
NOTICES OF EMERGENCY RULEMAKING

This section of the *Arizona Administrative Register* contains Notices of Emergency Rulemaking.

The Office of the Secretary of State is the filing office and publisher of these rules.

Questions about the interpretation of the emergency rules should be addressed to the agency proposing them. Refer to Item #5 to contact the person charged with the rulemaking.

NOTICE OF EMERGENCY RULEMAKING**TITLE 9. HEALTH SERVICES****CHAPTER 10. DEPARTMENT OF HEALTH SERVICES
HEALTH CARE INSTITUTIONS: LICENSING**

[R16-32]

PREAMBLE

- 1. Article, Part, or Section Affected (as applicable)** **Rulemaking Action**
R9-10-119 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(F)
Implementing statutes: A.R.S. §§ 36-132(A)(17), 36-405(A) and (B), 36-449.02(F), 36-2161
- 3. The effective date of the rule:**
The rule will take effect upon the expiration of the emergency rule adopted through the Notice of Emergency Rulemaking filed with the Office of the Secretary of State by the Office of the Attorney General on August 14, 2015. An exception from the effective date provisions in A.R.S. § 41-1032(A) is necessary to preserve public health by continuing to address the potential illegal sales of tissue from unborn children.
- 4. Citations to all related emergency rulemaking notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of this notice of emergency rulemaking:**
Notice of Emergency Rulemaking: 21 A.A.R. 1787, September 4, 2015
- 5. The agency's contact person who can answer questions about the rulemaking:**
Name: Colby Bower, Assistant Director
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Office of Administrative Counsel and Rules
1740 W. Adams St., Suite 203
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Fax: (602) 364-1150
E-mail: Robert.Lane@azdhs.gov
- 6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:**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. By reviewing the information submitted, the Department is better able to monitor health care institutions where abortions are performed for compliance with applicable laws and rules on the use of donated tissues, including the potential illegal sale of tissue from unborn children.

Based on the foregoing and pursuant to A.R.S. § 41-1026(D), the Department finds the continued existence of an emergency justifying an emergency rulemaking. Although the Department has submitted a Notice of Proposed Rulemaking to the Office of the Secretary of State, the current emergency rule will expire before the regular rulemaking is completed. To prevent the expiration of the emergency rule, filed with the Office of the Secretary of State on August 14, 2015, the Department has requested a renewal of the emergency rule. The Department is also amending the emergency rule to further reduce the burden on health care institutions. In the amended rule, licensed health care institutions that transfer custody 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 comply with the requirements in A.A.C. R18-13-1405 will not be required to report 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, or whether a patient has provided informed consent for the transfer of custody of the fetal tissue.

7. A reference to any study relevant to the rules that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rules, 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 related to this rulemaking package.

8. 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

9. A 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 increased staff 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.



10. **Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules. When applicable, matters shall include but are not limited to:**
 - 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:**
Not applicable
 - 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:**
The rule is not more stringent than federal law.
 - 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 analysis comparing competitiveness was received by the Department.
11. **A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rule:**
None
12. **An agency explanation about the situation justifying the rulemaking as an emergency rule:**
When the Department became aware of the potential for fetal tissue from an abortion to be sold, the Department immediately initiated an emergency rulemaking to address the situation. This situation was not caused by the Department's delay or inaction. Although the Department has submitted a Notice of Proposed Rulemaking to the Office of the Secretary of State, the current emergency rule will expire before the regular rulemaking is completed.
13. **The date the Attorney General approved the rule:**
February 8, 2016
14. **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. Abortion Reporting

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), 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; ~~except for a funeral establishment, as defined in A.R.S. § 32-1301, or a crematory, as defined in A.R.S. § 32-1301:~~
 - 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.
- ~~B-C.~~ For purposes of this Section, the following definition applies:
4. "Fetal tissue" means cells, or groups of cells with a specific function, obtained from an aborted human embryo or fetus.