

TITLE 9. HEALTH SERVICES
CHAPTER 10. DEPARTMENT OF HEALTH SERVICES
HEALTH CARE INSTITUTIONS: LICENSING
ARTICLE 15. ABORTION CLINICS

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ARTICLE 15. ABORTION CLINICS

R9-10-1501. Definitions

In addition to the definitions in A.R.S. §§ 36-401, 36-449.01, 36-449.03, 36-2151, 36-2158, and 36-2301.01 and R9-10-101, the following definitions apply in this Article, unless otherwise specified:

1. “Admission” means documented acceptance by a hospital of an individual as an inpatient as defined in R9-10-201 on the order of a physician.
- 2.1. “Admitting privileges” means permission extended by a hospital to a physician to allow admission of a patient an individual as an inpatient, as defined in R9-10-201:
 - a. By the patient’s own physician, or
 - b. Through a written agreement between the patient’s physician and another physician that states that the other physician has permission to personally admit the patient to a hospital in this state and agrees to do so.
3. “Conspicuously posted” means placed at a location within an abortion clinic that is accessible and visible to patients and the public.
- 4.2. “Course” means training or education, including hands-on practice under the supervision of a physician, training, or education.
5. “Discharge” means a patient no longer requires the medical services, nursing services, or health-related services provided by the abortion clinic.
6. Emergency means a potentially life-threatening occurrence that requires an immediate response or medical treatment.
- 7.3. “Employee” means an individual who receives compensation from a licensee, but does not provide medical services, nursing services, or health-related services.
- 8.4. “First trimester” means 1 through 14 weeks as measured from the first day of the last menstrual period or 1 through 12 weeks as measured from the date of fertilization.
- 9.5. “Incident” means an abortion-related patient death or serious injury to a patient or viable fetus delivered alive.
10. “Licensee” means an individual, a partnership, an association, a limited liability company, or corporation authorized by the Department to operate an abortion clinic.
- 11.6. “Local” means under the jurisdiction of a city or county in Arizona.
- 12.7. “Medical director” means a physician who is responsible for the direction of the medical services, nursing services, and health-related services provided to patients at an abortion clinic.
- 13.8. “Medical evaluation” means obtaining a patient’s medical history, performing a physical

examination of a patient's body, and conducting laboratory tests as provided in R9-10-1508.

- 14.9.** "Monitor" means to observe and document, continuously or intermittently, the values of certain physiologic variables on a patient such as pulse, blood pressure, oxygen saturation, respiration, and blood loss.
- 15.** ~~"Nationally recognized medical journal" means any publication distributed nationally that contains peer reviewed medical information, such as the *American Journal of Radiology* or the *Journal of Ultrasound in Medicine*.~~
- 10.** "Neonatal resuscitation" means procedures to assist in maintaining the life of a fetus delivered alive, as described in A.R.S. § 36-2301(D)(3).
- 16.11.** "Patient" means a female receiving medical services, nursing services, or health-related services related to an abortion.
- 17.12.** "Patient care staff member" means a physician, registered nurse practitioner, nurse, physician assistant, or surgical assistant who provides medical services, nursing services, or health-related services to a patient.
- 18.** ~~"Patient's representative" means a patient's legal guardian, an individual acting on behalf of a patient with the written consent of the patient, or a surrogate according to A.R.S. § 36-3201.~~
- 19.13.** "Patient transfer" means relocating a patient requiring medical services from an abortion clinic to another health care institution.
- 20.14.** "Personally identifiable patient information" means:
- a. The name, address, telephone number, e-mail address, Social Security number, and birth date of:
 - i. The patient,
 - ii. The patient's representative,
 - iii. The patient's emergency contact,
 - iv. The patient's children,
 - v. The patient's spouse,
 - vi. The patient's sexual partner, and
 - vii. Any other individual identified in the patient's medical record other than patient care staff;
 - b. The patient's place of employment;
 - c. The patient's referring physician;
 - d. The patient's insurance carrier or account;

- e. Any “individually identifiable health information” as proscribed in 45 CFR 164-514; and
- f. Any other information in the patient’s medical record that could reasonably lead to the identification of the patient.

~~21,15.~~ “Personnel” means patient care staff members, employees, and volunteers.

~~22.~~ “Physical facilities” means property that is:

- a. ~~Designated on an application for a license by the applicant; and~~
- b. ~~Licensed to provide services by the Department according to A.R.S. Title 36, Chapter 4.~~

~~23,16.~~ “Surgical assistant” means an individual who is not licensed as a physician, physician assistant, registered nurse practitioner, or nurse who performs duties as directed by a physician, physician assistant, registered nurse practitioner, or nurse.

~~24,17.~~ “Volunteer” means an individual who, without compensation, performs duties as directed by a ~~member of the patient care staff~~ member at an abortion clinic.

R9-10-1502. Application and Documentation Submission Requirements

- A.** An applicant shall submit an application for licensure that meets the requirements in A.R.S. § 36-422 and 9 A.A.C. 10, Article 1.
- B.** A licensee shall submit to the Department the documentation required according to A.R.S. § 36-449.02(B) with the applicable fees required in R9-10-106(C).

R9-10-1503. Administration

- A.** A licensee is responsible for the organization and management of an abortion clinic.
- B.** A licensee shall:
 - 1. Adopt policies and procedures for the administration and operation of an abortion clinic;
 - 2. Designate a medical director who:
 - a. ~~is~~ Is licensed according to A.R.S. Title 32, Chapter 13, 17, or 29; and
 - b. ~~The licensee and the medical director may~~ May be the same individual as the licensee; and
 - 3. Ensure the following documents are conspicuously posted ~~at the physical facilities on the~~ premises:
 - a. Current abortion clinic license issued by the Department; ;
 - b. Current telephone number and address of the unit in the Department responsible for licensing the abortion clinic; ;

- c. Evacuation map₂; and
- d. Signs that comply with A.R.S. § ~~36-2153(G)~~ 36-2153(H); and

4. Ensure that documentation required by this Article is provided to the Department within two hours after a Department request.

C. A medical director shall ensure written policies and procedures are established, documented, and implemented to protect the health and safety of a patient including for:

- 1. Personnel qualifications, duties, and responsibilities;
- 2. Individuals qualified to provide counseling in the abortion clinic and the amount and type of training required for an individual to provide counseling;
- 3. If the abortion clinic performs an abortion procedure at or after 20 weeks gestational age:
 - a. Individuals qualified in neonatal resuscitation and the amount and type of training required for an individual to provide neonatal resuscitation, and
 - b. Designation of an individual to arrange the transfer to a hospital of a fetus delivered alive;
- 3.4. Verification of the competency of the physician performing an abortion according to R9-10-1505;
- 4.5. The storage, administration, accessibility, disposal, and documentation of a medication, and a or controlled substance;
- 5.6. Accessibility and security of patient medical records;
- 6.7. Abortion procedures including:
 - a. ~~recovery~~ Recovery and follow-up care; and the
 - b. The minimum length of time a patient remains in the recovery room or area based on:
 - a-i. The type of abortion performed₂;
 - b-ii. The estimated gestational age of the fetus₂;
 - e-iii. The type and amount of medication administered₂; and
 - d-iv. The physiologic signs including vital signs and blood loss; and
 - c. If the abortion clinic performs an abortion procedure at or after 20 weeks gestational age, the requirements in A.R.S. § 36-2301(D);
- 7.8. Infection control including methods of sterilizing equipment and supplies;
- 8.9. Medical emergencies; and
- 9.10. Patient discharge and patient transfer.

D. For an abortion clinic that is not in substantial compliance or that is in substantial compliance but refuses to carry out a plan of correction acceptable to the Department, the Department may take

enforcement action as specified in R9-10-111.

R9-10-1503.01. Quality Management

A medical director shall ensure that:

1. A plan is established, documented, and implemented for an ongoing quality management program that, at a minimum, includes:
 - a. A method to identify, document, and evaluate incidents;
 - b. A method to collect data to evaluate services provided to patients;
 - c. A method to evaluate the data collected to identify a concern about the delivery of services related to patient care;
 - d. A method to make changes or take action as a result of the identification of a concern about the delivery of services related to patient care; and
 - e. The frequency of submitting a documented report required in subsection (2) to the licensee;
2. A documented report is submitted to the licensee that includes:
 - a. An identification of each concern about the delivery of services related to patient care, and
 - b. Any changes made or actions taken as a result of the identification of a concern about the delivery of services related to patient care; and
3. The report required in subsection (2) and the supporting documentation for the report are maintained for at least 12 months after the date the report is submitted to the licensee.

R9-10-1504. Incident Reporting

A. A licensee shall ensure that the Department is notified of an incident as follows:

1. For the death of a patient, verbal notification the next working day;
2. For fetus delivered alive, verbal notification the next working day; and
- 2-3. For a serious injury of a patient or viable fetus, written notification within 10 calendar days after the date of the serious injury.

B. A medical director shall conduct an investigation of an incident and document an incident report that includes:

1. The date and time of the incident_;
2. The name of the patient_;
3. A description of the incident_;
4. Names of individuals who observed the incident_;

5. Action taken by patient care staff members and employees during the incident and immediately following the incident; and
 6. Action taken by the patient care staff members and employees to prevent the incident from occurring in the future.
- C. A medical director shall ensure that the incident report is:
1. Submitted to the Department and, if the incident involved a licensed individual, the applicable professional licensing board within 10 calendar days after the date of the notification in subsection (A); and
 2. Maintained in the physical facilities on the premises for at least two years after the date of the incident.

R9-10-1505. Personnel Qualifications and Records

A licensee shall ensure that:

1. A physician who performs an abortion demonstrates to the medical director that the physician is competent to perform an abortion by:
 - a. The submission of documentation of education and experience; and
 - b. Observation by or interaction with the medical director;
2. Surgical assistants and volunteers who provide counseling and patient advocacy receive training in these specific responsibilities and any other responsibilities assigned and that documentation of the training received is maintained in the individual's personnel file of the training received;
3. An individual who performs an ultrasound provides documentation that the individual is:
 - a. A physician;
 - b. A physician assistant, registered nurse practitioner, or nurse who completed a hands-on course in performing ultrasounds under the supervision of a physician; or
 - c. An individual who:
 - i. Completed a hands-on course in performing ultrasounds under the supervision of a physician, and
 - ii. Is not otherwise precluded by law from performing an ultrasound;
4. An individual has completed a course for the type of ultrasound the individual performs;
5. If the abortion clinic performs an abortion procedure at or after 20 weeks gestational age, an individual who is available to perform neonatal resuscitation provides documentation that the individual:

- a. Is a:
 - i. Physician,
 - ii. Physician assistant,
 - iii. Registered nurse practitioner, or
 - iv. Nurse; and
- b. Has completed a course in performing neonatal resuscitation;

5-6. A personnel file for each member of the patient care staff member and each volunteer is maintained either electronically or in writing and includes:

- a. The individual's name and position title;
- b. The first and, if applicable, the last date of employment or volunteer service;
- c. Verification of qualifications, training, or licensure, as applicable;
- d. Documentation of cardiopulmonary resuscitation certification, as applicable;
- e. Documentation of verification of competency, as required in subsection (1), and signed and dated by the medical director;
- f. Documentation of training for surgical assistants and volunteers; and
- g. Documentation of completion of a course as required in subsection (3), for an individual performing ultrasounds; and
- h. Documentation of competency to perform neonatal resuscitation, as required in subsection (5), if applicable; and

6-7. Personnel files are maintained in the physical facilities on the premises for at least two years from after the ending date of employment or volunteer service.

R9-10-1506. Staffing Requirements

A. A licensee shall ensure that there is a sufficient number of patient care staff members and employees to:

- 1. Meet the requirements of this Article;²
- 2. Ensure the health and safety of a patient;² and
- 3. Meet the needs of a patient based on the patient's medical evaluation.

B. A licensee shall ensure that:

- 1. A member of the patient care staff member other than, except for a surgical assistant, who is current in cardiopulmonary resuscitation certification, is in the physical facilities on the premises until all patients are discharged;
- 2. A physician, with admitting privileges at a health care institution that is classified by the director as a hospital according to A.R.S. § 36-405(B), remains on the premises of the

abortion clinic until all patients who received a medication abortion are stable and ready to leave;

3. A physician, with admitting privileges at a health care institution that is classified by the director as a hospital according to A.R.S. § 36-405(B) and that is within 30 miles of the abortion clinic by road, as defined in A.R.S. § 17-451, remains on the abortion clinic's premises until all patients who received a surgical abortion are stable and ready to leave the recovery room; ~~and~~

4. ~~A physician, a nurse, a registered nurse practitioner, a physician assistant, or, if a physician is able to provide direct supervision as defined in A.R.S. § 32-1401 or A.R.S. § 32-1800 as applicable, a medical assistant under the direct supervision of the physician:~~
 - a. ~~Monitors each patient during the patient's recovery following the abortion; and~~
 - b. ~~Remains in the abortion clinic until each patient is discharged by a physician.~~

4. A patient care staff member is on the premises to comply with R9-10-1508(H); and

5. If the abortion clinic performs an abortion procedure at or after 20 weeks gestational age, a patient care staff member qualified according to policies and procedures to perform neonatal resuscitation is in the room where the abortion procedure is performed.

R9-10-1507. Patient Rights

A licensee shall ensure that a patient is afforded the following rights, and is informed of these rights:

1. To refuse treatment, or withdraw consent for treatment;
2. To have medical records kept confidential; and
3. To be informed of:
 - a. Billing procedures and financial liability before abortion services are provided;
 - b. Proposed medical or surgical procedures, associated risks, possible complications, and alternatives;
 - c. Counseling services that are provided ~~in the physical facilities on the premises;~~ ~~and~~
 - d. The right to review the ultrasound results with a physician, a physician assistant, a registered nurse practitioner, or a registered nurse before the abortion procedure; ~~and~~
 - e. The right to receive a print of the ultrasound image.

R9-10-1508. Abortion Procedures

- A. A medical director shall ensure that a medical evaluation of a patient is conducted before the

patient's abortion is performed that includes:

1. A medical history including:
 - a. Allergies to medications, antiseptic solutions, or latex;
 - b. Obstetrical and gynecological history;
 - c. Past surgeries;
 - d. Medication the patient is currently taking; and
 - e. Other medical conditions;
2. A physical examination, performed by a physician that includes a bimanual examination to estimate uterine size and palpation of adnexa; and
3. The following laboratory tests:
 - a. A urine or blood test to determine pregnancy;
 - b. Rh typing, unless the patient provides written documentation of blood type acceptable to the physician;
 - c. Anemia screening; and
 - d. Other laboratory tests recommended by the physician or medical director on the basis of the physical examination; and

4. An ultrasound imaging study of the fetus, performed as required in A.R.S. §§ 36-2156 and 36-2301.02(A).

B. If the medical evaluation indicates a patient is Rh negative, a medical director shall ensure that:

1. The patient receives information from a physician on this condition;
2. The patient is offered RhO(d) immune globulin within 72 hours after the abortion procedure;
3. If a patient refuses RhO(d) immune globulin, the patient signs and dates a form acknowledging the patient's condition and refusing the RhO(d) immune globulin;
4. The form in subsection (B)(3) is maintained in the patient's medical record; and
5. If a patient refuses RhO(d) immune globulin or if a patient refuses to sign and date an acknowledgment and refusal form, the physician documents the patient's refusal in the patient's medical record.

C. A physician ~~estimates~~ shall estimate the gestational age of the fetus, based on one of the following criteria, and ~~records~~ record the estimated gestational age in the patient's medical record. ~~The estimated age is based upon:~~

1. Ultrasound measurements of the biparietal diameter, length of femur, abdominal circumference, visible pregnancy sac, or crown-rump length or a combination of these; or
2. The date of the last menstrual period or the date of fertilization and a bimanual

examination of the patient.

D. A medical director shall ensure that:

1. ~~An~~ **The** ultrasound of a patient **required in subsection (A)(4)** is performed by an individual who meets the requirements in R9-10-1505(3);
2. **An ultrasound estimate of gestational age of a fetus is performed using methods and tables or charts published in a nationally recognized medical journal in a publication distributed nationally that contains peer-reviewed medical information, such as medical information derived from a publication describing research in obstetrics and gynecology or in diagnostic imaging;**
3. An original patient ultrasound ~~print image~~ **is:**
 - a. Interpreted by a physician; and
 - b. Maintained in the patient's medical record in either electronic or paper form; and
4. If requested by the patient, the ultrasound **image** is reviewed with the patient by a physician, physician assistant, registered nurse practitioner, or registered nurse.

E. A medical director shall ensure that before an abortion is performed on a patient:

1. Written consent, **that meets the requirements in A.R.S. § 36-2152 or 36-2153, as applicable,** is signed and dated by the patient or the patient's **legal guardian representative;** and
2. Information is provided to the patient on the abortion procedure, including alternatives, risks, and potential complications.

F. A medical director shall ensure that an abortion is performed according to the abortion clinic's policies and procedures and this Article.

G. ~~A medical director shall ensure that any medication, drug, or substance used to induce an abortion is administered in compliance with the protocol authorized by the United States Food and Drug Administration and that is outlined in the final printing labeling instructions for that medication, drug, or substance.~~

H.G. A medical director shall ensure that:

1. ~~Patient~~ **A patient** care staff member ~~monitor the~~ **monitors a** patient's vital signs throughout an abortion procedure to ensure the patient's health and safety;
2. Intravenous access is established and maintained on a patient undergoing an abortion after the first trimester unless the physician determines that establishing intravenous access is not appropriate for the particular patient and documents that fact in the patient's medical record;
3. **If an abortion procedure is performed at or after 20 weeks gestational age, a patient care**

staff member trained in neonatal resuscitation is in the room while the abortion procedure takes place; and

- 3.4. If a viable fetus shows signs of life is delivered alive:
- a. Resuscitative measures, including the following, are used to support life:
 - i. Warming and drying of the fetus,
 - ii. Clearing secretions from and positioning the airway of the fetus,
 - iii. Administering oxygen as needed to the fetus, and
 - iv. Assessing and monitoring the cardiopulmonary status of the fetus;
 - b. A determination is made of whether the fetus is a viable fetus;
 - c. A viable fetus is provided treatment to support life;
 - b.d. The A viable fetus is transferred as required in R9-10-1509; and
 - e.e. Resuscitative measures and the transfer, as applicable, are documented.

I.H. To ensure a patient's health and safety, A a medical director shall ensure that following the abortion procedure:

1. A patient's vital signs and bleeding are monitored by a physician, nurse, registered nurse practitioner, physician assistant, or, if a physician is able to provide direct supervision as defined in A.R.S. § 32-1401 or A.R.S. § 32-1800, as applicable, a medical assistant under the direct supervision of the physician to ensure the patient's health and safety;
 - a. A physician;
 - b. A physician assistant;
 - c. A registered nurse practitioner;
 - d. A nurse; or
 - e. If a physician is able to provide direct supervision, as defined in A.R.S. § 32-1401 or A.R.S. § 32-1800, as applicable, to a medical assistant, as defined in A.R.S. § 32-1401 or A.R.S. § 32-1800, a medical assistant under the direct supervision of the physician; and
2. A patient remains in the recovery room or recovery area until a physician, physician assistant, registered nurse practitioner, or nurse examines the patient and determines that the patient's medical condition is stable and the patient is ready to leave the recovery room or recovery area.

J.I. A medical director shall ensure that follow-up care includes:

1. With a patient's consent, a telephone call to the patient by a member of the patient care staff, except a surgical assistant, within 24 hours after the patient's discharge following a surgical abortion to assess the patient's recovery. If the patient care staff is unable to

2. Following a surgical abortion, a follow-up visit offered and scheduled, if requested, no more than 21 days after the abortion. The follow-up visit shall include:
- a. A physical examination;
 - b. A review of all laboratory tests as required in R9-10-1508(A)(3); and
 - e. A urine pregnancy test; and
3. Following a medication abortion, a follow-up visit offered and scheduled between seven and 21 days after the initial dose of a substance used to induce an abortion. The follow-up visit shall include:
- a. A urine pregnancy test; and
 - b. An assessment of the degree of bleeding.
1. For a surgical abortion is offered to a patient that includes:
- a. With a patient's consent, a telephone call made to the patient to assess the patient's recovery:
 - i. By a patient care staff member other than a surgical assistant; and
 - ii. Within 24 hours after the patient's discharge following a surgical abortion; and
 - b. A follow-up visit scheduled, if requested, no more than 21 calendar days after the abortion that includes:
 - i. A physical examination,
 - ii. A review of all laboratory tests as required in subsection (A)(3), and
 - iii. A urine pregnancy test;
2. For a medication abortion includes a follow-up visit, scheduled between seven and 21 calendar days after the initial dose of a substance used to induce an abortion, that includes:
- a. A urine pregnancy test, and
 - b. An assessment of the degree of bleeding; and
3. Is documented in the patient's medical record, including:
- a. A patient's acceptance or refusal of a follow-up visit following a surgical abortion;
 - b. If applicable, the results of the follow-up visit; and
 - c. If applicable, whether the patient consented to a telephone call and, if so, whether the patient care staff member making the telephone call to the patient;

- i. Spoke with the patient about the patient's recovery, or
- ii. Was unable to speak with the patient.

~~K.J.~~ If a continuing pregnancy is suspected as a result of the follow-up visit ~~required in subsection (J)(2) or (J)(3) (I)(1)(b) or (I)(2)~~, a physician who performs abortions shall be consulted.

R9-10-1509. Patient Transfer and Discharge

A. A medical director shall ensure that:

1. For a patient:

- a. A patient is transferred to a hospital for an emergency involving the patient;
- ~~2. A viable fetus requiring emergency care is transferred to a hospital;~~
- ~~3.b.~~ A patient transfer is documented in the patient's medical record; and
- ~~4.c.~~ Documentation of a medical evaluation, treatment given provided, and laboratory and diagnostic information is transferred with a patient; and

2. For a viable fetus:

- a. A viable fetus requiring emergency care is transferred to a hospital.
- b. The transfer of a viable fetus is documented in the viable fetus's medical record, and
- c. Documentation of an assessment of cardiopulmonary function and treatment provided to a viable fetus is transferred with the viable fetus.

B. A medical director shall ensure that before a patient is discharged:

- 1. A physician signs the patient's discharge order; and
- 2. A patient receives follow-up instructions at discharge that include:
 - a. Signs of possible complications[§];
 - b. When to access medical services in response to complications[§];
 - c. A telephone number of an individual or entity to contact for medical emergencies[§];
 - d. Information and precautions for resuming vaginal intercourse after the abortion[§] and
 - e. Information specific to the patient's abortion or condition.

R9-10-1510. Medications and Controlled Substances

A medical director shall ensure that:

- 1. The abortion clinic complies with the requirements for medications and controlled substances in A.R.S. Title 32, Chapter 18, and A.R.S. Title 36, Chapter 27;

2. A medication is administered in compliance with an order from a physician, physician assistant, registered nurse practitioner, or as otherwise provided by law;
3. A medication is administered to a patient or to a viable fetus by a physician or as otherwise provided by law;
4. Medications and controlled substances are maintained in a locked area in the physical facilities on the premises;
5. Only personnel designated by policies and procedures have access to the locked area containing medications and controlled substances;
6. Expired, mislabeled, or unusable medications and controlled substances are disposed of according to policies and procedures;
7. A medication error or an adverse reaction, including any actions taken in response to the medication error or adverse reaction, is immediately reported to the medical director and licensee, and recorded in the patient's medical record;
8. Medication information for a patient is maintained in a the patient's medical record and contains:
 - a. The patient's name, age, and weight;
 - b. The medications the patient is currently taking; and
 - c. Allergies or sensitivities to medications, antiseptic solutions, or latex; and
 - 9.d. If medication is administered to a the patient, the following are documented in the patient's medical record:
 - a.i. The date and time of administration;
 - b.ii. The name, strength, dosage form, amount of medication, and route of administration; and
 - e.iii. The identification and signature of the individual administering the medication; and
9. If administered to a fetus delivered alive, the following are documented in the fetus's medical record:
 - a. The date and time of oxygen administration;
 - b. The amount and flow rate of the oxygen;
 - c. The identification and signature of the individual administering the oxygen; and
 - d. For a viable fetus:
 - i. The date and time of medication administration;
 - ii. The name, strength, dosage form, amount of medication, and route of administration; and

- iii. The identification and signature of the individual administering the medication.

R9-10-1511. Medical Records

A. A licensee shall ensure that:

~~1.~~ A a medical record is established and maintained for a patient that contains:

~~a.1.~~ Patient identification including:

~~i.a.~~ The patient's name, address, and date of birth;

~~ii.b.~~ The designated patient's representative, if applicable; and

~~iii.c.~~ The name and telephone number of an individual to contact in an emergency;

~~b.2.~~ The patient's medical history required in R9-10-1508(A)(1);

~~c.3.~~ The patient's physical examination required in R9-10-1508(A)(2);

~~d.4.~~ The laboratory test results required in R9-10-1508(A)(3);

5. The ultrasound results, including the original print, required in R9-10-1508(A)(4);

~~e.6.~~ The physician's estimated gestational age of the fetus required in R9-10-1508(C);

~~f.~~ The ultrasound results, including the original print, required in R9-10-1508(D);

~~g.7.~~ Each consent form signed by the patient or the patient's legal guardian representative;

~~h.8.~~ Orders issued by a physician, physician assistant, or registered nurse practitioner;

~~i.9.~~ A record of medical services, nursing services, and health-related services provided to the patient; ~~and~~

~~j.10.~~ The patient's medication information; ~~and~~

11. Documentation related to follow-up care specified in R9-10-1508(I); and

12. If the abortion procedure was performed at or after 20 weeks gestational age and the fetus was not delivered alive, documentation from the physician and other patient care staff member present certifying that the fetus was not delivered alive.

B. A licensee shall ensure that a medical record is established and maintained for a fetus delivered alive that contains:

1. An identification of the fetus including:

a. The name of the patient from whom the fetus was delivered alive, and

b. The date the fetus was delivered alive;

2. Orders issued by a physician, physician assistant, or registered nurse practitioner;

3. A record of medical services, nursing services, and health-related services provided to the fetus delivered alive;

4. If applicable, information about medication administered to the fetus delivered alive; and

5. If the abortion procedure was performed at or after 20 weeks gestational age:
 - a. Documentation of the requirements in R9-10-1508(G)(4); and
 - b. If the fetus had a lethal fetal condition, the results of the confirmation of the lethal fetal condition.

C. A licensee shall ensure that:

- 2.1. A medical record is accessible only to the Department or personnel authorized by policies and procedures;
- 3.2. Medical record information is confidential and released only with the written informed consent of a patient or the patient's representative or as otherwise permitted by law;
- 4.3. A medical record is protected from loss, damage, or unauthorized use and is maintained and accessible for at least seven years after the date of an adult patient's discharge or if the patient is a child, either for at least three years after the child's 18th birthday or for at least seven years after the patient's discharge, whichever date occurs last;
- 5.4. A medical record is maintained at the abortion clinic for at least six months after the date of the patient's discharge; and
- 6.5. Vital records and vital statistics are retained according to A.R.S. § 36-343.

B. A licensee shall comply with Department requests for access to or copies of patient medical records as follows:

1. Subject to the redaction permitted in subsection (B)(5), for patient medical records requested for review in connection with a compliance inspection, the licensee shall provide the Department with the following patient medical records related to medical services associated with an abortion, including any follow-up visits to the abortion clinic in connection with the abortion:
 - a. Patient identification including:
 - i. The patient's name, address, and date of birth;
 - ii. The designated patient's representative, if applicable; and
 - iii. The name and telephone number of an individual to contact in an emergency;
 - b. The patient's medical history required in R9-10-1508(A)(1);
 - c. The patient's physical examination required in R9-10-1508(A)(2);
 - d. The laboratory test results required in R9-10-1508(A)(3);
 - e. The physician's estimated gestational age of the fetus required in R9-10-1508(C);
 - f. The ultrasound results required in R9-10-1508(D);
 - g. Each consent form signed by the patient or the patient's representative;

- h. Orders issued by a physician, physician assistant, or registered nurse practitioner;
 - i. A record of medical services, nursing services, and health-related services provided to the patient; and
 - j. The patient's medication information.
2. For patient medical records requested for review in connection with an initial licensing or compliance inspection, the licensee is not required to produce for review by the Department any patient medical records created or prepared by a referring physician or any of that referring physician's medical staff.; and
 3. The licensee is not required to provide patient medical records regarding medical services associated with an abortion that occurred before:
 - a. The effective date of these rules, or
 - b. A previous licensing or compliance inspection of the abortion clinic.
 4. The patient medical records may be provided to the Department in either paper or in an electronic format that is acceptable to the Department.
 5. When access to or copies of patient medical records are requested from a licensee by the Department, the licensee shall redact only personally identifiable patient information from the patient medical records before the disclosure of the patient medical records to the Department, except as provided in subsection (B)(8).
 6. For patient medical records requested for review in connection with an initial licensing or compliance inspection, the licensee shall provide the redacted copies of the patient medical records to the Department within two business days of the Department's request for the redacted medical records if the total number of patients for whom patient medical records are requested by the Department is from one to ten patients, unless otherwise agreed to by the Department and the licensee. The time within which the licensee shall produce redacted records to the Department shall be increased by two business days for each additional five patients for whom patient medical records are requested by the Department, unless otherwise agreed to by the Department and the licensee.
 7. Upon request by the Department, in addition to redacting only personally identifiable patient information, the licensee shall code the requested patient medical records by a means that allows the Department to track all patient medical records related to a specific patient without the personally identifiable patient information.
 8. For patient medical records requested for review in connection with a complaint investigation, the Department shall have access to or copies of unredacted patient medical records.

9. If the Department obtains copies of unredacted patient medical records, the Department shall:
 - a. Allow the examination and use of the unredacted patient medical records only by those Department employees who need access to the patient medical records to fulfill their investigative responsibilities and duties;
 - b. Maintain all unredacted patient medical records in a locked drawer, cabinet, or file or in a password-protected electronic file with access to the secured drawer, cabinet, or file limited to those individuals who have access to the patient medical records according to subsection (B)(9)(a);
 - c. Destroy all unredacted patient medical records at the termination of the Department's complaint investigation or at the termination of any administrative or legal action that is taken by the Department as the result of the Department's complaint investigation, whichever is later;
 - d. If the unredacted patient medical records are filed with a court or other judicial body, including any administrative law judge or panel, file the records only under seal; and
 - e. Prevent access to the unredacted records by anyone except as provided in subsection (B)(9)(a) or subsection (B)(9)(d).

D. If the Department requests patient medical records for review, the licensee:

1. Is not required to produce any patient medical records created or prepared by a referring physician's office;
2. May provide patient medical records to the Department either in paper or in an electronic format that is acceptable to the Department;
3. Shall provide the Department with the following patient medical records related to medical services associated with an abortion, including any follow-up visits to the abortion clinic in connection with the abortion:
 - a. The patient's medical history required in R9-10-1508(A)(1);
 - b. The patient's physical examination required in R9-10-1508(A)(2);
 - c. The laboratory test results required in R9-10-1508(A)(3);
 - d. The physician's estimate of gestational age of the fetus required in R9-10-1508(C);
 - e. The ultrasound results required in R9-10-1508(D)(2);
 - f. Each consent form signed by the patient or the patient's representative;
 - g. Orders issued by a physician, physician assistant, or registered nurse practitioner;

- b. An individual's initials if the individual's written signature already appears in the medical record;
 - e. A rubber stamp signature; or
 - d. An electronic signature;
3. An entry is not changed after it has been recorded, but additional information related to an entry may be recorded in the medical record;
 4. When a verbal or telephone order is entered in the medical record, the entry is authenticated within 21 calendar days by the individual who issued the order;
 5. If a rubber-stamp signature or an electronic signature is used:
 - a. An individual's rubber stamp or electronic signature is not used by another individual;
 - b. The individual who uses a rubber stamp or electronic signature signs a statement that the individual is responsible for the use of the rubber stamp or the electronic signature; and
 - c. The signed statement is included in the individual's personnel record; and
 6. If an abortion clinic maintains medical records electronically, the medical director shall ensure the date and time of an entry is recorded by the computer's internal clock.

D.F. As required by A.R.S. § ~~36-449.03(I)~~ 36-449.03(J), the Department shall not release any personally identifiable patient or physician information.

R9-10-1512. Environmental and Safety Standards

A licensee shall ensure that:

1. Physical facilities The premises and equipment:
 - a. Provide lighting and ventilation to ensure the health and safety of a patient;
 - b. Are maintained in a clean condition;
 - c. Are free from a condition or situation that may cause a patient to suffer physical injury;
 - d. Are maintained free from insects and vermin; and
 - e. Are smoke-free;
2. A warning notice is placed at the entrance to a room or area where oxygen is in use;
3. Soiled linen and clothing are kept:
 - a. In a covered container, and
 - b. Separate from clean linen and clothing;
4. Personnel wash hands after each direct patient contact and after handling soiled linen,

- soiled clothing, or biohazardous medical waste;
5. A written emergency plan is established, documented, and implemented that includes procedures for protecting the health and safety of patients and other individuals in a fire, natural disaster, loss of electrical power, or threat or incidence of violence; **and**
 6. An evacuation drill is conducted at least once every six months that includes all personnel **in the physical facilities on the premises on** the day of the evacuation drill; **and**
 7. Documentation of the evacuation drill is maintained **in the physical facilities on the premises** for **at least** one year after the date of the evacuation drill and includes:
 - a. The date and time of the evacuation drill; **and**
 - b. The names of personnel participating in the evacuation drill.

R9-10-1513. Equipment Standards

A licensee shall ensure that:

1. Equipment and supplies are maintained in a quantity sufficient to meet the needs of patients present in the abortion clinic;
2. Equipment to monitor vital signs is in each room in which an abortion is performed;
3. A surgical or gynecologic examination table is used for an abortion;
4. The following equipment and supplies are available in the abortion clinic:
 - a. Equipment to measure blood pressure;
 - b. A stethoscope;
 - c. A scale for weighing a patient;
 - d. Supplies for obtaining specimens and cultures and for laboratory tests; and
 - e. Equipment and supplies for use in a medical emergency including:
 - i. Ventilatory assistance equipment; **and**
 - ii. Oxygen source; **and**
 - iii. Suction apparatus; **and**
 - iv. Intravenous fluid equipment and supplies; and
 - f. Ultrasound equipment;
5. In addition to the requirements in subsection (4), the following equipment is available for an abortion procedure performed after the first trimester:
 - a. Drugs to support cardiopulmonary function **of a patient;** **and**
 - b. Equipment to monitor **the** cardiopulmonary status **of a patient;**
6. **In addition to the requirements in subsections (4) and (5), if the abortion clinic performs an abortion procedure at or after 20 weeks gestational age, the following equipment is**

available for the abortion procedure:

- a. Equipment to provide warmth and drying of a fetus delivered alive,
 - b. Equipment necessary to clear secretions from and position the airway of a fetus delivered alive,
 - c. Equipment necessary to administer oxygen to a fetus delivered alive,
 - d. Equipment to assess and monitor the cardiopulmonary status of a fetus delivered alive, and
 - e. Drugs to support cardiopulmonary function in a viable fetus;
- ~~6.7.~~ Equipment and supplies are clean and, if applicable, sterile before each use;
- ~~7.8.~~ Equipment required in this Section is maintained in working order, tested and calibrated at least once every 12 months or according to the manufacturer's recommendations, and used according to the manufacturer's recommendations; and
- ~~8.9.~~ Documentation of each equipment test, calibration, and repair is maintained in the physical facilities on the premises for one year at least 12 months after the date of the testing, calibration, or repair and provided to the Department for review within two hours after the Department requests the documentation.

R9-10-1514. Physical Facilities Plant Standards

- A.** A licensee shall ensure that an abortion clinic complies with all local building codes, ordinances, fire codes, and zoning requirements. If there are no local building codes, ordinances, fire codes, or zoning requirements, the abortion clinic shall comply with the applicable codes and standards incorporated by reference in A.A.C. R9-1-412 that were in effect on the date the abortion clinic's architectural plans and specifications were submitted to the Department for approval.
- B.** A licensee shall ensure that an abortion clinic provides areas or rooms:
1. That provide privacy for:
 - a. A patient's interview, medical evaluation, and counseling;
 - b. A patient to dress; and
 - c. Performing an abortion procedure;
 2. For personnel to dress;
 3. With a sink and a flushable toilet in working order;
 4. For cleaning and sterilizing equipment and supplies;
 5. For storing medical records;
 6. For storing equipment and supplies;
 7. For hand washing before the abortion procedure; and

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8. For a patient recovering after an abortion.
- C. A licensee shall ensure that an abortion clinic has an emergency exit to accommodate a stretcher or gurney.

R9-10-1515. Enforcement Repealed

- A.** For an abortion clinic that is not in substantial compliance or that is in substantial compliance but refuses to carry out a plan of correction acceptable to the Department, the Department may:
1. Assess a civil penalty according to A.R.S. § 36-431.01;
 2. Impose an intermediate sanction according to A.R.S. § 36-427;
 3. Suspend or revoke a license according to A.R.S. § 36-427;
 4. Deny a license, or
 5. Bring an action for an injunction according to A.R.S. § 36-430.
- B.** In determining the appropriate enforcement action, the Department shall consider the threat to the health, safety, and welfare of the abortion clinic's patients or the general public, including:
1. Whether the abortion clinic has repeated violations of statutes or rules;
 2. Whether the abortion clinic has engaged in a pattern of noncompliance; and
 3. The type, severity, and number of violations.