

Notices of Exempt Rulemaking

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 An agency's justification and reason why a rule should be made, amended, repealed, or renumbered to include an explanation about the rulemaking:

Arizona Revised Statutes (A.R.S.) §§ 36-132(A)(17) and 36-405 authorize the Department to license and regulate health care institutions, including abortion clinics. Under these statutes, the Department adopted the rules in 9 A.A.C. 10, Article 15. On April 15, 2014, the Governor signed HB 2284, which changes requirements for abortion clinics. HB 2284 was effective July 24, 2014. HB 2284 gives the Department exempt rulemaking authority to amend the rules for abortion clinics. After receiving an exception from the rulemaking moratorium, established by Executive Order 2012-03, the Department drafted rules that comply with the statutory changes. All changes conform to current rulemaking format and style requirements of the Governor's Regulatory Review Council and the Office of the Secretary of State.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not 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:

None

8. A showing of good cause why the rule 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. The summary of the economic, small business, and consumer impact, if applicable:

Not applicable

10. A description of any changes between the proposed rulemaking, including any supplemental proposed rulemaking, and final rulemaking package, (if applicable):

Not applicable

11. An agency's summary of the public or stakeholder comments made about the rulemaking and the agency response to the comments, if applicable:

Not applicable

12. 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 not be 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:

A.R.S. § 36-405 authorizes the Department to issue licenses to specific applicants based on specific circumstances, so a general permit is not appropriate and is not used.

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

Not applicable

13. A list of any incorporated by reference material and its location in the rules:

None

14. Whether this rule previously made, amended, repealed or renumbered as an emergency rule. If so, the agency shall state where the text changed between the emergency and the exempt rulemaking packages:

The rule was not previously made, amended, repealed, or renumbered as an emergency rule.

15. The full text of the rules follows:

Notices of Exempt Rulemaking

TITLE 9. HEALTH SERVICES

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

ARTICLE 15. ABORTION CLINICS

Section

- R9-10-1503. Administration
- R9-10-1511. Medical Records

ARTICLE 15. ABORTION CLINICS

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 is licensed according to A.R.S. Title 32, Chapter 13, 17, or 29. The licensee and the medical director may be the same individual; and
 - 3. ~~Ensure that the Department's director or director's representative is allowed access as follows:~~
 - a. ~~For a complaint inspection, upon presentation of an administrative search warrant authorizing the inspection of the abortion clinic; or~~
 - b. ~~For a licensing or compliance inspection, at a date and time agreed to by the licensee and the Department that is no later than 10 business days after the date the Department submits a written request to the licensee to schedule the licensing or compliance inspection, unless the Department agrees to a later date and time;~~
 - 4.3. Ensure the following documents are conspicuously posted at the physical facilities:
 - 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 map; and
 - d. Signs that comply with A.R.S. § 36-2153(G).
- C. A medical director shall ensure written policies and procedures are established, documented, and implemented 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. Verification of the competency of the physician performing an abortion according to R9-10-1505;
 - 4. The storage, administration, accessibility, disposal, and documentation of a medication, and a controlled substance;
 - 5. Accessibility and security of patient medical records;
 - 6. Abortion procedures including recovery and follow-up care; and the minimum length of time a patient remains in the recovery room or area based on:
 - a. The type of abortion performed;
 - b. The estimated gestational age of the fetus;
 - c. The type and amount of medication administered; and
 - d. The physiologic signs including vital signs and blood loss;
 - 7. Infection control including methods of sterilizing equipment and supplies;
 - 8. Medical emergencies; and
 - 9. Patient discharge and patient transfer.

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'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, including the original print, required in R9-10-1508(D);
 - g. Each consent form signed by the patient or the patient's legal guardian;

Notices of Exempt Rulemaking

- 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. A medical record is accessible only to the Department or personnel authorized by 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 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. A medical record is maintained at the abortion clinic for at least six months after the date of the patient's discharge; and
 6. 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.
 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 only according to an administrative search warrant specifically authorizing the disclosure of unredacted patient medical records by the licensee.~~
 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

Notices of Exempt Rulemaking

- 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).
- C. A medical director shall ensure that only personnel authorized by policies and procedures, 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. 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 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. As required by A.R.S. § 36-449.03(I), the Department shall not release any personally identifiable patient or physician information.