opening of the clinic, the applicant must inform the division of the anticipated date of opening.

(c) The initial license application includes the following:

(1) An application for a license to operate an abortion clinic on a form prescribed by the division to include the selection of only one (1) of the following procedure classifications:

(A) Surgical abortions only. The clinic is precluded from performing drug induced abortions.

(B) Both drug induced abortions and surgical abortions. The clinic must comply with 410 IAC 26 and LSA Document #X.

(2) Documents required by the application for a license to operate an abortion clinic.

(3) The appropriate license fee.

(d) The application for an abortion clinic license must require the applicant to:

(1) Disclose whether the applicant, or an owner or affiliate of the applicant, operated an abortion clinic that was closed as a direct result of patient health and safety concerns.

(2) Disclose whether a principal or clinic staff member was convicted of a felony.

(3) Disclose whether a principal or clinic staff member was ever employed by a facility owned or operated by the applicant that closed as a result of administrative or legal action.

(4) Provide copies of:

(A) administrative and legal documentation relating to the information required under subdivisions (1) and (2);

(B) inspection reports; and

(C) violation and remediation contracts.

(e) All changes in ownership, name, and address must be reported in writing to the division. Reapplication must be filed when a change of fifty percent (50%) or greater ownership occurs.

SECTION 8. (a) This SECTION supersedes 410 IAC 26-2-6.

(b) In order to renew its abortion clinic license, the clinic shall file an application for the

renewal of an abortion clinic license with the division at least one (1) month before the expiration of the current license.

(c) The renewal application includes the following:

(1) An application for the renewal of a license to operate an abortion clinic on a form prescribed by the division to include the selection of only one (1) of the following procedure classifications:

(A) Surgical abortions only. The clinic is precluded from performing drug induced abortions.

(B) Both drug induced abortions and surgical abortions. The clinic must comply with 410 IAC 26 and LSA Document #X.

(2) Documents required by the application for the renewal of a license to operate an abortion clinic.

(3) The appropriate license fee.

(d) Upon determination by the commissioner that the applicant has met the licensing requirements for an abortion clinic, the commissioner shall approve the application for the renewal of a license to operate an abortion clinic and issue a license.

SECTION 9. (a) This SECTION supersedes 410 IAC 26-3-2.

(b) The department will conduct a licensing survey of each abortion clinic at least one (1) time per calendar year. The licensing survey is conducted to ensure that the abortion clinic is operating in compliance with this document.

(c) Licensing surveys will be conducted during normal business hours of the abortion clinic unless the abortion clinic requests that the survey be conducted during nonbusiness hours.

(d) The division will notify the clinic of the results of the licensing survey in writing.

SECTION 10. (a) This SECTION supersedes 410 IAC 26-3-4.

(b) The abortion clinic must file an acceptable plan of correction with the division within ten (10) days of receipt of a survey report from the division that documents noncompliance with state rules.

(c) Unless the commissioner determines that there is a need for immediate release, the abortion clinic will have ten (10) days after notification of a noncompliance to submit to the division an acceptable plan of correction before the survey report is made available to the public.

(d) The plan of correction shall contain, for each deficient practice cited on the survey report, at least the following:

(1) How the deficient practice will be corrected.

(2) How the deficient practice will be prevented from reoccurrence.

(3) Who will be responsible for correction and prevention.

(4) The month, day, and year that the corrective action will be completed, not to exceed thirty (30) days from receipt of the notice of noncompliance.

(5) If the nature of the corrective action requires more than thirty (30) days from the date of receipt of the notice of noncompliance, the clinic shall submit justification and a completion date to the division.

(e) If the division determines all or part of the submitted plan is unacceptable, the clinic shall submit a revised plan of correction within five (5) days of receipt of the notice identifying the unacceptable plan or part thereof.

(f) Failure to submit any required plan of correction or failure to implement a corrective action by the completion date may result in an enforcement action pursuant to 410 IAC 26-2-8.

SECTION 11. (a) This SECTION supersedes 410 IAC 26-7-2.

(b) The medical record for surgical abortions must be accurate and contain sufficient information to do the following:

(1) Identify the patient to include name, age, and address.

(2) Document the following:

(A) Tests, examinations, and procedures performed.

(B) The course of the patient's stay in the clinic and the results.

(C) Evidence that the patient was provided the hotline telephone number for assistance to patients who are:

(i) coerced into an abortion; or

(ii) victims of sex trafficking.

(3) Evidence of appropriate informed consent for procedures and treatments as required by IC 16-34-2-1.1.

(4) Any report filed with a state agency or law enforcement agency pursuant to a statutory reporting requirement.

(c) Entries in the medical record must be as follows:

(1) Legible.

(2) Complete.

(3) Made by authorized individuals as specified in clinic and medical staff policies.

(4) Authenticated and dated in accordance with this document.

(d) Patient records for surgical abortions must document and contain, at a

minimum, the following:

(1) Appropriate medical history.

(2) Results of the following:

(A) A physical examination.

(B) Diagnostic or laboratory studies, or both (if performed).

(3) Any allergies and abnormal drug reactions.

(4) Entries related to anesthesia administration.

(5) A report describing techniques, findings, and tissue removed or altered.

(6) Authentication of entries by the physician or physicians and health care workers who treated or cared for the patient.

(7) Condition on discharge, disposition of the patient, and time of discharge.

(8) Discharge entry to include instructions to the patient or patient's legal representative.

(9) A copy of the following:

(A) The transfer form if the patient was referred to a hospital or other facility.

(B) The terminated pregnancy report filed with the department.

(C) Any document signed by the patient.

(e) An appropriate history and physical examination report must be in the patient's chart before a surgical abortion. The report shall include, but is not limited to, the following:

(1) Vital signs.

(2) Allergies.

(3) Any significant risk factors.

(4) The date written.

SECTION 12. (a) This SECTION supersedes 410 IAC 26-8-3.

(b) The clinic must do the following:

(1) Develop, implement, and maintain a policy and procedure for the orientation of new employees, contractors, and agency personnel providing direct care and services to patients.

(2) Orientate all new employees, including contract and agency personnel, to applicable clinic and personnel policies.

(c) The clinic shall ensure cardiopulmonary resuscitation (CPR) competence in accordance with current standards of practice and clinic policy for all health care workers including contract and agency personnel who provide direct patient care.

(d) The clinic shall ensure all employees receive annual training by law enforcement officers on identifying and assisting women who are:

(1) coerced into an abortion; or

(2) victims of sex trafficking.

(e) The clinic shall document in each employee's personnel file evidence of annual training provided by a law enforcement officer on identifying and assisting women who are:

(1) coerced into an abortion; or

(2) victims of sex trafficking.

SECTION 13. (a) This SECTION supersedes 410 IAC 26-10-1.

(b) All patient care services must:

(1) meet the needs of the patient, within the scope of the service offered, in accordance with acceptable standards of practice;

(2) be under the direction of a qualified person or persons; and

(3) require that:

(A) patient care services rendered are:

(i) reviewed and analyzed at regular meetings of patient care personnel; and

(ii) used as a basis for evaluating the quality of services provided; and

(B) personnel with appropriate training are available at all times to handle possible emergencies involving patients of the clinic.

(c) Written patient care policies and procedures must be available to personnel and must include, but not be limited to, the following:

(1) A provision that a reliable method of patient identification must be used.

(2) A provision for instruction or instructions to be given to the patient or the patient's legal representative regarding follow-up care and transportation needed by the patient on discharge following a surgical abortion to include at least the following:

(A) Signs and symptoms of possible complications.

(B) Activities allowed and to be avoided.

(C) Hygienic and other postdischarge procedures to be followed.

(D) Clinic emergency phone numbers available on a twenty-four (24) hour basis for the patient to contact the clinic for a complication and be triaged for care and:

(i) be seen the same day by a practitioner; or

(ii) be referred to an appropriate site of care.

- (E) Follow-up appointment, if indicated.**
- (F) Counseling regarding Rh typing.**
- (G) Administration of Rh immune globulin, if indicated, unless:
 - (i) the patient signs a waiver refusing the administration; or**
 - (ii) other arrangements for administration are documented.****
- (3) A provision to maintain a written system of documentation of patients who report post-procedure complications and the clinic's interventions. The interventions must be documented in the medical record.**
- (4) A provision that facilities, reusable equipment, and supplies must be thoroughly cleaned or sterilized following use according to clinic policies and procedures.**
- (5) A provision that all patients must be observed during the recovery period by qualified personnel.**

SECTION 14. (a) This SECTION supersedes 410 IAC 26-13-1.

(b) The clinic must provide adequate anesthesia services to meet the needs of the patient, within the scope of the services offered, in accordance with acceptable standards of practice, under the direction of a licensed physician with specialized training or experience in the administration of anesthetics.

(c) Anesthesia services must be provided in compliance with IC 25 and rules adopted under that title.

(d) Anesthesia services in a clinic are limited to the following:

- (1) Minimal sedation.**
- (2) Moderate sedation.**

The clinic may not use deep sedation or general anesthesia.

(e) The medical director shall adopt and implement policies and procedures that include, but are not limited to, the following:

- (1) Safety rules to be followed relating to the administration of anesthesia.**
- (2) Safety training required of personnel.**

(f) Anesthesia must be administered by one (1) of the following:

- (1) A qualified physician with appropriate training and experience.**
- (2) A registered nurse acting under the direction of and in the immediate presence of the operating physician or other physician and who holds a certificate of completion of a course in anesthesia approved by the:**

(A) American Association of Nurse Anesthetists; or

(B) medical licensing board.

(g) The clinic shall ensure the delineation of preanesthesia, intraoperative, and postanesthesia responsibilities as follows:

- (1) The completion, within forty-eight (48) hours before a surgical abortion, of a preanesthesia evaluation for each patient by an individual qualified to administer anesthesia. If completed more than forty-eight (48) hours before the surgical abortion, the preanesthesia evaluation shall be updated according to clinic policy.**
- (2) When using moderate sedation, the patient shall be monitored by qualified personnel other than the physician performing the procedure that must include and document at five (5) minute intervals the following:**

- (A) Pulse oximetry.**
- (B) Observed pulmonary ventilation.**
- (C) Heart rate.**
- (D) Blood pressure.**
- (E) Response to verbal commands.**

(3) The completion of a postanesthetic evaluation for proper anesthesia recovery of each patient before discharge in accordance with written policies and procedures approved by the medical staff.

(4) The requirement that all postoperative patients must be discharged from the postanesthetic care unit by the physician responsible for the patient's care in accordance with clinic policy.

SECTION 15. (a) This SECTION supersedes 410 IAC 26-17-2.

(b) Building entrances used to reach the clinic shall be as follows:

(1) At grade level.

(2) Clearly marked.

(3) Located so that patients need not go through other activity areas.

When the abortion clinic is part of another facility, separation of and access to the clinic shall be maintained. Lobbies of multioccupancy buildings may be shared. The design of the clinic shall preclude unrelated traffic from the clinic.

(c) The clinic design shall ensure appropriate levels of patient:

(1) audible and visual privacy; and

(2) dignity;

throughout the care process.

(d) For common administration and authorized visitor areas, the clinic shall be able to accommodate wheelchairs and provide the following:

(1) A reception and information counter. The reception and information counter or desk shall be as follows:

(A) Located to provide visual control of the entrance to the clinic.

(B) Immediately apparent from the entrance.

(2) A waiting area. The waiting area shall be under staff control. The seating area shall contain not fewer than two (2) spaces for each examination and procedure room.

(3) At least one (1) conveniently accessible toilet room containing a lavatory for hand washing.

(4) Conveniently accessible drinking water.

(5) Interview space for private interviews related, for example, to social services or credit.

(6) General storage facilities for supplies and equipment needed for continuing operation.

(e) Requirements for clinical facilities are as follows:

(1) Procedure rooms shall be segregated and removed from general traffic flow and be a minimum of:

(A) one hundred twenty (120) square feet, exclusive of vestibules, toilets, and closets for procedures requiring only local analgesia or nitrous oxide; and

(B) two hundred fifty (250) square feet, exclusive of vestibules, toilets, or closets for procedures that require conscious sedation.

(2) Rooms exclusively used for examinations shall be a minimum of eighty (80) square feet exclusive of vestibules, toilets, or closets.

(3) A hand washing station shall be included within each procedure room.

(4) Scrub facilities:

(A) shall be provided near the entrance of procedure rooms;

(B) may provide service to multiple procedure rooms if needed; and

(C) shall be arranged to minimize splatter on nearby personnel or supply

carts.

(5) A separate recovery room or area shall be included and provide for the following:

(A) A minimum clear area of two (2) feet, six (6) inches around three (3) sides of each recovery cart or lounge chair for work and circulation.

(B) A method of providing privacy for each patient in the room or area.

(C) A work station with the following:

(i) A countertop.

(ii) Space for supplies.

(iii) Provisions for charting.

(iv) A communication system.

(6) A drug distribution station will be included. The station:

(A) may be a part of the work station; and

(B) shall include a:

(i) work counter;

(ii) sink;

(iii) refrigerator (if needed); and

(iv) locked storage for biologicals and drugs.

(7) A toilet room containing a lavatory for hand washing shall be accessible from all examination and procedure rooms. Where a clinic has no more than a total of three (3) examination and procedure rooms, the patient toilet may also serve as the toilet for the waiting area.

(f) Requirements for design standards are as follows:

(1) At least one (1) housekeeping room with:

(A) a service sink; and

(B) adequate storage for housekeeping supplies and equipment;

shall be provided.

(2) Hand washing stations shall:

(A) be located and arranged to meet the needs of the clinic; and

(B) permit proper use and operation.

Provisions for hand drying shall be included at all hand washing stations except scrub sinks.

(3) There shall be an equipment room or rooms for:

(A) heating;

(B) air conditioning;

(C) hot water;

(D) other mechanical; and

(E) electrical;

equipment.

(4) Incinerators, if used, shall also conform to the building standards prescribed by area air pollution regulations.

(5) The minimum corridor width shall be forty-four (44) inches. Items such as drinking fountains, telephones, and vending machines, shall not:

(A) restrict corridor traffic; or

(B) reduce the corridor width below the required minimum.

(6) The minimum nominal door width for patient use shall be three (3) feet.

(7) Each building shall have at least two (2) exits that are remote from each other.

(8) An approved antiscald device shall be provided on the hot water supply to all hand washing facilities limiting the water temperature to a maximum of one

hundred ten (110) degrees Fahrenheit (forty-three (43) degrees Celsius).

SECTION 16. (a) This SECTION supersedes 410 IAC 26-18-1.

(b) If the clinic provides other services not covered in specific sections of 410 IAC 26, the services must meet the needs of the patients served, within the scope of the service offered, and in accordance with acceptable standards of practice.

(c) The services must be as follows:

(1) Under the direction of a qualified person or persons.

(2) Staffed in accordance with written clinic policies and in compliance with the applicable state and federal rules.

SECTION 17. Abortion clinics must provide informed consent brochures, as described in IC 16-34-2-1.5, in English, Spanish, and German, inside the abortion clinic.

SECTION 18. Abortion clinics currently licensed under 410 IAC 26 do not need to be licensed as a surgical abortion clinic under this document or a drug induced abortion clinic under LSA #X until the abortion clinic renews its license.