NOTICE OF PROPOSED EXPEDITED RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES

HEALTH CARE INSTITUTIONS: LICENSING

PREAMBLE

1.	**Article, Part, or Section Affected (as applicable)**	**Rulemaking Action**
	R9-10-119	Amend
	R9-10-1505	Amend
	R9-10-1509	Amend

2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statutes: A.R.S. §§ 36-132(A)(1), 36-136(G)

Implementing statutes: A.R.S. §§ 36-132(A)(17), 36-405(A) and (B), 36-406, 36-449.03, 36-2161 and Laws 2018, Ch. 219

3. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the proposed rule:

Notice of Rulemaking Docket Opening: 25 A.A.R. 678, March 15, 2018

4. The agency's contact person who can answer questions about the rulemaking:

Name: Colby Bower, Assistant Director

Address: Department of Health Services

Public Health Licensing Services

150 N. 18th Ave., Suite 510

Phoenix, AZ 85007

Telephone: (602) 542-6383

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E-mail: Colby.Bower@azdhs.gov

or

Name: Robert Lane, Chief

Address: Arizona Department of Health Services

Office of Administrative Counsel and Rules

150 N. 18th Avenue, Suite 200

Phoenix, AZ 85007

Telephone: (602) 542-1020
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5. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

In order to ensure public health, safety, and welfare, Arizona Revised Statutes (A.R.S.) §§ 36-405 and 36-406 require the Arizona Department of Health Services (Department) to adopt rules establishing minimum standards and requirements for construction, modification, and licensure of health care institutions. A.R.S. § 36-449.03 requires the Department to adopt rules that establish minimum standards and requirements for abortion clinics, a class of health care institutions. Laws 2018, Ch. 219 amends A.R.S. §§ 36-2161 and 36-2162 to require abortion providers to: supply additional information to the Department in abortion procedure and complication reports; request additional information from women seeking abortions; and provide information to women seeking abortions who are victims of certain crimes. After obtaining an exception from the rulemaking moratorium established by Executive Order 2018-02, the Department is revising rules in 9 A.A.C. 10, Articles 1 and 15 to comply with Laws 2018, Ch. 219. The Department is revising the rules in 9 A.A.C. 10, Article 15, Abortion Clinics, to include new requirements for reporting complications according to A.R.S § 36-2161(A)(15), requesting information specified in A.R.S. § 36-2161(A)(12) from a patient, and providing information required in A.R.S. § 36-2161(C) to a patient, if applicable. In addition, A.A.C. R9-10-119 is being revised to update cross-references to new subsections in A.R.S. § 36-2161. The Department believes the rulemaking meets the criteria for expedited rulemaking since the changes to be made will not increase the cost of regulatory compliance, increase a fee, or reduce procedural rights of persons regulated, but amends rules that became outdated with the statutory revisions made by Laws 2018, Ch. 219. The proposed amendments will conform to rulemaking format and style requirements of the Governor's Regulatory Review Council and the Office of the Secretary of State.

6. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Department did not review or rely on any study for this rulemaking.

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

Not applicable

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

Under A.R.S. § 41-1055(D)(2), the Department is not required to provide an economic, small business, and consumer impact statement.

9. The agency's contact person who can answer questions about the economic, small business, and consumer impact statement:

Not applicable

10. Where, when, and how persons may provide written comment to the agency on the proposed expedited rules under A.R.S. § 41-1027(C):

Close of record: Monday, May 13, 2019, 4:00 p.m.

A person may submit written comments on the proposed expedited rules no later than the close of record to either of the individuals listed in item 4.

11. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

A.R.S. § 36-407 prohibits a person from establishing, conducting, or maintaining "a health care institution or any class or subclass of health care institution unless that person holds a current and valid license issued by the [D]epartment specifying the class or subclass of health care institution the person is establishing, conducting or maintaining." A health care institution license is specific to the licensee, class or subclass of health care institution, facility location, and scope of services provided. As such, a general permit is not applicable and is not used.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

Not applicable

c. **Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:**

No business competitiveness analysis was received by the Department.

12. **A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:**

Not applicable

13. **The full text of the rules follows:**

TITLE 9. HEALTH SERVICES

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES

HEALTH CARE INSTITUTIONS: LICENSING

ARTICLE 1. GENERAL

Section

ARTICLE 15. ABORTION CLINICS

Section

ARTICLE 1. GENERAL

R9-10-119. Abortion Reporting

A. A licensed health care institution where abortions are performed shall submit to the Department, in a Department-provided format and according to A.R.S. § ~~36-2161(B) and (C)~~ 36-2161(D) and (E), a report that contains the information required in A.R.S. § 36-2161(A) and the following:

1. The final disposition of the fetal tissue from the abortion; and
2. Except as provided in subsection (B), if custody of the fetal tissue is transferred to another person or persons:
    a. The name and address of the person or persons accepting custody of the fetal tissue,
    b. The amount of any compensation received by the licensed health care institution for the transferred fetal tissue, and
    c. Whether a patient provided informed consent for the transfer of custody of the fetal tissue.

B. A licensed health care institution where abortions are performed is not required to include the information specified in subsections (A)(2)(a) through (c) in the report required in subsection (A) if the licensed health care institution where abortions are performed:

1. Transfers custody of the fetal tissue:
    a. To a funeral establishment, as defined in A.R.S. § 32-1301;
    b. To a crematory, as defined in A.R.S. § 32-1301; or
    c. According to requirements in A.A.C. R18-13-1406, A.A.C. R18-13-1407, and A.A.C. R18-13-1408; or
2. Complies with requirements in A.A.C. R18-13-1405.

C. For purposes of this Section, the following definition applies: “Fetal tissue” means cells, or groups of cells with a specific function, obtained from an aborted human embryo or fetus.

ARTICLE 15. ABORTION CLINICS

R9-10-1505. 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 a fetus delivered alive, verbal notification the next working day; and
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, including, if applicable, information required in A.R.S. § 36-2161(A)(15);
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 on the premises for at least two years after the date of the incident.

R9-10-1509. 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;
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 shall estimate the gestational age of the fetus, based on one of the following criteria, and record the estimated gestational age in the patient's medical record:

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. The ultrasound of a patient required in subsection (A)(4) is performed by an individual who meets the requirements in R9-10-1506(3);
2. An ultrasound estimate of gestational age of a fetus is performed using methods and tables or charts 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 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, and A.R.S. § 36-2158 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~~.~~;
3. Information specified in A.R.S. 36-2161(A)(12) is requested from the patient; and
4. If applicable, information required in A.R.S. § 36-2161(C) is provided to the patient.

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. A patient care staff member 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 qualified in neonatal resuscitation, other than the physician performing the abortion procedure, is in the room in which the abortion procedure takes place before the delivery of the fetus; and
4. If a fetus 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;

d. A viable fetus is transferred as required in R9-10-1510; and

e. Resuscitative measures and the transfer, as applicable, are documented.

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

1. A patient's vital signs and bleeding are monitored by:
   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.

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

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.

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