

NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), 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)

NOTICE OF PROPOSED RULEMAKING – CORRECTION

TITLE 9. HEALTH SERVICES

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

Correction Notice: The following Notice of Proposed Rulemaking is a correction for 15 A.A.C. 590, April 10, 2009. In the previous printing, R9-10-1501(40) was printed incorrectly, inadvertently altering its meaning substantively. The following reprint has the originally submitted verbiage. The meeting in item 10 has been updated to reflect 30 days from the printing in this issue (15 A.A.R. 786, May 15, 2009).

Editor's Note: The following Notice of Proposed Rulemaking was reviewed per the Governor's Regulatory Review Plan memorandum, January 22, 2009. (See a copy of the memorandum in this issue on page 800.) The Governor's Office authorized the notice to proceed through the rulemaking process on March 13, 2009.

[R09-33]

PREAMBLE

1. Sections Affected

R9-10-1501
R9-10-1503
R9-10-1505
R9-10-1506
R9-10-1507
R9-10-1508
R9-10-1511

Rulemaking Action

Amend
Amend
Amend
Amend
Amend
Amend
Amend

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

Authorizing statutes: A.R.S. §§ 36-104(3), 36-132(A)(3), and 36-136
Implementing statutes: A.R.S. §§ 36-405, 36-406, and 36-449.03

3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 15 A.A.R. 300, January 30, 2009
Notice of Proposed Rulemaking: 15 A.A.C. 590, April 10, 2009

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

Name: Jessica Johnson, Assistant Administrative Counsel
Address: Department of Health Services
1740 W. Adams St., Suite 200
Phoenix, AZ 85007
Telephone: (602) 542-1513
Fax: (602) 364-1150
E-mail: johnsojm@azdhs.gov
or
Name: Kathy McCanna, Program Manager

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Address: Department of Health Services, Division of Licensing Services
Office of Medical Facilities
150 N. 18th Ave.
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5. An explanation of the rule, including the agency's reasons for initiating the rules:

A.R.S. § 36-405(A) requires the Department to adopt rules establishing minimum standards and requirements for the construction, modification and licensure of health care institutions necessary to assure the public health, safety and welfare. It further requires that the standards and requirements relate to the construction, equipment, sanitation, staffing for medical, nursing, and personal care services, and recordkeeping pertaining to the administration of medical, nursing, and personal care services according to generally accepted practices of health care. A.R.S. § 36-405(B) allows the Department to class and subclass health care institutions according to character, size, range of services provided, medical or dental specialty offered, duration of care and standard of patient care required. Laws 1999, Ch. 311, § 2 defined and added abortion clinics as a health care institution class.

A.R.S. §§ 36-449 and 36-449.01 through 36-449.03, effective August 6, 1999, establish the requirements for abortion clinics. A.R.S. § 36-449.01 defines "abortion clinic" as 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." A.R.S. § 36-449.03 directs the Department to adopt rules regarding an abortion clinic's physical facilities, personnel, medical screening and evaluation of patients, abortion procedures, incident reporting, and standards for supplies, equipment, recovery rooms, and follow-up visits.

A.A.C. Title 9, Chapter 10, Article 15, provides the minimum standards and requirements for abortion clinics in Arizona. The rules address an abortion clinic's application requirements, administration, incident reporting, personnel qualifications and records, staffing requirements, patient rights, abortion procedures, patient transfer and discharge, medications and controlled substances, medical records, environmental and safety standards, equipment standards, and physical facilities. The rules were adopted by exempt rulemaking, effective April 1, 2000 and amended by exempt rulemaking, effective January 1, 2001.

On March 1, 2000, the Center for Reproductive Rights filed a federal challenge to the abortion clinic rules on behalf of several abortion providers, including Tucson Woman's Clinic, seeking to block implementation. After the suit was filed, the Department agreed not to enforce the rules during the District Court proceedings and subsequent appeals. Accordingly, the abortion clinic rules have not been implemented.

In *Tucson Woman's Clinic v. Eden*, No. CV-00-00141-RCC (D). Arizona Sept. 30, 2002, the District Court in substantial part upheld the abortion clinic rules but struck down rule provisions that provided state officials with unannounced access to abortion clinics during business hours and allowed state officials to review unredacted patient records and ultrasound prints. The District Court's decision was appealed to the U.S. Court of Appeals for the Ninth Circuit and the decision was affirmed in part, reversed in part, and remanded to the District Court for further proceedings. *Tucson Woman's Clinic v. Eden*, No. 02-17375, No. 02-17382, 2004 U.S. App. LEXIS 12015 (9th Cir. June 18, 2004). In the ruling, the Court of Appeals:

- Agreed with the District Court that the statutory and regulatory scheme authorized boundless, warrantless searches and violated the plaintiffs' Fourth Amendment rights;
- Held that allowing access to unredacted medical records and sending ultrasound prints to a private contractor violated a patient's right to privacy;
- Agreed with the District Court that some provisions were not clear enough to let physicians know when they have violated the rule and were unconstitutionally vague; and
- Disagreed with the District Court's decision that the law did not impose an undue burden on the plaintiffs and ruled that this was an issue of material fact, remanding the matter for trial.

On September 10, 2008, the Department and the other defendants and the plaintiffs filed a Stipulation of Settlement and a Joint Request for an Order Approving and Mandating Compliance with Stipulation of Settlement that was approved by the District Court. Within 120 calendar days of the District Court's approval, the Department agreed to begin the rulemaking process to amend the abortion clinic rules according to Exhibit A of the Stipulation. A Notice of Rulemaking Docket Opening for 9 A.A.C. 10, Article 15, Abortion Clinics, was filed on January 6, 2009. The Department also agreed to follow all requirements in the rulemaking process in proposing and supporting the rule revisions in the Stipulation. This rulemaking contains the amendments that the Department agreed to propose and support as part of the Stipulation including:

- Adding definitions for "admission," "admitting privileges," "hospital," and "personally identifiable patient information";
- Deleting provisions requiring the Department's immediate access to the abortion clinic and adding provisions for the Department's access to the abortion clinic by appointment or with an administrative search warrant;

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- Amending provisions for training requirements for individuals performing ultrasounds;
- Deleting requirements for a patient care staff and volunteer written work schedule;
- Deleting the requirement for a patient to be treated with consideration, respect, and full recognition of the patient’s dignity and individuality;
- Amending the requirement for establishing an intravenous access on a patient undergoing an abortion after the first trimester;
- Deleting the requirement for submitting an ultrasound to a person or corporation contracted with the Department in compliance with A.R.S. § 36-2301.02;
- Amending the requirements for scheduling a follow-up visit; and
- Amending the requirements for providing patient medical records for the Department’s review.

Currently there are licensed health care institutions regulated by the Department that provide abortion services. These health care institutions are required to comply with the rules in 9 A.A.C. 10 for the health care institution’s applicable class or subclass. When the abortion clinic rules are implemented, health care institutions that provide abortion services and meet the definition of “abortion clinic” in A.R.S. § 36-449.01 will be required to meet the requirements in the abortion clinic rules when providing abortion services. If the health care institution provides medical services, nursing services, or health-related services other than abortion services, the health care institution will continue to be required to comply with the rules in 9 A.A.C. 10 that are applicable to the health care institution’s class or subclass. The only way for a facility to comply with the abortion clinic rules and any other applicable health care institution rules is to have premises for the abortion clinic that are separate from the premises for the licensed health care institution. A facility could accomplish this by providing a separate physical location for providing abortion services and maintaining medical records for abortion services patients or by only providing abortion services on a specific day or days and separating the medical records for abortion services provided to patients from the medical records for other medical services, nursing services, or health-related services provided to the same patients. If the abortion clinic rules had been implemented when the abortion clinic rules were initially adopted April 1, 2000, a facility meeting the definition of abortion clinic and already licensed as a health care institution would have had to provide separate premises for providing abortion services under an abortion clinic license and the Department would have had unlimited access to the abortion clinic and the abortion clinic’s medical records. The Department continues to have unlimited access to a health care institution where medical services, nursing services, and health-related services other than abortion services are provided under the applicable health care institution license but the amendments in this rule package limit the Department’s access to the abortion clinic and the abortion clinic’s medical records. Because of the limitations on the Department’s access imposed by the rules, the methods used to separate abortion services and abortion services medical records from other medical services, nursing services, and health-related services and the corresponding medical records must completely separate the abortion clinic premises and medical records from premises where other medical services, nursing services, and health-related services are provided and where the corresponding medical records for the other medical services, nursing services and health-related services are stored.

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:

No studies were reviewed.

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rules 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:

Annual costs/revenue changes are designated as minimal when less than \$10,000, moderate when between \$10,000 and \$50,000, substantial when greater than \$50,000, and significant when meaningful or important but not readily subject to quantification.

Description of Affected Groups	Description of Effect	Increased Cost/ Decreased Revenue	Decreased Cost/ Increased Revenue
A. State and Local Government Agencies			
Department	Limiting access to the abortion clinic and medical records by requiring an: - appointment for a licensing or compliance inspection, and - administrative search warrant for a complaint investigation	Minimal-to-moderate	None
	Removing the requirement to submit ultrasound to a person contracted by the Department	None	Substantial

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B. Privately Owned Business			
Abortion clinics (non-accredited hospitals, outpatient treatment centers (OTCs), outpatient surgical centers (OSCs), and physicians in private practice licensed as abortion clinics)	Limiting access to the abortion clinic and medical records by requiring an: - appointment for a licensing or compliance inspection, and - administrative search warrant for a complaint investigation	Minimal-to-moderate	Significant
	Removing requirement to maintain schedules of staff assigned to provide services and actually providing services	None	Minimal/significant
	Clarifying that intravenous (IV) access is not required if a physician determines that IV access is not appropriate for the patient	Minimal	Minimal
	Clarifying that an ultrasound may be maintained in a patient's medical record in either electronic or paper form	None	Minimal-to-moderate
	Removing requirement to submit ultrasound to a person contracted by the Department	None	Minimal-to-moderate
Physicians and other staff of an abortion clinic	Revising requirements to perform an ultrasound	None	Minimal
	Removing requirement to maintain schedules of staff assigned to provide services and actually providing services	None	Significant
C. Consumers			
Women seeking abortion services	Limiting access to the abortion clinic and medical records by requiring an: - appointment for a licensing or compliance inspection - administrative search warrant for a complaint investigation	Minimal	Significant
	Clarifying that intravenous (IV) access is not required if a physician determines that IV access is not appropriate for the patient	None	Minimal/significant
	Removing requirement to submit ultrasound to a person contracted by the Department	None	Significant

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Jessica Johnson, Assistant Administrative Counsel

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1740 W. Adams St., Suite 200
Phoenix, AZ 85007

Telephone: (602) 542-1513

Fax: (602) 364-1150

E-mail: johnsojm@azdhs.gov

or

Name: Kathy McCanna, Program Manager

Address: Department of Health Services
Division of Licensing Services

Office of Medical Facilities
150 N. 18th Ave.
Phoenix, AZ 85007

Telephone: (602) 364-2841
Fax: (602) 364-4764
E-mail: mccannk@azdhs.gov

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

Date: June 18, 2009
Time: 1:00 p.m.
Location: 1740 W. Adams St., Conf. room 411A
Phoenix, AZ 85007
Close of record: 5:00 p.m. June 18, 2009

A person may submit written comments on the proposed rules or the preliminary summary of the economic, small business, and consumer impact no later than 5:00 p.m. on June 18, 2009, to the individuals listed in items 4 and 9. Persons with a disability may request reasonable accommodations by contacting Valerie Grina at grinav@azdhs.gov or (602) 364-2580. Requests should be made as early as possible to allow sufficient time to arrange for the accommodation.

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

None

12. Incorporations by reference and their 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 15. ABORTION CLINICS

Section

R9-10-1501. Definitions
R9-10-1503. Administration
R9-10-1505. Personnel Qualifications
R9-10-1506. Staffing Requirements
R9-10-1507. Patient Rights
R9-10-1508. Abortion Procedures
R9-10-1511. Medical Records

ARTICLE 15. ABORTION CLINICS

R9-10-1501. Definitions

In this Article, unless the context otherwise requires:

1. No change
2. No change
3. “Admission” means documented acceptance by a hospital of an individual as an inpatient as defined in R9-10-201 on the order of a physician.
4. “Admitting privileges” means permission extended by a hospital to a physician to allow admission of a patient:
 - a. By the patient’s own physician, or
 - b. Through a written agreement between the patient’s physician and another physician that states that the other physician has permission to personally admit the patient to a hospital within 30 miles of the abortion clinic and agrees to do so.

5. “Adverse reaction” means an unexpected occurrence that threatens the health and safety of a patient.

~~4-6.~~ No change

~~5-7.~~ No change

~~6-8.~~ No change

~~7-9.~~ No change

~~8-10.~~ No change

~~9-11.~~ No change

~~10-12.~~ No change

~~11-13.~~ No change

~~12-14.~~ No change

~~13-15.~~ No change

~~14-16.~~ No change

~~15-17.~~ No change

~~16-18.~~ No change

~~17-19.~~ No change

~~18-20.~~ No change

21. “Hospital” has the same meaning as in R9-10-201.

~~19-22.~~ No change

~~20-23.~~ No change

~~21-24.~~ No change

~~22-25.~~ No change

~~23-26.~~ No change

~~24-27.~~ No change

~~25-28.~~ No change

~~26-29.~~ No change

~~27-30.~~ No change

~~28-31.~~ No change

~~29-32.~~ No change

~~30-33.~~ No change

~~31-34.~~ No change

~~32-35.~~ No change

~~33-36.~~ No change

~~34-37.~~ No change

~~35-38.~~ No change

~~36-39.~~ No change

40. “Personally identifiable patient information” means the name, address, telephone number, e-mail address, Social Security number, and birth date of the patient, the patient’s representative, the patient’s emergency contact, the patient’s children, the patient’s spouse, the patient’s sexual partner, and any other individual identified in the patient’s medical record other than patient care staff, the patient’s place of employment, the patient’s referring physician, the patient’s insurance or account, and any other information in the medical record that could reasonably lead to the identification of the patient.

~~37-41.~~ No change

~~38-42.~~ No change

~~39-43.~~ No change

~~40-44.~~ No change

~~41-45.~~ No change

~~42-46.~~ No change

~~43-47.~~ No change

~~44-48.~~ No change

~~45-49.~~ No change

R9-10-1503. Administration

A. No change

B. A licensee shall:

1. No change

2. No change

3. No change

4. Ensure that the Department’s director or director’s designee is allowed ~~immediate access to the abortion clinic during the hours of operation;~~ 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;
- 5. No change
 - a. No change
 - b. No change
 - c. No change
- C. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
 - 6. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - 7. No change
 - 8. No change
 - 9. No change

R9-10-1505. Personnel Qualifications

A licensee shall ensure that:

- 1. No change
 - a. No change
 - b. No change
- 2. No change
- 3. No change
 - a. A physician who:
 - i. ~~Has 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 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 (3)(a); or~~
 - c. An individual who ~~completed:~~
 - i. ~~A postsecondary education institution course in performing ultrasound;~~ Completed a hands-on course in performing ultrasounds under the supervision of a physician, and
 - ii. ~~The hands-on course required in subsection (3)(b)~~ Is not otherwise precluded by law from performing an ultrasound.
- 4. No change
- 5. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
- 6. No change

R9-10-1506. Staffing Requirements

- A. No change
 - 1. No change
 - 2. No change
 - 3. No change
- B. No change
 - 1. No change

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2. A physician with admitting privileges at an accredited hospital in this state ~~is in the physical facilities~~ remains on the premises of the abortion clinic until each patient is all patients are stable and ready to leave the recovery room; and
3. ~~If a physician is not present in the facility, A~~ a nurse, a nurse practitioner or a physician assistant:
 - a. No change
 - b. Remains in the ~~physical facilities~~ facility until each patient is discharged by a physician; ~~and~~
4. ~~A written schedule is maintained in the physical facilities for at least six 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~~
 - 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;~~
- ~~2-1.~~ To refuse treatment, or withdraw consent for treatment;
- ~~3-2.~~ No change
- ~~4-3.~~ No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change

R9-10-1508. Abortion Procedures

- A.** No change
 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 2. No change
 3. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
- B.** No change
 1. No change
 2. No change
 3. No change
 4. No change
 5. No change
- C.** No change
 1. No change
 2. No change
- D.** No change
 1. No change
 2. No change
 3. No change
 - a. No change
 - b. Maintained in the patient's medical record in either electronic or paper form; and
 4. No change
- E.** No change
 1. No change
 2. No change
- F.** No change
- G.** No change
 1. No change

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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; and
3. No change
 - a. No change
 - b. No change
 - c. No change

H. No change

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 recovery; and
2. A patient remains in the recovery room or recovery area until a physician, 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. ~~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. No change

1. No change
2. A follow-up visit offered and scheduled, if requested, at least three weeks no more than 21 days after the abortion, ~~which includes. The follow-up visit shall include:~~
 - 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. No change

R9-15-1511. Medical Records

A. No change

1. No change
 - a. No change
 - i. No change
 - ii. No change
 - iii. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - g. No change
 - h. No change
 - i. No change
 - j. No change
2. No change
3. No change
4. No change
- ~~5.~~ No change
 - b. ~~A medical record maintained at the abortion clinic is provided to the Department for review no later than two hours from the time the Department requests the medical record; and~~
 - e. ~~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;~~

~~5-6.~~ No change

~~6-7.~~ No change

B. A licensee shall comply with Department requests for access to or copies of patient medical records as follows:

1. 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 facility in connection with the abortion:
 - a. Name and address of patient and patient's representative;
 - b. Written acknowledgement of the receipt of patient rights;
 - c. Documentation of advance directives;
 - d. Admitting diagnosis;
 - e. Medical history and physical examination reports;

- f. Laboratory and radiology reports, if any;
 - g. Consent forms;
 - h. Physician orders and notations;
 - i. Surgeon's operative report;
 - j. Anesthesia report;
 - k. Nursing care notations;
 - l. Medications and treatments administered; and
 - m. Written acknowledgement of receipt of discharge instructions by the patient or patient's representative.
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, including any follow-up visits to the facility in connection with an abortion, that occurred before the effective date of these rules or before a previous licensing or compliance inspection of the licensee by the Department.
 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 (B)(6).
 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 10 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. The Department shall have access to or copies of unredacted patient medical records only pursuant 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 electronic file with access to the secured drawer, cabinet, or file limited to those individuals who have access to the patient medical records pursuant to (B)(9)(a);
 - c. Destroy all unredacted patient medical records at the termination of the Department's investigation or at the termination of any administrative or legal action that is taken by the Department as the result of the Department's investigation, whichever is later;
 - d. File the unredacted patient medical records with a court or other judicial body, including any administrative law judge or panel, 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).

~~B.C.~~ No change

1. No change
2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
3. No change
4. No change
5. No change
 - a. No change
 - b. No change
 - c. No change
6. No change

~~C.D.~~ No change