TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Emergency Rule
LSA Document #19-8(E)

DIGEST

Temporarily adds a new rule regulating abortion clinics performing drug induced abortions. Statutory authority: IC 16-19-3-5; IC 16-21-2-2.5. Effective January 10, 2019.

SECTION 1. **This document applies to abortion clinics that provide an abortion inducing drug for the purpose of inducing an abortion. An abortion clinic that performs surgical abortion procedures must comply with 410 IAC 26.**

SECTION 2. **(a) The definitions in this SECTION apply throughout this document except as otherwise indicated.**

(b) "Abortion" has the meaning set forth in IC 16-18-2-1.

(c) "Abortion clinic" means the following:
(1) A health care provider that provides abortion inducing drugs for the purpose of inducing an abortion.
(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.

(d) "Affiliate" has the meaning set forth in IC 16-18-2-9.4.

(e) "ASA Class I patient" means a normal, healthy patient.

(f) "Authenticate" means the author or responsible individual has reviewed the clinical content of the order and validated an entry in the record by:
(1) a full signature, including first initial, last name, and discipline;
(2) written initials if full signature appears on the same page; or
(3) a unique identifier such as a number or computer key.

(g) "Biologics" means a biological product, such as:
(1) a globulin;
(2) a serum;
(3) a vaccine;
(4) an antitoxin;
(5) blood; or
(6) an antigen;
used in the prevention or treatment of disease.

(h) "Burn" means any injury or damage to the tissues of the body caused by exposure to any of the following:
(1) Fire.
(2) Heat.
(3) Chemicals.
(4) Electricity.
(5) Radiation.
(6) Gases.

(i) "Clinic" means an abortion clinic.

(j) "Commissioner" means the state health commissioner or the state health commissioner's designee.

(k) "Department" means the Indiana state department of health.

(l) "Division" means the division of acute care of the department.

(m) "Elopement" means any situation in which a registered or admitted patient, excluding events involving adults with decision making capacity, leaves the clinic without staff being aware that the patient has done so.

(n) "Governing body" means:
(1) board of trustees;
(2) governing board;
(3) board of directors; or
(4) other body or individual responsible for governing an abortion clinic.

(o) "Health care provider" has the meaning set forth in IC 16-18-2-163.

(p) "Health care worker" means a person who provides services whether as an individual health care provider, volunteer, or student at or employee of a clinic.

(q) "Hypoglycemia" means a physiologic state in which:
(1) the blood sugar falls below sixty (60) mg/dl (forty (40) mg/dl in neonates); and
(2) physiological or neurological, or both, dysfunction begins.

(r) "Immediately postoperative" means within twenty-four (24) hours after either of the following:
(1) Administration of anesthesia (if surgery or other invasive procedure is not completed).
(2) Completion of surgery or other invasive procedure.

(s) "Joint movement therapy" means all types of manual techniques, to include:
(1) mobilization (movement of the spine or a joint within its physiologic range of motion);
(2) manipulation (movement of the spine or a joint beyond its normal voluntary physiologic range of motion); or
(3) any other type of manual musculoskeletal therapy;
regardless of their precise anatomic and physiologic focus or their discipline of origin.

(t) "Kernicterus" means the medical condition in which elevated levels of bilirubin cause brain damage.

(u) "Licensed health professional" has the meaning set forth in IC 25-23-1-27.1.

(v) "Low-risk pregnancy" means a woman sixteen (16) to thirty-nine (39) years of age, with no previous diagnosis of any of the following:
(1) Essential hypertension.
(2) Renal disease.
(3) Collagen-vascular disease.
(4) Liver disease.
(5) Preeclampsia.
(6) Cardiovascular disease.
(7) Placenta previa.
(8) Multiple gestation.
(9) Intrauterine growth retardation.
(10) Smoking.
(11) Pregnancy-induced hypertension.
(12) Premature rupture of membranes.
(13) Other previously documented condition that poses a high risk of pregnancy-related mortality.

(w) "Medical staff" means physicians appointed by the governing body or contracted with by the governing body and responsible to the governing body for the following:
(1) The clinical and scientific work of the clinic.
(2) Advice regarding professional matters and policies.
(3) Review of the professional practices in the clinic for the purposes of reducing morbidity and

mortality and for the improvement of the care of patients in the clinic, including the following:
(A) The quality and necessity of care provided.
(B) The preventability of complications and deaths occurring in the clinic.

(x) "Pharmacist" means an individual licensed under IC 25-26-13.

(y) "Physician" means an individual licensed under IC 25-22.5-5.

(z) "Registered nurse" means an individual licensed under IC 25-23-1.

(aa) "Serious disability" means either of the following:
(1) Significant loss of function including sensory, motor, physiologic, or intellectual impairment:
(A) not present on admission and requiring continued treatment; or
(B) for which there is a high probability of long term or permanent lifestyle change at discharge.
(2) Unintended loss of a body part.

(bb) "Sexual assault" means a crime included under IC 35-42-4 or IC 35-46-1-3.

(cc) "Surgery or other invasive procedure", for purposes of SECTION 22 of this document, means surgical or other invasive procedures that involve a skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. A procedure begins at the time of the skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. A procedure ends when the surgical incision has been closed or operative devices such as probes have been removed. The procedures include, but are not limited to, the following:
(1) Open or percutaneous surgical procedures.
(2) Percutaneous aspiration.
(3) Selected injections.
(4) Biopsy.
(5) Percutaneous cardiac and vascular diagnostic or interventional procedures.
(6) Laparoscopies.
(7) Endoscopies.
(8) Colonoscopies.
The term excludes intravenous therapy, venipuncture for phlebotomy, or diagnostic tests without intravenous contrast agents.

(dd) "Toxic substance" means chemicals that are present in sufficient concentration to pose a hazard to human health.

SECTION 3. **(a) A license must be obtained from the 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;
(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.

SECTION 4. **(a) The department will not issue a provisional license to operate an abortion clinic until the clinic has passed a preoccupancy inspection by the department.**

(b) Once a new construction, addition, or renovation of an abortion clinic is complete, the abortion

clinic must notify the department that the clinic is ready for occupancy. The department will then schedule and perform a preoccupancy inspection. The preoccupancy inspection is to determine compliance of the abortion clinic with SECTIONS 38 and 39 of this document.

SECTION 5. **(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) Drug induced abortions only.
(B) Both drug induced abortions and surgical abortions.
(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:
(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;
if any.

(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.

SECTION 6. **(a) Upon receipt of a completed application for an abortion clinic license, the department will review the application and accompanying documentation to determine that the applicant has met the requirements of IC 16-21-2-11(a)(1) and IC 16-21-2-11(a)(2).**

(b) Upon determination by the commissioner that the applicant has failed to comply with this document, the commissioner may:
(1) request additional information concerning the application;
(2) conduct a further investigation to determine whether a provisional license should be granted; or
(3) deny the application.

(c) Upon determination by the commissioner that the applicant has complied with the provisional licensing requirements for an abortion clinic under this document, the commissioner will:
(1) provisionally approve the application for an abortion clinic license; and
(2) issue a provisional license to operate an abortion clinic.
The provisional license expires ninety (90) days after issue.

(d) After the opening of the clinic and before the expiration of the provisional license, the department will conduct a licensing survey to ensure that the clinic is operating in compliance with this document.

(e) If the clinic is found on the initial licensing survey to be in compliance with this document, the commissioner will issue a full license to operate an abortion clinic. If the clinic is not found to be in compliance with this document, the commissioner may extend the provisional license for up to ninety (90) days. If the provisional license is extended, a revisit survey will be conducted or additional documentation will be requested, or both, before the end of the provisional period to ensure compliance with this document. If the clinic is found to be in compliance with this document, the commissioner will issue a full license to operate an abortion clinic. If the clinic is not found to be in compliance with this document after the extended provisional period, the commissioner may:

(1) request additional information concerning the application;
(2) conduct a further investigation to determine whether a provisional license should be granted; or
(3) deny the application.

SECTION 7. **The commissioner may deny a license to operate an abortion clinic for any of the following reasons:**
(1) If the licensee or licensees are not of reputable and responsible character.
(2) If the abortion clinic is not in compliance with the minimum standards for an abortion clinic adopted under this document.
(3) For violation of any of the provisions of IC 16-21 or this document.
(4) For permitting, aiding, or abetting the commission of any illegal act in the clinic.
(5) For 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.
(6) If conduct or practices of the clinic are found to be detrimental to the patients of the abortion clinic.
(7) If the application for a license to operate an abortion clinic or supporting documentation provided inaccurate statements or information.

SECTION 8. **(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) Drug induced abortions only.
(B) Both drug induced abortions and surgical abortions.
(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.

SECTION 9. **A license issued under this document must be conspicuously posted on the premises in an area open to patients.**

SECTION 10. **(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 document.
(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 department to be detrimental to the welfare of the patients of an abortion clinic.

SECTION 11. **A probationary license may be:**

(1) issued for a period of three (3) months; and
(2) reissued;
but no more than three (3) probationary licenses may be issued during a twelve (12) month period. The issuance of a probationary license results in the automatic expiration of any other license held under this document.

SECTION 12. **(a) The abortion clinic shall fully cooperate with surveys conducted by representatives of the department. Upon arrival of department surveyors at the clinic, the clinic may immediately contact the department to confirm the identity of the surveyors. Upon confirmation by the department of the survey and surveyors, the clinic shall:**
(1) immediately admit the surveyors to the clinic; and
(2) not delay the survey.

(b) Documents, registers, reports, records, and minutes of the abortion clinic must be made available to the department upon request for inspection and copying.

(c) Before any information is copied for use by the department, the abortion clinic shall redact all information that identifies or could be used to identify a patient or staff member. Department surveyors may review the unredacted original in the abortion clinic.

(d) Documents, registers, reports, records, and minutes required to be maintained by the abortion clinic include, but are not limited to, the following:
(1) Documents showing ownership and a copy of articles of incorporation (if incorporated).
(2) All documents pertaining to quality assurance and improvement of patient care and medical care.
(3) Personnel records.
(4) Medical records relating to drug induced abortions.
(5) Reports under IC 16-21-2-6.
(6) Policies and procedures of the abortion clinic.

(e) If the governing body of the clinic is an individual responsible for governing the abortion clinic, the clinic is not required to prepare and maintain the documents referenced in this subsection. If the governing body is not an individual with sole authority and responsibility for the clinic, the clinic must prepare and maintain the following documents, registers, reports, records, and minutes to include, but not be limited to:
(1) The constitution and bylaws of the governing body.
(2) Minutes of meetings of the governing body and committees thereof.

(f) Documents, registers, reports, records, and minutes must be complete and up-to-date.

SECTION 13. **(a) 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.**

(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.

SECTION 14. **(a) In accordance with division policy, the division shall investigate credible complaints received by the division that allege noncompliance with this document.**

(b) Complaints will be assigned a priority for investigation in accordance with division policy.

(c) A licensing survey may be conducted simultaneously with and in addition to a complaint survey.

(d) The division shall notify the abortion clinic of the results of the complaint survey in writing.

SECTION 15. **(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 day, date, 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 pursuant to SECTION 10 of this document.

SECTION 16. **The department shall maintain the confidentiality of patient identities, patient information, and patient records.**

SECTION 17. **(a) The governing body:**

(1) shall function as the ultimate authority; and

(2) is responsible for the conduct and management;

of the abortion clinic.

(b) If the governing body is an individual who has sole authority and responsibility for the clinic, that individual may also serve as the clinic administrator or medical director, or both, if qualified. A clinic administrator appointed by the governing body may also serve as the medical director if qualified.

(c) The governing body shall do the following:

(1) Assume responsibility for:

(A) determining;

(B) implementing; and

(C) monitoring;

policies governing the clinic's operation.

(2) Ensure that:

(A) clinic policies are followed so as to provide quality health care in a safe environment; and

(B) the clinic complies with:

(i) this document;

(ii) IC 16-21; and

(iii) IC 16-34.

(3) Review, at least every six (6) months, reports of management operations, including, but not limited to, the following:

(A) Quality assessment and improvement program.

(B) Patient services provided.

(C) Results attained.

(D) Recommendations made.

(E) Actions taken.

(F) Follow-up.

(4) Maintain documents, registers, and reports that show the following:

(A) Ownership.

(B) Compliance with local, state, and federal laws and regulations.

(C) Adherence to clinic bylaws (if applicable) and clinic policies.

(5) Approve all appointments to or contracts with medical staff.

(6) Ensure the following:

(A) Maintenance of the physical plant.

(B) That the clinic is:
(i) equipped; and
(ii) staffed;
to meet the needs of the patients.
(7) Ensure that clinic policies and procedures are:
(A) updated as needed; and
(B) reviewed at least triennially.
(8) Establish the following:
(A) A policy and procedure for communication with physicians concerning a patient emergency.
(B) A process for the following:
(i) Reporting licensed health professionals who fail to comply with state professional licensing requirements as found in IC 25-22.5.
(ii) Documenting actions against licensed health professionals who fail to comply with the clinic policies and procedures.
(iii) Reporting information that statute requires the abortion clinic to report to a state agency or law enforcement agency.

(d) If the governing body is not an individual responsible for the governing of the clinic, the governing body must do the following:
(1) Adopt bylaws and operate in compliance with the bylaws.
(2) Review the bylaws at least triennially.

(e) If the governing body is not an individual who is also serving as the medical director, the governing body shall do the following:
(1) Designate a medical director who has the responsibility for the direction of:
(A) medical;
(B) nursing; and
(C) health-related;
services to patients.
(2) Maintain a liaison with the medical director.

(f) If the governing body is not an individual who is also serving as the clinic administrator, the governing body shall do the following:
(1) Designate a clinic administrator who has the responsibility and authority to carry out the day-to-day operation of the clinic.
(2) Develop criteria, which include, but are not limited to, defining educational and experience requirements for the clinic administrator.
(3) Delineate in writing the responsibility and authority of the clinic administrator.
(4) Require the following:
(A) That the clinic administrator or a designee:
(i) attend meetings of the governing body and its committees; and
(ii) act as its representative at medical staff meetings.
(B) That the clinic administrator:
(i) designate in writing an administrative officer to serve during his or her absence; and
(ii) participate in the development and implementation of appropriate policies and programs.

SECTION 18. **(a) The medical staff of the clinic:**
(1) consists of physicians appointed to or contracted with to provide medical services at the clinic; and
(2) must be composed of at least one (1) physician.

(b) The medical director must be a physician licensed to practice in the state of Indiana.

(c) If the medical staff consists of more than one (1) physician:
(1) the medical director shall serve as coordinator of the medical staff; and
(2) a current roster of members of the medical staff shall be maintained.

(d) In appointing or contracting with medical staff, the governing body shall do the following:
(1) Ensure that appointments to or contracts with medical staff are acted upon with the advice and recommendation of the medical director.
(2) Examine credentials of candidates for appointment, reappointment, or contracting to the medical

staff in accordance with the following:
(A) Clinic policy.
(B) Applicable state and federal law.
(3) Ensure that criteria for selection for medical staff include the following:
(A) Individual character.
(B) Competence.
(C) Education.
(D) Training.
(E) Experience.
(F) Judgment.
(4) Maintain a reasonably accessible hard copy or electronic file for each member of the medical staff, which includes, but is not limited to, the following:
(A) A completed, signed application.
(B) The date and year of completion of all Accreditation Council for Graduate Medical Education (ACGME) accredited residency training programs, if applicable.
(C) A current copy of the individual's credentials as follows:
(i) An Indiana license showing date of licensure and number or available data provided by the Indiana professional licensing agency. A copy of practice restrictions, if any, must be attached to the license issued by the Indiana professional licensing agency through the appropriate licensing board.
(ii) Indiana controlled substance registration showing number as applicable.
(iii) Drug Enforcement Agency registration showing number as applicable.
(iv) Documentation of experience in the practice of medicine.
(v) Documentation of specialty board certification as applicable.

(e) The governing body is responsible for the conduct of the medical staff activities related to the abortion clinic. The governing body shall ensure that the medical staff is accountable and responsible to the governing body for the quality of care provided to patients.

(f) The governing body is responsible for ensuring that quality patient care is provided. In accordance with clinic policy, the governing body shall ensure that a qualified licensed physician who is a member of the medical staff is responsible for the care and treatment of each patient.

(g) The governing body is responsible for services delivered in the clinic by contractors for medical services. The governing body shall ensure the following:
(1) That a contractor of any service furnishes those services in such a manner as to permit the clinic to comply with all applicable statutes and rules.
(2) That the services performed under a contract are:
(A) provided in a safe and effective manner; and
(B) included in the clinic's quality assessment and improvement program.
(3) That the clinic maintains a list of all contracted services, including the scope and nature of the services provided.

SECTION 19. **The clinic administrator is responsible for day-to-day operations of the abortion clinic to include, but not be limited to, the following functions:**
(1) Employing qualified staff:
(A) commensurate with assigned duties and responsibilities; and
(B) in accordance with the employee's:
(i) licensure;
(ii) certification;
(iii) experience; and
(iv) competence.
(2) Ensuring that sufficient staff is present to provide quality patient care.
(3) Implementation of internal and external disaster and emergency preparedness plans with documentation of outcome.

SECTION 20. **(a) The clinic shall develop, implement, and maintain the following:**
(1) Written medical staff policies.
(2) Written procedures for the following:
(A) Emergencies.
(B) Initial treatment.

(b) The clinic shall provide immediate lifesaving measures, within the scope of service available, to all persons in the clinic, to include, but not be limited to, the following:

(1) Timely assessment.

(2) Basic life support.

(3) Appropriate transfer.

(c) The clinic shall develop, implement, and maintain the following:

(1) Policies that cover health care worker practice problems, including, but not limited to, the following:

(A) Impaired health care workers.

(B) Criminal history.

(C) Disciplinary action.

(2) A written policy to address the internal review of unusual occurrences and disasters. This policy must include, but not be limited to, the following:

(A) Patient injuries or marked deterioration of patient condition occurring under unanticipated or unexpected circumstances.

(B) Unexplained loss of or theft of a controlled substance.

(C) Deaths occurring within the clinic.

SECTION 21. **(a) The abortion clinic must develop or adopt, implement, and maintain an effective, organized, clinic-wide, comprehensive quality assessment and improvement program in which all areas of the clinic involved in the provision of abortions participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:**

(1) All services, including services furnished by a contractor.

(2) All functions, including, but not limited to, the following:

(A) Infection control.

(B) Response to patient emergencies.

(3) All services performed in the clinic with regard to the following:

(A) Appropriateness of diagnoses and treatments related to a standard of care.

(B) Anticipated or expected outcomes.

(4) Medical and medication errors.

(b) The clinic shall take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program as follows:

(1) The action must be documented.

(2) The outcome of the action must be documented as to its effectiveness, continued follow-up, and impact on patient care.

SECTION 22. **(a) The clinic's quality assessment and improvement program under SECTION 21 of this document 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) 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) 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.

SECTION 23. **(a) The abortion clinic must do the following:**
(1) Create and maintain a medical record on each drug induced abortion patient.
(2) Have a written policy that ensures responsibility for and maintenance of drug induced abortion records as follows:
(A) The clinic must establish and implement the following:

(i) Policies and procedures to ensure that the care and services provided to each patient are appropriately documented.

(ii) A system to ensure that medical records are readily available in accordance with clinic policy and systematically organized to facilitate the compilation and retrieval of information.

(B) The policy must provide safeguards to ensure protection of the medical records from the following:

(i) Fire.

(ii) Water.

(iii) Other sources of damage.

(C) All original medical records or legally reproduced medical records must be maintained by the clinic for a period of at least seven (7) years or the applicable statute of limitation, whichever is longer. Original medical records must be maintained in the clinic for at least two (2) years. Records over two (2) years old may be kept off-site but must be retrievable within forty-eight (48) business hours.

(b) A medical record must be maintained with documentation of service rendered for each abortion patient of the clinic as follows:

(1) Medical records:

(A) are documented accurately and in a timely manner;

(B) are readily accessible; and

(C) permit prompt retrieval of information.

(2) A unit record system of filing should be utilized. When this is not practicable, a system must be established by the clinic to retrieve, when necessary, all divergently located record components.

(3) The clinic shall use a system of author identification and record maintenance that:

(A) ensures the integrity of the authentication; and

(B) protects the security of all record entries.

Each entry must be authenticated in accordance with the clinic and medical staff policies.

(4) Medical records must be retained in their original or legally reproduced form as required by federal or state law.

(5) Plain paper facsimile orders, reports, and documents are acceptable for inclusion in the medical record if allowed by the clinic policies.

(6) The clinic shall have a system of coding and indexing medical records that allows for timely retrieval of records in order to support continuous quality assessment and improvement activities.

(7) The clinic shall ensure the confidentiality of patient records. The clinic must develop, implement, and maintain the following:

(A) A procedure for releasing information or copies of records only to authorized individuals in accordance with federal and state laws.

(B) A procedure that ensures that unauthorized individuals cannot gain access to medical records.

(c) A written or electronic register must be kept of all patients treated that provides the following:

(1) Identification data.

(2) Treatment rendered.

(3) Attending physician.

(4) Other data deemed necessary by the clinic.

SECTION 24. **(a) The medical record for drug induced 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 results.

(C) Evidence that the patient was provide 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.

(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 *[document]***.**

(c) Patient records for drug induced 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) Authentication of entries by the physician or physicians and health care workers who treated or cared for the patient.
(5) 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.
(D) A copy of the signed patient agreement form and the signed physician's agreement form required by the manufacturer as required by IC 16-34-2-1(a)(1).
(6) Any report filed with a state agency or law enforcement agency pursuant to a statutory reporting requirement.

SECTION 25. **(a) The abortion clinic shall maintain current and accurate personnel records for all employees. Personnel records shall:**
(1) be maintained for each employee of the clinic; and
(2) include personal data to include:
(A) education;
(B) experience;
(C) date of employment;
(D) a copy of current license when required;
(E) evidence of participation in job-related educational and training activities; and
(F) health records of employees that relate to post offer and subsequent:
(i) physical examinations;
(ii) tests; and
(iii) immunizations.

(b) If the clinical administrator is not the governing body, the clinic must establish employment criteria for the clinic administrator to include, but not be limited to, the following:
(1) Educational requirements.
(2) Experience requirements.
(3) Professional certification, licensing, or registration requirements where appropriate.

(c) The clinic must do the following:
(1) Maintain current job descriptions with reporting responsibilities for all personnel and annual performance evaluations, based on the job description, for each employee and contract and agency personnel.
(2) Ensure that all health care workers, including contract and agency personnel, for whom a license, registration, or certification is required:
(A) maintain current license, registration, or certification; and
(B) keep documentation of same.

SECTION 26. **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 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 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.

SECTION 27. **(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) 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.

SECTION 28. **(a) The medical staff of the clinic is:**
(1) accountable to the governing body of the clinic; and
(2) responsible to the governing board for the quality of medical care and services provided to patients.

(b) The medical director must do the following:
(1) Examine credentials of candidates for appointment, reappointment, or contracting to the medical staff.
(2) Make recommendations to the governing body on the appointment or reappointment of medical staff.

(c) The medical director must develop and maintain policies and procedures for the provision of medical services. The policies must provide for and the medical staff must ensure the following:
(1) An appropriate and timely medical history and physical examination is performed.
(2) All physician orders:
(A) are in writing or acceptable computerized form;
(B) must be authenticated by a responsible physician as allowed by clinic policies not to exceed thirty (30) days.
(3) There is a provision for personnel authorized to take a verbal order.

SECTION 29. **(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 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 in order for the patient to contact the clinic for a complication and be triaged for 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 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.

SECTION 30. **If the clinic employs licensed nurses, the clinic must ensure the following:**
(1) Registered nurses and licensed practical nurses are currently licensed in Indiana.
(2) Nursing personnel meet annual inservice requirements as established by clinic and federal and state requirements.

SECTION 31. **(a) The clinic must do the following:**
(1) Provide a safe and healthful environment that minimizes infection exposure and risk to the following:
(A) Patients.
(B) Health care workers.
(C) Persons who accompany patients.
(2) Maintain a written infection control policy that provides for an active and effective clinic-wide infection control program. The policy must include a system designed for the:
(A) identification;
(B) surveillance;
(C) investigation;
(D) control; and
(E) prevention;
of infections and communicable diseases in patients and health care workers.

(b) The infection control program must identify and evaluate trends or clusters of clinic generated infections or communicable diseases.

(c) The clinic must designate a person qualified by training or experience as responsible for the following:
(1) Ongoing infection control activities.
(2) The development and implementation of policies governing control of infections and communicable diseases.

(d) The clinic administrator must do the following:
(1) Be responsible for the implementation of successful corrective action plans in affected problem areas and ensure that infection control policies are followed.
(2) Provide for appropriate infection control input into plans for renovation and new construction to

ensure awareness of federal, state, and local rules that affect infection control practices as well as plan for appropriate protection of patients and employees during construction or renovation.

(e) The clinic must establish a committee to monitor and guide the infection control program in the clinic as follows:

(1) The infection control committee must meet at least quarterly. Membership must include, but is not limited to, the following:

(A) The person directly responsible for management of the infection surveillance, prevention, and control program as established in subsection (c).

(B) The medical director.

(C) A representative from the nursing staff (if the clinic employs a licensed nurse).

(D) Representatives from other appropriate services within the clinic as needed.

(2) The infection control committee responsibilities must include, but are not limited to, the following:

(A) Establishing techniques and systems for:

(i) identifying;

(ii) reviewing; and

(iii) reporting;

infections in the clinic.

(B) Recommending corrective action plans, reviewing outcomes, and ensuring resolution of identified problems.

(C) Reviewing employee exposure incidents and making appropriate recommendations to minimize risk.

(D) Written reports of quarterly meetings.

(E) Reviewing and recommending changes in procedures, policies, and programs that are pertinent to infection control. These include, but are not limited to, the following:

(i) Sanitation.

(ii) Universal precautions, including infectious waste management.

(iii) Cleaning, disinfection, and sterilization.

(iv) Aseptic technique and equipment usage.

(v) Reuse of disposables.

(vi) A system for handling patients with communicable diseases.

(vii) A system, which complies with state and federal law, to monitor the immune status of health care workers exposed to communicable diseases.

(viii) An employee health program to determine the communicable disease history of new personnel as well as an ongoing program for current personnel as required by state and federal agencies.

(ix) Requirements for personal hygiene and attire that meet acceptable standards of practice.

(x) A program of linen management.

SECTION 32. **(a) Sterilization of equipment and supplies must be provided, within the scope of the service offered, in accordance with acceptable standards of practice or manufacturer's recommendations and applicable state laws and rules (to include 410 IAC 1-4, Universal Precautions). Sterilization services must be directed by a qualified person or persons and must provide for the following:**

(1) Biological indicators must be used to check sterilization processes at least monthly. Chemical sterilizing indicators must be used to check the sterilizing process of individual packs.

(2) Written policies and procedures must be available and followed by personnel responsible for sterilizing equipment and supplies, including, but not limited to, the following:

(A) Minimum time and temperature for processing various size bundles and packs.

(B) Instructions for:

(i) loading;

(ii) operating;

(iii) cleaning; and

(iv) maintaining;

sterilizers.

(C) Instructions for:

(i) cleaning;

(ii) packaging;

(iii) storing;

(iv) labeling; and

(v) dispensing of;

sterile supplies.

(D) The procedure for maintaining and recording the particular sterilizing cycle.
(E) Sterilization of heat labile reusable equipment.
(3) Records of results must be maintained and evaluated periodically to include, but not be limited to, the following:
(A) Records of recording thermometers or a daily record of the sterilizing cycle:
(i) date;
(ii) time;
(iii) temperature;
(iv) pressure; and
(v) contents;
for each sterilizer load.
(B) Results of biological indicators used in testing the sterilizing processes.

(b) Environmental surfaces and equipment not requiring sterilization that have been contaminated by blood or other potentially infectious materials must be cleaned then decontaminated in accordance with acceptable standards of practice and applicable state laws and rules (to include 410 IAC 1-4, Universal Precautions).

SECTION 33. **The clinic, whether it operates its own laundry or uses outside laundry service, must ensure that the laundry process complies with a recognized laundry standard as follows:**
(1) Clean linen must be separated from soiled linen at all times.
(2) Contaminated linens must be clearly identified and bagged.
(3) Central clean linen storage space must be provided as follows:
(A) If commercial laundry services are utilized:
(i) a soiled linen collection area must be provided; and
(ii) a hand washing facility is required in each area where unbagged soiled linen is handled.
(B) If laundry is processed in the clinic:
(i) a laundry processing area must be provided;
(ii) clean linen storage and mending must be separated from soiled linen handling and storage; and
(iii) employee hand washing facilities must be available in each room where clean or soiled linen is processed and handled.

SECTION 34. **The clinic must have a readily accessible written protocol for the following:**
(1) Managing medical emergencies that occur within the clinic. The protocol must ensure physician coverage and provide for a timely response for emergencies.
(2) The transfer of patients requiring further emergency care to a hospital.

SECTION 35. **(a) If nourishment and other dietary needs of the patients are provided in the clinic, the clinic must comply with 410 IAC 7-24.**

(b) If nourishments are to be prepared, a nourishment area with a hand washing lavatory and refrigeration must be provided.

(c) If prepackaged single-service nourishments are provided, refrigeration storage of nourishments and other food products must be separate from refrigeration storage for pharmaceuticals.

SECTION 36. **(a) The clinic must provide, or make available, those pathology and medical laboratory services and consultations necessary to meet the needs of patients as determined by the medical staff.**

(b) The laboratory performs tests, examines specimens, and reports the evaluation only upon the written request of individuals authorized by law.

(c) The clinic must ensure that all laboratory services provided to its patients are performed in a facility possessing a valid certificate, in accordance with 42 CFR 493 (excluding Subparts F, R, Q, and T) authorizing the performance of testing in the specialty or subspecialty of service for level of complexity in which the test is categorized.

(d) Laboratory supervisory and testing personnel qualifications must be:
(1) consistent with the work assignments; and
(2) in compliance with 42 CFR 493.

(e) All nursing and other clinic personnel performing laboratory testing must have competency assessed annually with documentation of assessment maintained in the employee file for the procedures performed.

(f) The clinic must develop, implement, and maintain written quality control and quality assurance policies and procedures for complexity of testing performed that are consistent with and include all standards found in 42 CFR 493.

SECTION 37. **The clinic must provide drugs and biologicals in a safe and effective manner in accordance with accepted professional practice. The clinic must have the following:**

(1) A:
(A) designated professional person with prescriptive authority; or
(B) pharmacist;
who is responsible for the control of drug stocks in the clinic.
(2) Records of stock supplies of all scheduled substances, including an accounting for all items purchased and dispensed.
(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:
(A) Drug:
(i) handling;
(ii) storing;
(iii) labeling;
(iv) dispensing; and
(v) administration according to established clinic policies and acceptable standards of practice.
(B) Reporting of adverse reactions and medication errors to the:
(i) physician responsible for the patient; and
(ii) appropriate committee;
and documented in the patient's record.
(C) Drugs must be accurately and clearly labeled and stored in specially designated, well-illuminated cabinets, closets, or storerooms and the following:
(i) Drug cabinets must be accessible only to authorized personnel.
(ii) Drug cabinets for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse must be permanently affixed compartments that are separately locked.
(iii) Drug carts, if used, with controlled drugs as designated in item (ii) must be securely affixed when not in use.
(D) Instructions to the patient on the use of take home medication is the responsibility of the prescribing physician.
(4) A formulary.

SECTION 38. **(a) The clinic must be constructed, arranged, and maintained to ensure the safety of the patient and to provide facilities for services authorized under the clinic license as follows:**

(1) The plant operations and maintenance service, equipment maintenance, and environmental services must be as follows:
(A) Staffed to meet the scope of the services provided.
(B) Under the direction of a person or persons qualified by education, training, or experience according to clinic policy approved by the governing body.
(2) The clinic must provide a physical plant and equipment that meets the statutory requirements and regulatory provisions of the fire prevention and building safety commission (IC 22, 675 IAC 22), Indiana fire prevention codes (675 IAC 22), and Indiana building codes (675 IAC 13).

(b) Any full or partial replacement of the physical plant of a clinic, any addition or renovation to the physical plant of a clinic, or any acquisitions of additional buildings under the license of an existing abortion clinic shall:

(1) comply with:
(A) this document; and
(B) all building, fire safety, and handicapped accessibility codes, and rules adopted and administered by the state building commission; and
(2) be provided with water supply and sewage disposal services from municipal or community services.

SECTION 39. **(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 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.

(d) Requirements for clinical facilities are as follows:

(1) Examination rooms shall be segregated and removed from general traffic flow and be a minimum of eighty (80) square feet, exclusive of vestibules, toilets, and closets.

(2) A hand washing station shall be included within each examination room.

(3) 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.

(4) A toilet room containing a lavatory for hand washing shall be accessible from all examination rooms. Where a clinic has no more than a total of three (3) examination 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, 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 40. **The condition of the physical plant and the overall clinic environment must be developed and maintained in such a manner that the safety and well-being of patients is ensured as follows:**

(1) No condition in the clinic or on the grounds may be maintained that may be conducive to the harboring or breeding of:

(A) insects;

(B) rodents; or

(C) other vermin.

(2) No condition may be created or maintained that may result in a hazard to:

(A) patients;

(B) authorized visitors; or

(C) employees.

(3) Provision must be made for the periodic inspection, preventive maintenance, and repair of the physical plant and equipment by qualified personnel as follows:

(A) Operation, maintenance, and spare parts manuals must be available, along with training or instruction, or both, of the appropriate clinic personnel, in the maintenance and operation of fixed and movable equipment.

(B) All mechanical equipment (pneumatic, electric, sterilizing, or other) must be on a documented maintenance schedule of appropriate frequency in accordance with one (1) of the following:

(i) Acceptable standards of practice.

(ii) The manufacturer's recommended maintenance schedule.

(C) Operational and maintenance control records must be as follows:

(i) Established and analyzed at least triennially.

(ii) Readily available on the premises.

(D) Maintenance and repairs must be carried out in accordance with applicable codes, rules, standards, and requirements of the following:

(i) Local jurisdictions.

(ii) The state fire marshal.

(iii) The department.

SECTION 41. **All patient care equipment must be in good working order and regularly serviced and maintained as follows:**

(1) All patient care equipment must be on a documented maintenance schedule of appropriate frequency in accordance with one (1) of the following:

(A) Acceptable standards of practice.

(B) The manufacturer's recommended maintenance schedule.

(2) There must be evidence of preventive maintenance on all patient care equipment.

(3) Appropriate records must be:

(A) kept pertaining to:

(i) equipment maintenance;

(ii) repairs; and

(iii) electrical current leakage checks; and

(B) analyzed at least triennially.

SECTION 42. **The building or buildings, including fixtures, walls, floors, ceiling, and furnishings throughout, must be kept clean and orderly in accordance with current standards of practice, including the following:**

(1) Environmental services must be provided in such a way as to guard against transmission of disease to patients, health care workers, the public, and visitors by using the current principles of the following:

(A) Asepsis.

(B) Cross-contamination prevention.

(C) Safe practice.
(2) Refuse, biohazards, infectious waste, and garbage must be:
(A) collected;
(B) transported;
(C) sorted; and
(D) disposed of;
by methods that will minimize nuisances or hazards in compliance with federal, state, and local laws and rules.

SECTION 43. **(a) A safety management program must include, but not be limited to, the following:**
(1) A review of safety functions.
(2) Development, implementation, and monitoring of a safety management program to include, but not be limited to, the following:
(A) Periodic equipment inspections.
(B) Insect, rodent, or other vermin control.
(C) Instructions for operating and maintaining the building or building portion and equipment.
(D) Chemical substance use and storage.
(E) General housekeeping precautions.
(3) An ongoing clinic-wide process to evaluate and collect information about hazards and safety practices.
(4) A safety program that includes, but is not limited to, the following:
(A) Patient safety.
(B) Health care worker safety.
(C) Public and visitor safety.
(5) A written fire control plan that contains provisions for the following:
(A) Prompt reporting of fires.
(B) Extinguishing of fires.
(C) Protection of the following:
(i) Patients.
(ii) Personnel.
(iii) Guests.
(D) Evacuation.
(E) Cooperation with firefighting authorities.
(F) Fire drills.
(6) Maintenance of written evidence of regular inspection and approval by state or local fire control agencies in accordance with the following:
(A) Clinic policy.
(B) State and local regulations.
(7) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies.

(b) The clinic must maintain adequate battery-powered lighting and sufficient equipment needed to provide for the:
(1) completion of services; and
(2) safety of patients and staff;
in the event of a power loss.

SECTION 44. **(a) If the clinic provides other services not covered in specific SECTIONS of this document, 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.

SECTION 45. **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 46. **(a) 42 CFR 493 (October 1, 2017) is hereby incorporated by reference as part of this rule** *[document]***.**

(b) Federal rules that have been incorporated by reference do not include any later amendments than those specified in the incorporated citation. The incorporated rules may be found at:
https://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR

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

SECTION 47. **Abortion clinics currently licensed under 410 IAC 26 do not need to be licensed as a drug induced abortion clinic under this document or a surgical abortion clinic under LSA Document #19-9(E) until the abortion clinic renews its license.**

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