TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Proposed Rule
LSA Document #19-164

DIGEST

Amends 410 IAC 26-1-3, 410 IAC 26-2-1, 410 IAC 26-2-3, 410 IAC 26-2-6, 410 IAC 26-2-8, 410 IAC 26-3-2, 410 IAC 26-3-4, 410 IAC 26-6-2, 410 IAC 26-7-2, 410 IAC 26-8-2, 410 IAC 26-8-3, 410 IAC 26-10-1, 410 IAC 26-13-1, 410 IAC 26-17-2, 410 IAC 26-18-1, and 410 IAC 26-19-1 and adds 410 IAC 26-0.5, 410 IAC 26-1-3.2, 410 IAC 26-1-14.3, 410 IAC 26-1-14.6, and 410 IAC 26-18.5 to make the rules applicable only to abortion clinics providing surgical abortions; to update and add definitions; 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, physical plant requirements, and documents incorporated by reference; and to add informed consent brochure requirements. Removes outdated references and makes technical corrections. Repeals 410 IAC 26-1-7. Effective 30 days after filing with the Publisher.

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

410 IAC 26-0.5; 410 IAC 26-1-3; 410 IAC 26-1-3.2; 410 IAC 26-1-7; 410 IAC 26-1-14.3; 410 IAC 26-1-14.6; 410 IAC 26-2-1; 410 IAC 26-2-3; 410 IAC 26-2-6; 410 IAC 26-2-8; 410 IAC 26-3-2; 410 IAC 26-3-4; 410 IAC 26-6-2; 410 IAC 26-7-2; 410 IAC 26-8-2; 410 IAC 26-8-3; 410 IAC 26-10-1; 410 IAC 26-13-1; 410 IAC 26-17-2; 410 IAC 26-18-1; 410 IAC 26-18.5; 410 IAC 26-19-1

SECTION 1. 410 IAC 26-0.5 IS ADDED TO READ AS FOLLOWS:

Rule 0.5. Applicability

410 IAC 26-0.5-1 Applicability

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-19-3; IC 16-21-1

Sec. 1. This article 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 410 IAC 26.5.

(Indiana State Department of Health; 410 IAC 26-0.5-1)

SECTION 2. 410 IAC 26-1-3 IS AMENDED TO READ AS FOLLOWS:

410 IAC 26-1-3 "Abortion clinic" defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-18-2-163; IC 16-21-1; IC 16-21-2

Sec. 3. **(a)** "Abortion clinic" ~~has the meaning set forth in IC 16-18-2-1.5.~~ **means a health care provider (as defined in IC 16-18-2-163(d)(1)) that performs surgical abortion procedures.**

(b) The term does not include the following:
(1) A hospital that is licensed as a hospital under IC 16-21-2.
(2) An ambulatory outpatient surgical center that is licensed as an ambulatory outpatient surgical center under IC 16-21-2.
(3) 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.

(Indiana State Department of Health; 410 IAC 26-1-3; filed May 11, 2006, 9:36 a.m.: 29 IR 3355; readopted filed Jul 12, 2012, 12:08 p.m.: 20120808-IR-410120196RFA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

SECTION 3. 410 IAC 26-1-3.2 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-1-3.2 "Affiliate" defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-18-2-9.4; IC 16-21-1; IC 16-21-2

Sec. 3.2. "Affiliate" has the meaning set forth in IC 16-18-2-9.4.

(Indiana State Department of Health; 410 IAC 26-1-3.2)

SECTION 4. 410 IAC 26-1-14.3 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-1-14.3 "Minimal sedation" defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-21-1; IC 16-21-2

Sec. 14.3. "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.

(Indiana State Department of Health; 410 IAC 26-1-14.3)

SECTION 5. 410 IAC 26-1-14.6 IS ADDED TO READ AS FOLLOWS:

410 IAC 26-1-14.6 "Moderate sedation" defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-21-1; IC 16-21-2

Sec. 14.6. "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.

(Indiana State Department of Health; 410 IAC 26-1-14.6)

SECTION 6. 410 IAC 26-2-1 IS AMENDED TO READ AS FOLLOWS:

410 IAC 26-2-1 License

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 4-21.5-3-5; IC 16-21-2

Sec. 1. (a) 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.

(b) A license to operate an abortion clinic:
(1) expires one (1) year after the date of issuance;
(2) is not assignable or transferable; ~~and~~
(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.

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

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

(Indiana State Department of Health; 410 IAC 26-2-1; filed May 11, 2006, 9:36 a.m.: 29 IR 3356; readopted filed Jul 12, 2012, 12:08 p.m.: 20120808-IR-410120196RFA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

SECTION 7. 410 IAC 26-2-3 IS AMENDED TO READ AS FOLLOWS:

410 IAC 26-2-3 Application for initial license

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-21-1; IC 16-21-2

Sec. 3. (a) 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.

(b) 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 this article and 410 IAC 26.5.
(2) Documents required by the application for a license to operate an abortion clinic.
(3) The appropriate license fee.

(c) The application for an abortion clinic license must require the applicant to do the following:
(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.

~~(c)~~ **(d)** 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.

(Indiana State Department of Health; 410 IAC 26-2-3; filed May 11, 2006, 9:36 a.m.: 29 IR 3356; readopted filed Jul 12, 2012, 12:08 p.m.: 20120808-IR-410120196RFA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

SECTION 8. 410 IAC 26-2-6 IS AMENDED TO READ AS FOLLOWS:

410 IAC 26-2-6 Renewal of license

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-21-1; IC 16-21-2

Sec. 6. (a) 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.

(b) 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 this article and 410 IAC 26.5.
(2) Documents required by the application for the renewal of a license to operate an abortion clinic.
(3) The appropriate license fee.

(c) 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.

(Indiana State Department of Health; 410 IAC 26-2-6; filed May 11, 2006, 9:36 a.m.: 29 IR 3357; readopted filed Jul 12, 2012, 12:08 p.m.: 20120808-IR-410120196RFA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

SECTION 9. 410 IAC 26-2-8 IS AMENDED TO READ AS FOLLOWS:

410 IAC 26-2-8 Enforcement actions

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-21-2; IC 16-21-3; IC 27-13-1

Sec. 8. (a) The commissioner may take any of the following actions on any of the grounds listed in subsection (b):
(1) Issue a letter of correction.
(2) Issue a probationary license.
(3) Conduct a resurvey.
(4) Deny the renewal of a license.
(5) Revoke a license.
(6) Impose a civil penalty in an amount not to exceed ten thousand dollars ($10,000).

(b) The commissioner may take action under subsection (a) on any of the following grounds:
(1) Violation of any provision of this article.
(2) Permitting, aiding, or abetting the commission of any illegal act in an abortion clinic.
(3) Knowingly collecting or attempting to collect from:
(A) a subscriber (as defined in IC 27-13-1-32); or
(B) an enrollee (as defined in IC 27-13-1-12);
of a health maintenance organization (as defined in IC 27-13-1-19) any amounts that are owed by the health maintenance organization.
(4) Conduct or practice found by the ~~council~~ **department** to be detrimental to the welfare of the patients of an abortion clinic.

(Indiana State Department of Health; 410 IAC 26-2-8; filed May 11, 2006, 9:36 a.m.: 29 IR 3358; readopted filed Jul 12, 2012, 12:08 p.m.: 20120808-IR-410120196RFA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

SECTION 10. 410 IAC 26-3-2 IS AMENDED TO READ AS FOLLOWS:

410 IAC 26-3-2 Licensing surveys

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-21-1; IC 16-21-2

Sec. 2. (a) The department will conduct a licensing survey of each abortion clinic at least ~~once every two (2) years.~~ **one (1) time per calendar year.** The licensing survey is conducted to ensure that the abortion clinic is operating in compliance with this article.

(b) 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.

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

~~(d) The division may accept as the licensing survey an accreditation or certification survey report from a nationally recognized abortion accreditation or certification agency, association, or organization that is deemed by the division to have survey standards consistent with this article. The clinic may request that the division accept an accreditation or certification survey as the licensing survey. The request must be filed by the clinic with the department following an accreditation or certification survey and prior to a licensing survey. Upon request by the clinic, the division will review the accreditation or certification survey report for the clinic. If the division finds that, based on the accreditation or certification report, the clinic was in compliance with this article, the division will accept the accreditation or certification report as a licensing survey. If, based on the accreditation or certification report, the clinic failed to comply with this article, the division may:~~

~~(1) request a plan of correction and evaluate the plan of correction for compliance; or~~

~~(2) conduct a licensing survey.~~

~~While the division may accept an accreditation or certification survey in place of a licensing survey, over the course of each four (4) year survey period, the division will conduct at least one (1) licensing survey at each clinic.~~

(Indiana State Department of Health; 410 IAC 26-3-2; filed May 11, 2006, 9:36 a.m.: 29 IR 3359; readopted filed Jul 12, 2012, 12:08 p.m.: 20120808-IR-410120196RFA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

SECTION 11. 410 IAC 26-3-4 IS AMENDED TO READ AS FOLLOWS:

410 IAC 26-3-4 Plan of correction

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-21-1; IC 16-21-2

Sec. 4. (a) 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.

(b) 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.

(c) 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.

(d) 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.

(e) 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 under 410 IAC 26-2-8.

(Indiana State Department of Health; 410 IAC 26-3-4; filed May 11, 2006, 9:36 a.m.: 29 IR 3359; readopted filed Jul 12, 2012, 12:08 p.m.: 20120808-IR-410120196RFA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

SECTION 12. 410 IAC 26-6-2 IS AMENDED TO READ AS FOLLOWS:

410 IAC 26-6-2 Reportable events

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1; IC 25

Sec. 2. (a) The clinic's quality assessment and improvement program under section 1 of this rule shall include the following:

(1) A process for determining the occurrence of the following reportable events within the clinic:

(A) The following surgical events:

(i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:

(AA) that occur in the course of surgery; or

(BB) whose exigency precludes obtaining informed consent;

or both.

(ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.

(iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:

(AA) that occur in the course of surgery; or

(BB) whose exigency precludes obtaining informed consent;

or both.

(iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded:

(AA) Objects intentionally implanted as part of a planned intervention.

(BB) Objects present before surgery that were intentionally retained.

(CC) Objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention, such as microneedles or broken screws.

(v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.

(B) The following product or device events:

(i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the clinic. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.

(ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:

(AA) Catheters.

(BB) Drains and other specialized tubes.

(CC) Infusion pumps.

(DD) Ventilators.

(iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the clinic. Excluded are deaths or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(C) The following patient protection events:

(i) Infants discharged to the wrong person.

(ii) Patient death or serious disability associated with patient elopement.

(iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the clinic, defined as events that result from patient actions after admission to the clinic. Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the clinic.

(D) The following care management events:

(i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:

(AA) drug;

(BB) dose;

(CC) patient;

(DD) time;

(EE) rate;

(FF) preparation; or
(GG) route of administration.
Excluded are reasonable differences in clinical judgment on drug selection and dose. Includes administration of a medication to which a patient has a known allergy and drug-drug interactions for which there is known potential for death or serious disability.
(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products.
(iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the clinic. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:
(AA) Pulmonary or amniotic fluid embolism.
(BB) Acute fatty liver of pregnancy.
(CC) Cardiomyopathy.
(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the clinic.
(v) Death or serious disability (kernicterus) associated with the failure to identify and treat hyperbilirubinemia in neonates.
(vi) Stage 3 or 4 pressure ulcers acquired after admission to the clinic. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable because of the presence of eschar.
(vii) Patient death or serious disability resulting from joint movement therapy performed in the clinic.
(viii) Artificial insemination with the wrong donor sperm or wrong egg.
(E) The following environmental events:
(i) Patient death or serious disability associated with an electric shock while being cared for in the clinic. Excluded are events involving planned treatment, such as electrical countershock or elective cardioversion.
(ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient:
(AA) contains the wrong gas; or
(BB) is contaminated by toxic substances.
(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the clinic.
(iv) Patient death or serious disability associated with a fall while being cared for in the clinic.
(v) Patient death or serious disability associated with the use of restraints or bed rails while being cared for in the clinic.
(F) The following criminal events:
(i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.
(ii) Abduction of a patient of any age.
(iii) Sexual assault on a patient within or on the grounds of the clinic.
(iv) Death or significant injury of a patient or staff member resulting from a physical assault, that is, battery, that occurs within or on the grounds of the clinic.
(2) A process for reporting to the department each reportable event listed in subdivision (1) that is determined by the clinic's quality assessment and improvement program to have occurred within the clinic.

(b) ~~Subject to subsection (c),~~ The process for determining the occurrence of the reportable events listed in subsection (a)(1) by the clinic's quality assessment and improvement program shall be designed by the clinic to accurately determine the occurrence of any of the reportable events listed in subsection (a)(1) within the clinic in a timely manner.

(c) ~~Subject to subsection (c),~~ The process for reporting the occurrence of a reportable event listed in subsection (a)(1) shall comply with the following:
(1) The report shall:
(A) be made to the department;
(B) be submitted not later than fifteen (15) working days after the reportable event is determined to have occurred by the clinic's quality assessment and improvement program;
(C) be submitted not later than four (4) months after the potential reportable event is brought to the program's attention; and
(D) identify the reportable event, the quarter of occurrence, and the clinic, but shall not include any identifying information for any:
(i) patient;
(ii) individual licensed under IC 25; or

(iii) clinic employee involved;
or any other information.

(2) A potential reportable event may be identified by a clinic that:
(A) receives a patient as a transfer; or
(B) admits a patient subsequent to discharge;
from another health care facility subject to a reportable event requirement. In the event that a clinic identifies a potential reportable event originating from another health care facility subject to a reportable event requirement, the identifying clinic shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.

(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.

(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.

(d) The clinic's report of a reportable event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of reportable events occurring within each clinic. The department's public report will be issued annually.

~~(e) Any reportable event listed in subsection (a)(1) that:~~
~~(1) is determined to have occurred within the clinic between:~~
~~(A) January 1, 2009; and~~
~~(B) the effective date of this rule; and~~
~~(2) has not been previously reported;~~
~~must be reported within five (5) days of the effective date of this rule.~~

(Indiana State Department of Health; 410 IAC 26-6-2; filed Nov 21, 2006, 7:20 a.m.: 20061220-IR-410050321FRA; filed Oct 7, 2008, 10:26 a.m.: 20081105-IR-410080061FRA; readopted filed Jul 12, 2012, 12:08 p.m.: 20120808-IR-410120196RFA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

SECTION 13. 410 IAC 26-7-2 IS AMENDED TO READ AS FOLLOWS:

410 IAC 26-7-2 Content of the medical record

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-21-1; IC 16-21-2; IC 16-34-2-1.1

Sec. 2. (a) 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.
(D) Evidence of appropriate informed consent for procedures and treatments as required by IC 16-34-2-1.1.
(E) Any report filed with a state agency or law enforcement agency pursuant to a statutory reporting requirement.

(b) 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 article.

(c) Patient records for surgical abortions must document and contain, at a minimum, the following:
~~(1) Patient identification.~~
~~(2)~~ **(1)** Appropriate medical history.
~~(3)~~ **(2)** Results of the following:
(A) A physical examination.
(B) Diagnostic or laboratory studies, or both (if performed).
~~(4)~~ **(3)** Any allergies and abnormal drug reactions.
~~(5)~~ **(4)** Entries related to anesthesia administration.
~~(6) Evidence of appropriate informed consent for procedures and treatments as required by IC 16-34-2-1.1.~~
~~(7)~~ **(5)** A report describing techniques, findings, and tissue removed or altered.
~~(8)~~ **(6)** Authentication of entries by the physician or physicians and health care workers who treated or cared for the patient.
~~(9)~~ **(7)** Condition on discharge, disposition of the patient, and time of discharge.
~~(10)~~ **(8)** Discharge entry to include instructions to the patient or patient's legal representative.
~~(11)~~ **(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.
~~(12) Any report filed with a state agency or law enforcement agency pursuant to a statutory reporting requirement.~~

(d) 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.

(Indiana State Department of Health; 410 IAC 26-7-2; filed May 11, 2006, 9:36 a.m.: 29 IR 3363; readopted filed Jul 12, 2012, 12:08 p.m.: 20120808-IR-410120196RFA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

SECTION 14. 410 IAC 26-8-2 IS AMENDED TO READ AS FOLLOWS:

410 IAC 26-8-2 Employee health monitoring

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-21-1; IC 16-21-2

Sec. 2. The clinic shall do the following:
(1) Develop, implement, and maintain a written policy for the control of communicable disease in compliance with applicable federal and state laws.
(2) Monitor employee health in accordance with the clinic's infection control program.
(3) Ensure that all employees, staff members, and contractors having direct patient contact are evaluated at least annually for tuberculosis as follows:
(A) Any person with a negative history of tuberculosis or a negative test result must have a baseline two-step tuberculin skin test using the Mantoux method or a quantiferon-TB assay unless the individual has documentation that a tuberculin skin test has been applied at any time during the previous twelve (12) months and the result was negative.
(B) The second step of a two-step tuberculin skin ~~tests~~ **test** using the Mantoux method must be administered one (1) to three (3) weeks after the first tuberculin skin test was administered.
(C) Any person with a documented history of tuberculosis, documented previously positive test result for tuberculosis, documented completion of treatment for tuberculosis, or newly positive results to the tuberculin skin test must have one (1) chest radiograph to exclude a diagnosis of tuberculosis.
(D) After baseline testing, tuberculosis screening must be completed annually and must include at a minimum a tuberculin skin test using the Mantoux method or a quantiferon-TB assay unless the individual was subject to ~~subdivision "C" of this subsection~~ **clause (C).**
(E) Any person having a positive finding on a tuberculosis evaluation may not work in the abortion clinic or provide direct patient contact unless approved by a physician to work.

(F) The abortion clinic must maintain documentation of tuberculosis evaluations showing that any person working for the abortion clinic or having direct patient contact has had a negative finding on a tuberculosis examination within the previous twelve (12) months.

(Indiana State Department of Health; 410 IAC 26-8-2; filed May 11, 2006, 9:36 a.m.: 29 IR 3364; readopted filed Jul 12, 2012, 12:08 p.m.: 20120808-IR-410120196RFA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

SECTION 15. 410 IAC 26-8-3 IS AMENDED TO READ AS FOLLOWS:

410 IAC 26-8-3 Orientation and training requirements

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-21-1; IC 16-21-2

Sec. 3. (a) 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.

(b) 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.

(c) 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.

(d) 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.

(Indiana State Department of Health; 410 IAC 26-8-3; filed May 11, 2006, 9:36 a.m.: 29 IR 3364; readopted filed Jul 12, 2012, 12:08 p.m.: 20120808-IR-410120196RFA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

SECTION 16. 410 IAC 26-10-1 IS AMENDED TO READ AS FOLLOWS:

410 IAC 26-10-1 Patient care

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-21-1; IC 16-21-2

Sec. 1. (a) 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.

(b) 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 either:**
(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.

(Indiana State Department of Health; 410 IAC 26-10-1; filed May 11, 2006, 9:36 a.m.: 29 IR 3365; readopted filed Jul 12, 2012, 12:08 p.m.: 20120808-IR-410120196RFA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

SECTION 17. 410 IAC 26-13-1 IS AMENDED TO READ AS FOLLOWS:

410 IAC 26-13-1 Anesthesia services

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-21-1; IC 16-21-2; IC 25

Sec. 1. (a) 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.

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

(c) Anesthesia services in a clinic are limited to the following:
(1) ~~Local anesthesia/analgesia.~~ **Minimal sedation.**
(2) ~~Nitrous oxide.~~ **Moderate sedation.**
~~(3) Conscious sedation.~~
The clinic may not use deep sedation or general anesthesia.

(d) 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.

(e) 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 **of Indiana.**

(f) 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 ~~conscious~~ **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) ~~Frequent checking for verbal responses.~~ **Pulse oximetery.**
~~(B) Monitoring of a degree that can be expected to detect the:~~
~~(i) respiratory;~~
~~(ii) cardiovascular; and~~
~~(iii) neurological;~~
~~effects of the drugs being used.~~
(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.

(Indiana State Department of Health; 410 IAC 26-13-1; filed May 11, 2006, 9:36 a.m.: 29 IR 3367; readopted filed Jul 12, 2012, 12:08 p.m.: 20120808-IR-410120196RFA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

SECTION 18. 410 IAC 26-17-2 IS AMENDED TO READ AS FOLLOWS:

410 IAC 26-17-2 Specifications of physical plant

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-21-1; IC 16-21-2

Sec. 2. (a) 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.

(b) The clinic design shall ensure appropriate levels of patient:
(1) audible and visual privacy; and
(2) dignity;
throughout the care process.

(c) 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) ~~A~~ Conveniently accessible drinking ~~fountain.~~ **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.

(d) 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.

~~(2)~~ **(3)** A hand washing station shall be included within each procedure room.

~~(3)~~ **(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.

~~(4)~~ **(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.

~~(5)~~ **(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.

~~(6)~~ **(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 procedures rooms, the patient toilet may also serve as the toilet for the waiting area.

(e) 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, **or** vending machines ~~etc.,~~ 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 ~~a~~ **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).

~~(f) Clinics operating before July 1, 2006, are exempted from requirements of this section.~~

(Indiana State Department of Health; 410 IAC 26-17-2; filed May 11, 2006, 9:36 a.m.: 29 IR 3370; readopted filed Jul 12, 2012, 12:08 p.m.: 20120808-IR-410120196RFA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

SECTION 19. 410 IAC 26-18-1 IS AMENDED TO READ AS FOLLOWS:

410 IAC 26-18-1 Other services

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-21-1; IC 16-21-2

Sec. 1. (a) If the clinic provides other ~~surgical abortion~~ services not covered in specific sections of this article, 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.

(b) 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.

(Indiana State Department of Health; 410 IAC 26-18-1; filed May 11, 2006, 9:36 a.m.: 29 IR 3372; readopted filed Jul 12, 2012, 12:08 p.m.: 20120808-IR-410120196RFA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

SECTION 20. 410 IAC 26-18.5 IS ADDED TO READ AS FOLLOWS:

Rule 18.5. Informed Consent Brochures

410 IAC 26-18.5-1 Informed consent brochures

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-21-1; IC 16-21-2; IC 16-34-2-1.5

Sec. 1. 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.

(Indiana State Department of Health; 410 IAC 26-18.5-1)

SECTION 21. 410 IAC 26-19-1 IS AMENDED TO READ AS FOLLOWS:

410 IAC 26-19-1 Incorporation by reference

Authority: IC 16-21-1-7; IC 16-21-2-2.5
Affected: IC 16-21-1; IC 16-21-2

Sec. 1. (a) 42 CFR 493 (October 1, ~~2004)~~ **2017)** is hereby incorporated by reference as part of this ~~rule.~~ **article.**

(b) Federal rules that have been incorporated by reference do not include any later amendments than those specified in the incorporated citation. ~~Sales of~~ The Code of Federal Regulations ~~are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402.~~ **is found at https://www.gpo.gov/fdsys/browse/ collectionCfr.action?collectionCode=CFR.**

(c) All incorporated material is available for public review at the department.

(Indiana State Department of Health; 410 IAC 26-19-1; filed May 11, 2006, 9:36 a.m.: 29 IR 3372; readopted filed Jul 12, 2012, 12:08 p.m.: 20120808-IR-410120196RFA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

SECTION 22. 410 IAC 26-1-7 IS REPEALED.

Notice of Public Hearing

Posted: 06/12/2019 by Legislative Services Agency
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