
NOTICES OF PROPOSED RULEMAKING

This section of the *Arizona Administrative Register* contains Notices of Proposed Rulemakings.

A proposed rulemaking is filed by an agency upon completion and submittal of a Notice of Rulemaking Docket Opening. Often these two documents are filed at the same time and published in the same *Register* issue.

When an agency files a Notice of Proposed Rulemaking under the Administrative Procedure Act (APA), the notice is published in the *Register* within three weeks of filing. See the publication schedule in the back of each issue of the *Register* for more information.

Under the APA, an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

The Office of the Secretary of State is the filing office and publisher of these rules. Questions about the interpretation of the proposed rules should be addressed to the agency that promulgated the rules. Refer to item #4 below to contact the person charged with the rulemaking and item #10 for the close of record and information related to public hearings and oral comments.

NOTICE OF PROPOSED RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES HEALTH CARE INSTITUTIONS: LICENSING

[R16-09]

PREAMBLE

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| 1. <u>Article, Part, or Section Affected (as applicable)</u>
R9-10-119 | <u>Rulemaking Action</u>
New Section |
|--|--|
- 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(F)
Implementing statutes: A.R.S. §§ 36-132(A)(17), 36-405(A) and (B), 36-449.02(F), 36-2161
- 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: 21 A.A.R. 2474, October 23, 2015
Notice of Emergency Rulemaking: 21 A.A.R. 1787, September 4, 2015
- 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
Fax: (602) 364-4808
E-mail: Colby.Bower@azdhs.gov
or
Name: Robert Lane, Manager
Address: Arizona Department of Health Services
Office of Administrative Counsel and Rules
1740 W. Adams St., Suite 203
Phoenix, AZ 85007
Telephone: (602) 542-1020
Fax: (602) 364-1150
E-mail: Robert.Lane@azdhs.gov



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 An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

When the Arizona Department of Health Services (Department) became aware of the potential sale of aborted fetal tissue by Arizona health care institutions where abortions are performed, the Department initiated emergency rulemaking after receiving an exception from the Governor's rulemaking moratorium, established by Executive Order 2015-01. Through this emergency rulemaking, the Department clarified, in the health care institution licensing rules in 9 A.A.C. 10, the abortion reporting requirements in A.R.S. § 36-2161. The Department also added a requirement for a licensed health care institution where abortions are performed to include information on the final disposition of the fetal tissue, the person or persons taking custody of the fetal tissue, the amount of any compensation received by the licensed health care institution for the fetal tissue, and whether a patient has provided informed consent for the transfer of custody of the fetal tissue, consistent with 42 U.S.C. §§ 289g-1 and 289g-2. An exception was made in the reporting rule for a transfer of custody to a funeral establishment or a crematory for final disposition. The Notice of Emergency Rulemaking was filed with the Office of the Secretary of State on August 14, 2015. To prevent the expiration of the rule established through emergency rulemaking, the Department is adopting the rule through regular rulemaking. The Department is also clarifying other situations where a transfer of custody would not require reporting, to further reduce the burden on health care institutions.

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:

The Department anticipates that cost bearers may include the Department and licensed health care institutions where abortions are performed. These licensed health care institutions where abortions are performed may include hospitals, outpatient treatment centers, and abortion clinics. Beneficiaries may include the Department, health care institutions, and the general public. Annual costs/revenues changes are designated as minimal when \$1,000 or less, moderate when between \$1,000 and \$10,000, and substantial when \$10,000 or greater in additional costs or revenues. A cost is listed as significant when meaningful or important, but not readily subject to quantification.

The Department currently receives approximately 12,750 reports per year under A.R.S. § 36-2161 from about 18 health care institutions where abortions are performed. Of the 4,195 reports received for abortions performed between August 14, 2015, when the emergency rulemaking became effective, and December 23, 2015, 58 indicated that fetal tissue had been transferred for burial/cremation, two did not indicate a disposition, and the rest indicated that there had been no transfer of custody.

Based on these data, the Department anticipates that the review of the additional information required in the proposed rule will impose at most a minimal cost on the Department and may provide a significant benefit to the Department from having accurate information about the final disposition of fetal tissue. Licensed health care institutions where abortions are performed may incur a minimal cost from the added time to comply with the requirement for reporting the final disposition of the fetal tissue. The Department anticipates that, if a licensed health care institution where abortions are performed transfers custody of fetal tissue to a person other than a funeral establishment, a crematory, or according to the requirements in A.A.C. R18-13-1406, A.A.C. R18-13-1407, and A.A.C. R18-13-1408 or does not comply with the requirements in A.A.C. R18-13-1405, the licensed health care institution where abortions are performed may incur a minimal-to-moderate cost from the added time to compile the additional information on the name and address of the person or persons accepting custody of the fetal tissue, the amount of any compensation received by the licensed health care institution for the transferred fetal tissue, and whether a patient provided informed consent for the transfer of custody of the fetal tissue. A licensed health care institution where abortions are performed that meets the reporting exception requirements in subsection (B) of the rule may receive a significant benefit from assuring the general public that such transfers are not occurring at the health care institution. The general public may receive a significant benefit from the assurance that transfers of fetal tissue to a person other than a funeral establishment or crematory are being monitored by the Department.

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

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Phoenix, AZ 85007
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Fax: (602) 364-4808
 E-mail: Colby.Bower@azdhs.gov
 or
 Name: Robert Lane, Manager
 Address: Arizona Department of Health Services
 Office of Administrative Counsel and Rules
 1740 W. Adams St., Suite 203
 Phoenix, AZ 85007
 Telephone: (602) 542-1020
 Fax: (602) 364-1150
 E-mail: Robert.Lane@azdhs.gov

10. The time, place, and nature of the proceedings to make, amend, repeal, or renumber the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

The Department has scheduled the following oral proceeding:

Date and time: Wednesday, March 23, 2016, 3:00 p.m.
 Location: 150 N. 18th Ave., DLS Training Room, 4th Floor
 Phoenix, AZ 85007
 Close of record: Wednesday, March 23, 2016, 4:30 p.m.

A person may submit written comments on the proposed rules no later than the close of record to either of the individuals listed in items 4 and 9.

A person with a disability may request a reasonable accommodation, such as a sign language interpreter, by contacting Robert Lane at Robert.Lane@azdhs.gov or (602) 542-1020. Requests should be made as early as possible to allow time to arrange the accommodation.

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:

The rule does not require a permit.

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

R9-10-119. ~~Reserved~~ Abortion Reporting

ARTICLE 1. GENERAL

R9-10-119. ~~Reserved~~ 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), 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.