

NOTICES OF EXEMPT RULEMAKING

The Administrative Procedure Act requires the Register publication of the rules adopted by the state's agencies under an exemption from all or part of the Administrative Procedure Act. Some of these rules are exempted by A.R.S. §§ 41-1005 or 41-1057; other rules are exempted by other statutes; rules of the Corporation Commission are exempt from Attorney General review pursuant to a court decision as determined by the Corporation Commission.

Editor's note: In accordance with A.A.C. R1-1-109(D), the following Notice of Exempt Rulemaking is republished to correct printing errors in the text and replaces Notice of Exempt Rulemaking: 6 A.A.R. 3755 - 3762, September 29, 2000.

NOTICE OF EXEMPT RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES

HEALTH CARE INSTITUTIONS: LICENSURE

PREAMBLE

1. Sections Affected

Article 15	Amend
R9-10-1501	Amend
R9-10-1505	Amend
R9-10-1506	Amend
R9-10-1507	Amend
R9-10-1508	Amend
R9-10-1510	Amend
R9-10-1511	Amend
R9-10-1514	Amend

Rulemaking Action

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 36-132(A) and 36-136(F)

Implementing statutes: A.R.S. §§ 36-449, 36-2301.02, and Laws 2000, Chapter 365

3. The effective date of the rules:

January 1, 2001

4. A list of all previous notices appearing in the Register addressing the exempt rule:

Not applicable

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Vicki A. Conditt, Rules Analyst

Address: 1647 East Morten Ave., Suite 230
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6. An explanation of the rule, including the agency's reasons for initiating the rule, including the statutory citation to the exemption from the regular rulemaking procedures:

Laws 2000, Chapter 365 was enacted to replace the requirement for a pathological examination with an ultrasound examination to estimate gestational age of a fetus. The Laws 2000, Chapter 365 (HB 2647) provides an exemption from the requirements of A.R.S. Title 41, Chapter 6.

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of the state:

Not applicable

8. The summary of the economic, small business and consumer impact:

Not applicable under an exemption pursuant to Laws 2000, Chapter 365

9. A description of the changes between proposed rules, including supplemental notices, and final rules (if applicable):

Not applicable

10. A summary of the principal comments and the agency response to them:

Not applicable

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

12. Incorporations by reference and their location in the rules:

None

13. Was the rule previously adopted as an emergency rule?

No

14. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES

HEALTH CARE INSTITUTIONS: LICENSURE

ARTICLE 15. ABORTION CLINICS

Sections

R9-10-1501. Definitions

R9-10-1505. Personnel Qualifications and Records

R9-10-1506. Staffing Requirements

R9-10-1507. Patient Rights

R9-10-1508. Abortion Procedures

R9-10-1510. Medications and Controlled Substances

R9-10-1511. Medical Records

R9-10-1514. Physical Facilities

ARTICLE 15. ABORTION CLINICS

R9-10-1501. Definitions

In this Article, unless the context otherwise requires:

1. "Abortion" means the use of a surgical instrument or a machine with the intent to terminate a woman's pregnancy for reasons other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, to terminate an ectopic pregnancy or to remove a dead fetus. Abortion does not include birth control devices or oral contraceptives.
2. "Abortion clinic" means a facility, other than an accredited hospital, in which five or more first trimester abortions in any month or any second or third trimester abortions are performed.
3. "Adverse reaction" means an unexpected occurrence that threatens the health and safety of a patient.
4. "Biohazardous medical waste" means cultures and stocks, waste human blood and blood products, bodily fluids, uterine contents, and discarded medical sharps.
5. "Conspicuously posted" means placed at a location within an abortion clinic that is accessible and visible to patients and the public.

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6. "Controlled substance" means the same as defined in A.R.S. § 32-1901(12).
7. "Course" means hands-on practice under the supervision of a physician, training, or education.
8. "Current" means up-to-date, extending to the present time.
9. "Department" means the same as defined in A.R.S. § 36-401.
10. "Direction" means the same as defined in A.R.S. § 36-401.
11. "Discharge" means a patient no longer requires the medical services, nursing services, or health-related services provided by the abortion clinic.
12. "Documentation" means written, supportive evidence.
13. "Emergency" means a potentially life-threatening occurrence that requires an immediate response or medical treatment.
14. "Employee" means an individual who receives compensation from a licensee, but does not provide medical services, nursing services, or health-related services.
15. ~~"Fetus" means an individual human organism from fertilization until birth.~~ "Fetus" means an individual human organism from fertilization until birth.
16. "First trimester" means 1 through 14 weeks as measured from the 1st day of the last menstrual period or 1 through 12 weeks as measured from the date of fertilization.
17. "Gestational age" means the number of completed weeks of the unborn fetus as calculated from the 1st day of the last menstrual period or the date of fertilization.
18. "Health-related services" means the same as defined in A.R.S. § 36-401.
19. "Immediately" means without delay.
20. "Incident" means an abortion related patient death or serious injury to a patient or viable fetus.
21. "Infection control" means to identify, prevent, monitor, and minimize infections.
22. "Licensee" means an individual, a partnership, an association, a limited liability company, or corporation authorized by the Department to operate an abortion clinic.
23. "Local" means under the jurisdiction of a city or county in Arizona.
24. "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.
25. "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.
26. "Medical services" means the same as defined in A.R.S. § 36-401.
27. "Medication" means a prescription medication as defined in A.R.S. § 32-1901 or a nonprescription drug or over-the-counter drug as defined in A.R.S. § 32-1901.
28. "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.
29. "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.
- ~~29~~30. "Nurse" means an individual licensed and in good standing as a registered nurse or a practical nurse according to A.R.S. Title 32, Chapter 15.
- ~~30~~31. "Nurse practitioner" means an individual licensed and in good standing as a registered nurse practitioner according to A.R.S. Title 32, Chapter 15.
- ~~31~~32. "Nursing services" means the same as defined in A.R.S. § 36-401.
- ~~32~~33. "Patient" means a female receiving medical services, nursing services, or health-related services related to an abortion.
- ~~33~~34. "Patient care staff" means a physician, nurse practitioner, nurse, physician assistant, or surgical assistant who provides medical services, nursing services, or health-related services to a patient.
- ~~34~~35. "Patient 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(13).
- ~~35~~36. "Patient transfer" means relocating a patient requiring medical services from an abortion clinic to another health care institution.
- ~~36~~37. "Personnel" means patient care staff, employees, and volunteers.
- ~~37~~38. "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.
- ~~38~~39. "Physician" means an individual licensed according to A.R.S. Title 32, Chapter 13 or 17.
- ~~39~~40. "Physician assistant" means an individual licensed according to A.R.S. Title 32, Chapter 25.
- ~~40~~41. *"Serious injury" means an injury that occurs at an abortion clinic and that creates a serious risk of substantial impairment of a major body organ.*
- ~~41~~42. *"Supervision" means direct overseeing and inspection of the act of accomplishing a function or activity.*

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- ~~4243.~~ “Surgical assistant” means an individual who is not licensed as a physician, ~~physician’s physician~~ assistant, nurse practitioner, or nurse who performs duties as directed by a physician, ~~physician’s physician~~ assistant, nurse practitioner or nurse.
- ~~4344.~~ “Viable fetus” means the same as defined in A.R.S. § 36-2301.01.
- ~~4445.~~ “Volunteer” means an individual who, without compensation, performs duties as directed by a member of the patient care staff at an abortion clinic.

R9-10-1505. Personnel Qualifications and Records

A licensee shall ensure that:

- ~~1.~~ ~~Personnel are 18 years of age or older;~~
- ~~21.~~ 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;
- ~~32.~~ Surgical assistants and volunteers who provide counseling and patient advocacy receive training in these specific responsibilities and any other responsibilities assigned and that documentation is maintained in the individual’s personnel file of the training received;
- ~~43.~~ An individual who performs an ultrasound provides documentation that the individual is:
 - a. A physician who:
 - i. ~~Has Completed~~ completed a course in performing an ultrasound from a manufacturer or distributor of ultrasound equipment; or
 - ii. Has performed ultrasounds during the physician’s medical education;
 - b. A ~~physician’s physician~~ assistant, nurse practitioner, or nurse who completed a hands-on course in performing ultrasounds under the supervision of a physician qualified as required in subsection ~~(4)(3)(a)~~; or
 - c. An individual who completed:
 - i. A postsecondary education institution course in performing ultrasound; and
 - ii. The hands-on course required in subsection ~~(4)(3)(b)~~.
- ~~54.~~ An individual has completed a course for the type of ultrasound the individual performs;
- ~~65.~~ A personnel file for each member of the patient care staff and each volunteer is maintained either electronically or in writing and includes:
 - a. The individual’s name, position title, and the 1st and last date of employment or volunteer service, if applicable;
 - b. Verification of qualifications, training, or licensure, if applicable;
 - c. Documentation of cardiopulmonary resuscitation certification, if applicable;
 - d. Documentation of verification of competency, as required in subsection ~~(2)(1)~~, and signed and dated by the medical director;
 - e. Documentation of training for surgical assistants and volunteers; and
 - f. Documentation of completion of a course as required in subsection ~~(4)(3)~~, for an individual performing ultrasounds; and
- ~~76.~~ Personnel files are maintained in the physical facilities for at least 2 years from the ending date of employment or volunteer service.

R9-10-1506. Staffing Requirements

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

1. Meet the requirements of this Article;
2. Ensure the health and safety of a patient; 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, except for a surgical assistant, who is current in cardiopulmonary resuscitation certification is in the physical facilities until all patients are discharged;
2. A physician with admitting privileges at an accredited hospital in this state is in the physical facilities until each patient is stable and ready to leave the recovery room;
3. If a physician is not present, a nurse, a nurse practitioner or a ~~physician’s physician~~ assistant:
 - a. Monitors each patient during the patient’s recovery following the abortion; and
 - b. Remains in the physical facilities until each patient is discharged by a physician; and
4. A written schedule is maintained in the physical facilities for at least 6 months from the last date on the schedule and includes:
 - a. The date, work hours, and name of the patient care staff assigned to provide medical services, nursing services, health-related services, and the name of the volunteers assigned to provide volunteer services; and

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- b. The date, work hours and name of the patient care staff and volunteers who actually provided medical services, nursing services, health-related services, or volunteer services.

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 be treated with consideration, respect, and full recognition of the patient's dignity and individuality;
2. To refuse treatment, or withdraw consent for treatment ~~at any time~~;
3. To have medical records kept confidential; and
4. 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; and
 - d. If an ultrasound is performed, the right to review the ultrasound results with a physician, a ~~physician's~~ physician assistant, a nurse practitioner, or a registered nurse before the abortion procedure.

R9-10-1508. Abortion Procedures

A. A medical director shall ensure that a medical evaluation of a patient is conducted before performing an abortion and 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 if an ultrasound examination is not performed;
 - 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.

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 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 the gestational age of the fetus, and records the estimated 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. If a physical examination or other information obtained from the patient or laboratory tests indicates the gestational age of the fetus is greater than 12 weeks, a medical director shall ensure that:

1. An ultrasound is performed by an individual who meets the requirements in R9-10-1505~~(4)~~(3);
2. An ultrasound estimate of gestational age is performed using methods and tables or charts published in a nationally recognized medical journal;
- ~~23.~~ An original ultrasound print is:
 - a. Interpreted by a physician; and
 - b. Maintained in the patient's medical record; and
- ~~34.~~ If requested by the patient, the ultrasound is reviewed with the patient by a physician, a ~~physician's~~ physician assistant, a nurse practitioner, or a registered nurse.

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

1. Written consent is signed and dated by the patient or the patient's representative; and
2. Information is provided to the patient on the abortion procedure including alternatives, risks and potential complications.

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- 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:
1. Patient care staff monitor the patient's vital signs throughout the 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 1st trimester; and
 3. If a viable fetus shows signs of life:
 - a. Resuscitative measures are used to support life;
 - b. The viable fetus is transferred as required in R9-10-1509; and
 - c. Resuscitative measures and the transfer are documented.
- H.** A medical director shall ensure that following the abortion procedure:
1. A patient's vital signs and bleeding are monitored by a member of the patient care staff, except a surgical assistant, to ensure the patient's health and safety;
 2. A patient remains in the recovery room or recovery area until a physician, a ~~physician's~~ physician assistant, a nurse practitioner or a 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; and
 - ~~3. The fetal remains are submitted to a laboratory according to A.R.S. § 36-2301.02.~~
 3. An ultrasound result print of each fetus with a gestational age estimate of more than 12 weeks is sent to persons or corporations contracted with the Department in compliance with A.R.S. § 36-2301.02.
- 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 of the patient's discharge to assess the patient's recovery. If the patient care staff is unable to speak with the patient, for any reason, the attempt to contact the patient is documented in the patient's medical record; and
 2. A follow-up visit offered at least 3 weeks after the abortion, which includes:
 - a. A physical examination;
 - b. A review of all laboratory tests as required in R9-10-1508(A)(3); and
 - c. A urine pregnancy test.
- J.** If a continuing pregnancy is suspected as a result of the follow-up visit required in subsection (I)(2), a physician who performs abortions shall be consulted.

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's~~ physician assistant, nurse practitioner, or as otherwise provided by law;
3. A medication is administered to a patient by a physician or as otherwise provided by law;
4. Medications and controlled substances are maintained in a locked area in the physical facilities;
5. Only personnel designated in the abortion clinic's policies and procedures have access to the locked area containing the medications and controlled substances;
6. Expired, mislabeled, or unusable medications and controlled substances are disposed of according to the abortion clinic's policies and procedures;
7. Medication errors and adverse reactions, including any actions taken in response to the medication errors or adverse reactions, are immediately reported to the medical director and licensee, and recorded in the patient's medical record;
8. Medication information is maintained in a 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. If medication is administered to a patient, the following are documented in the patient's medical record:
 - a. The date and time of administration;
 - b. The name, strength, dosage form, amount of medication, and route of administration; and
 - c. The identification and signature of the individual administering the medication.

R9-10-1511. Medical Records

- A.** A licensee shall ensure that:
1. A medical record is established and maintained for a patient that contains:
 - a. Patient identification including:
 - i. The patient's name, address, and date of birth;
 - ii. The designated patient 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) or (D);
 - f. The ultrasound results, if applicable, including the original print as required in R9-10-1508(D);
 - g. Each consent form signed by the patient or the patient's representative;
 - h. A record of all orders issued by a physician, ~~physician's~~ physician assistant or nurse practitioner;
 - i. A record of all medical, nursing, and health-related services provided to the patient; and
 - j. The patient's medication information;
 2. A medical record is accessible only to the Department or personnel authorized by the abortion clinic's policies and procedures;
 3. 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. A medical record is protected from loss, damage or unauthorized use and is maintained and accessible for 5 7 years from the date of the an adult patient's discharge or if the patient is a child, either for at least 3 years after the child's 18th birthday or for at least 7 years after the patient's discharge, whichever date occurs last;
 - a. A medical record is maintained at the abortion clinic for at least 6 months from the date of the patient's discharge;
 - b. A medical record maintained at the abortion clinic is provided to the Department for review no later than 2 hours from the time the Department requests the medical record; and
 - c. A medical record maintained off-site is provided to the Department for review no later than 24 hours from the time the Department requests the medical record;
 5. Vital records and vital statistics are retained according to A.R.S. § 36-343; and
 6. If an abortion clinic ceases operations, the Department is notified in writing, not less than 30 days before ceasing operations, of the location of the abortion clinic's medical records.
- B.** A medical director shall ensure that only personnel authorized by an abortion clinic's policies records or signs an entry in a medical record and:
1. An entry in a medical record is dated and legible;
 2. An entry is authenticated by:
 - a. A written signature;
 - b. An individual's initials if the individual's written signature already appears in the medical record;
 - c. A rubber-stamp signature; or
 - d. A computer code;
 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 days by the individual who issued the order;
 5. If a rubber-stamp signature or a computer code is used:
 - a. An individual's rubber stamp or computer code is not used by another individual;
 - b. The individual who uses a rubber stamp or computer code signs a statement that the individual is responsible for the use of the rubber stamp or the computer code; 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.
- C.** As required by A.R.S. § 36-449.03(I), the Department shall not release any personally identifiable patient or physician information.

R9-10-1514. Physical Facilities

- A.** A licensee shall ensure that an abortion clinic complies with all local building codes, ordinances, fire codes, and zoning requirements ~~and any applicable codes incorporated by reference in A.A.C. R9-1-412~~. 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.

- 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 in working order and a flushable toilet;
 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
 8. For a patient recovering after an abortion.
- C.** A licensee shall ensure that an abortion clinic has an emergency exit ~~that is a minimum of 36 inches in width~~ to accommodate a stretcher or gurney.