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SUPERIOR COURT OF ARIZONA

MARICOPA COUNTY

Planned Parenthood Arizona, Inc.; William Richardson, M.D.; and William H. Richardson, M.D., P.C., doing business as Tucson Women's Center, Plaintiffs, vs. Will Humble, Director of the Arizona Department of Health Services, in his official capacity, Defendants.	Case No. CV2014-006633 **PLAINTIFFS' SEPARATE STATEMENT OF FACTS IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT** (Assigned to the Hon. J. Richard Gama) **(Oral Argument Requested)**

Plaintiffs Planned Parenthood Arizona, Inc. ("PPAZ"), William Richardson, M.D., and William Richardson, M.D., P.C., submit the following Separate Statement of Facts in support of their motion for summary judgment.

1. Plaintiffs are Arizona health care providers who for more than a decade have offered their patients the option of an early, safe abortion using medications alone.

See Ariz. Dep't of Health Servs., Div. of Licensing Servs., *available at* hsapps.azdhs.gov/ls/sod/SearchProv.aspx?type=MED (last visited May 12, 2014) choose "abortion clinic" from the drop-down menu) (listing five Planned Parenthood health centers and Tucson Women's Center as licensed abortion clinics).

2. Arizona has enacted an abortion restriction that either entirely eliminates or drastically restricts access to this option, the only non-surgical alternative available. *See* A.R.S. § 36-449.03 (effective April 12, 2012).

3. The regulation took effect April 1, 2014, but has been preliminarily blocked since April 2, 2014 by the U.S. Court of Appeals for the Ninth Circuit, in a suit brought under the Fourteenth Amendment to the United States Constitution. *See Planned Parenthood Ariz. v. Humble*, D.C. No. 4:14-cv-01910-DCB, ECF Nos. 5 & 15 (9th Cir. Apr. 2, 2014) (copies of orders granting and extending stay attached hereto as Exhibits 1 and 2 respectively).

4. Plaintiffs filed the present suit on April 7, 2014, and personally served Defendant on April 15, 2014. *See* Compl., filed 04/07/14; Cert. of Serv., filed 04/22/14.

5. Defendant moved for an indefinite stay; Plaintiffs' opposition to that motion is also being filed today. *See* Def.'s Mot. to Stay or, In the Alternative, Mot. to Extend Time to File Ans. or Responsive Mot., filed May 1, 2014.

6. On April 10, 2012, the Arizona Legislature passed House Bill 2036 ("HB 2036") (copy attached hereto as Exhibit 3) and on April 12, 2012, Governor Brewer signed it into law. *See* 2012 Ariz. Legis. Serv. Ch. 250 (HB 2036) (effective Apr. 12, 2012).

7. HB 2036 mandates that the Director of the Arizona Department of Health Services ("ADHS") adopt a number of rules regarding abortion. *See id* § 2, codified at A.R.S. § 36–449.03(A).

8. In particular, HB 2036 directs ADHS to promulgate regulations requiring "[t]hat any medication, drug or other substance used to induce an abortion is administered in compliance with the protocol that is authorized by the United States Food and Drug Administration [("FDA")] and that is outlined in the final printing labeling instructions [("FPL")] for that medication, drug or substance." *See id.*, codified at A.R.S. § 36-449.03(E)(6).

9. Section 10 of HB 2036 states, "[f]or the purposes of this act, the department of health services is exempt from the rule making requirements of title 41, chapter 6, Arizona Revised Statutes, for two years after the effective date of this act." *See id.* § 10.

10. ADHS did not begin its rulemaking process under the Statute until late 2013. *See* 19 A.A.R. 3944 (Notice of Exempt Rulemaking) (copy attached hereto as Exhibit 4), *available at* http://www.azsos.gov/aar/2014/8/exempt.pdf (last visited May 13, 2014).

11. ADHS maintains a website entitled "Office of Administrative Counsel & Rules: Rulemaking Process" that establishes an "Exempt Rulemaking Process" for rules that are "exempt from the rulemaking requirements in A.R.S § [sic] Title 41, Chapter 6 . . . if authorized by a specific statute or bill." *See* Ariz. Dep't of Health Servs., Office of Admin. Counsel & Rules, Rulemaking Process, Exempt Rulemaking, *available at* www.azdhs.gov/ops/oacr/rules/rulemakings/ process.htm (under "Exempt Rulemaking" tab) (last visited May 13, 2014).

12. In late 2013 and early 2014, when ADHS was developing the Regulation, the "Exempt Rulemaking" policy on the ADHS website required ADHS to provide the public and affected persons substantial opportunity for input into exempt rulemaking. *See* Decl. of Tiseme Zegeye ("Zegeye Decl.") (copy attached hereto as Exhibit 5) ¶¶ 2-3 & Ex. A.

13. The policy required ADHS to draft a proposed rule, post it for comment, meet with affected and interested persons, revise the draft based on comments received, post the revised draft, revise it again for comments received, file a Notice of Public Information with the Secretary of State posting the revised draft, take further comments, further revise the draft based on those comments, and finally file a Notice of Exempt Rulemaking. *See id.*

14. The process required ADHS, after initially proposing the rules, to receive comments and make revisions *three times*, including (during the first iteration) by *meeting* with affected and interested persons. *See id*.

15. On November 21, 2013, more than a year and a half after HB 2036 was signed into law, ADHS posted "Draft Rules Issued for Abortion Clinics" online. *See* Draft R9-10-1501 through R9-10-1515 (copy attached hereto as Exhibit 6) *available at* www.azdhs.gov/ops/oacr/rules/documents/rulemaking/abortion/draft-rules-abortion-clinics-nov13.pdf (last visited May 13, 2014).

16. Eight days later, the Secretary of State published a Notice of Public Information in the Arizona Administrative Register. *See* 19 A.A.R. 3944 (Ex. 4, cited in paragraph 10).

17. ADHS did not open an Online Survey for comments until December 19, 2013.

18. On January 27, 2014, ADHS promulgated all of HB 2036's implementing regulations, including the Regulation, with an effective date of April 1, 2014. *See* Notice of Exempt Rulemaking originally posted on ADHS website as filed with Secretary of State but before publication in AAR (copy attached hereto as Exhibit 7).

19. The Regulation repeats the language of the Statute essentially verbatim; it requires the medical director of a facility licensed as an abortion clinic to "ensure that any

medication, drug or other substance used to induce an abortion is administered in compliance with the protocol that is authorized by the United States Food and Drug Administration and that is outlined in the final printing labeling instructions for that medication, drug or substance." A.A.C. R9-10-1508(G).

20. Any clinic that fails to comply with the Regulation is subject to a civil penalty, license suspension or revocation, or other enforcement actions by ADHS. A.A.C. R9-10-1515.

21. On April 17, 2014, after Plaintiffs filed this case, ADHS removed the policy discussed above from its website and replaced it with a new one. *See* http://www.azdhs.gov/ops/oacr/rules/rulemakings/process.htm (revised rule stating that ADHS "*may* meet with interested persons" (emphasis added), as compared to the prior version that mandated this).

22. Under the new policy, opportunities for public comment, meetings with stakeholders, and making revisions are optional, rather than mandatory – each is described as a step which ADHS "may" take. *See* Ariz. Dep't of Health Servs., Office of Admin. Counsel & Rules, Rulemaking Process, *available at* http://www.azdhs.gov/ops/oacr/rules/rulemakings/process.htm (last visited May 13, 2014). This change of policy was itself not provided in draft form for public notice and comment, nor discussed with affected persons, nor, indeed, publicized in any way.

23. The FDA is the federal agency charged with approving drugs for sale and marketing in the United States. *See* 21 U.S.C. § 355(a).

24. The FDA is not authorized to, and does not, regulate how physicians use and prescribe medication once it has been approved for sale. *See* 21 U.S.C. § 396.

25. A manufacturer seeking approval to market a drug submits a New Drug Application ("NDA") to the FDA, including data demonstrating that the drug is safe and

effective for its proposed use(s), and that its benefits outweigh its risks. *See* 21 U.S.C. § 355(b); Decl. of Lisa Rarick ("Rarick Decl.") (copy attached hereto as Exhibit 8) ¶ 4.

26. As part of the NDA, the manufacturer includes a proposed drug label, containing information such as the drug's indications, dosage, and route of administration. *See* Rarick Decl. ¶ 5; 21 CFR 201.56(d)(1).

27. The FDA may propose changes. *See* Rarick Decl. ¶ 5.

28. Once the NDA is approved, often after some back-and-forth between the manufacturer and the FDA, the label becomes known the drug's FPL. *See id.*

29. Although the FDA must review and approve the FPL, the responsibility for its text lies entirely with the manufacturer, which is solely responsible for creating its content. *See* Rarick Decl. at ¶ 6. In other words, the FPL is a drug company document—it does not constitute a federal law and does not impose binding obligations on physicians. *See id.*

30. After a drug has been approved by the FDA, physicians may prescribe it for purposes and in doses other than those set forth in the FPL, which is known as "off-label" or "evidence-based" use. *See* Rarick Decl. ¶ 8.

31. Evidence-based use is neither prohibited nor discouraged by the FDA. *See id*. ¶ 9.

32. The FDA has repeatedly acknowledged that evidence-based use is common and sometimes is required by good medical practice. *See United States v. Caronia*, 703 F.3d 149, 152-53 (2d Cir. 2012) (reviewing case law and the FDA's repeated recognition that evidence-based use has important benefits and sometimes constitutes the standard of care); Rarick Decl. ¶ 9.

33. The FDA is prohibited from limiting a physician's best judgment regarding the use of the drugs it has approved. *See* 21 U.S.C. § 396; *Buckman Co. v. Pls.' Legal*

Comm., 531 U.S. 341, 350 (2001) ("[T]he FDA is charged with the difficult task of regulating . . . marketing and distribution . . . without intruding upon decisions statutorily committed to the discretion of health care professionals."); *Caronia*, 703 F.3d at 153 (noting that "the FDA generally does not regulate how physicians use approved drugs"); Rarick Decl. ¶¶ 9-11.

34. Any changes to a drug's FPL to reflect new uses or protocols are also proposed and drafted by the drug's manufacturer. *See* Rarick Decl. ¶ 7. Because these changes must be supported by further clinical study data, they are often purely commercial decisions, based on whether the cost of undertaking the studies is justified by the expected return from the new marketing opportunities. *See id*.; FDA, *Guidance for Industry Changes to an Approved NDA or ANDA* at pp. 24-25, § X(B) (citing 21 CFR 314.70 (b)(2)(v)(A)), *available at* www.fda.gov/downloads/Drugs/GuidanceCompliance Regulatory Information/Guidances/ucm077097.pdf (last visited May 13, 2014).

RESPECTFULLY SUBMITTED this 15th day of May, 2014.

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Exhibit 1

FILED

APR 02 2014

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

PLANNED PARENTHOOD OF ARIZONA, INC.; et al., Plaintiffs - Appellants, v. WILLIAM HUMBLE, Director of the Arizona Department of Health Services, in his official capacity, Defendant - Appellee.	No. 14-15624 D.C. No. 4:14-cv-01910-DCB District of Arizona, Tucson ORDER

Before: GOODWIN, CANBY, and McKEOWN, Circuit Judges.

The court has received appellants' emergency motion for a preliminary injunction seeking to enjoin the operation of Arizona Revised Statute § 36-449.03(E)(6) and implementing regulation A.A.C. R9-10-1508(G). Appellants' motion to file an oversized brief is granted.

The enforcement of the Arizona statute and regulation is enjoined temporarily in order to provide the court with an opportunity to receive and consider full briefing on appellants' emergency motion.

SLL/MOATT

The following briefing schedule shall govern this emergency motion. Appellee's opposition is due Friday, April 4, 2014, at noon. Appellants' optional reply is due Monday, April 7, 2014, at 9:00 a.m.

Exhibit 2

FILED

APR 08 2014

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

PLANNED PARENTHOOD OF ARIZONA, INC.; et al., Plaintiffs - Appellants, v. WILLIAM HUMBLE, Director of the Arizona Department of Health Services, in his official capacity, Defendant - Appellee.	No. 14-15624 D.C. No. 4:14-cv-01910-DCB District of Arizona, Tucson ORDER

Before: GOODWIN, CANBY, and McKEOWN, Circuit Judges.

Appellee's motion to file an over-length opposition to the emergency motion for an injunction pending appeal is granted. The opposition was filed on April 4, 2014. Appellants' motion to file an over-length reply in support of the emergency motion is granted. The reply was filed on April 7, 2014.

Given the similarity of the issues already briefed for this motion and the issues on appeal, as well as the public interests at stake, the court sua sponte expedites the appeal.

SLL/MOATT

The court has considered the emergency motion for an injunction pending appeal of the district court's March 31, 2014 order denying a preliminary injunction, and the opposition and reply thereto.

Upon our initial review, we conclude that this appeal, which presents an issue of first impression in this circuit regarding regulation of medication abortions, raises serious legal questions regarding the proper application of the "undue burden" standard to abortion regulations purporting to promote maternal health. *See Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 877-78 (1992); *Tucson Woman's Clinic v. Eden*, 379 F.3d 531, 540 (9th Cir. 2004). We also conclude that the balance of the hardships tips sharply in favor of the appellants, whose patients will likely suffer irreparable harm absent an injunction pending appeal because they will immediately lose access to a common abortion procedure as soon as the law takes effect. In light of these factors, as well as consideration of the public interest, appellants' emergency motion for an injunction pending appeal is granted. *See Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *Alliance for Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011). Enforcement of A.R.S. § 36-449.03(E)(6) and A.A.C. R9-10-1508(G) is temporarily enjoined to allow the court time to conduct a full review of the merits of the appeal and the propriety of a continued injunction.

The expedited briefing schedule shall proceed as follows: appellants' opening brief is due April 18, 2014; appellee's answering brief is due April 28, 2014; and appellants' optional reply brief is due May 2, 2014.

The Clerk shall calendar this case before a regularly scheduled merits panel for oral argument during the week of May 12, 2014, in San Francisco, California.

Exhibit 3

State of Arizona
House of Representatives
Fiftieth Legislature
Second Regular Session
2012

CHAPTER 250

HOUSE BILL 2036

AN ACT

AMENDING SECTIONS 36-449.01, 36-449.03, 36-2151, 36-2152, 36-2153 AND 36-2156, ARIZONA REVISED STATUTES; AMENDING TITLE 36, CHAPTER 20, ARTICLE 1, ARIZONA REVISED STATUTES, BY ADDING SECTIONS 36-2158 AND 36-2159; AMENDING SECTION 36-2163, ARIZONA REVISED STATUTES; RELATING TO ABORTION.

(TEXT OF BILL BEGINS ON NEXT PAGE)

Be it enacted by the Legislature of the State of Arizona:

Section 1. Section 36-449.01, Arizona Revised Statutes, is amended to read:

36-449.01. Definitions

In this article, unless the context otherwise requires:

1. "Abortion" means the use of any means with the intent to terminate a woman's pregnancy for reasons other than to increase the probability of a live birth, to preserve the life or health of the child after a live birth, to terminate an ectopic pregnancy or to remove a dead fetus. Abortion does not include birth control devices or oral contraceptives.

2. "Abortion clinic" means a facility, other than a hospital, in which five or more first trimester abortions in any month or any second or third trimester abortions are performed.

3. "Director" means the director of the department of health services.

4. "MEDICATION ABORTION" MEANS THE USE OF ANY MEDICATION, DRUG OR OTHER SUBSTANCE THAT IS INTENDED TO CAUSE OR INDUCE AN ABORTION.

~~4.~~ 5. "Perform" includes the initial administration of any medication, drug or other substance intended to cause or induce an abortion.

6. "SURGICAL ABORTION" HAS THE SAME MEANING PRESCRIBED IN SECTION 36-2151.

~~5.~~ 7. "Viable fetus" has the same meaning prescribed in section 36-2301.01.

Sec. 2. Section 36-449.03, Arizona Revised Statutes, is amended to read:

36-449.03. Abortion clinics; rules; civil penalties

A. The director shall adopt rules for an abortion clinic's physical facilities. At a minimum these rules shall prescribe standards for:

1. Adequate private space that is specifically designated for interviewing, counseling and medical evaluations.

2. Dressing rooms for staff and patients.

3. Appropriate lavatory areas.

4. Areas for preprocedure hand washing.

5. Private procedure rooms.

6. Adequate lighting and ventilation for abortion procedures.

7. Surgical or gynecologic examination tables and other fixed equipment.

8. Postprocedure recovery rooms that are supervised, staffed and equipped to meet the patients' needs.

9. Emergency exits to accommodate a stretcher or gurney.

10. Areas for cleaning and sterilizing instruments.

11. Adequate areas for the secure storage of medical records and necessary equipment and supplies.

12. The display in the abortion clinic, in a place that is conspicuous to all patients, of the clinic's current license issued by the department.

B. The director shall adopt rules to prescribe abortion clinic supplies and equipment standards, including supplies and equipment that are

required to be immediately available for use or in an emergency. At a minimum these rules shall:

1. Prescribe required equipment and supplies, including medications, required for the conduct, in an appropriate fashion, of any abortion procedure that the medical staff of the clinic anticipates performing and for monitoring the progress of each patient throughout the procedure and recovery period.

2. Require that the number or amount of equipment and supplies at the clinic is adequate at all times to assure sufficient quantities of clean and sterilized durable equipment and supplies to meet the needs of each patient.

3. Prescribe required equipment, supplies and medications that shall be available and ready for immediate use in an emergency and requirements for written protocols and procedures to be followed by staff in an emergency, such as the loss of electrical power.

4. Prescribe required equipment and supplies for required laboratory tests and requirements for protocols to calibrate and maintain laboratory equipment at the abortion clinic or operated by clinic staff.

5. Require ultrasound equipment ~~in those facilities that provide abortions after twelve weeks' gestation~~.

6. Require that all equipment is safe for the patient and the staff, meets applicable federal standards and is checked annually to ensure safety and appropriate calibration.

C. The director shall adopt rules relating to abortion clinic personnel. At a minimum these rules shall require that:

1. The abortion clinic designate a medical director of the abortion clinic who is licensed pursuant to title 32, chapter 13, 17 or 29.

2. Physicians performing ~~surgery~~ ABORTIONS are licensed pursuant to title 32, chapter 13 or 17, demonstrate competence in the procedure involved and are acceptable to the medical director of the abortion clinic.

3. A physician ~~with admitting privileges at an accredited hospital in this state~~ is available: ~~.~~

(a) FOR A SURGICAL ABORTION WHO HAS ADMITTING PRIVILEGES AT A HEALTH CARE INSTITUTION THAT IS CLASSIFIED BY THE DIRECTOR AS A HOSPITAL PURSUANT TO SECTION 36-405, SUBSECTION B AND THAT IS WITHIN THIRTY MILES OF THE ABORTION CLINIC.

(b) FOR A MEDICATION ABORTION WHO HAS ADMITTING PRIVILEGES AT A HEALTH CARE INSTITUTION THAT IS CLASSIFIED BY THE DIRECTOR AS A HOSPITAL PURSUANT TO SECTION 36-405, SUBSECTION B.

4. If a physician is not present, a registered nurse, nurse practitioner, licensed practical nurse or ~~physician's~~ PHYSICIAN assistant is present and remains at the clinic when abortions are performed to provide postoperative monitoring and care, OR MONITORING AND CARE AFTER INDUCING A MEDICATION ABORTION, until each patient who had an abortion that day is discharged.

5. Surgical assistants receive training in counseling, patient advocacy and the specific responsibilities of the services the surgical assistants provide.

6. Volunteers receive training in the specific responsibilities of the services the volunteers provide, including counseling and patient advocacy as provided in the rules adopted by the director for different types of volunteers based on their responsibilities.

D. The director shall adopt rules relating to the medical screening and evaluation of each abortion clinic patient. At a minimum these rules shall require:

1. A medical history, including the following:

(a) Reported allergies to medications, antiseptic solutions or latex.

(b) Obstetric and gynecologic history.

(c) Past surgeries.

2. A physical examination, including a bimanual examination estimating uterine size and palpation of the adnexa.

3. The appropriate laboratory tests, including:

(a) ~~For an abortion in which an ultrasound examination is not performed before the abortion procedure,~~ Urine or blood tests for pregnancy performed before the abortion procedure.

(b) A test for anemia.

(c) Rh typing, unless reliable written documentation of blood type is available.

(d) Other tests as indicated from the physical examination.

4. An ultrasound evaluation for all patients ~~who elect to have an abortion after twelve weeks' gestation~~. The rules shall require that if a person who is not a physician performs an ultrasound examination, that person shall have documented evidence that the person completed a course in the operation of ultrasound equipment as prescribed in rule. The physician or other health care professional shall review, at the request of the patient, the ultrasound evaluation results with the patient before the abortion procedure is performed, including the probable gestational age of the fetus.

5. That the physician is responsible for estimating the gestational age of the fetus based on the ultrasound examination and obstetric standards in keeping with established standards of care regarding the estimation of fetal age as defined in rule and shall write the estimate in the patient's medical history. The physician shall keep original prints of each ultrasound examination of a patient in the patient's medical history file.

E. The director shall adopt rules relating to the abortion procedure. At a minimum these rules shall require:

1. That medical personnel is available to all patients throughout the abortion procedure.

2. Standards for the safe conduct of abortion procedures that conform to obstetric standards in keeping with established standards of care regarding the estimation of fetal age as defined in rule.

3. Appropriate use of local anesthesia, analgesia and sedation if ordered by the physician.

4. The use of appropriate precautions, such as the establishment of intravenous access at least for patients undergoing second or third trimester abortions.

5. The use of appropriate monitoring of the vital signs and other defined signs and markers of the patient's status throughout the abortion procedure and during the recovery period until the patient's condition is deemed to be stable in the recovery room.

6. THAT ANY MEDICATION, DRUG OR OTHER SUBSTANCE USED TO INDUCE AN ABORTION IS ADMINISTERED IN COMPLIANCE WITH THE PROTOCOL THAT IS AUTHORIZED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION AND THAT IS OUTLINED IN THE FINAL PRINTING LABELING INSTRUCTIONS FOR THAT MEDICATION, DRUG OR SUBSTANCE.

F. The director shall adopt rules that prescribe minimum recovery room standards. At a minimum these rules shall require that:

1. FOR A SURGICAL ABORTION, immediate postprocedure care, OR CARE PROVIDED AFTER INDUCING A MEDICATION ABORTION, consists of observation in a supervised recovery room for as long as the patient's condition warrants.

2. The clinic arrange hospitalization if any complication beyond the management capability of the staff occurs or is suspected.

3. A licensed health professional who is trained in the management of the recovery area and is capable of providing basic cardiopulmonary resuscitation and related emergency procedures remains on the premises of the abortion clinic until all patients are discharged.

4. FOR A SURGICAL ABORTION, a physician with admitting privileges at ~~an accredited hospital in this state~~ A HEALTH CARE INSTITUTION THAT IS CLASSIFIED BY THE DIRECTOR AS A HOSPITAL PURSUANT TO SECTION 36-405, SUBSECTION B AND THAT IS WITHIN THIRTY MILES OF THE ABORTION CLINIC remains on the premises of the abortion clinic until all patients are stable and are ready to leave the recovery room and to facilitate the transfer of emergency cases if hospitalization of the patient or viable fetus is necessary. A physician shall sign the discharge order and be readily accessible and available until the last patient is discharged.

5. A physician discusses RhO(d) immune globulin with each patient for whom it is indicated and assures it is offered to the patient in the immediate postoperative period or that it will be available to her within seventy-two hours after completion of the abortion procedure. If the patient refuses, a refusal form approved by the department shall be signed by the patient and a witness and included in the medical record.

6. Written instructions with regard to postabortion coitus, signs of possible problems and general aftercare are given to each patient. Each patient shall have specific instructions regarding access to medical care for complications, including a telephone number to call for medical emergencies.

7. There is a specified minimum length of time that a patient remains in the recovery room by type of abortion procedure and duration of gestation.

8. The physician assures that a licensed health professional from the abortion clinic makes a good faith effort to contact the patient by telephone, with the patient's consent, within twenty-four hours after ~~surgery~~ A SURGICAL ABORTION to assess the patient's recovery.

9. Equipment and services are located in the recovery room to provide appropriate emergency resuscitative and life support procedures pending the transfer of the patient or viable fetus to the hospital.

G. The director shall adopt rules that prescribe standards for follow-up visits. At a minimum these rules shall require that:

1. FOR A SURGICAL ABORTION, a postabortion medical visit is offered and, if requested, scheduled for three weeks after the abortion, including a medical examination and a review of the results of all laboratory tests. FOR A MEDICATION ABORTION, THE RULES SHALL REQUIRE THAT A POSTABORTION MEDICAL VISIT IS SCHEDULED BETWEEN ONE WEEK AND THREE WEEKS AFTER THE INITIAL DOSE OF A MEDICATION ABORTION TO CONFIRM THE PREGNANCY IS COMPLETELY TERMINATED AND TO ASSESS THE DEGREE OF BLEEDING.

2. A urine pregnancy test is obtained at the time of the follow-up visit to rule out continuing pregnancy. If a continuing pregnancy is suspected, the patient shall be evaluated and a physician who performs abortions shall be consulted.

H. The director shall adopt rules to prescribe minimum abortion clinic incident reporting. At a minimum these rules shall require that:

1. The abortion clinic records each incident resulting in a patient's or viable fetus' serious injury occurring at an abortion clinic and shall report them in writing to the department within ten days after the incident. For the purposes of this paragraph, "serious injury" means an injury that occurs at an abortion clinic and that creates a serious risk of substantial impairment of a major body organ AND INCLUDES ANY INJURY OR CONDITION THAT REQUIRES AMBULANCE TRANSPORTATION OF THE PATIENT.

2. If a patient's death occurs, other than a fetal death properly reported pursuant to law, the abortion clinic reports it to the department not later than the next department work day.

3. Incident reports are filed with the department and appropriate professional regulatory boards.

I. THE DIRECTOR SHALL ADOPT RULES RELATING TO ENFORCEMENT OF THIS ARTICLE. AT A MINIMUM, THESE RULES SHALL REQUIRE THAT:

1. FOR AN ABORTION CLINIC THAT IS NOT IN SUBSTANTIAL COMPLIANCE WITH THIS ARTICLE AND THE RULES ADOPTED PURSUANT TO THIS ARTICLE OR THAT IS IN SUBSTANTIAL COMPLIANCE BUT REFUSES TO CARRY OUT A PLAN OF CORRECTION ACCEPTABLE TO THE DEPARTMENT OF ANY DEFICIENCIES THAT ARE LISTED ON THE DEPARTMENT'S STATE OF DEFICIENCY, THE DEPARTMENT MAY DO ANY OF THE FOLLOWING:

(a) ASSESS A CIVIL PENALTY PURSUANT TO SECTION 36-431.01.

(b) IMPOSE AN INTERMEDIATE SANCTION PURSUANT TO SECTION 36-427.

(c) SUSPEND OR REVOKE A LICENSE PURSUANT TO SECTION 36-427.

(d) DENY A LICENSE.

(e) BRING AN ACTION FOR AN INJUNCTION PURSUANT TO SECTION 36-430.

2. IN DETERMINING THE APPROPRIATE ENFORCEMENT ACTION, THE DEPARTMENT CONSIDERS THE THREAT OF THE HEALTH, SAFETY AND WELFARE OF THE ABORTION CLINIC'S PATIENTS OR THE GENERAL PUBLIC, INCLUDING:

(a) WHETHER THE ABORTION CLINIC HAS REPEATED VIOLATIONS OF STATUTES OR RULES.

(b) WHETHER THE ABORTION CLINIC HAS ENGAGED IN A PATTERN OF NONCOMPLIANCE.

(c) THE TYPE, SEVERITY AND NUMBER OF VIOLATIONS.

~~I.~~ J. The department shall not release personally identifiable patient or physician information.

~~J.~~ K. The rules adopted by the director pursuant to this section do not limit the ability of a physician or other health professional to advise a patient on any health issue.

Sec. 3. Section 36-2151, Arizona Revised Statutes, is amended to read:

36-2151. Definitions

In this article, unless the context otherwise requires:

1. "Abortion" means the use of any means to terminate the clinically diagnosable pregnancy of a woman with knowledge that the termination by those means will cause, with reasonable likelihood, the death of the unborn child. Abortion does not include birth control devices, oral contraceptives used to inhibit or prevent ovulation, conception or the implantation of a fertilized ovum in the uterus or the use of any means to ~~increase the probability of a live birth~~ SAVE THE LIFE OR PRESERVE THE HEALTH OF THE UNBORN CHILD, to preserve the life or health of the child after a live birth, to terminate an ectopic pregnancy or to remove a dead fetus.

2. "Auscultation" means the act of listening for sounds made by internal organs of the unborn child, specifically for a heartbeat, using an ultrasound transducer and fetal heart rate monitor.

3. "Conception" means the fusion of a human spermatozoon with a human ovum.

4. "Gestational age" means the age of the unborn child as calculated from the first day of the last menstrual period of the pregnant woman.

5. "Health professional" has the same meaning prescribed in section 32-3201.

6. "Medical emergency" means a condition that, on the basis of the physician's good faith clinical judgment, so complicates the medical condition of a pregnant woman as to necessitate the immediate abortion of her pregnancy to avert her death or for which a delay will create serious risk of substantial and irreversible impairment of a major bodily function.

7. "MEDICATION ABORTION" MEANS THE USE OF ANY MEDICATION, DRUG OR OTHER SUBSTANCE THAT IS INTENDED TO CAUSE OR INDUCE AN ABORTION.

~~7.~~ 8. "Physician" means a person who is licensed pursuant to title 32, chapter 13 or 17.

~~8.~~ 9. "Pregnant" or "pregnancy" means a female reproductive condition of having a developing unborn child in the body and that begins with conception.

~~9.~~ 10. "Probable gestational age" means the gestational age of the unborn child at the time the abortion is planned to be performed and as determined with reasonable probability by the attending physician.

~~10.~~ 11. "Surgical abortion" means the use of a surgical instrument or a machine to terminate the clinically diagnosable pregnancy of a woman with knowledge that the termination by those means will cause, with reasonable likelihood, the death of the unborn child. Surgical abortion does not include the use of any means to increase the probability of a live birth, to preserve the life or health of the child after a live birth, to terminate an ectopic pregnancy or to remove a dead fetus. Surgical abortion does not include patient care incidental to the procedure.

~~11.~~ 12. "Ultrasound" means the use of ultrasonic waves for diagnostic or therapeutic purposes to monitor a developing unborn child.

~~12.~~ 13. "Unborn child" means the offspring of human beings from conception until birth.

Sec. 4. Section 36-2152, Arizona Revised Statutes, is amended to read:

36-2152. Parental consent; exception; hearings; time limits; violation; classification; civil relief; statute of limitations

A. In addition to the OTHER requirements of ~~section 36-2153~~ THIS CHAPTER, a person shall not knowingly perform an abortion on a pregnant unemancipated minor unless the attending physician has secured the written and notarized consent from one of the minor's parents or the minor's guardian or conservator or unless a judge of the superior court authorizes the physician to perform the abortion pursuant to subsection B of this section. Notwithstanding section 41-319, the notarized statement of parental consent and the description of the document or notarial act recorded in the notary journal are confidential and are not public records.

B. A judge of the superior court, on petition or motion, and after an appropriate hearing, shall authorize a physician to perform the abortion if the judge determines that the pregnant minor is mature and capable of giving informed consent to the proposed abortion. If the judge determines that the pregnant minor is not mature or if the pregnant minor does not claim to be mature, the judge shall determine whether the performance of an abortion on her without the consent from one of her parents or her guardian or conservator would be in her best interests and shall authorize a physician to perform the abortion without consent if the judge concludes that the pregnant minor's best interests would be served.

C. If the pregnant minor claims to be mature at a proceeding held pursuant to subsection B of this section, the minor must prove by clear and convincing evidence that she is sufficiently mature and capable of giving informed consent without consulting her parent or legal guardian based on her experience level, perspective and judgment. In assessing the pregnant minor's experience level, the court may consider, among other relevant factors, the minor's age and experiences working outside the home, living away from home, traveling on her own, handling personal finances and making

other significant decisions. In assessing the pregnant minor's perspective, the court may consider, among other relevant factors, what steps the minor took to explore her options and the extent to which she considered and weighed the potential consequences of each option. In assessing the pregnant minor's judgment, the court may consider, among other relevant factors, the minor's conduct since learning of her pregnancy and her intellectual ability to understand her options and to make an informed decision.

D. The pregnant minor may participate in the court proceedings on her own behalf. The court shall appoint a guardian ad litem for her. The court shall advise her that she has the right to court appointed counsel and, on her request, shall provide her with counsel unless she appears through private counsel or she knowingly and intelligently waives her right to counsel.

E. Proceedings in the court under this section are confidential and have precedence over other pending matters. Members of the public shall not inspect, obtain copies of or otherwise have access to records of court proceedings under this section unless authorized by law. A judge who conducts proceedings under this section shall make in writing specific factual findings and legal conclusions supporting the decision and shall order a confidential record of the evidence to be maintained, including the judge's own findings and conclusions. The minor may file the petition using a fictitious name. For purposes of this subsection, public does not include judges, clerks, administrators, professionals or other persons employed by or working under the supervision of the court or employees of other public agencies who are authorized by state or federal rule or law to inspect and copy closed court records.

F. The court shall hold the hearing and shall issue a ruling within forty-eight hours, excluding weekends and holidays, after the petition is filed. If the court fails to issue a ruling within this time period, the petition is deemed to have been granted and the consent requirement is waived.

G. An expedited confidential appeal is available to a pregnant minor for whom the court denies an order authorizing an abortion without parental consent. The appellate court shall hold the hearing and issue a ruling within forty-eight hours, excluding weekends and holidays, after the petition for appellate review is filed. Filing fees are not required of the pregnant minor at either the trial or the appellate level.

H. Parental consent or judicial authorization is not required under this section if either:

1. The pregnant minor certifies to the attending physician that the pregnancy resulted from sexual conduct with a minor by the minor's parent, stepparent, uncle, grandparent, sibling, adoptive parent, legal guardian or foster parent or by a person who lives in the same household with the minor and the minor's mother. The physician performing the abortion shall report the sexual conduct with a minor to the proper law enforcement officials

pursuant to section 13-3620 and shall preserve and forward a sample of the fetal tissue to these officials for use in a criminal investigation.

2. The attending physician certifies in the pregnant minor's medical record that, on the basis of the physician's good faith clinical judgment, the pregnant minor has a condition that so complicates her medical condition as to necessitate the immediate abortion of her pregnancy to avert her death or for which a delay will create serious risk of substantial and irreversible impairment of major bodily function.

I. A person who performs an abortion in violation of this section is guilty of a class 1 misdemeanor. A person is not subject to any liability under this section if the person establishes by written evidence that the person relied on evidence sufficient to convince a careful and prudent person that the representations of the pregnant minor regarding information necessary to comply with this section are true.

J. In addition to other remedies available under the common or statutory law of this state, one or both of the minor's parents or the minor's guardian may bring a civil action in the superior court in the county in which the parents or the guardian resides to obtain appropriate relief for a violation of this section, unless the pregnancy resulted from the criminal conduct of the parent or guardian. The civil action may be based on a claim that failure to obtain consent was a result of simple negligence, gross negligence, wantonness, wilfulness, intention or any other legal standard of care. THE CIVIL ACTION MAY BE BROUGHT AGAINST THE PERSON WHO PERFORMS THE ABORTION IN VIOLATION OF THIS SECTION AND ANY PERSON WHO CAUSES, AIDS OR ASSISTS A MINOR TO OBTAIN AN ABORTION WITHOUT MEETING THE REQUIREMENTS OF THIS SECTION. Relief pursuant to this subsection includes the following:

1. Money damages for all psychological, emotional and physical injuries that result from the violation of this section.

2. Statutory damages in an amount equal to five thousand dollars or three times the cost of the abortion, whichever is greater.

3. Reasonable attorney fees and costs.

K. A civil action brought pursuant to this section must be initiated within six years after the violation occurred.

L. THE CONSENT REQUIRED BY THIS SECTION MUST BE OBTAINED ON A FORM PRESCRIBED BY THE DEPARTMENT OF HEALTH SERVICES. AT A MINIMUM, THE FORM MUST:

1. LIST THE POSSIBLE MEDICAL RISKS THAT MAY OCCUR WITH ANY SURGICAL, MEDICAL OR DIAGNOSTIC PROCEDURE, INCLUDING THE POTENTIAL FOR INFECTION, BLOOD CLOTS, HEMORRHAGE, ALLERGIC REACTIONS AND DEATH.

2. LIST THE POSSIBLE MEDICAL RISKS THAT MAY OCCUR WITH A SURGICAL ABORTION, INCLUDING HEMORRHAGE, UTERINE PERFORATION, STERILITY, INJURY TO THE BOWEL OR BLADDER, A POSSIBLE HYSTERECTOMY AS A RESULT OF A COMPLICATION OR INJURY DURING THE PROCEDURE AND FAILURE TO REMOVE ALL PRODUCTS OF CONCEPTION THAT MAY RESULT IN AN ADDITIONAL PROCEDURE.

3. LIST THE POSSIBLE MEDICAL RISKS THAT MAY OCCUR WITH A MEDICATION ABORTION, INCLUDING HEMORRHAGE, INFECTION, FAILURE TO REMOVE ALL PRODUCTS OF

CONCEPTION THAT MAY RESULT IN AN ADDITIONAL PROCEDURE, STERILITY AND THE POSSIBLE CONTINUATION OF THE PREGNANCY.

4. REQUIRE THE PREGNANT MINOR'S AND THE PREGNANT MINOR'S PARENT'S INITIALS ON EACH PAGE OF THE FORM AND A FULL SIGNATURE ON THE FINAL PAGE OF THE FORM.

5. INCLUDE A SPACE FOR THE NOTARY'S SIGNATURE AND SEAL ON THE FINAL PAGE OF THE FORM.

M. THE PHYSICIAN MUST MAINTAIN THE FORM IN THE PREGNANT MINOR'S RECORDS FOR SEVEN YEARS AFTER THE DATE OF THE PROCEDURE OR FIVE YEARS AFTER THE DATE OF THE MINOR'S MATURITY, WHICHEVER IS LONGER.

Sec. 5. Section 36-2153, Arizona Revised Statutes, is amended to read:

36-2153. Informed consent; requirements; information; website; signs; violation; civil relief; statute of limitations

A. An abortion shall not be performed or induced without the voluntary and informed consent of the woman on whom the abortion is to be performed or induced. Except in the case of a medical emergency AND IN ADDITION TO THE OTHER REQUIREMENTS OF THIS CHAPTER, consent to an abortion is voluntary and informed only if all of the following are true:

1. At least twenty-four hours before the abortion, the physician who is to perform the abortion or the referring physician has informed the woman, orally and in person, of:

(a) The name of the physician who will perform the abortion.

(b) The nature of the proposed procedure or treatment.

(c) The immediate and long-term medical risks associated with the procedure that a reasonable patient would consider material to the decision of whether or not to undergo the abortion.

(d) Alternatives to the procedure or treatment that a reasonable patient would consider material to the decision of whether or not to undergo the abortion.

(e) The probable gestational age of the unborn child at the time the abortion is to be performed.

(f) The probable anatomical and physiological characteristics of the unborn child at the time the abortion is to be performed.

(g) The medical risks associated with carrying the child to term.

2. At least twenty-four hours before the abortion, the physician who is to perform the abortion, the referring physician or a qualified physician, physician assistant, nurse, psychologist or licensed behavioral health professional to whom the responsibility has been delegated by either physician has informed the woman, orally and in person, that:

(a) Medical assistance benefits may be available for prenatal care, childbirth and neonatal care.

(b) The father of the unborn child is liable to assist in the support of the child, even if he has offered to pay for the abortion. In the case of rape or incest, this information may be omitted.

(c) Public and private agencies and services are available to assist the woman during her pregnancy and after the birth of her child if she chooses not to have an abortion, whether she chooses to keep the child or place the child for adoption.

(d) It is unlawful for any person to coerce a woman to undergo an abortion.

(e) The woman is free to withhold or withdraw her consent to the abortion at any time without affecting her right to future care or treatment and without the loss of any state or federally funded benefits to which she might otherwise be entitled.

(f) THE DEPARTMENT OF HEALTH SERVICES MAINTAINS A WEBSITE THAT DESCRIBES THE UNBORN CHILD AND LISTS THE AGENCIES THAT OFFER ALTERNATIVES TO ABORTION.

(g) THE WOMAN HAS A RIGHT TO REVIEW THE WEBSITE AND THAT A PRINTED COPY OF THE MATERIALS ON THE WEBSITE WILL BE PROVIDED TO HER FREE OF CHARGE IF SHE CHOOSES TO REVIEW THESE MATERIALS.

3. The information in paragraphs 1 and 2 of this subsection is provided to the woman individually and in a private room to protect her privacy and to ensure that the information focuses on her individual circumstances and that she has adequate opportunity to ask questions.

4. The woman certifies in writing before the abortion that the information required to be provided pursuant to paragraphs 1 and 2 of this subsection has been provided.

B. If a medical emergency compels the performance of an abortion, the physician shall inform the woman, before the abortion if possible, of the medical indications supporting the physician's judgment that an abortion is necessary to avert the woman's death or to avert substantial and irreversible impairment of a major bodily function.

C. THE DEPARTMENT OF HEALTH SERVICES SHALL ESTABLISH A WEBSITE WITHIN NINETY DAYS AFTER THE EFFECTIVE DATE OF THIS AMENDMENT TO THIS SECTION AND SHALL ANNUALLY UPDATE THE WEBSITE. THE WEBSITE MUST INCLUDE A LINK TO A PRINTABLE VERSION OF ALL MATERIALS LISTED ON THE WEBSITE. THE MATERIALS MUST BE WRITTEN IN AN EASILY UNDERSTOOD MANNER AND PRINTED IN A TYPEFACE THAT IS LARGE ENOUGH TO BE CLEARLY LEGIBLE. THE WEBSITE MUST INCLUDE ALL OF THE FOLLOWING MATERIALS:

1. INFORMATION THAT IS ORGANIZED GEOGRAPHICALLY BY LOCATION AND THAT IS DESIGNED TO INFORM THE WOMAN ABOUT PUBLIC AND PRIVATE AGENCIES AND SERVICES THAT ARE AVAILABLE TO ASSIST A WOMAN THROUGH PREGNANCY, AT CHILDBIRTH AND WHILE HER CHILD IS DEPENDENT, INCLUDING ADOPTION AGENCIES. THE MATERIALS SHALL INCLUDE A COMPREHENSIVE LIST OF THE AGENCIES, A DESCRIPTION OF THE SERVICES THEY OFFER AND THE MANNER IN WHICH THESE AGENCIES MAY BE CONTACTED, INCLUDING THE AGENCIES' TELEPHONE NUMBERS AND WEBSITE ADDRESSES.

2. INFORMATION ON THE AVAILABILITY OF MEDICAL ASSISTANCE BENEFITS FOR PRENATAL CARE, CHILDBIRTH AND NEONATAL CARE.

3. A STATEMENT THAT IT IS UNLAWFUL FOR ANY PERSON TO COERCE A WOMAN TO UNDERGO AN ABORTION.

4. A STATEMENT THAT ANY PHYSICIAN WHO PERFORMS AN ABORTION ON A WOMAN WITHOUT OBTAINING THE WOMAN'S VOLUNTARY AND INFORMED CONSENT OR WITHOUT AFFORDING HER A PRIVATE MEDICAL CONSULTATION MAY BE LIABLE TO THE WOMAN FOR DAMAGES IN A CIVIL ACTION.

5. A STATEMENT THAT THE FATHER OF A CHILD IS LIABLE TO ASSIST IN THE SUPPORT OF THAT CHILD, EVEN IF THE FATHER HAS OFFERED TO PAY FOR AN ABORTION, AND THAT THE LAW ALLOWS ADOPTIVE PARENTS TO PAY COSTS OF PRENATAL CARE, CHILDBIRTH AND NEONATAL CARE.

6. INFORMATION THAT IS DESIGNED TO INFORM THE WOMAN OF THE PROBABLE ANATOMICAL AND PHYSIOLOGICAL CHARACTERISTICS OF THE UNBORN CHILD AT TWO-WEEK GESTATIONAL INCREMENTS FROM FERTILIZATION TO FULL TERM, INCLUDING PICTURES OR DRAWINGS REPRESENTING THE DEVELOPMENT OF UNBORN CHILDREN AT TWO-WEEK GESTATIONAL INCREMENTS AND ANY RELEVANT INFORMATION ON THE POSSIBILITY OF THE UNBORN CHILD'S SURVIVAL. THE PICTURES OR DRAWINGS MUST CONTAIN THE DIMENSIONS OF THE UNBORN CHILD AND MUST BE REALISTIC AND APPROPRIATE FOR EACH STAGE OF PREGNANCY. THE INFORMATION PROVIDED PURSUANT TO THIS PARAGRAPH MUST BE OBJECTIVE, NONJUDGMENTAL AND DESIGNED TO CONVEY ONLY ACCURATE SCIENTIFIC INFORMATION ABOUT THE UNBORN CHILD AT THE VARIOUS GESTATIONAL AGES.

7. OBJECTIVE INFORMATION THAT DESCRIBES THE METHODS OF ABORTION PROCEDURES COMMONLY EMPLOYED, THE MEDICAL RISKS COMMONLY ASSOCIATED WITH EACH PROCEDURE, THE POSSIBLE DETRIMENTAL PSYCHOLOGICAL EFFECTS OF ABORTION AND THE MEDICAL RISKS COMMONLY ASSOCIATED WITH CARRYING A CHILD TO TERM.

~~C.~~ D. An individual who is not a physician shall not perform a surgical abortion.

~~D.~~ E. A person shall not write or communicate a prescription for a drug or drugs to induce an abortion or require or obtain payment for a service provided to a patient who has inquired about an abortion or scheduled an abortion until the expiration of the twenty-four hour reflection period required by subsection A OF THIS SECTION.

~~E.~~ F. A person shall not intimidate or coerce in any way any person to obtain an abortion. A parent, A guardian or any other person shall not coerce a minor to obtain an abortion. If a minor is denied financial support by the minor's parents, guardians or custodian due to the minor's refusal to have an abortion performed, the minor is deemed emancipated for the purposes of eligibility for public assistance benefits, except that the emancipated minor may not use these benefits to obtain an abortion.

G. AN ABORTION CLINIC AS DEFINED IN SECTION 36-449.01 SHALL CONSPICUOUSLY POST SIGNS THAT ARE VISIBLE TO ALL WHO ENTER THE ABORTION CLINIC, THAT ARE CLEARLY READABLE AND THAT STATE IT IS UNLAWFUL FOR ANY PERSON TO FORCE A WOMAN TO HAVE AN ABORTION AND A WOMAN WHO IS BEING FORCED TO HAVE AN ABORTION HAS THE RIGHT TO CONTACT ANY LOCAL OR STATE LAW ENFORCEMENT OR SOCIAL SERVICE AGENCY TO RECEIVE PROTECTION FROM ANY ACTUAL OR THREATENED PHYSICAL, EMOTIONAL OR PSYCHOLOGICAL ABUSE. THE SIGNS SHALL BE POSTED IN THE WAITING ROOM, CONSULTATION ROOMS AND PROCEDURE ROOMS.

H. A PERSON SHALL NOT REQUIRE A WOMAN TO OBTAIN AN ABORTION AS A PROVISION IN A CONTRACT OR AS A CONDITION OF EMPLOYMENT.

~~F.~~ I. A physician who knowingly violates this section commits an act of unprofessional conduct and is subject to license suspension or revocation pursuant to title 32, chapter 13 or 17.

~~G.~~ J. In addition to other remedies available under the common or statutory law of this state, any of the following may file a civil action to obtain appropriate relief for a violation of this section:

1. A woman on whom an abortion has been performed without her informed consent as required by this section.

2. The father of the unborn child if married to the mother at the time she received the abortion, unless the pregnancy resulted from the plaintiff's criminal conduct.

3. The maternal grandparents of the unborn child if the mother was not at least eighteen years of age at the time of the abortion, unless the pregnancy resulted from the plaintiff's criminal conduct.

~~H.~~ K. A civil action filed pursuant to subsection ~~G~~ J OF THIS SECTION shall be brought in the superior court in the county in which the woman on whom the abortion was performed resides and may be based on a claim that failure to obtain informed consent was a result of simple negligence, gross negligence, wantonness, wilfulness, intention or any other legal standard of care. Relief pursuant to subsection ~~G~~ J OF THIS SECTION includes the following:

1. Money damages for all psychological, emotional and physical injuries resulting from the violation of this section.

2. Statutory damages in an amount equal to five thousand dollars or three times the cost of the abortion, whichever is greater.

3. Reasonable attorney fees and costs.

~~I.~~ L. A civil action brought pursuant to this section must be initiated within six years after the violation occurred.

Sec. 6. Section 36-2156, Arizona Revised Statutes, is amended to read:

36-2156. Informed consent; ultrasound required; violation; civil relief; statute of limitations

A. An abortion shall not be performed or induced without the voluntary and informed consent of the woman on whom the abortion is to be performed or induced. Except in the case of a medical emergency and in addition to the OTHER requirements of ~~section 36-2153~~ THIS CHAPTER, consent to an abortion is voluntary and informed only if both of the following are true:

1. At least ~~one hour~~ TWENTY-FOUR HOURS before the woman having any part of an abortion performed or induced, and before the administration of any anesthesia or medication in preparation for the abortion on the woman, the physician who is to perform the abortion, the referring physician or a qualified person working in conjunction with either physician shall:

(a) Perform fetal ultrasound imaging and auscultation of fetal heart tone services on the woman undergoing the abortion.

(b) Offer to provide the woman with an opportunity to view the active ultrasound image of the unborn child and hear the heartbeat of the unborn child if the heartbeat is audible. The active ultrasound image must be of a quality consistent with standard medical practice in the community, contain the dimensions of the unborn child and accurately portray the presence of external members and internal organs, if present or viewable, of the unborn child. The auscultation of fetal heart tone must be of a quality consistent with standard medical practice in the community.

(c) Offer to provide the woman with a simultaneous explanation of what the ultrasound is depicting, including the presence and location of the unborn child within the uterus, the number of unborn children depicted, the dimensions of the unborn child and the presence of any external members and internal organs, if present or viewable.

(d) Offer to provide the patient with a physical picture of the ultrasound image of the unborn child.

2. The woman certifies in writing before the abortion that she has been given the opportunity to view the active ultrasound image and hear the heartbeat of the unborn child if the heartbeat is audible and that she opted to view or not view the active ultrasound image and hear or not hear the heartbeat of the unborn child.

B. A physician who knowingly violates this section commits an act of unprofessional conduct and is subject to license suspension or revocation pursuant to title 32, chapter 13 or 17.

C. In addition to other remedies available under the common or statutory law of this state, any of the following may file a civil action to obtain appropriate relief for a violation of this section:

1. A woman on whom an abortion has been performed without her informed consent as required by this section.

2. The father of the unborn child if married to the mother at the time she received the abortion, unless the pregnancy resulted from the plaintiff's criminal conduct.

3. The maternal grandparents of the unborn child if the mother was not at least eighteen years of age at the time of the abortion, unless the pregnancy resulted from the plaintiff's criminal conduct.

D. A civil action filed pursuant to subsection C of this section shall be brought in the superior court in the county in which the woman on whom the abortion was performed resides and may be based on a claim that failure to obtain informed consent was a result of simple negligence, gross negligence, wantonness, wilfulness, intention or any other legal standard of care. Relief pursuant to subsection C of this section includes any of the following:

1. Money damages for all psychological, emotional and physical injuries resulting from the violation of this section.

2. Statutory damages in an amount equal to five thousand dollars or three times the cost of the abortion, whichever is greater.

3. Reasonable attorney fees and costs.

E. A civil action brought pursuant to this section must be initiated within six years after the violation occurred.

Sec. 7. Title 36, chapter 20, article 1, Arizona Revised Statutes, is amended by adding sections 36-2158 and 36-2159, to read:

36-2158. Informed consent; fetal condition; website; violation; civil relief; statute of limitations; definitions

A. A PERSON SHALL NOT PERFORM OR INDUCE AN ABORTION WITHOUT FIRST OBTAINING THE VOLUNTARY AND INFORMED CONSENT OF THE WOMAN ON WHOM THE ABORTION IS TO BE PERFORMED OR INDUCED. EXCEPT IN THE CASE OF A MEDICAL EMERGENCY AND IN ADDITION TO THE OTHER REQUIREMENTS OF THIS CHAPTER, CONSENT TO AN ABORTION IS VOLUNTARY AND INFORMED ONLY IF ALL OF THE FOLLOWING OCCUR:

1. IN THE CASE OF A WOMAN SEEKING AN ABORTION OF HER UNBORN CHILD DIAGNOSED WITH A LETHAL FETAL CONDITION, AT LEAST TWENTY-FOUR HOURS BEFORE THE ABORTION THE PHYSICIAN WHO IS TO PERFORM THE ABORTION OR THE REFERRING PHYSICIAN HAS INFORMED THE WOMAN, ORALLY AND IN PERSON, THAT:

(a) PERINATAL HOSPICE SERVICES ARE AVAILABLE AND THE PHYSICIAN HAS OFFERED THIS CARE AS AN ALTERNATIVE TO ABORTION.

(b) THE DEPARTMENT OF HEALTH SERVICES MAINTAINS A WEBSITE THAT LISTS PERINATAL HOSPICE PROGRAMS THAT ARE AVAILABLE BOTH IN THIS STATE AND NATIONALLY AND THAT ARE ORGANIZED GEOGRAPHICALLY BY LOCATION.

(c) THE WOMAN HAS A RIGHT TO REVIEW THE WEBSITE AND THAT A PRINTED COPY OF THE MATERIALS ON THE WEBSITE WILL BE PROVIDED TO HER FREE OF CHARGE IF SHE CHOOSES TO REVIEW THESE MATERIALS.

2. IN THE CASE OF A WOMAN SEEKING AN ABORTION OF HER UNBORN CHILD DIAGNOSED WITH A NONLETHAL FETAL CONDITION, AT LEAST TWENTY-FOUR HOURS BEFORE THE ABORTION THE PHYSICIAN WHO IS TO PERFORM THE ABORTION OR THE REFERRING PHYSICIAN HAS INFORMED THE WOMAN, ORALLY AND IN PERSON:

(a) OF UP-TO-DATE, EVIDENCE-BASED INFORMATION CONCERNING THE RANGE OF OUTCOMES FOR INDIVIDUALS LIVING WITH THE DIAGNOSED CONDITION, INCLUDING PHYSICAL, DEVELOPMENTAL, EDUCATIONAL AND PSYCHOSOCIAL OUTCOMES.

(b) THAT THE DEPARTMENT OF HEALTH SERVICES MAINTAINS A WEBSITE THAT LISTS INFORMATION REGARDING SUPPORT SERVICES, HOTLINES, RESOURCE CENTERS OR CLEARINGHOUSES, NATIONAL AND LOCAL PEER SUPPORT GROUPS AND OTHER EDUCATION AND SUPPORT PROGRAMS AVAILABLE TO ASSIST THE WOMAN AND HER UNBORN CHILD, ANY NATIONAL OR LOCAL REGISTRIES OF FAMILIES WILLING TO ADOPT NEWBORNS WITH THE NONLETHAL FETAL CONDITION AND CONTACT INFORMATION FOR ADOPTION AGENCIES WILLING TO PLACE NEWBORNS WITH THE NONLETHAL FETAL CONDITION WITH FAMILIES WILLING TO ADOPT.

(c) THAT THE WOMAN HAS A RIGHT TO REVIEW THE WEBSITE AND THAT A PRINTED COPY OF THE MATERIALS ON THE WEBSITE WILL BE PROVIDED TO HER FREE OF CHARGE IF SHE CHOOSES TO REVIEW THESE MATERIALS.

3. THE WOMAN CERTIFIES IN WRITING BEFORE THE ABORTION THAT THE INFORMATION REQUIRED TO BE PROVIDED PURSUANT TO THIS SUBSECTION HAS BEEN PROVIDED.

B. THE DEPARTMENT OF HEALTH SERVICES SHALL ESTABLISH A WEBSITE WITHIN NINETY DAYS AFTER THE EFFECTIVE DATE OF THIS SECTION AND SHALL ANNUALLY

UPDATE THE WEBSITE. THE WEBSITE SHALL INCLUDE THE INFORMATION PRESCRIBED IN SUBSECTION A, PARAGRAPH 1, SUBDIVISION (b) AND PARAGRAPH 2, SUBDIVISION (b) OF THIS SECTION.

C. A PHYSICIAN WHO KNOWINGLY VIOLATES THIS SECTION COMMITS AN ACT OF UNPROFESSIONAL CONDUCT AND IS SUBJECT TO LICENSE SUSPENSION OR REVOCATION PURSUANT TO TITLE 32, CHAPTER 13 OR 17.

D. IN ADDITION TO OTHER REMEDIES AVAILABLE UNDER THE COMMON OR STATUTORY LAW OF THIS STATE, ANY OF THE FOLLOWING INDIVIDUALS MAY FILE A CIVIL ACTION TO OBTAIN APPROPRIATE RELIEF FOR A VIOLATION OF THIS SECTION:

1. A WOMAN ON WHOM AN ABORTION HAS BEEN PERFORMED WITHOUT HER INFORMED CONSENT AS REQUIRED BY THIS SECTION.

2. THE FATHER OF THE UNBORN CHILD IF THE FATHER IS MARRIED TO THE MOTHER AT THE TIME SHE RECEIVED THE ABORTION, UNLESS THE PREGNANCY RESULTED FROM THE FATHER'S CRIMINAL CONDUCT.

3. THE MATERNAL GRANDPARENTS OF THE UNBORN CHILD IF THE MOTHER WAS NOT AT LEAST EIGHTEEN YEARS OF AGE AT THE TIME OF THE ABORTION, UNLESS THE PREGNANCY RESULTED FROM EITHER OF THE MATERNAL GRANDPARENT'S CRIMINAL CONDUCT.

E. A CIVIL ACTION FILED PURSUANT TO SUBSECTION D OF THIS SECTION SHALL BE BROUGHT IN THE SUPERIOR COURT IN THE COUNTY IN WHICH THE WOMAN ON WHOM THE ABORTION WAS PERFORMED RESIDES AND MAY BE BASED ON A CLAIM THAT FAILURE TO OBTAIN INFORMED CONSENT WAS A RESULT OF SIMPLE NEGLIGENCE, GROSS NEGLIGENCE, WANTONNESS, WILFULNESS, INTENTION OR ANY OTHER LEGAL STANDARD OF CARE. RELIEF PURSUANT TO THIS SUBSECTION INCLUDES THE FOLLOWING:

1. MONEY DAMAGES FOR ALL PSYCHOLOGICAL, EMOTIONAL AND PHYSICAL INJURIES RESULTING FROM THE VIOLATION OF THIS SECTION.

2. STATUTORY DAMAGES IN AN AMOUNT EQUAL TO FIVE THOUSAND DOLLARS OR THREE TIMES THE COST OF THE ABORTION, WHICHEVER IS GREATER.

3. REASONABLE ATTORNEY FEES AND COSTS.

F. A CIVIL ACTION BROUGHT PURSUANT TO THIS SECTION MUST BE INITIATED WITHIN SIX YEARS AFTER THE VIOLATION OCCURRED.

G. FOR THE PURPOSES OF THIS SECTION:

1. "LETHAL FETAL CONDITION" MEANS A FETAL CONDITION THAT IS DIAGNOSED BEFORE BIRTH AND THAT WILL RESULT, WITH REASONABLE CERTAINTY, IN THE DEATH OF THE UNBORN CHILD WITHIN THREE MONTHS AFTER BIRTH.

2. "NONLETHAL FETAL CONDITION" MEANS A FETAL CONDITION THAT IS DIAGNOSED BEFORE BIRTH AND THAT WILL NOT RESULT IN THE DEATH OF THE UNBORN CHILD WITHIN THREE MONTHS AFTER BIRTH BUT MAY RESULT IN PHYSICAL OR MENTAL DISABILITY OR ABNORMALITY.

3. "PERINATAL HOSPICE" MEANS COMPREHENSIVE SUPPORT TO THE PREGNANT WOMAN AND HER FAMILY THAT INCLUDES SUPPORTIVE CARE FROM THE TIME OF DIAGNOSIS THROUGH THE TIME OF BIRTH AND DEATH OF THE INFANT AND THROUGH THE POSTPARTUM PERIOD. SUPPORTIVE CARE MAY INCLUDE COUNSELING AND MEDICAL CARE BY MATERNAL-FETAL MEDICAL SPECIALISTS, OBSTETRICIANS, NEONATOLOGISTS, ANESTHESIA SPECIALISTS, CLERGY, SOCIAL WORKERS AND SPECIALTY NURSES WHO ARE FOCUSED ON

ALLEVIATING FEAR AND ENSURING THAT THE WOMAN AND HER FAMILY EXPERIENCE THE LIFE AND DEATH OF THE CHILD IN A COMFORTABLE AND SUPPORTIVE ENVIRONMENT.

36-2159. Abortion; gestational age; violation; classification; statute of limitations

A. EXCEPT IN A MEDICAL EMERGENCY, A PERSON SHALL NOT PERFORM, INDUCE OR ATTEMPT TO PERFORM OR INDUCE AN ABORTION UNLESS THE PHYSICIAN OR THE REFERRING PHYSICIAN HAS FIRST MADE A DETERMINATION OF THE PROBABLE GESTATIONAL AGE OF THE UNBORN CHILD. IN MAKING THAT DETERMINATION, THE PHYSICIAN OR REFERRING PHYSICIAN SHALL MAKE ANY INQUIRIES OF THE PREGNANT WOMAN AND PERFORM OR CAUSE TO BE PERFORMED ALL MEDICAL EXAMINATIONS, IMAGING STUDIES AND TESTS AS A REASONABLY PRUDENT PHYSICIAN IN THE COMMUNITY, KNOWLEDGEABLE ABOUT THE MEDICAL FACTS AND CONDITIONS OF BOTH THE WOMAN AND THE UNBORN CHILD INVOLVED, WOULD CONSIDER NECESSARY TO PERFORM AND CONSIDER IN MAKING AN ACCURATE DIAGNOSIS WITH RESPECT TO GESTATIONAL AGE.

B. EXCEPT IN A MEDICAL EMERGENCY, A PERSON SHALL NOT KNOWINGLY PERFORM, INDUCE OR ATTEMPT TO PERFORM OR INDUCE AN ABORTION ON A PREGNANT WOMAN IF THE PROBABLE GESTATIONAL AGE OF HER UNBORN CHILD HAS BEEN DETERMINED TO BE AT LEAST TWENTY WEEKS.

C. A PERSON WHO KNOWINGLY VIOLATES THIS SECTION COMMITS A CLASS 1 MISDEMEANOR.

D. A PHYSICIAN WHO KNOWINGLY VIOLATES THIS SECTION COMMITS AN ACT OF UNPROFESSIONAL CONDUCT AND IS SUBJECT TO LICENSE SUSPENSION OR REVOCATION PURSUANT TO TITLE 32, CHAPTER 13 OR 17.

E. IN ADDITION TO OTHER REMEDIES AVAILABLE UNDER THE COMMON OR STATUTORY LAW OF THIS STATE, ANY OF THE FOLLOWING INDIVIDUALS MAY FILE A CIVIL ACTION TO OBTAIN APPROPRIATE RELIEF FOR A VIOLATION OF THIS SECTION:

1. A WOMAN ON WHOM AN ABORTION HAS BEEN PERFORMED IN VIOLATION OF THIS SECTION.

2. THE FATHER OF THE UNBORN CHILD IF THE FATHER IS MARRIED TO THE MOTHER AT THE TIME SHE RECEIVED THE ABORTION, UNLESS THE PREGNANCY RESULTED FROM THE FATHER'S CRIMINAL CONDUCT.

3. THE MATERNAL GRANDPARENTS OF THE UNBORN CHILD IF THE MOTHER WAS NOT AT LEAST EIGHTEEN YEARS OF AGE AT THE TIME OF THE ABORTION, UNLESS THE PREGNANCY RESULTED FROM EITHER OF THE MATERNAL GRANDPARENT'S CRIMINAL CONDUCT.

F. A CIVIL ACTION FILED PURSUANT TO SUBSECTION E OF THIS SECTION SHALL BE BROUGHT IN THE SUPERIOR COURT IN THE COUNTY IN WHICH THE WOMAN ON WHOM THE ABORTION WAS PERFORMED RESIDES. RELIEF PURSUANT TO THIS SUBSECTION INCLUDES THE FOLLOWING:

1. MONEY DAMAGES FOR ALL PSYCHOLOGICAL, EMOTIONAL AND PHYSICAL INJURIES RESULTING FROM THE VIOLATION OF THIS SECTION.

2. STATUTORY DAMAGES IN AN AMOUNT EQUAL TO FIVE THOUSAND DOLLARS OR THREE TIMES THE COST OF THE ABORTION, WHICHEVER IS GREATER.

3. REASONABLE ATTORNEY FEES AND COSTS.

G. A CIVIL ACTION BROUGHT PURSUANT TO THIS SECTION MUST BE INITIATED WITHIN SIX YEARS AFTER THE VIOLATION OCCURRED.

H. A WOMAN ON WHOM AN ABORTION IS PERFORMED OR INDUCED IN VIOLATION OF THIS SECTION MAY NOT BE PROSECUTED UNDER THIS SECTION OR FOR CONSPIRACY TO COMMIT A VIOLATION OF THIS SECTION.

Sec. 8. Section 36-2163, Arizona Revised Statutes, is amended to read:

36-2163. Reports; confidentiality; annual statistical report; violations; classification; unprofessional conduct

A. A report required by this article shall not contain the name of the woman, common identifiers such as the woman's social security number, driver license number or insurance carrier identification numbers or any other information or identifiers that would make it possible to identify in any manner or under any circumstances an individual who has obtained or seeks to obtain an abortion.

B. The department of health services shall collect all abortion reports and complication reports and prepare a comprehensive annual statistical report based on the data gathered in the reports. The statistical report shall not lead to the disclosure of the identity of any person filing a report or about whom a report is filed. The department shall make the statistical report available on its website and for public inspection and copying.

C. The report prepared by the department pursuant to subsection B of this section shall include statistics from the administrative office of the courts containing the following information:

1. The number of petitions filed pursuant to section 36-2152, subsection B.

2. Of the petitions filed pursuant to section 36-2152, subsection B, the number in which the judge appointed a guardian ad litem or court-appointed counsel for the minor pursuant to section 36-2152, subsection D.

3. Of the petitions filed pursuant to section 36-2152, subsection B, the number in which the judge issued an order authorizing an abortion without parental consent.

4. Of the petitions filed pursuant to section 36-2152, subsection B, the number in which the judge issued an order denying the petition.

5. Of the petitions denied, the number appealed to the court of appeals.

6. The number of those appeals that resulted in the denials being affirmed.

7. The number of those appeals that resulted in the denial being reversed.

D. Except for a statistical report as provided in subsection B of this section, a report filed pursuant to this article is not a public record and is not available for public inspection, except that disclosure may be made to law enforcement officials on an order of a court after application showing good cause. The court may condition disclosure of the information on any appropriate safeguards it may impose.

E. Original copies of all reports filed pursuant to sections 36-2161 and 36-2162 shall be available to the Arizona medical board and the Arizona board of osteopathic examiners in medicine and surgery for use in the performance of their official duties. The Arizona medical board and the Arizona board of osteopathic examiners in medicine and surgery shall maintain the confidentiality of any reports obtained pursuant to this subsection.

F. An employee, agent or contractor of the department who wilfully discloses any information obtained from reports filed pursuant to this article, other than disclosure authorized under subsections B, D and E of this section or as otherwise authorized by law, is guilty of a class 3 misdemeanor.

G. A person who is required by this article to file a report, keep any records or supply any information and who wilfully fails to file that report, keep records or supply information as required by law is guilty of unprofessional conduct and is subject to discipline, including license suspension or revocation.

H. A person who wilfully delivers or discloses to the department any report, record or information known by that person to be false commits a class 1 misdemeanor.

I. In addition to the penalties prescribed by subsections F, G and H of this section, an organization or facility that wilfully violates the reporting requirements of this article is subject to discipline by the department including the ~~same~~ civil penalties ~~as~~ prescribed in section ~~36-126~~ 36-431.01. IF AN ORGANIZATION OR FACILITY THAT IS LICENSED PURSUANT TO CHAPTER 4, ARTICLE 10 OF THIS TITLE WILFULLY VIOLATES THE REPORTING REQUIREMENTS OF THIS ARTICLE, THE DEPARTMENT MAY ASSESS A CIVIL PENALTY PURSUANT TO SECTION 36-431.01, IMPOSE AN INTERMEDIATE SANCTION PURSUANT TO SECTION 36-427, SUSPEND OR REVOKE A LICENSE PURSUANT TO SECTION 36-427, DENY A LICENSE OR BRING AN ACTION FOR AN INJUNCTION PURSUANT TO SECTION 36-430.

Sec. 9. Findings and purposes

A. The legislature finds that:

1. Abortion can cause serious both short-term and long-term physical and psychological complications for women, including but not limited to uterine perforation, uterine scarring, cervical perforation or other injury, infection, bleeding, hemorrhage, blood clots, failure to actually terminate the pregnancy, incomplete abortion (retained tissue), pelvic inflammatory disease, endometritis, missed ectopic pregnancy, cardiac arrest, respiratory arrest, renal failure, metabolic disorder, shock, embolism, coma, placenta previa in subsequent pregnancies, preterm delivery in subsequent pregnancies, free fluid in the abdomen, organ damage, adverse reactions to anesthesia and other drugs, psychological or emotional complications such as depression, anxiety or sleeping disorders and death. *See, e.g.*, P.K. Coleman, *Abortion and Mental Health: Quantitative Synthesis and Analysis of Research Published 1995-2009*, Brit. J. of Psychiatry 199:180-86 (2011); P. Shah et al., *Induced termination of pregnancy and low birth weight and preterm birth: a systematic review and meta-analysis*, B.J.O.G. 116(11):1425 (2009); H.M. Swingle et al.,

Abortion and the Risk of Subsequent Preterm Birth: A Systematic Review and Meta-Analysis, J. Reprod. Med. 54:95 (2009); R.H. van Oppenraaij et al., *Predicting adverse obstetric outcome after early pregnancy events and complications: a review*, Human Reprod. Update Advance Access 1:1 (Mar. 7, 2009); R.E. Behrman, Preterm Birth: Causes, Consequences, and Prevention 519 (2006); J.M. Thorp et al., *Long-Term Physical and Psychological Health Consequences of Induced Abortion: Review of the Evidence*, Obstet. & Gynecol. Survey 58[1]:67, 75 (2003) J.M. Barrett, *Induced Abortion: A Risk Factor for Placenta Previa*, Am. J. Obstet. & Gynecol. 141:7 (1981).

2. Abortion has a higher medical risk when the procedure is performed later in pregnancy. Compared to an abortion at eight weeks of gestation or earlier, the relative risk increases exponentially at higher gestations. L. Bartlett et al., Risk factors for legal induced abortion-related mortality in the United States, *Obstetrics & Gynecology* 103(4):729-737 (2004).

3. The incidence of major complications is highest after twenty weeks of gestation. J. Pregler & A. DeCherney, *Women's Health: Principles and Clinical Practice* 232 (2002).

4. The risk of death associated with abortion increases with the length of pregnancy, from one death for every one million abortions at or before eight weeks gestation to one per 29,000 abortions at sixteen to twenty weeks and one per 11,000 abortions at twenty-one or more weeks. L. Bartlett et al., Risk factors for legal induced abortion-related mortality in the United States, *Obstetrics & Gynecology* 103(4):729-737 (2004). After the first trimester, the risk of hemorrhage from an abortion, in particular, is greater, and the resultant complications may require a hysterectomy, other reparative surgery or a blood transfusion.

5. The State of Arizona has a legitimate concern for the public's health and safety. *Williamson v. Lee Optical*, 348 U.S. 483, 486 (1985); *Cohen v. State*, 121 Ariz. 6, 10, 588 P.2d 299, 303 (1978).

6. The State of Arizona "has legitimate interests from the outset of pregnancy in protecting the health of women." *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 847 (1992); *Planned Parenthood Arizona, Inc. v. American Ass'n of Pro-Life Obstetricians & Gynecologists*, 257 P.3d 181, 194 (Ariz. App. Div. 1, 2011). More specifically, Arizona "has a legitimate concern with the health of women who undergo abortions." *Akron v. Akron Ctr. for Reproductive Health, Inc.*, 462 U.S. 416, 428-29 (1983).

7. There is substantial and well-documented medical evidence that an unborn child by at least twenty weeks of gestation has the capacity to feel pain during an abortion. K. Anand, Pain and its effects in the human neonate and fetus, *New England Journal of Medicine*, 317:1321-29 (1987).

8. The United States Food and Drug Administration approved the drug mifepristone, a first-generation (selective) progesterone receptor modulator ([S]PRM), as an abortion-inducing drug with a specific gestation, dosage and administration protocol.

9. As approved by the United States Food and Drug Administration, and as outlined in the drug label, an abortion by mifepristone consists of three 200 mg tablets of mifepristone taken orally, followed by two 200 mcg tablets of misopristol taken orally, through forty-nine days LMP (a gestational measurement using the first day of the woman's "last menstrual period" as a marker). The patient is to return for a follow-up visit in order to confirm that a complete termination of pregnancy has occurred. *Mifeprex Prescribing Information*, Danco Laboratories (July 2005), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020687s013lbl.pdf; *Mifeprex Medication Guide*, Danco Laboratories (June 8, 2011), available at www.accessdata.fda.gov/drugsatfda_docs/label/2011/020687s014lbl.pdf.

10. The aforementioned treatment requires three office visits by the patient, and the dosages may only be administered in a clinic, medical office or hospital and under supervision of a physician.

11. Court testimony demonstrates that some abortion providers fail to follow the mifepristone protocol as tested and approved by the United States Food and Drug Administration, and as outlined in the drug label. See, e.g., *Planned Parenthood v. Goddard*, CV2009-029110, Declaration of Beth Otterstein at 3 (Sept. 10, 2009); *Planned Parenthood v. Horne*, CV2010-030230, Declaration of Paul D. Blumenthal, M.D., M.P.H. (June 29, 2011); and *Planned Parenthood Cincinnati Region v. Taft*, 459 F. Supp. 2d 626, 630 n. 7 (S.D. Oh. 2006).

12. The use of mifepristone presents significant medical risks to women, including but not limited to C. sordellii bacterial infection, septic shock, toxic shock syndrome, adult respiratory distress syndrome from sepsis, Escheria coli sepsis, group B Streptococcus septicemia, disseminated intravascular coagulopathy (DIC) with heptic and renal failure, severe pelvic infection and massive hemorrhage.

13. Abortion-inducing drugs are associated with an increased risk of complications relative to surgical abortion. The risk of complications increases with increasing gestational age, and, in the instance of mifepristone, with failure to complete the two-step dosage process.

14. Medical studies have indicated that 1 to 2 out of every 1,000 women who undergo mifepristone abortions will require emergency blood transfusion for massive hemorrhage. By April 30, 2011, the United States Food and Drug Administration reported that at least 339 women required blood transfusions for massive bleeding after mifepristone abortions. A total of 612 United States women have been hospitalized due to complications, and fourteen women in the United States have died following administration of mifepristone. The majority of reported deaths in the United States were from fatal infection. Mifepristone U.S. Postmarketing Adverse Events Summary through 04/30/2011, United States Food and Drug Administration, available at www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf. This infection is atypical to the usual presentation of sepsis and may occur without the typical signs of infection, such as fever and tenderness. This atypical presentation requires that

mifepristone be dispensed only in a closely supervised clinical setting under the direction of a licensed physician who has the direct ability to counsel the patient regarding the risks, and also to examine the patient prior to and after administration of mifepristone.

15. The absence of proper follow-up care after mifepristone abortions has resulted in at least 58 women having undetected ectopic pregnancies, including two deaths from ectopic rupture. Mifepristone U.S. Postmarketing Adverse Events Summary through 04/30/2011, United States Food and Drug Administration, available at www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf.

B. For these reasons, the legislature's purposes in promulgating this act include to:

1. Prohibit abortions at or after twenty weeks of gestation, except in cases of a medical emergency, based on the documented risks to women's health and the strong medical evidence that unborn children feel pain during an abortion at that gestational age.

2. Protect women from the dangerous and potentially deadly off-label use of abortion-inducing drugs, such as, for example, mifepristone.

3. Ensure that physicians abide by the protocol tested and approved by the United States Food and Drug Administration for such abortion-inducing drugs, as outlined in the drug labels.

Sec. 10. Exemption from rule making

For the purposes of this act, the department of health services is exempt from the rule making requirements of title 41, chapter 6, Arizona Revised Statutes, for two years after the effective date of this act.

Sec. 11. Construction

This act does not establish or recognize a right to an abortion and does not make lawful an abortion that is currently unlawful.

Sec. 12. Severability

If a provision of this act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

APPROVED BY THE GOVERNOR APRIL 12, 2012.

FILED IN THE OFFICE OF THE SECRETARY OF STATE APRIL 12, 2012.

Exhibit 4

NOTICES OF EXEMPT RULEMAKING

The Administrative Procedure Act requires the *Register* publication of the rules adopted by the state's agencies under an exemption from all or part of the Administrative Procedure Act. Some of these rules are exempted by A.R.S. §§ 41-1005 or 41-1057; other rules are exempted by other statutes; rules of the Corporation Commission are exempt from Attorney General review pursuant to a court decision as determined by the Corporation Commission.

NOTICE OF FINAL EXEMPT RULEMAKING

TITLE 9. HEALTH SERVICES

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

Editor's Note: The following Notice of Final Exempt Rulemaking was reviewed per Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 475.) The Governor's Office authorized the notice to proceed through the rulemaking process on August 16, 2012.

[R14-13]

PREAMBLE

1. Article, Part or Sections Affected (as applicable) — **Rulemaking Action**

R9-10-1501	Amend
R9-10-1502	Amend
R9-10-1503	Amend
R9-10-1504	Amend
R9-10-1505	Amend
R9-10-1506	Amend
R9-10-1507	Amend
R9-10-1508	Amend
R9-10-1509	Amend
R9-10-1510	Amend
R9-10-1511	Amend
R9-10-1512	Amend
R9-10-1513	Amend
R9-10-1514	Amend
R9-10-1515	New Section

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

Authorizing statutes: A.R.S. § 36-136(F)

Implementing statutes: A.R.S. §§ 36-132(A)(17), 36-405, 36-449.01 through 36-449.03, 36-2151 through 36-2153, 36-2156, 36-2158, and 36-2159

Statute or session law authorizing the exemption: Laws 2012, Ch. 250, § 10

3. The effective date of the rule and the agency's reason it selected the effective date:

April 1, 2014

This date will provide abortion clinics with over two months after the date of filing for the abortion clinics to implement changes required by the rules.

4. A list of all notices published in the *Register* as specified in R9-1-409(A) that pertain to the record of the exempt rulemaking:

Notice of Public Information: 19 A.A.R. 3944, November 29, 2013

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

Name: Kathryn McCanna, Branch Chief

Address: Department of Health Services
Division of Licensing Services
150 N. 18th Ave., Suite 405
Phoenix, AZ 85007

Telephone:	(602) 364-2536
Fax:	(602) 364-4764
E-mail:	Kathryn.McCanna@azdhs.gov
or	
Name:	Robert Lane, Acting Manager
Address:	Department of Health Services Office of Administrative Counsel and Rules 1740 W. Adams, Suite 203 Phoenix, AZ 85007
Telephone:	(602) 542-1020
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:

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. The Department has implemented A.R.S. §§ 36-132(A)(17) and 36-405 for abortion clinics in Arizona Administrative Code (A.A.C.) Title 9, Chapter 10, Article 15. On April 12, 2012, the Governor signed HB 2036, which changed requirements for abortion clinics. HB 2036 was effective August 2, 2012. HB 2036 gives the Arizona Department of Health Services (Department) exempt rulemaking authority to amend the rules for abortion clinics. After receiving an exception from the Governor's rulemaking moratorium, established by Executive Order 2012-03, for this rulemaking, the Department has revised the rules in 9 A.A.C. 10, Article 15 to delete unnecessary and obsolete provisions, address technical changes, and 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:

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 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:

TITLE 9. HEALTH SERVICES

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

ARTICLE 15. ABORTION CLINICS

Section
R9-10-1501. Definitions
R9-10-1502. Application Requirements
R9-10-1503. Administration
R9-10-1504. Incident Reporting
R9-10-1505. Personnel Qualifications
R9-10-1506. Staffing Requirements
R9-10-1507. Patient Rights
R9-10-1508. Abortion Procedures
R9-10-1509. Patient Transfer and Discharge
R9-10-1510. Medications and Controlled Substances
R9-10-1511. Medical Records
R9-10-1512. Environmental and Safety Standards
R9-10-1513. Equipment Standards
R9-10-1514. Physical Facilities
R9-10-1515. Enforcement

ARTICLE 15. ABORTION CLINICS

R9-10-1501. Definitions
In addition to the definitions in A.R.S. §§ 36-401, 36-449.01, 36-449.03, and R9-10-101, the following definitions apply in this Article, unless ~~the context~~ otherwise ~~requires~~ specified:

~~1. *"Abortion" means the use of a surgical instrument or a machine with the intent to terminate a woman's pregnancy for reasons other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, to terminate an ectopic pregnancy or to remove a dead fetus. Abortion does not include birth control devices or oral contraceptives.*~~

~~2. *"Abortion clinic" means 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.*~~

~~3.~~1. "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.~~2. "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 in this state and agrees to do so.

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

~~6. "Biohazardous medical waste" means cultures and stocks, waste human blood and blood products, bodily fluids, uterine contents, and discarded medical sharps.~~

~~7.~~3. "Conspicuously posted" means placed at a location within an abortion clinic that is accessible and visible to patients and the public.

~~8. "Controlled substance" means the same as defined in A.R.S. § 32-1901(12).~~

~~9.~~4. "Course" means hands-on practice under the supervision of a physician, training, or education.

~~10. "Current" means up-to-date, extending to the present time.~~

~~11. "Department" means the same as defined in A.R.S. § 36-401.~~

~~12. "Direction" means the same as defined in A.R.S. § 36-401.~~

~~13.~~5. "Discharge" means a patient no longer requires the medical services, nursing services, or health-related services provided by the abortion clinic.

~~14. "Documentation" means written, supportive evidence.~~

~~15.~~6. ~~"~~Emergency~~"~~ means a potentially life-threatening occurrence that requires an immediate response or medical treatment.

~~16.~~7. "Employee" means an individual who receives compensation from a licensee, but does not provide medical services, nursing services, or health-related services.

~~17. "*Fetus" means an individual human organism from fertilization until birth.*~~

~~18.~~8. "First trimester~~"~~ means 1 through 14 weeks as measured from the first day of the last menstrual period or 1 through 12 weeks as measured from the date of fertilization.

~~19. "Gestational age" means the number of completed weeks of the unborn fetus as calculated from the first day of the last menstrual period or the date of fertilization.~~

~~20. "Health-related services" means the same as defined in A.R.S. § 36-401.~~

~~21. "Immediately" means without delay.~~

~~22.~~9. "Incident" means an abortion related patient death or serious injury to a patient or viable fetus.

~~23. "Infection control" means to identify, prevent, monitor, and minimize infections.~~

~~24.~~10. "Licensee" means an individual, a partnership, an association, a limited liability company, or corporation authorized by the Department to operate an abortion clinic.

~~25.~~11. "Local" means under the jurisdiction of a city or county in Arizona.

~~26.~~12. "Medical director" means a physician who is responsible for the direction of the medical services, nursing services, and health-related services provided to patients at an abortion clinic.

~~27.~~13. "Medical evaluation" means obtaining a patient's medical history, performing a physical examination of a patient's body, and conducting laboratory tests as provided in R9-10-1508.

~~28. "Medical services" means the same as defined in A.R.S. § 36-401~~.

~~29. "Medication" means a prescription medication as defined in A.R.S. § 32-1901 or a nonprescription drug or over-the-counter drug as defined in A.R.S. § 32-1901.~~

~~30.~~14. "Monitor" means to observe and document, continuously or intermittently, the values of certain physiologic variables on a patient such as pulse, blood pressure, oxygen saturation, respiration, and blood loss.

~~31.~~15. "Nationally recognized medical journal" means any publication distributed nationally that contains peer-reviewed medical information, such as the *American Journal of Radiology* or the *Journal of Ultrasound in Medicine*.

~~32. "Nurse" means an individual licensed and in good standing as a registered nurse or a practical nurse according to A.R.S. Title 32, Chapter 15.~~

~~33. "Nurse practitioner" means an individual licensed and in good standing as a registered nurse practitioner according to A.R.S. Title 32, Chapter 15.~~

~~34. "Nursing services" means the same as defined in A.R.S. § 36-401.~~

~~35.~~16. "Patient" means a female receiving medical services, nursing services, or health-related services related to an abortion.

~~36.~~17. "Patient care staff" means a physician, registered nurse practitioner, nurse, physician assistant, or surgical assistant who provides medical services, nursing services, or health-related services to a patient.

~~37.~~18. "~~Patient~~ Patient's representative" means a patient's legal guardian, an individual acting on behalf of a patient with the written consent of the patient, or a surrogate according to A.R.S. § 36-3201~~(13)~~.

~~38.~~19. "Patient transfer" means relocating a patient requiring medical services from an abortion clinic to another health care institution.

~~39.~~20. "Personally identifiable patient information" means:

a. The name, address, telephone number, e-mail address, Social Security number, and birth date of:
   i. The patient,
   ii. The patient's representative,
   iii. The patient's emergency contact,
   iv. The patient's children,
   v. The patient's spouse,
   vi. The patient's sexual partner, and
   vii. Any other individual identified in the patient's medical record other than patient care staff;
b. The patient's place of employment;
c. The patient's referring physician;
d. The patient's insurance carrier or account;
e. Any "individually identifiable health information" as proscribed in 45 CFR 164-514; and
f. Any other information in the patient's medical record that could reasonably lead to the identification of the patient.

~~40.~~21. "Personnel" means patient care staff, employees, and volunteers.

~~41.~~22. "Physical facilities" means property that is:

a. Designated on an application for a license by the applicant; and
b. Licensed to provide services by the Department according to A.R.S. Title 36, Chapter 4.

~~42. "Physician" means an individual licensed according to A.R.S. Title 32, Chapter 13 or 17.~~
~~43. "Physician assistant" means an individual licensed according to A.R.S. Title 32, Chapter 25.~~
~~44. *"Serious injury" means an injury that occurs at an abortion clinic and that creates a serious risk of substantial impairment of a major body organ.*~~
~~45. *"Supervision" means direct overseeing and inspection of the act of accomplishing a function or activity.*~~
~~46.~~23. "Surgical assistant" means an individual who is not licensed as a physician, physician assistant, registered nurse practitioner, or nurse who performs duties as directed by a physician, physician assistant, registered nurse practitioner or nurse.
~~47. "Viable fetus" means the same as defined in A.R.S. § 36-2301.01.~~
~~48.~~24."Volunteer" means an individual who, without compensation, performs duties as directed by a member of the patient care staff at an abortion clinic.

R9-10-1502. Application Requirements
An applicant shall submit an application for licensure that meets the requirements in A.R.S. § 36-422 and 9 A.A.C. 10, Article 1.

R9-10-1503. Administration
A. A licensee is responsible for the organization and management of an abortion clinic.
B. A licensee shall:
~~1. Ensure compliance with federal and state laws, rules, and local ordinances;~~
~~2.~~1. Adopt policies and procedures for the administration and operation of an abortion clinic;
~~3.~~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;
~~4.~~3. Ensure that the Department's director or director's ~~designee~~ 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;
~~5.~~4. 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's Office of Medical Facilities~~ 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 ~~developed~~ 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.

R9-10-1504. 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; and
2. For a serious injury, written notification within 10 calendar days ~~from~~ after the date of the serious injury.
B. A medical director shall conduct an investigation of an incident and ~~develop a written~~ document an incident report that includes:
1. The date and time of the incident;
2. The name of the patient;

3. ~~Description~~ A description of the incident;
4. Names of individuals who observed the incident;
5. Action taken by patient care staff and employees during the incident ~~or~~ and immediately following the incident; and
6. Action taken by the patient care staff and employees to prevent the incident from occurring in the future.

C. A medical director shall ensure that the ~~written~~ incident report is:
1. Submitted to the Department and, if the incident involved a licensed individual, the applicable ~~a~~ professional licensing board~~, if applicable,~~ within 10 calendar days ~~from~~ after the date of the notification in subsection (A); and
2. Maintained in the physical facilities for at least two years ~~from~~ after the date of the ~~report~~ incident.

R9-10-1505. Personnel Qualifications and Records

A licensee shall ensure that:
1. A physician who performs an abortion demonstrates to the medical director that the physician is competent to perform an abortion by:
   a. The submission of documentation of education and experience; and
   b. Observation by or interaction with the medical director;
2. Surgical assistants and volunteers who provide counseling and patient advocacy receive training in these specific responsibilities and any other responsibilities assigned and that documentation is maintained in the individual's personnel file of the training received;
3. An individual who performs an ultrasound provides documentation that the individual is:
   a. A physician;
   b. A physician assistant, registered nurse practitioner, or nurse who completed a hands-on course in performing ultrasounds under the supervision of a physician; or
   c. An individual who:
      i. Completed a hands-on course in performing ultrasounds under the supervision of a physician, and
      ii. Is not otherwise precluded by law from performing an ultrasound;
4. An individual has completed a course for the type of ultrasound the individual performs;
5. A personnel file for each member of the patient care staff and each volunteer is maintained either electronically or in writing and includes:
   a. The individual's name~~,~~ and position title~~,~~; ~~and~~
   b. ~~the~~ The first and, if applicable, the last date of employment or volunteer service~~, if applicable~~;
   b. Verification of qualifications, training, or licensure, ~~if~~ as applicable;
   c. Documentation of cardiopulmonary resuscitation certification, ~~if~~ as applicable;
   d. Documentation of verification of competency, as required in subsection (1), and signed and dated by the medical director;
   e. Documentation of training for surgical assistants and volunteers; and
   f. Documentation of completion of a course as required in subsection (3), for an individual performing ultrasounds; and
6. Personnel files are maintained in the physical facilities for at least two years from the ending date of employment or volunteer service.

R9-10-1506. Staffing Requirements

A. A licensee shall ensure that there ~~are~~ is a sufficient number of patient care staff and employees to:
1. Meet the requirements of this Article;
2. Ensure the health and safety of a patient; and
3. Meet the needs of a patient based on the patient's medical evaluation.

B. A licensee shall ensure that:
1. A member of the patient care staff, except for a surgical assistant, who is current in cardiopulmonary resuscitation certification is in the physical facilities until all patients are discharged;
2. A physician, with admitting privileges at ~~an accredited hospital in this state~~ a health care institution that is classified by the director as a hospital according to A.R.S. § 36-405(B), remains on the premises of the abortion clinic until all patients who received a medication abortion are stable and ready to leave ~~the recovery room~~; ~~and~~
3. A physician, with admitting privileges at a health care institution that is classified by the director as a hospital according to A.R.S. § 36-405(B) and that is within 30 miles of the abortion clinic by road, as defined in A.R.S. § 17-451, remains on the abortion clinic's premises until all patients who received a surgical abortion are stable and ready to leave the recovery room; and
~~3.~~4. A physician, a nurse, a registered nurse practitioner, a physician assistant, or, 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, a medical assistant under the direct supervision of the physician:
   a. Monitors each patient during the patient's recovery following the abortion; and
   b. Remains in the ~~facility~~ abortion clinic until each patient is discharged by a physician.

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 refuse treatment, or withdraw consent for treatment;
2. To have medical records kept confidential; and
3. To be informed of:
   a. Billing procedures and financial liability before abortion services are provided;
   b. Proposed medical or surgical procedures, associated risks, possible complications, and alternatives;
   c. Counseling services that are provided in the physical facilities; and
   d. ~~If an ultrasound is performed the,~~ The right to review the ultrasound results with a physician, a physician assistant, a registered nurse practitioner, or a registered nurse before the abortion procedure.

R9-10-1508. Abortion Procedures

A. A medical director shall ensure that a medical evaluation of a patient is conducted before ~~performing an~~ the patient's abortion is performed ~~and~~ 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; and
   3. The following laboratory tests:
      a. A urine or blood test to determine pregnancy ~~if an ultrasound examination is not performed~~;
      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.

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 estimates the gestational age of the fetus, and records the estimated age in the patient's medical record. The estimated age is based upon:
   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. ~~If a physical examination or other information obtained from the patient or laboratory tests indicates the gestational age of the fetus is greater than 12 weeks, a~~ A medical director shall ensure that:
   1. An ultrasound of a patient is performed by an individual who meets the requirements in R9-10-1505(3);
   2. An ultrasound estimate of gestational age of a fetus is performed using methods and tables or charts published in a nationally recognized medical journal;
   3. An original patient ultrasound print 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 is reviewed with the patient by a physician, ~~a~~ physician assistant, ~~a~~ registered nurse practitioner, or ~~a~~ registered nurse.

E. A medical director shall ensure that before an abortion is performed on a patient:
   1. Written consent is signed and dated by the patient or the patient's ~~representative~~ legal guardian; and
   2. Information is provided to the patient on the abortion procedure including alternatives, risks, and potential complications.

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 any medication, drug, or substance used to induce an abortion is administered in compliance with the protocol authorized by the United States Food and Drug Administration and that is outlined in the final printing labeling instructions for that medication, drug, or substance.

~~G.~~**H.** A medical director shall ensure that:
1. Patient care staff monitor the patient's vital signs throughout ~~the~~ 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; and
3. If a viable fetus shows signs of life:
   a. Resuscitative measures are used to support life;
   b. The viable fetus is transferred as required in R9-10-1509; and
   c. Resuscitative measures and the transfer are documented.

~~H.~~**I.** A medical director shall ensure that following the abortion procedure:
1. A patient's vital signs and bleeding are monitored by a physician, ~~a~~ nurse, ~~a~~ registered nurse practitioner, ~~a~~ physician assistant, or, 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, a medical assistant under the direct supervision of the physician to ensure the patient's health and safety; and
2. A patient remains in the recovery room or recovery area until a physician, ~~a~~ physician assistant, ~~a~~ registered 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.

~~I.~~**J.** A medical director shall ensure that follow-up care includes:
1. With a patient's consent, a telephone call to the patient by a member of the patient care staff, except a surgical assistant, within 24 hours ~~of~~ after the patient's discharge following a surgical abortion to assess the patient's recovery. If the patient care staff is unable to speak with the patient, for any reason, the attempt to contact the patient is documented in the patient's medical record; ~~and~~
2. ~~A~~ Following a surgical abortion, a follow-up visit offered and scheduled, if requested, no more than 21 days after the abortion. 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; and
3. Following a medication abortion, a follow-up visit offered and scheduled between seven and 21 days after the initial dose of a substance used to induce an abortion. The follow-up visit shall include:
   a. A urine pregnancy test; and
   b. An assessment of the degree of bleeding.

~~J.~~**K.** If a continuing pregnancy is suspected as a result of the follow-up visit required in subsection ~~(I)(2)~~ (J)(2) or (J)(3), a physician who performs abortions shall be consulted.

R9-10-1509. Patient Transfer and Discharge

A. A medical director shall ensure that:
1. A patient is transferred to a hospital for an emergency involving the patient;
2. A viable fetus requiring emergency care is transferred to a hospital;
3. A patient transfer is documented in the patient's medical record; and
4. Documentation of a medical evaluation, treatment given, and laboratory~~,~~ and diagnostic information is transferred with a patient.

B. A medical director shall ensure that before a patient is discharged:
1. A physician signs the patient's discharge order; and
2. A patient receives ~~written information~~ follow-up instructions at discharge that ~~includes~~ include:
   a. Signs of possible complications;
   b. When to access medical ~~care~~ services in response to complications;
   c. A telephone number of an individual or entity to contact for medical emergencies;
   d. ~~Instructions~~ Information and precautions for resuming vaginal intercourse after the abortion; and
   e. ~~Instructions~~ Information specific to the patient's abortion or condition.

R9-10-1510. Medications and Controlled Substances

A medical director shall ensure that:
1. The abortion clinic complies with the requirements for medications and controlled substances in A.R.S. Title 32, Chapter 18, and A.R.S. Title 36, Chapter 27;
2. A medication is administered in compliance with an order from a physician, physician assistant, registered nurse practitioner, or as otherwise provided by law;
3. A medication is administered to a patient by a physician or as otherwise provided by law;
4. Medications and controlled substances are maintained in a locked area in the physical facilities;
5. Only personnel designated by ~~in the abortion clinic's~~ policies and procedures have access to the locked area contain-

ing ~~the~~ medications and controlled substances;
6. Expired, mislabeled, or unusable medications and controlled substances are disposed of according to ~~the abortion clinic's~~ policies and procedures;
7. ~~Medication errors and adverse reactions~~ A medication error or an adverse reaction, including any actions taken in response to the medication ~~errors~~ error or adverse ~~reactions~~ reaction, ~~are~~ is immediately reported to the medical director and licensee, and recorded in the patient's medical record;
8. Medication information is maintained in a patient's medical record and contains:
   a. The patient's name, age, and weight;
   b. The medications the patient is currently taking; and
   c. Allergies or sensitivities to medications, antiseptic solutions, or latex; and
9. If medication is administered to a patient, the following are documented in the patient's medical record:
   a. The date and time of administration;
   b. The name, strength, dosage form, amount of medication, and route of administration; and
   c. The identification and signature of the individual administering the medication.

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~~ 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, ~~if applicable,~~ including the original print, ~~as~~ required in R9-10-1508(D);
   g. Each consent form signed by the patient or the patient's ~~representative~~ legal guardian;
   h. ~~A record of all orders~~ Orders issued by a physician, physician assistant or registered nurse practitioner;
   i. A record of ~~all~~ 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 ~~the abortion clinic's~~ 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 ~~from~~ 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 ~~from~~ after the date of the patient's discharge; and
6. Vital records and vital statistics are retained according to A.R.S. § 36-343~~; and.~~
~~7. If an abortion clinic ceases operations, the Department is notified in writing, not less than 30 days before ceasing operations, of the location of the abortion clinic's medical records.~~

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 ~~facility~~ 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~~ 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~~, if applicable, including the original print as~~ required in R9-10-1508(D);
   g. Each consent form signed by the patient or the patient's representative;
   h. ~~A record of all orders~~ Orders issued by a physician, physician assistant, or registered nurse practitioner;
   i. A record of ~~all~~ 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. The Department shall have access to or copies of unredacted patient medical records only ~~pursuant~~ 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 electronic file with access to the secured drawer, cabinet, or file limited to those individuals who have access to the patient medical records ~~pursuant~~ according to subsection (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. 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 ~~an abortion clinic's~~ 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. ~~A computer code~~ 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 ~~a computer code~~ an electronic signature is used:
   a. An individual's rubber stamp or ~~computer code~~ electronic signature is not used by another individual;
   b. The individual who uses a rubber stamp or ~~computer code~~ electronic signature signs a statement that the individual is responsible for the use of the rubber stamp or the ~~computer code~~ 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.

R9-10-1512. Environmental and Safety Standards

A licensee shall ensure that:

1. Physical facilities:
   a. Provide lighting and ventilation to ensure the health and safety of a patient;
   b. Are maintained in a clean condition;
   c. Are free from a condition or situation that may cause a patient to suffer physical injury;
   d. Are maintained free from insects and vermin; and
   e. Are smoke-free;
2. A warning notice is placed at the entrance to a room or area where oxygen is in use;
3. Soiled linen and clothing are kept:
   a. ~~in~~ In a covered container, and ~~in a~~
   b. ~~separate area~~ Separate from clean linen and clothing;
4. Personnel wash hands after each direct patient contact and after handling soiled linen, soiled clothing, or biohazardous medical waste;
5. A written emergency plan is ~~developed~~ established, documented, and implemented that includes procedures for protecting the health and safety of patients and other individuals in a fire, natural disaster, loss of electrical power, or threat or incidence of violence; and
6. An evacuation drill is conducted at least once every six months that includes all personnel in the physical facilities the day of the evacuation drill. Documentation of the evacuation drill is maintained in the physical facilities for one year ~~from~~ after the date of the evacuation drill and includes:
   a. The date and time of the evacuation drill; and
   b. The names of personnel participating in the evacuation drill.

R9-10-1513. Equipment Standards

A licensee shall ensure that:

1. Equipment and supplies are maintained in a quantity sufficient to meet the needs of ~~all~~ patients present in the abortion clinic;
2. Equipment to monitor vital signs is in each room in which an abortion is performed;
3. A surgical or gynecologic examination table is used for an abortion;
4. The following equipment and supplies are ~~provided~~ available in the abortion clinic:
   a. Equipment to measure blood pressure;
   b. A stethoscope;
   c. A scale for weighing a patient;
   d. Supplies for obtaining specimens~~,~~ and cultures and ~~other~~ for laboratory tests; and
   e. Equipment and supplies for use in a medical emergency including:
      i. Ventilatory assistance equipment;
      ii. Oxygen source;
      iii. Suction apparatus; and
      iv. Intravenous fluid equipment and supplies; and
   f. Ultrasound equipment;
5. In addition to the requirements in subsection (4), the following equipment is available for an abortion procedure performed after the first trimester:
   ~~a. Ultrasound equipment;~~
   ~~b.~~a. Drugs to support cardiopulmonary function; and
   ~~c.~~b. Equipment to monitor cardiopulmonary status;
6. Equipment and supplies are clean and, if applicable, sterile~~, if applicable,~~ before each use;
7. Equipment required in this Section is maintained in working order, tested and calibrated at least once every 12 months or according to the manufacturer's recommendations, and used according to the manufacturer's recommendations; and
8. Documentation of each equipment test, calibration, and repair is maintained in the physical facilities for one year ~~from~~ after the date of the testing, calibration, or repair and provided to the Department for review within two hours ~~from the time~~ after the Department requests the documentation.

R9-10-1514. Physical Facilities

A. A licensee shall ensure that an abortion clinic complies with all local building codes, ordinances, fire codes, and zoning requirements. If there are no local building codes, ordinances, fire codes, or zoning requirements, the abortion clinic shall comply with the applicable codes and standards incorporated by reference in A.A.C. R9-1-412 that were in effect on the date the abortion clinic's architectural plans and specifications were submitted to the Department for approval.

B. A licensee shall ensure that an abortion clinic provides areas or rooms:

1. That provide privacy for:
   a. A patient's interview, medical evaluation, and counseling;
   b. A patient to dress; and
   c. Performing an abortion procedure;
2. For personnel to dress;
3. With a sink ~~in working order~~ and a flushable toilet in working order;
4. For cleaning and sterilizing equipment and supplies;
5. For storing medical records;
6. For storing equipment and supplies;
7. For hand washing before the abortion procedure; and
8. For a patient recovering after an abortion.

C. A licensee shall ensure that an abortion clinic has an emergency exit to accommodate a stretcher or gurney.

R9-10-1515. Enforcement

A. For an abortion clinic that is not in substantial compliance or that is in substantial compliance but refuses to carry out a plan of correction acceptable to the Department, the Department may:
1. Assess a civil penalty according to A.R.S. § 36-431.01,
2. Impose an intermediate sanction according to A.R.S. § 36-427,
3. Suspend or revoke a license according to A.R.S. § 36-427,
4. Deny a license, or
5. Bring an action for an injunction according to A.R.S. § 36-430.

B. In determining the appropriate enforcement action, the Department shall consider the threat to the health, safety, and welfare of the abortion clinic's patients or the general public, including:
1. Whether the abortion clinic has repeated violations of statutes or rules;
2. Whether the abortion clinic has engaged in a pattern of noncompliance; and
3. The type, severity, and number of violations.

Exhibit 5

Christopher A. LaVoy
State Bar No. 016609

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SUPERIOR COURT OF ARIZONA

MARICOPA COUNTY

Planned Parenthood Arizona, Inc.; William Richardson, M.D.; and William H. Richardson, M.D., P.C., doing business as Tucson Women's Center, Plaintiffs, vs. Will Humble, Director of the Arizona Department of Health Services, in his official capacity, Defendants.	Case No. **DECLARATION OF TISEME ZEGEYE**

I, TISEME ZEGEYE, do hereby declare as follows:

1. I am an attorney for the Center for Reproductive Rights and am duly admitted to practice in New York. I am assisting David Brown, admitted in this matter as counsel for Plaintiff William Richardson, M.D., and submit this declaration on behalf of all Plaintiffs. If called to testify, I would state the following based on my own personal knowledge:

2. On February 12, 2014, I reviewed the Arizona Department of Health Services ("ADHS") Office of Administrative Counsel & Rules website (azdhs.gov/ops/oacrr/rules/rulemakings/process.htm), clicked on the link entitled "Exempt Rulemaking," and saved a copy of the web resulting web page, entitled "Exempt Rulemaking

Process." A true and correct copy of the web page I saved on February 12, 2014 is attached as Exhibit A.

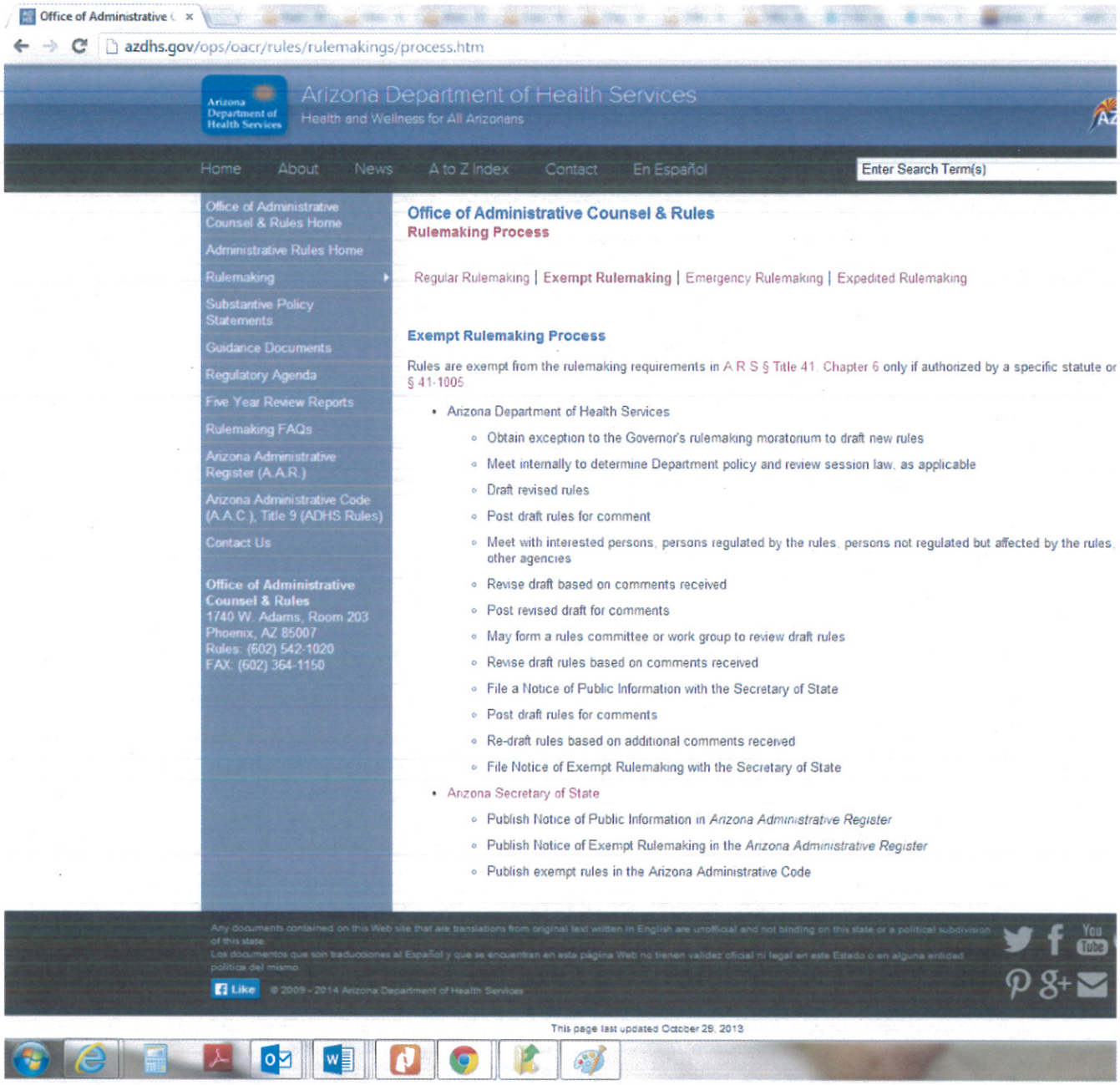
3. The Internet Archive is a non-profit organization that preserves "snapshots" of the content of web pages and other internet material for history and posterity, much as a conventional library preserves books. *See* "About the Internet Archive," https://archive.org/about/. On April 28, 2014, I visited the website of the Internet Archive to see if it contained any records of the contents of ADHS' Administrative Counsel & Rules website from other dates. I found two such records, purporting to date from September 21, 2013, and March 27, 2014. Although the formatting is slightly different, it appears that the policy appearing under "Exempt Rulemaking Process" in each of them is identical to the policy I had personally viewed saved on February 12, 2014. A true and correct copy of each of these two saved web pages I saved on April 28, 2014, are attached as Exhibit B and Exhibit C.

I declare under the penalty of perjury that the foregoing is true and correct.

Dated 5/8/2014.

TISEME ZEGEYE

Exhibit A


Office of Administrative
azdhs.gov/ops/oacr/rules/rulemakings/process.htm
Arizona Department of Health Services
Health and Wellness for All Arizonans
Home
About
News
A to Z Index
Contact
En Español
Enter Search Term(s)
Office of Administrative Counsel & Rules Home
Administrative Rules Home
Rulemaking
Substantive Policy Statements
Guidance Documents
Regulatory Agenda
Five Year Review Reports
Rulemaking FAQs
Arizona Administrative Register (A.A.R.)
Arizona Administrative Code (A.A.C.), Title 9 (ADHS Rules)
Contact Us
Office of Administrative Counsel & Rules
1740 W. Adams, Room 203
Phoenix, AZ 85007
Rules: (602) 542-1020
FAX: (602) 364-1150
Office of Administrative Counsel & Rules
Rulemaking Process
Regular Rulemaking | Exempt Rulemaking | Emergency Rulemaking | Expedited Rulemaking
Exempt Rulemaking Process
Rules are exempt from the rulemaking requirements in A.R.S. § Title 41, Chapter 6 only if authorized by a specific statute or § 41-1005.
Arizona Department of Health Services
Obtain exception to the Governor's rulemaking moratorium to draft new rules
Meet internally to determine Department policy and review session law, as applicable
Draft revised rules
Post draft rules for comment
Meet with interested persons, persons regulated by the rules, persons not regulated but affected by the rules, other agencies
Revise draft based on comments received
Post revised draft for comments
May form a rules committee or work group to review draft rules
Revise draft rules based on comments received
File a Notice of Public Information with the Secretary of State
Post draft rules for comments
Re-draft rules based on additional comments received
File Notice of Exempt Rulemaking with the Secretary of State
Arizona Secretary of State
Publish Notice of Public Information in Arizona Administrative Register
Publish Notice of Exempt Rulemaking in the Arizona Administrative Register
Publish exempt rules in the Arizona Administrative Code
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This page last updated October 29, 2013

Exhibit B

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ADHS

Arizona Department of Health Services

Health and Wellness for All Arizonans

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Due to scheduled maintenance, many ADHS online websites and applications will be unavailable Sunday, September 8, 2013 from 1:00 a.m. to 6:30 a.m.

Office of Administrative Counsel & Rules

Rulemaking Process

- Regular Rulemaking
- Exempt Rulemaking
- Emergency Rulemaking
- Expedited Rulemaking

Regular Rulemaking Process

- Arizona Department of Health Services
  - Rule Drafting
    - Obtain exception to the Governor's rulemaking moratorium to draft new rules
    - File a Notice of Rulemaking Docket Opening with the Secretary of State
    - Meet internally to determine Department policy
    - Draft revised rules
    - Post draft rules for comment
    - Meet with interested persons, persons regulated by the rules, persons not regulated but affected by the rules, and other agencies
    - Revise draft based on comments received
    - Post revised draft for comments
    - May form a rules committee or work group to review draft rules
    - Revise draft rules based on comments received
    - Draft economic impact statement (EIS)
  - Formal Rulemaking
    - File a Notice of Proposed Rulemaking with the Secretary of State
    - Hold oral proceedings no sooner than 30 days after publication of the Notice of Proposed Rulemaking
    - Receive public comments (written/oral), make changes to the proposed rules, and finalize the EIS
    - Submit a Notice of Final Rulemaking to the Governor's Regulatory Review Council for approval
- Governor's Regulatory Review Council
  - Review and comment on final rulemaking
  - Hold regularly scheduled public meetings to review final rulemakings
  - Submit approved Notices of Final Rulemaking to the Secretary of State
- Arizona Secretary of State
  - Publish Notice of Rulemaking Docket Opening in the Arizona Administrative Register
  - Publish Notice of Proposed Rulemaking in the Arizona Administrative Register
  - Publish Notice of Final Rulemaking in the Arizona Administrative Register
  - Publish the final rules in the Arizona Administrative Code

Exempt Rulemaking Process

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- Arizona Secretary of State
    - Publish Notice of Public Information in Arizona Administrative Register
    - Publish Notice of Exempt Rulemaking in the Arizona Administrative Register
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Emergency Rulemaking Process

An agency may make a finding that a rule is necessary as an emergency measure according to A.R.S. § 41-1026

- Arizona Department of Health Services
    - Obtain exception to the Governor's rulemaking moratorium to draft new rules
    - Meet internally to determine Department policy or case law, as applicable
    - Draft revised rules
    - Revised draft rules based on comments received
    - Submit Notice of Emergency Rulemaking to Attorney General's Office
- Arizona Attorney General
    - Review and approve Notice of Emergency Rulemaking
    - Files Notice of Emergency Rulemaking with the Secretary of State
- Arizona Secretary of State
    - Publish Notice of Emergency Rulemaking in the Arizona Administrative Register
    - Publish the emergency rules in the Arizona Administrative Code
- Arizona Department of Health Services
    - The Department will complete a regular rulemaking within 180 days after the Attorney General files the Notice of Emergency Rulemaking with the Secretary of State.

Expedited Rulemaking Process

An agency may conduct expedited rulemaking according to A.R.S. § 41-1027 if the rulemaking does not increase the cost of regulatory compliance, increase a fee or reduce procedural rights of persons regulated, and helps to correct or simplify existing rules.

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This page last updated August 22, 2013

Exhibit C

ADHS

Arizona Department of Health Services

Health and Wellness for All Arizonans

Office of Administrative Counsel & Rules
1740 W. Adams, Room 203
Phoenix, AZ 85007
Rules: (602) 542-1020
FAX: (602) 364-1150

Due to technical difficulties, all Medical Marijuana online applications will be unavailable until 8AM, Tuesday, March 11th. We apologize for the inconvenience and thank you for your patience.

Office of Administrative Counsel & Rules

Rulemaking Process

- Regular Rulemaking
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- Arizona Secretary of State
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This page last updated October 29, 2013

Exhibit 6

TITLE 9. HEALTH SERVICES

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES

SECTION

ARTICLE 15. ABORTION CLINICS

R9-10-1501. Definitions

In addition to the definitions in A.R.S. §§ 36-401, 36-449.01, 36-449.03 and R9-10-101, the following definitions apply in this Article, unless ~~the context~~ otherwise ~~requires~~ specified:

~~1. *"Abortion" means the use of a surgical instrument or a machine with the intent to terminate a woman's pregnancy for reasons other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, to terminate an ectopic pregnancy or to remove a dead fetus. Abortion does not include birth control devices or oral contraceptives.*~~

~~2. *"Abortion clinic" means 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.*~~

~~3.~~ 1. "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.~~ 2. "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 in this state and agrees to do so.

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

~~6. "Biohazardous medical waste" means cultures and stocks, waste human blood and blood products, bodily fluids, uterine contents, and discarded medical sharps.~~

~~7.~~ 3. "Conspicuously posted" means placed at a location within an abortion clinic that is accessible and visible to patients and the public.

~~8. "Controlled substance" means the same as defined in A.R.S. § 32-1901(12).~~

~~9.~~ 4. "Course" means hands-on practice under the supervision of a physician, training, or education.

~~10. "Current" means up-to-date, extending to the present time.~~

~~11. "Department" means the same as defined in A.R.S. § 36-401.~~

~~12. "Direction" means the same as defined in A.R.S. § 36-401.~~

~~13.~~ 5. "Discharge" means a patient no longer requires the medical services, nursing services, or health-related services provided by the abortion clinic.

~~14. "Documentation" means written, supportive evidence.~~

~~15.~~ 6. "Emergency" means a potentially life-threatening occurrence that requires an immediate response or medical treatment.

~~16.~~ 7. "Employee" means an individual who receives compensation from a licensee, but does not provide medical services, nursing services, or health-related services.

~~17. *"Fetus" means an individual human organism from fertilization until birth.*~~

~~18.~~ 8. "First trimester" means 1 through 14 weeks as measured from the first day of the last menstrual period or 1 through 12 weeks as measured from the date of fertilization.

~~19. "Gestational age" means the number of completed weeks of the unborn fetus as calculated from the first day of the last menstrual period or the date of fertilization.~~

~~20. "Health-related services" means the same as defined in A.R.S. § 36-401.~~

~~21. "Immediately" means without delay.~~

~~22.~~ 9. "Incident" means an abortion related patient death or serious injury to a patient or viable fetus.

~~23. "Infection control" means to identify, prevent, monitor, and minimize infections.~~

~~24.~~ 10. "Licensee" means an individual, a partnership, an association, a limited liability company, or corporation authorized by the Department to operate an abortion clinic.

~~25.~~ 11. "Local" means under the jurisdiction of a city or county in Arizona.

~~26.~~ 12. "Medical director" means a physician who is responsible for the direction of the medical services, nursing services, and health-related services provided to patients at an abortion clinic.

~~27.~~ 13. "Medical evaluation" means obtaining a patient's medical history, performing a physical examination of a patient's body, and conducting laboratory tests as provided in R9-10-1508.

~~28. "Medical services" means the same as defined in A.R.S. § 36-401~~.

~~29. "Medication" means a prescription medication as defined in A.R.S. § 32-1901 or a nonprescription drug or over-the-counter drug as defined in A.R.S. § 32-1901.~~

~~30.~~ 14. "Monitor" means to observe and document, continuously or intermittently, the values of certain physiologic variables on a patient such as pulse, blood pressure, oxygen saturation, respiration and blood loss.

~~31.~~ 15. "Nationally recognized medical journal" means any publication distributed nationally that contains peer-reviewed medical information, such as the *American Journal of Radiology* or the *Journal of Ultrasound in Medicine*.

~~32. "Nurse" means an individual licensed and in good standing as a registered nurse or a practical nurse according to A.R.S. Title 32, Chapter 15.~~

~~33. "Nurse practitioner" means an individual licensed and in good standing as a registered nurse practitioner according to A.R.S. Title 32, Chapter 15.~~

~~34. "Nursing services" means the same as defined in A.R.S. § 36-401.~~

~~35.~~ 16. "Patient" means a female receiving medical services, nursing services, or health-related services related to an abortion.

~~36.~~ 17. "Patient care staff" means a physician, registered nurse practitioner, nurse, physician assistant, or surgical assistant who provides medical services, nursing services, or health-related services to a patient.

~~37.~~ 18. "~~Patient~~ Patient's representative" means a patient's legal guardian, an individual acting on behalf of a patient with the written consent of the patient, or a surrogate according to A.R.S. § 36-3201~~(13)~~.

~~38.~~ 19. "Patient transfer" means relocating a patient requiring medical services from an abortion clinic to another health care institution.

~~39.~~ 20. "Personally identifiable patient information" means:

a. The name, address, telephone number, e-mail address, Social Security number, and birth date of:
   i. The patient,
   ii. The patient's representative,
   iii. The patient's emergency contact,
   iv. The patient's children,
   v. The patient's spouse,
   vi. The patient's sexual partner, and
   vii. Any other individual identified in the patient's medical record other than patient care staff;

b. The patient's place of employment;

c. The patient's referring physician;

d. The patient's insurance carrier or account;

e. Any "individually identifiable health information" as proscribed in 45 CFR 164-514; and

f. Any other information in the patient's medical record that could reasonably lead to the identification of the patient.

~~40.~~ 21. "Personnel" means patient care staff, employees, and volunteers.

~~41.~~ 22. "Physical facilities" means property that is:

a. Designated on an application for a license by the applicant; and

b. Licensed to provide services by the Department according to A.R.S. Title 36, Chapter 4.

~~42. "Physician" means an individual licensed according to A.R.S. Title 32, Chapter 13 or 17.~~

~~43. "Physician assistant" means an individual licensed according to A.R.S. Title 32, Chapter 25.~~

~~44. *"Serious injury" means an injury that occurs at an abortion clinic and that creates a serious risk of substantial impairment of a major body organ.*~~

~~45. *"Supervision" means direct overseeing and inspection of the act of accomplishing a function or activity.*~~

~~46.~~ 23. "Surgical assistant" means an individual who is not licensed as a physician, physician assistant, registered nurse practitioner, or nurse who performs duties as directed by a physician, physician assistant, registered nurse practitioner or nurse.

~~47. "Viable fetus" means the same as defined in A.R.S. § 36-2301.01.~~

~~48.~~ 25. "Volunteer" means an individual who, without compensation, performs duties as directed by a member of the patient care staff at an abortion clinic.

R9-10-1502. Application Requirements

An applicant shall submit an application for licensure that meets the requirements in A.R.S. § 36-422 and 9 A.A.C. 10, Article 1.

R9-10-1503. Administration

A. A licensee is responsible for the organization and management of an abortion clinic.

B. A licensee shall:

~~1. Ensure compliance with federal and state laws, rules, and local ordinances;~~

~~2.~~ 1. Adopt policies and procedures for the administration and operation of an abortion clinic;

~~3.~~ 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;

~~4.~~ 3. Ensure that the Department's director or director's ~~designee~~ 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;

~~5.~~4. 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's Office of Medical Facilities~~ 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 ~~developed~~ 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.

R9-10-1504. 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; and

2. For a serious injury, written notification within 10 calendar days ~~from~~ after the date of the serious injury.

B. A medical director shall conduct an investigation of an incident and ~~develop a written~~ document an incident report that includes:

1. The date and time of the incident;
2. The name of the patient;
3. ~~Description~~ A description of the incident;
4. Names of individuals who observed the incident;
5. Action taken by patient care staff and employees during the incident ~~or~~ and immediately following the incident; and
6. Action taken by the patient care staff and employees to prevent the incident from occurring in the future.

C. A medical director shall ensure that the ~~written~~ incident report is:
1. Submitted to the Department and, if the incident involved a licensed individual, the applicable ~~a~~ professional licensing board~~, if applicable,~~ within 10 calendar days ~~from~~ after the date of the notification in subsection (A); and
2. Maintained in the physical facilities for at least two years ~~from~~ after the date of the ~~report~~ incident.

R9-10-1505. Personnel Qualifications and Records

A licensee shall ensure that:
1. A physician who performs an abortion demonstrates to the medical director that the physician is competent to perform an abortion by:
   a. The submission of documentation of education and experience; and
   b. Observation by or interaction with the medical director;
2. Surgical assistants and volunteers who provide counseling and patient advocacy receive training in these specific responsibilities and any other responsibilities assigned and that documentation is maintained in the individual's personnel file of the training received;
3. An individual who performs an ultrasound provides documentation that the individual is:
   a. A physician;
   b. A physician assistant, registered nurse practitioner, or nurse who completed a hands-on course in performing ultrasounds under the supervision of a physician; or
   c. An individual who:
      i. Completed a hands-on course in performing ultrasounds under the supervision of a physician, and
      ii. Is not otherwise precluded by law from performing an ultrasound;
4. An individual has completed a course for the type of ultrasound the individual performs;

5. A personnel file for each member of the patient care staff and each volunteer is maintained either electronically or in writing and includes:
   a. The individual's name~~,~~ and position title~~,~~; and
   b. ~~the~~ The first and, if applicable, the last date of employment or volunteer service~~, if applicable~~;
   b. Verification of qualifications, training, or licensure, ~~if~~ as applicable;
   c. Documentation of cardiopulmonary resuscitation certification, ~~if~~ as applicable;
   d. Documentation of verification of competency, as required in subsection (1), and signed and dated by the medical director;
   e. Documentation of training for surgical assistants and volunteers; and
   f. Documentation of completion of a course as required in subsection (3), for an individual performing ultrasounds; and
6. Personnel files are maintained in the physical facilities for at least two years from the ending date of employment or volunteer service.

R9-10-1506. Staffing Requirements

A. A licensee shall ensure that there ~~are~~ is a sufficient number of patient care staff and employees to:
   1. Meet the requirements of this Article;
   2. Ensure the health and safety of a patient; and
   3. Meet the needs of a patient based on the patient's medical evaluation.

B. A licensee shall ensure that:
   1. A member of the patient care staff, except for a surgical assistant, who is current in cardiopulmonary resuscitation certification is in the physical facilities until all patients are discharged;
   2. A physician with admitting privileges at ~~an accredited~~ a health care institution that is classified by the director as a hospital according to A.R.S. § 36-405(B), remains on the premises of the abortion clinic until all patients who received a medication abortion are stable and ready to leave the recovery room;
   3. A physician, with admitting privileges at a health care institution that is classified by the director as a hospital according to A.R.S. § 36-405(B) and that is within thirty miles of the abortion clinic by road, as defined in A.R.S. § 17-451, remains on the abortion clinic's premises until all patients who received a surgical abortion are stable and ready to leave the recovery room; and

~~3.~~ 4. A physician, a nurse, a registered nurse practitioner, a physician assistant, or, 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, a medical assistant under the direct supervision of the physician:

a. Monitors each patient during the patient's recovery following the abortion; and

b. Remains in the ~~facility~~ abortion clinic until each patient is discharged by a physician.

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 refuse treatment, or withdraw consent for treatment;
2. To have medical records kept confidential; and
3. To be informed of:
   a. Billing procedures and financial liability before abortion services are provided;
   b. Proposed medical or surgical procedures, associated risks, possible complications and alternatives;
   c. Counseling services that are provided in the physical facilities; and
   d. ~~If an ultrasound is performed the,~~ The right to review the ultrasound results with a physician, a physician assistant, a registered nurse practitioner, or a registered nurse before the abortion procedure

R9-10-1508. Abortion Procedures

A. A medical director shall ensure that a medical evaluation of a patient is conducted before ~~performing an~~ the patient's abortion is performed ~~and~~ 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; and
3. The following laboratory tests:
   a. A urine or blood test to determine pregnancy ~~if an ultrasound examination is not performed~~;
   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.

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 estimates the gestational age of the fetus, and records the estimated age in the patient's medical record. The estimated age is based upon:

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. ~~If a physical examination or other information obtained from the patient or laboratory tests indicates the gestational age of the fetus is greater than 12 weeks, a~~ A medical director shall ensure that:

1. An ultrasound of a patient is performed by an individual who meets the requirements in R9-10-1505(3);
2. An ultrasound estimate of gestational age of a fetus is performed using methods and tables or charts published in a nationally recognized medical journal;
3. An original patient ultrasound print 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 is reviewed with the patient by a physician, ~~a~~ physician assistant, ~~a~~ registered nurse practitioner, or ~~a~~ registered nurse

E. A medical director shall ensure that before an abortion is performed on a patient:

1. Written consent is signed and dated by the patient or the patient's ~~representative~~ legal guardian; and

2. Information is provided to the patient on the abortion procedure including alternatives, risks, and potential complications.

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 any medication, drug, or substance used to induce an abortion is administered in compliance with the protocol authorized by the United States Food and Drug Administration and that is outlined in the final printing labeling instructions for that medication, drug, or substance.

~~G.~~ H. A medical director shall ensure that:

1. Patient care staff monitor the patient's vital signs throughout ~~the~~ 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; and
3. If a viable fetus shows signs of life:
   a. Resuscitative measures are used to support life;
   b. The viable fetus is transferred as required in R9-10-1509; and
   c. Resuscitative measures and the transfer are documented.

~~H.~~ I. A medical director shall ensure that following the abortion procedure:

1. A patient's vital signs and bleeding are monitored by a physician, ~~a~~ nurse, ~~a~~ registered nurse practitioner, ~~a~~ physician assistant, or, 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, a medical assistant under the direct supervision of the physician to ensure the patient's health and safety; and
2. A patient remains in the recovery room or recovery area until a physician, ~~a~~ physician assistant, ~~a~~ registered 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.

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

1. With a patient's consent, a telephone call to the patient by a member of the patient care staff, except a surgical assistant, within 24 hours ~~of~~ after the patient's discharge following a surgical abortion to assess the patient's recovery. If the patient care staff is unable to

speak with the patient, for any reason, the attempt to contact the patient is documented in the patient's medical record; and

2. Following a surgical abortion, a follow-up visit offered and scheduled, if requested, no more than 21 days after the abortion. 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.
3. Following a medication abortion, a follow-up visit offered and scheduled, requested, between seven and 21 days after the initial dose of a substance used to induce an abortion. The follow-up visit shall include:
   a. A urine pregnancy test; and
   b. An assessment of the degree of bleeding.

~~J.~~ K. If a continuing pregnancy is suspected as a result of the follow-up visit required in subsection ~~(I)(2)~~ (J)(2) or (J)(3), a physician who performs abortions shall be consulted.

R9-10-1509. Patient Transfer and Discharge

A. A medical director shall ensure that:
1. A patient is transferred to a hospital for an emergency involving the patient;
2. A viable fetus requiring emergency care is transferred to a hospital;
3. A patient transfer is documented in the patient's medical record; and
4. Documentation of a medical evaluation, treatment given, and laboratory~~,~~ and diagnostic information is transferred with a patient.

B. A medical director shall ensure that before a patient is discharged:
1. A physician signs the patient's discharge order; and
2. A patient receives ~~written information~~ patient follow-up instructions at discharge that ~~includes~~ include:
   a. Signs of possible complications;
   b. When to access medical ~~care~~ services in response to complications;
   c. A telephone number of an individual or entity to contact for medical emergencies;
   d. ~~Instructions~~ Information and precautions for resuming vaginal intercourse after the abortion; and
   e. ~~Instructions~~ Information specific to the patient's abortion or condition.

R9-10-1510. Medications and Controlled Substances

A medical director shall ensure that:

1. The abortion clinic complies with the requirements for medications and controlled substances in A.R.S. Title 32, Chapter 18, and A.R.S. Title 36, Chapter 27.
2. A medication is administered in compliance with an order from a physician, physician assistant, registered nurse practitioner, or as otherwise provided by law;
3. A medication is administered to a patient by a physician or as otherwise provided by law;
4. Medications and controlled substances are maintained in a locked area in the physical facilities;
5. Only personnel designated by ~~in the abortion clinic's~~ policies and procedures have access to the locked area containing ~~the~~ medications and controlled substances;
6. Expired, mislabeled, or unusable medications and controlled substances are disposed of according to ~~the abortion clinic's~~ policies and procedures;
7. ~~Medication errors and adverse reactions~~ A medication error or an adverse reaction, including any actions taken in response to the medication ~~errors~~ error or adverse ~~reactions~~ reaction, ~~are~~ is immediately reported to the medical director and licensee, and recorded in the patient's medical record;
8. Medication information is maintained in a patient's medical record and contains:
    a. The patient's name, age, and weight;
    b. The medications the patient is currently taking; and
    c. Allergies or sensitivities to medications, antiseptic solutions, or latex; and
9. If medication is administered to a patient, the following are documented in the patient's medical record:
    a. The date and time of administration;
    b. The name, strength, dosage form, amount of medication, and route of administration; and
    c. The identification and signature of the individual administering the medication.

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~~ 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~~, if applicable,~~ including the original print as required in R9-10-1508(D);

g. Each consent form signed by the patient or the patient's ~~representative~~ legal guardian;

h. ~~A record of all orders~~ Orders issued by a physician, physician assistant or registered nurse practitioner;

i. A record of ~~all~~ 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 ~~the abortion clinic's~~ 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 ~~from~~ 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 ~~from~~ after the date of the patient's discharge; and

6. Vital records and vital statistics are retained according to A.R.S. § 36-343~~; and~~ .

~~7. If an abortion clinic ceases operations, the Department is notified in writing, not less than 30 days before ceasing operations, of the location of the abortion clinic's medical records.~~ (in Article 1)

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 ~~facility~~ 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~~ 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~~, if applicable, including the original print~~ as required in R9-10-1508(D);

g. Each consent form signed by the patient or the patient's representative;

h. ~~A record of all orders~~ Orders issued by a physician, physician assistant, or registered nurse practitioner;

i. A record of ~~all~~ 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. The Department shall have access to or copies of unredacted patient medical records only ~~pursuant~~ 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 electronic file with access to the secured drawer, cabinet, or file limited to those individuals who have access to the patient medical records ~~pursuant~~ according to subsection (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. 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 ~~an abortion clinic's~~ 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. ~~A computer code~~ 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 ~~a computer code~~ an electronic signature is used:

a. An individual's rubber stamp or ~~computer code~~ electronic signature is not used by another individual;

b. The individual who uses a rubber stamp or ~~computer code~~ electronic signature signs a statement that the individual is responsible for the use of the rubber stamp or the ~~computer code~~ 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.

R9-10-1512. Environmental and Safety Standards

A licensee shall ensure that:

1. Physical facilities:

a. Provide lighting and ventilation to ensure the health and safety of a patient;

b. Are maintained in a clean condition;

c. Are free from a condition or situation that may cause a patient to suffer physical injury;

d. Are maintained free from insects and vermin; and

e. Are smoke-free;

2. A warning notice is placed at the entrance to a room or area where oxygen is in use;

3. Soiled linen and clothing are kept:

a. ~~in~~ In a covered container, and ~~in a~~

b. ~~separate area~~ Separate from clean linen and clothing;

4 Personnel wash hands after each direct patient contact and after handling soiled linen, soiled clothing, or biohazardous medical waste;

5. A written emergency plan is ~~developed~~ established, documented, and implemented that includes procedures for protecting the health and safety of patients and other individuals in a fire, natural disaster, loss of electrical power, or threat or incidence of violence; and

6. An evacuation drill is conducted at least once every six months that includes all personnel in the physical facilities the day of the evacuation drill. Documentation of the evacuation drill is maintained in the physical facilities for one year ~~from~~ after the date of the evacuation drill and includes:

   a. The date and time of the evacuation drill; and

   b. The names of personnel participating in the evacuation drill.

R9-10-1513. Equipment Standards

A licensee shall ensure that:

1. Equipment and supplies are maintained in a quantity sufficient to meet the needs of ~~all~~ patients present in the abortion clinic;

2. Equipment to monitor vital signs is in each room in which an abortion is performed;

3. A surgical or gynecologic examination table is used for an abortion;

4. The following equipment and supplies are ~~provided~~ available in the abortion clinic:

   a. Equipment to measure blood pressure;

   b. A stethoscope;

   c. A scale for weighing a patient;

   d. Supplies for obtaining specimens~~,~~ and cultures and ~~other~~ for laboratory tests; and

   e. Equipment and supplies for use in a medical emergency including:

      i. Ventilatory assistance equipment;

      ii. Oxygen source;

      iii. Suction apparatus; and

      iv. Intravenous fluid equipment and supplies; and

   f. Ultrasound equipment;

5. In addition to the requirements in subsection (4), the following equipment is available for an abortion procedure performed after the first trimester:

   ~~a. Ultrasound equipment;~~

   ~~b.~~ a. Drugs to support cardiopulmonary function; and

   ~~c.~~ b. Equipment to monitor cardiopulmonary status;

6. Equipment and supplies are clean and, if applicable, sterile~~, if applicable,~~ before each use;
7. Equipment required in this Section is maintained in working order, tested and calibrated at least once every 12 months or according to the manufacturer's recommendations, and used according to the manufacturer's recommendations; and
8. Documentation of each equipment test, calibration, and repair is maintained in the physical facilities for one year ~~from~~ after the date of the testing, calibration, or repair and provided to the Department for review within two hours ~~from the time~~ after the Department requests the documentation.

R9-10-1514. Physical Facilities

A. A licensee shall ensure that an abortion clinic complies with all local building codes, ordinances, fire codes, and zoning requirements. If there are no local building codes, ordinances, fire codes, or zoning requirements, the abortion clinic shall comply with the applicable codes and standards incorporated by reference in A.A.C. R9-1-412 that were in effect on the date the abortion clinic's architectural plans and specifications were submitted to the Department for approval.

B. A licensee shall ensure that an abortion clinic provides areas or rooms:
1. That provide privacy for:
a. A patient's interview, medical evaluation, and counseling;
b. A patient to dress; and
c. Performing an abortion procedure;
2. For personnel to dress;
3. With a sink ~~in working order~~ and a flushable toilet in working order;
4. For cleaning and sterilizing equipment and supplies;
5. For storing medical records;
6. For storing equipment and supplies;
7. For hand washing before the abortion procedure; and
8. For a patient recovering after an abortion.

C. A licensee shall ensure that an abortion clinic has an emergency exit to accommodate a stretcher or gurney.

R9-10-1515. Enforcement

A. For an abortion clinic that is not in substantial compliance or that is in substantial compliance but refuses to carry out a plan of correction acceptable to the Department, the Department may:
1. Assess a civil penalty according to A.R.S. § 36-431.01,
2. Impose an intermediate sanction according to A.R.S. § 36-427,

3. Suspend or revoke a license according to A.R.S. § 36-427,

4. Deny a license, or

5. Bring an action for an injunction according to A.R.S. § 36-430.

B. In determining the appropriate enforcement action, the Department shall consider the threat to the health, safety and welfare of the abortion clinic's patients or the general public, including:

1. Whether the abortion clinic has repeated violations of statutes or rules,

2. Whether the abortion clinic has engaged in a pattern of noncompliance, and

3. The type, severity and number of violations.

Exhibit 7

NOTICE OF EXEMPT RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES

HEALTH CARE INSTITUTIONS: LICENSING

ARTICLE 15. ABORTION CLINICS

PREAMBLE

1.	Article, Part or Sections Affected (as applicable)	Rulemaking Action
	R9-10-1501	Amend
	R9-10-1502	Amend
	R9-10-1503	Amend
	R9-10-1504	Amend
	R9-10-1505	Amend
	R9-10-1506	Amend
	R9-10-1507	Amend
	R9-10-1508	Amend
	R9-10-1509	Amend
	R9-10-1510	Amend
	R9-10-1511	Amend
	R9-10-1512	Amend
	R9-10-1513	Amend
	R9-10-1514	Amend
	R9-10-1515	New Section

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

Authorizing statutes: A.R.S. § 36-136(F)

Implementing statutes: A.R.S. §§ 36-132(A)(17), 36-405, 36-449.01 through 36-449.03, 36-2151 through 36-2153, 36-2156, 36-2158, and 36-2159

Statute or session law authorizing the exemption: Laws 2012, Ch. 250, § 10

3. The effective date of the rule and the agency's reason it selected the effective date:

April 1, 2014

This date will provide abortion clinics with over two months after the date of filing for the

abortion clinics to implement changes required by the rules.

4. A list of all notices published in the *Register* as specified in R9-1-409(A) that pertain to the record of the exempt rulemaking:

Notice of Public Information 19 A.A.R. 3944, November 29, 2013

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

Name: Kathryn McCanna, Branch Chief

Address: Arizona Department of Health Services
Division of Licensing Services
150 N. 18th Ave., Suite 405
Phoenix, AZ 85007

Telephone: (602) 364-2536

Fax: (602) 364-4764

E-mail: Kathryn.McCanna@azdhs.gov

or

Name: Robert Lane, Acting Manager

Address: Arizona Department of Health Services
Office of Administrative Counsel and Rules
1740 W. Adams, Suite 203
Phoenix, AZ 85007

Telephone: (602) 542-1020

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:

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. The Department has implemented A.R.S. §§ 36-132(A)(17) and 36-405 for abortion clinics in Arizona Administrative Code (A.A.C.) Title 9, Chapter 10, Article 15. On April 12, 2012, the Governor signed HB 2036, which changed requirements for abortion clinics. HB 2036 was effective August 2, 2012. HB 2036 gives the Arizona Department of Health Services (Department) exempt rulemaking authority to amend the rules for abortion clinics. After receiving an exception from the Governor's rulemaking moratorium, established by Executive Order 2012-03, for this rulemaking, the Department has revised the rules in 9 A.A.C. 10, Article 15 to delete unnecessary and obsolete provisions, address technical changes, and 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:

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 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:

TITLE 9. HEALTH SERVICES

CHAPTER 10. DEPARTMENT OF HEALTH SERVICES

HEALTH CARE INSTITUTIONS: LICENSING

ARTICLE 15. ABORTION CLINICS

ARTICLE 15. ABORTION CLINICS

R9-10-1501. Definitions

In addition to the definitions in A.R.S. §§ 36-401, 36-449.01, 36-449.03, and R9-10-101, the following definitions apply in this Article, unless ~~the context~~ otherwise ~~requires~~ specified:

~~1. *"Abortion" means the use of a surgical instrument or a machine with the intent to terminate a woman's pregnancy for reasons other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, to terminate an ectopic pregnancy or to remove a dead fetus. Abortion does not include birth control devices or oral contraceptives.*~~

~~2. *"Abortion clinic" means 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.*~~

~~3.~~1. "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.~~2. "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 in this state and agrees to do so.

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

~~6. "Biohazardous medical waste" means cultures and stocks, waste human blood and blood products, bodily fluids, uterine contents, and discarded medical sharps.~~

~~7.~~3. "Conspicuously posted" means placed at a location within an abortion clinic that is accessible and visible to patients and the public.

~~8. "Controlled substance" means the same as defined in A.R.S. § 32-1901(12).~~

~~9.~~4. "Course" means hands-on practice under the supervision of a physician, training, or education.

~~10. "Current" means up-to-date, extending to the present time.~~

~~11. "Department" means the same as defined in A.R.S. § 36-401.~~

~~12. "Direction" means the same as defined in A.R.S. § 36-401.~~

~~13.~~5. "Discharge" means a patient no longer requires the medical services, nursing services, or health-related services provided by the abortion clinic.

~~14. "Documentation" means written, supportive evidence.~~

~~15.~~6. "Emergency" means a potentially life-threatening occurrence that requires an immediate response or medical treatment.

~~16.~~7. "Employee" means an individual who receives compensation from a licensee, but does not provide medical services, nursing services, or health-related services.

~~17. *"Fetus" means an individual human organism from fertilization until birth.*~~

~~18.~~8. "First trimester" means 1 through 14 weeks as measured from the first day of the last menstrual period or 1 through 12 weeks as measured from the date of fertilization.

~~19. "Gestational age" means the number of completed weeks of the unborn fetus as calculated from the first day of the last menstrual period or the date of fertilization.~~

~~20. "Health-related services" means the same as defined in A.R.S. § 36-401.~~

~~21. "Immediately" means without delay.~~

~~22.~~9. "Incident" means an abortion related patient death or serious injury to a patient or viable fetus.

~~23. "Infection control" means to identify, prevent, monitor, and minimize infections.~~

~~24.~~10. "Licensee" means an individual, a partnership, an association, a limited liability company, or corporation authorized by the Department to operate an abortion clinic.

~~25.~~11. "Local" means under the jurisdiction of a city or county in Arizona.

~~26.~~12. "Medical director" means a physician who is responsible for the direction of the medical services, nursing services, and health-related services provided to patients at an abortion clinic.

~~27.~~13. "Medical evaluation" means obtaining a patient's medical history, performing a physical examination of a patient's body, and conducting laboratory tests as provided in R9-10-1508.

~~28. "Medical services" means the same as defined in A.R.S. § 36-401~~.

~~29. "Medication" means a prescription medication as defined in A.R.S. § 32-1901 or a nonprescription drug or over-the-counter drug as defined in A.R.S. § 32-1901.~~

~~30.~~14. "Monitor" means to observe and document, continuously or intermittently, the values of certain physiologic variables on a patient such as pulse, blood pressure, oxygen saturation, respiration, and blood loss.

~~31.~~15. "Nationally recognized medical journal" means any publication distributed nationally that contains peer-reviewed medical information, such as the *American Journal of Radiology* or the *Journal of Ultrasound in Medicine*.

~~32. "Nurse" means an individual licensed and in good standing as a registered nurse or a practical nurse according to A.R.S. Title 32, Chapter 15.~~

~~33. "Nurse practitioner" means an individual licensed and in good standing as a registered nurse practitioner according to A.R.S. Title 32, Chapter 15.~~

~~34. "Nursing services" means the same as defined in A.R.S. § 36-401.~~

~~35.~~16. "Patient" means a female receiving medical services, nursing services, or health-related services related to an abortion.

~~36.~~17. "Patient care staff" means a physician, registered nurse practitioner, nurse, physician assistant, or surgical assistant who provides medical services, nursing services, or health-related services to a patient.

~~37.~~18. "~~Patient~~ Patient's representative" means a patient's legal guardian, an individual acting on behalf of a patient with the written consent of the patient, or a surrogate according to A.R.S. § 36-3201~~(13)~~.

~~38.~~19. "Patient transfer" means relocating a patient requiring medical services from an abortion clinic to another health care institution.

~~39.~~20. "Personally identifiable patient information" means:

a. The name, address, telephone number, e-mail address, Social Security number, and birth date of:
   i. The patient,
   ii. The patient's representative,
   iii. The patient's emergency contact,
   iv. The patient's children,
   v. The patient's spouse,
   vi. The patient's sexual partner, and
   vii. Any other individual identified in the patient's medical record other than patient care staff;

b. The patient's place of employment;

c. The patient's referring physician;

d. The patient's insurance carrier or account;

e. Any "individually identifiable health information" as proscribed in 45 CFR 164-514; and

f. Any other information in the patient's medical record that could reasonably lead to the identification of the patient.

~~40.~~21. "Personnel" means patient care staff, employees, and volunteers.

~~41.~~22. "Physical facilities" means property that is:

a. Designated on an application for a license by the applicant; and

b. Licensed to provide services by the Department according to A.R.S. Title 36, Chapter 4.

~~42. "Physician" means an individual licensed according to A.R.S. Title 32, Chapter 13 or 17.~~

~~43. "Physician assistant" means an individual licensed according to A.R.S. Title 32, Chapter 25.~~

~~44. *"Serious injury" means an injury that occurs at an abortion clinic and that creates a serious risk of substantial impairment of a major body organ.*~~

~~45. *"Supervision" means direct overseeing and inspection of the act of accomplishing a function or activity.*~~

~~46.~~23. "Surgical assistant" means an individual who is not licensed as a physician, physician assistant, registered nurse practitioner, or nurse who performs duties as directed by a physician, physician assistant, registered nurse practitioner or nurse.

~~47. "Viable fetus" means the same as defined in A.R.S. § 36-2301.01.~~

~~48.~~24. "Volunteer" means an individual who, without compensation, performs duties as directed by a member of the patient care staff at an abortion clinic.

R9-10-1502. Application Requirements

An applicant shall submit an application for licensure that meets the requirements in A.R.S. § 36-422 and 9 A.A.C. 10, Article 1.

R9-10-1503. Administration

A. A licensee is responsible for the organization and management of an abortion clinic.

B. A licensee shall:

~~1. Ensure compliance with federal and state laws, rules, and local ordinances;~~

~~2.~~1. Adopt policies and procedures for the administration and operation of an abortion clinic;

~~3.~~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;

~~4.~~3. Ensure that the Department's director or director's ~~designee~~ 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;

~~5.~~4. 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's Office of Medical Facilities~~ 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 ~~developed~~ 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.

R9-10-1504. 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; and

2. For a serious injury, written notification within 10 calendar days ~~from~~ after the date of the serious injury.

B. A medical director shall conduct an investigation of an incident and ~~develop a written~~ document an incident report that includes:

1. The date and time of the incident;
2. The name of the patient;
3. ~~Description~~ A description of the incident;
4. Names of individuals who observed the incident;
5. Action taken by patient care staff and employees during the incident ~~or~~ and immediately following the incident; and
6. Action taken by the patient care staff and employees to prevent the incident from occurring in the future.

C. A medical director shall ensure that the ~~written~~ incident report is:
1. Submitted to the Department and, if the incident involved a licensed individual, the applicable ~~a~~ professional licensing board~~, if applicable,~~ within 10 calendar days ~~from~~ after the date of the notification in subsection (A); and
2. Maintained in the physical facilities for at least two years ~~from~~ after the date of the ~~report~~ incident.

R9-10-1505. Personnel Qualifications and Records

A licensee shall ensure that:
1. A physician who performs an abortion demonstrates to the medical director that the physician is competent to perform an abortion by:
   a. The submission of documentation of education and experience; and
   b. Observation by or interaction with the medical director;
2. Surgical assistants and volunteers who provide counseling and patient advocacy receive training in these specific responsibilities and any other responsibilities assigned and that documentation is maintained in the individual's personnel file of the training received;
3. An individual who performs an ultrasound provides documentation that the individual is:
   a. A physician;
   b. A physician assistant, registered nurse practitioner, or nurse who completed a hands-on course in performing ultrasounds under the supervision of a physician; or
   c. An individual who:
      i. Completed a hands-on course in performing ultrasounds under the supervision of a physician, and
      ii. Is not otherwise precluded by law from performing an ultrasound;
4. An individual has completed a course for the type of ultrasound the individual performs;

5. A personnel file for each member of the patient care staff and each volunteer is maintained either electronically or in writing and includes:
   a. The individual's name~~,~~ and position title~~,~~; ~~and~~
   b. ~~the~~ The first and, if applicable, the last date of employment or volunteer service~~, if applicable~~;
   b. Verification of qualifications, training, or licensure, ~~if~~ as applicable;
   c. Documentation of cardiopulmonary resuscitation certification, ~~if~~ as applicable;
   d. Documentation of verification of competency, as required in subsection (1), and signed and dated by the medical director;
   e. Documentation of training for surgical assistants and volunteers; and
   f. Documentation of completion of a course as required in subsection (3), for an individual performing ultrasounds; and
6. Personnel files are maintained in the physical facilities for at least two years from the ending date of employment or volunteer service.

R9-10-1506. Staffing Requirements

A. A licensee shall ensure that there ~~are~~ is a sufficient number of patient care staff and employees to:
   1. Meet the requirements of this Article;
   2. Ensure the health and safety of a patient; and
   3. Meet the needs of a patient based on the patient's medical evaluation.

B. A licensee shall ensure that:
   1. A member of the patient care staff, except for a surgical assistant, who is current in cardiopulmonary resuscitation certification is in the physical facilities until all patients are discharged;
   2. A physician, with admitting privileges at ~~an accredited hospital in this state~~ a health care institution that is classified by the director as a hospital according to A.R.S. § 36-405(B), remains on the premises of the abortion clinic until all patients who received a medication abortion are stable and ready to leave ~~the recovery room~~; ~~and~~
   3. A physician, with admitting privileges at a health care institution that is classified by the director as a hospital according to A.R.S. § 36-405(B) and that is within thirty miles of the abortion clinic by road, as defined in A.R.S. § 17-451, remains on the abortion clinic's premises until all patients who received a surgical abortion are stable and ready to leave the recovery room; and

~~3.~~ 4. A physician, a nurse, a registered nurse practitioner, a physician assistant, or, 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, a medical assistant under the direct supervision of the physician:

a. Monitors each patient during the patient's recovery following the abortion; and

b. Remains in the ~~facility~~ abortion clinic until each patient is discharged by a physician.

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 refuse treatment, or withdraw consent for treatment;
2. To have medical records kept confidential; and
3. To be informed of:
   a. Billing procedures and financial liability before abortion services are provided;
   b. Proposed medical or surgical procedures, associated risks, possible complications, and alternatives;
   c. Counseling services that are provided in the physical facilities; and
   d. ~~If an ultrasound is performed the,~~ The right to review the ultrasound results with a physician, a physician assistant, a registered nurse practitioner, or a registered nurse before the abortion procedure.

R9-10-1508. Abortion Procedures

A. A medical director shall ensure that a medical evaluation of a patient is conducted before ~~performing an~~ the patient's abortion is performed ~~and~~ 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; and
3. The following laboratory tests:
   a. A urine or blood test to determine pregnancy ~~if an ultrasound examination is not performed~~;
   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.

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 estimates the gestational age of the fetus, and records the estimated age in the patient's medical record. The estimated age is based upon:

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. ~~If a physical examination or other information obtained from the patient or laboratory tests indicates the gestational age of the fetus is greater than 12 weeks, a~~ A medical director shall ensure that:

1. An ultrasound of a patient is performed by an individual who meets the requirements in R9-10-1505(3);

2. An ultrasound estimate of gestational age of a fetus is performed using methods and tables or charts published in a nationally recognized medical journal;

3. An original patient ultrasound print 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 is reviewed with the patient by a physician, ~~a~~ physician assistant, ~~a~~ registered nurse practitioner, or ~~a~~ registered nurse.

E. A medical director shall ensure that before an abortion is performed on a patient:

1. Written consent is signed and dated by the patient or the patient's ~~representative~~ legal guardian; and

2. Information is provided to the patient on the abortion procedure including alternatives, risks, and potential complications.

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 any medication, drug, or substance used to induce an abortion is administered in compliance with the protocol authorized by the United States Food and Drug Administration and that is outlined in the final printing labeling instructions for that medication, drug, or substance.

~~G.~~H. A medical director shall ensure that:

1. Patient care staff monitor the patient's vital signs throughout ~~the~~ 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; and
3. If a viable fetus shows signs of life:
   a. Resuscitative measures are used to support life;
   b. The viable fetus is transferred as required in R9-10-1509; and
   c. Resuscitative measures and the transfer are documented.

~~H.~~I. A medical director shall ensure that following the abortion procedure:

1. A patient's vital signs and bleeding are monitored by a physician, ~~a~~ nurse, ~~a~~ registered nurse practitioner, ~~a~~ physician assistant, or, 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, a medical assistant under the direct supervision of the physician to ensure the patient's health and safety; and
2. A patient remains in the recovery room or recovery area until a physician, ~~a~~ physician assistant, ~~a~~ registered 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.

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

1. With a patient's consent, a telephone call to the patient by a member of the patient care staff, except a surgical assistant, within 24 hours ~~of~~ after the patient's discharge following a surgical abortion to assess the patient's recovery. If the patient care staff is unable to

speak with the patient, for any reason, the attempt to contact the patient is documented in the patient's medical record; ~~and~~

2. ~~A~~ Following a surgical abortion, a follow-up visit offered and scheduled, if requested, no more than 21 days after the abortion. 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; and
3. Following a medication abortion, a follow-up visit offered and scheduled between seven and 21 days after the initial dose of a substance used to induce an abortion. The follow-up visit shall include:
   a. A urine pregnancy test; and
   b. An assessment of the degree of bleeding.

~~J.~~K. If a continuing pregnancy is suspected as a result of the follow-up visit required in subsection ~~(I)(2)~~ (J)(2) or (J)(3), a physician who performs abortions shall be consulted.

R9-10-1509. Patient Transfer and Discharge

A. A medical director shall ensure that:
   1. A patient is transferred to a hospital for an emergency involving the patient;
   2. A viable fetus requiring emergency care is transferred to a hospital;
   3. A patient transfer is documented in the patient's medical record; and
   4. Documentation of a medical evaluation, treatment given, and laboratory~~,~~ and diagnostic information is transferred with a patient.

B. A medical director shall ensure that before a patient is discharged:
   1. A physician signs the patient's discharge order; and
   2. A patient receives ~~written information~~ follow-up instructions at discharge that ~~includes~~ include:
      a. Signs of possible complications;
      b. When to access medical ~~care~~ services in response to complications;
      c. A telephone number of an individual or entity to contact for medical emergencies;
      d. ~~Instructions~~ Information and precautions for resuming vaginal intercourse after the abortion; and
      e. ~~Instructions~~ Information specific to the patient's abortion or condition.

R9-10-1510. Medications and Controlled Substances

A medical director shall ensure that:

1. The abortion clinic complies with the requirements for medications and controlled substances in A.R.S. Title 32, Chapter 18, and A.R.S. Title 36, Chapter 27;
2. A medication is administered in compliance with an order from a physician, physician assistant, registered nurse practitioner, or as otherwise provided by law;
3. A medication is administered to a patient by a physician or as otherwise provided by law;
4. Medications and controlled substances are maintained in a locked area in the physical facilities;
5. Only personnel designated by ~~in the abortion clinic's~~ policies and procedures have access to the locked area containing ~~the~~ medications and controlled substances;
6. Expired, mislabeled, or unusable medications and controlled substances are disposed of according to ~~the abortion clinic's~~ policies and procedures;
7. ~~Medication errors and adverse reactions~~ A medication error or an adverse reaction, including any actions taken in response to the medication ~~errors~~ error or adverse ~~reactions~~ reaction, ~~are~~ is immediately reported to the medical director and licensee, and recorded in the patient's medical record;
8. Medication information is maintained in a patient's medical record and contains:
    a. The patient's name, age, and weight;
    b. The medications the patient is currently taking; and
    c. Allergies or sensitivities to medications, antiseptic solutions, or latex; and
9. If medication is administered to a patient, the following are documented in the patient's medical record:
    a. The date and time of administration;
    b. The name, strength, dosage form, amount of medication, and route of administration; and
    c. The identification and signature of the individual administering the medication.

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~~ 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, ~~if applicable,~~ including the original print, ~~as~~ required in R9-10-1508(D);

g. Each consent form signed by the patient or the patient's ~~representative~~ legal guardian;

h. ~~A record of all orders~~ Orders issued by a physician, physician assistant or registered nurse practitioner;

i. A record of ~~all~~ 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 ~~the abortion clinic's~~ 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 ~~from~~ 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 ~~from~~ after the date of the patient's discharge; and

6. Vital records and vital statistics are retained according to A.R.S. § 36-343~~; and~~.

~~7. If an abortion clinic ceases operations, the Department is notified in writing, not less than 30 days before ceasing operations, of the location of the abortion clinic's medical records.~~

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 ~~facility~~ 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~~ 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~~, if applicable, including the original print as~~ required in R9-10-1508(D);

g. Each consent form signed by the patient or the patient's representative;

h. ~~A record of all orders~~ Orders issued by a physician, physician assistant, or registered nurse practitioner;

i. A record of ~~all~~ 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. The Department shall have access to or copies of unredacted patient medical records only ~~pursuant~~ 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 electronic file with access to the secured drawer, cabinet, or file limited to those individuals who have access to the patient medical records ~~pursuant~~ according to subsection (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. 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 ~~an abortion clinic's~~ 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. ~~A computer code~~ 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 ~~a computer code~~ an electronic signature is used:

a. An individual's rubber stamp or ~~computer code~~ electronic signature is not used by another individual;

b. The individual who uses a rubber stamp or ~~computer code~~ electronic signature signs a statement that the individual is responsible for the use of the rubber stamp or the ~~computer code~~ 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.

R9-10-1512. Environmental and Safety Standards

A licensee shall ensure that:

1. Physical facilities:

a. Provide lighting and ventilation to ensure the health and safety of a patient;

b. Are maintained in a clean condition;

c. Are free from a condition or situation that may cause a patient to suffer physical injury;

d. Are maintained free from insects and vermin; and

e. Are smoke-free;

2. A warning notice is placed at the entrance to a room or area where oxygen is in use;

3. Soiled linen and clothing are kept:

a. ~~in~~ In a covered container, and ~~in a~~

b. ~~separate area~~ Separate from clean linen and clothing;

4. Personnel wash hands after each direct patient contact and after handling soiled linen, soiled clothing, or biohazardous medical waste;

5. A written emergency plan is ~~developed~~ established, documented, and implemented that includes procedures for protecting the health and safety of patients and other individuals in a fire, natural disaster, loss of electrical power, or threat or incidence of violence; and
6. An evacuation drill is conducted at least once every six months that includes all personnel in the physical facilities the day of the evacuation drill. Documentation of the evacuation drill is maintained in the physical facilities for one year ~~from~~ after the date of the evacuation drill and includes:
    a. The date and time of the evacuation drill; and
    b. The names of personnel participating in the evacuation drill.

R9-10-1513. Equipment Standards

A licensee shall ensure that:

1. Equipment and supplies are maintained in a quantity sufficient to meet the needs of ~~all~~ patients present in the abortion clinic;
2. Equipment to monitor vital signs is in each room in which an abortion is performed;
3. A surgical or gynecologic examination table is used for an abortion;
4. The following equipment and supplies are ~~provided~~ available in the abortion clinic:
    a. Equipment to measure blood pressure;
    b. A stethoscope;
    c. A scale for weighing a patient;
    d. Supplies for obtaining specimens~~,~~ and cultures and ~~other~~ for laboratory tests; and
    e. Equipment and supplies for use in a medical emergency including:
        i. Ventilatory assistance equipment;
        ii. Oxygen source;
        iii. Suction apparatus; and
        iv. Intravenous fluid equipment and supplies; and
    f. Ultrasound equipment;
5. In addition to the requirements in subsection (4), the following equipment is available for an abortion procedure performed after the first trimester:
    ~~a. Ultrasound equipment;~~
    ~~b.~~a. Drugs to support cardiopulmonary function; and
    ~~c.~~b. Equipment to monitor cardiopulmonary status;
6. Equipment and supplies are clean and, if applicable, sterile~~, if applicable,~~ before each use;

7. Equipment required in this Section is maintained in working order, tested and calibrated at least once every 12 months or according to the manufacturer's recommendations, and used according to the manufacturer's recommendations; and

8. Documentation of each equipment test, calibration, and repair is maintained in the physical facilities for one year ~~from~~ after the date of the testing, calibration, or repair and provided to the Department for review within two hours ~~from the time~~ after the Department requests the documentation.

R9-10-1514. Physical Facilities

A. A licensee shall ensure that an abortion clinic complies with all local building codes, ordinances, fire codes, and zoning requirements. If there are no local building codes, ordinances, fire codes, or zoning requirements, the abortion clinic shall comply with the applicable codes and standards incorporated by reference in A.A.C. R9-1-412 that were in effect on the date the abortion clinic's architectural plans and specifications were submitted to the Department for approval.

B. A licensee shall ensure that an abortion clinic provides areas or rooms:

1. That provide privacy for:
   a. A patient's interview, medical evaluation, and counseling;
   b. A patient to dress; and
   c. Performing an abortion procedure;
2. For personnel to dress;
3. With a sink ~~in working order~~ and a flushable toilet in working order;
4. For cleaning and sterilizing equipment and supplies;
5. For storing medical records;
6. For storing equipment and supplies;
7. For hand washing before the abortion procedure; and
8. For a patient recovering after an abortion.

C. A licensee shall ensure that an abortion clinic has an emergency exit to accommodate a stretcher or gurney.

R9-10-1515. Enforcement

A. For an abortion clinic that is not in substantial compliance or that is in substantial compliance but refuses to carry out a plan of correction acceptable to the Department, the Department may:

1. Assess a civil penalty according to A.R.S. § 36-431.01,
2. Impose an intermediate sanction according to A.R.S. § 36-427,
3. Suspend or revoke a license according to A.R.S. § 36-427,
4. Deny a license, or

5. Bring an action for an injunction according to A.R.S. § 36-430.

B. In determining the appropriate enforcement action, the Department shall consider the threat to the health, safety, and welfare of the abortion clinic's patients or the general public, including:

1. Whether the abortion clinic has repeated violations of statutes or rules;

2. Whether the abortion clinic has engaged in a pattern of noncompliance; and

3. The type, severity, and number of violations.

Exhibit 8

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SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

Planned Parenthood Arizona, Inc.; William Richardson, M.D.; and William H. Richardson, M.D., P.C., doing business as Tucson Women's Center, Plaintiffs, vs. Will Humble, Director of the Arizona Department of Health Services, in his official capacity, Defendants.	Case No. **DECLARATION OF LISA RARICK**

LISA D. RARICK, M.D., declares and states the following:

1. I provide the following facts and opinions as an expert in reproductive health and the regulation of drugs by the United States Food and Drug Administration ("FDA"). I am a Board-certified obstetrician-gynecologist licensed to practice medicine in the State of Maryland and the District of Columbia. I worked at the FDA from 1988 to 2003. A copy of my curriculum vitae, which summarizes my professional experience, is annexed hereto as Exhibit A.

2. My work at the FDA began with a part-time position in the Center for Drug Evaluation and Research ("CDER") investigating the effects of drug exposure on fetal development. Later,

I became a full-time Medical Officer in the Division of Metabolic and Endocrine Drug Products. In 1996, I was named Director of the newly created Division of Reproductive and Urologic Drug Products. In 1999, I was promoted to Deputy Office Director for the Office of Drug Evaluation 2, and in 2000, I was promoted to Associate Director of CDER for Quality Assurance. In 2002, I moved to the Office of the Commissioner, where I served as a Medical Officer in the Office of Women's Health.

3. I left the FDA in 2003 and have been working as a private consultant since then, providing consulting services to pharmaceutical companies, venture capital firms, advocacy groups, and individuals regarding regulatory affairs and reproductive health.

4. Every new drug submitted for FDA approval for sale and marketing in the United States is the subject of a New Drug Application ("NDA"), in which the company seeking approval, called the drug sponsor, submits the results of clinical trials demonstrating that the drug is safe and effective in its proposed use(s), and that the benefits of the drug outweigh the risks.

5. As part of the NDA, the sponsor includes a proposed drug label, containing information such as the drug's indications, dosage, and route of administration. The FDA reviews the proposed label and may suggest revisions to the drug sponsor. The drug sponsor may make those revisions or may propose others in response to the FDA's concerns. When the FDA approves the NDA, the finalized label becomes known as the drug's Final Printed Labeling ("FPL").

6. In sum, an FPL is an informational document that provides physicians with guidance about how to use a drug in accordance with how the drug sponsor requested and received FDA approval for its use. The drug sponsor bears responsibility for its contents. The FPL does not constitute a federal law and does not impose binding obligations on physicians.

7. If a manufacturer seeks to market a drug for a new use or using a new regimen, it can submit to the FDA a supplement to the NDA to request approval of a change in the drug's FPL. This is a commercial decision that manufacturers may make when there is some expected benefit to offset the substantial cost of developing and submitting new study data.

8. After a drug has been approved by the FDA, physicians may prescribe it for indications and in dosages other than those expressly approved by the FDA and set forth in the drug's label. That common practice by physicians is known as "off-label" use.

9. Off-label use is neither prohibited nor discouraged by the FDA. In guidance documents, the FDA has repeatedly acknowledged that off-label use is common and is sometimes required by good medical practice.

10. For example, in an April 1982 *"FDA Drug Bulletin,"* this topic was specifically addressed. Here the FDA stated that "…The FD&C Act does not…limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such "unapproved" or, more precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature." The Bulletin goes on to state: "….accepted medical practice often includes drug use that is not reflected in approved drug labeling." A copy of that FDA Drug Bulletin is annexed hereto as Exhibit B.

11. In 2011 the FDA reaffirmed its stance in an Information Sheet entitled *"Off-Label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices*, stating that: "Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment. If physicians use

a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effect." *See* http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm.

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/ / /

I declare under the penalty of perjury that the foregoing is true and correct.

Dated 29-Apr-2014

Lisa D Rarick, MD

LISA D. RARICK, M.D.

Exhibit A

CURRICULUM VITAE

LISA D. RARICK, M.D.
RAR Consulting, LLC
Reproductive Health and Regulatory Affairs Consultant

EDUCATION/TRAINING

July 1977-June 1978	University of California, Riverside
July 1978-June 1980	Pacific Union College Angwin, California
July 1980-June 1984	Loma Linda University School of Medicine Loma Linda, California B.S. and M.D., June 1984
July 1984-June 1988	Resident Dept of Obstetrics and Gynecology Georgetown University School of Medicine Washington, D.C.
July 1987-June 1988	Administrative Chief Resident Dept of Ob/Gyn Georgetown University School of Medicine Washington, D.C.

APPOINTMENTS

July 1988-Sept. 1989	Instructor, Dept of Ob/Gyn Georgetown University School of Medicine
Dec. 1988-Nov. 1995	Medical Officer Division of Metabolism and Endocrine Drug Products CDER, FDA Sample Review Assignments: Gonadotropin Releasing Hormones for women (Agonists and Antagonists) Norplant and other implantable contraceptives Transdermal contraceptives Vaginal contraceptives Dopamine receptor agonists Oral Contraceptives Non-surgical sterilization Intrauterine Devices (IUDs) Drugs for Premenstrual Syndrome Anti-sperm vaccines Vaginal hormone replacement therapy
Sept. 1989-Feb. 1993	Member, Columbia Hospital for Women Physician Group
Sept. 1993-June 1996	Volunteer, Zaccheaus Free Clinic, Washington, D.C.
Nov. 1995-June.1996	Acting Deputy Director Division of Metabolism and Endocrine Drug Products CDER Served as Medical Officer group leader and as Deputy to the Division Director in the field of Reproductive and Urologic Drug Products
June 1996-Dec. 1999	Director Division of Reproductive and Urologic Drug Products CDER Was responsible for review, approval and policy for all reproductive and urologic health drugs
Dec. 1999-Nov. 2000	Deputy Director Office of Drug Evaluation 2 CDER Served as Deputy Office Director for Office with responsibility for Pulmonary, Allergy, Endocrine, Metabolic, Anesthesia, Critical Care and Addiction Drug Products

Nov. 2000-July 2002	Associate Director for Quality Assurance, Director, Review Standards Staff Office of the Center Director CDER
	Headed team with the mission to advance CDER-wide high priority initiatives, and lead Office for good review practice development and risk management strategic planning
July 2002-July 2003	Medical Officer Office of Women's Health Office of the Commissioner, FDA
	Facilitated Agency work for improving health of women, including promotion and analysis of women in clinical trials, efforts to understand and improve health during and after pregnancy, pregnancy prevention strategies, menopausal hormone therapy, HIV prevention and issues related to aging
July 2003-Present	Consultant, Reproductive Health and Regulatory Affairs

LICENSURE/CERTIFICATION

D.C. License Number: 16656, issued June 17, 1987

Maryland License Number: D0060729, issued July 31, 2003

Diplomate of the National Board of Medical Examiners: March 1985

Board Certification: American Board of Obstetrics and Gynecology: Certified December 1990; Recertified annually as required for continued board certification beginning 2001 to present

COMMITTEE ACTIVITIES

Nov. 1989-1996	FDA Liaison to American College of Obstetricians and Gynecologists Committee on Gynecologic Practice
June 1990-1996	FDA Liaison to the Technical Advisory Committee to Contraceptive Research and Development (CONRAD)
Oct.1992-1996	FDA Liaison to the International Committee for Contraception Research (Population Council)
Fall 1992-June 1995	Medication Error Subcommittee of the Drug Nomenclature Committee, FDA
June 1993-June 1995	Member, Women's Health Subcommittee of the CDER Medical Policy Coordinating Committee

Jan. 1995-July 1995	Chair, Medication Errors Response Subcommittee of the CDER Medical Policy Coordinating Committee
Spring 1994-2002	Member, CDER Good Review Practices Steering Committee
July 1995-2002	Chair, Track XI, Good Review Practices Core Committee member, several subcommittees of GRP Track XI, including reviewer education, orientation, mentoring, newsletter, scientific rounds improvement, etc.
Spring 1994-2003	FDA clinical topic lead, Multi disciplinary subgroup (M3) of the International Conference for Harmonization
Apr. 1996-1998	Chair, FDA Pregnancy Labeling Taskforce
Nov. 1998-2003	Member, FDA Pregnancy Labeling Taskforce
May 1996-2003	Subcommittee chair (pregnancy issues), Gender Effects Steering Committee
May 1996-2002	Liaison to USP re: products used in Obstetrics and Gynecology
Dec. 1995-2002	Member of taskforce addressing class labeling and labeling change policies

PROFESSIONAL SOCIETIES

Sept. 1991-Present	Fellow, American College of Obstetricians and Gynecologists (ACOG)
July 1988-1998	Member, Washington Gynecological Society
1994-1996	Secretary, Washington Gynecological Society
Mar. 1991-2003	Member, FDA-ACOG Special Interest Group
1990-1999	Member, Federal Physicians Association
1991	Vice President, Federal Physicians Association
1992-1995	Officer at Large, Federal Physicians Association

HONORS RECEIVED/PRESENTATIONS

"Resident of the Year," Georgetown University Division of Reproductive Endocrinology and Infertility - June 1987.

First Prize - Residents' Research Day Paper Presentation, Georgetown University Dept. of Ob/Gyn - Oct. 1987.

FDA Award of Merit for participation as member of Reviewer Education Subcommittee of Track XI, GRPs - May 1996.

FDA Award of Merit for providing outstanding leadership and management of ORM resources resulting in rapid delivery of safe, effective new drug products to the public - May 1997.

FDA Outstanding Group Recognition Award for outstanding performance in reviewing and analyzing complex scientific data and regulatory issues related to conjugated estrogens - Sept. 1997.

FDA Commendable Service Award for exemplary ability to facilitate and develop new CDER review staff through the New Reviewer Workshop - 1998.

CDER Leadership Excellence Award - Nov. 1998.

FDA Commendable Service Award for outstanding commitment and cooperation between FDA staff in handling post-marketing adverse events noted with the drug Viagra - 1998.

FDA Outstanding Service Award for excellence in revising estrogen labeling, class labeling guidance, and clinical trials guidance in rapid response to new risk data from the Women's Health Initiative - May 2003.

FDA Commissioner's Special Citation for the collective outstanding performance of the "Menopause and Hormones Information Campaign", which resulted in the launch of a national public awareness outreach campaign - May 2004.

Selected to present original paper entitled "Analysis of International Studies of Birth Weight" at the Annual District IV meeting of the American College of Obstetricians and Gynecologists, in joint conference with the Royal College of Obstetricians and Gynecologists, London, U.K. - Sept. 1989.

Gave multiple presentations and participated in meetings concerning regulatory affairs, public health issue policies, women's health, international harmonization of preclinical requirements to support human studies, Advisory Committee meetings, etc. Participated as faculty in several Pharmaceutical Education and Research Institute, Inc. (PERI) and Drug Information Association (DIA) courses - 1996-2007.

PUBLISHING ACTIVITIES

Rarick, LD, Shangold, MM and Ahmed, S. Cervical mucus and serum estradiol as predictors of response to progestin challenge. Fertility and Sterility, Aug. 1990.

Marshall, LW, RR Bridges, JF English, GL Lipkin, RB Miller, LD Rarick, NJ Shotwell, AH Wiseman. Incidence of post operative infections in patients undergoing abdominal hysterectomies. Abstract #S5 Infection Control and Hospital Epidemiology, Oct. 1992. Presented at the American Society of Hospital Epidemiologists, Baltimore, Maryland, Apr. 1992.

Rarick, L and L Yin, Vaginal contraceptive drugs and devices: regulatory requirements. Chapter, Barrier Contraceptives: Current Status and Future Prospects, Editors, C. Mauck, et al., Wiley-Liss, Inc., 1994.

Rarick, LD, Clinical study design working group report. Chapter, Barrier Contraceptives: Current Status and Future Prospects, Editors, C. Mauck, et al., Wiley Liss, Inc., 1994.

Reviewer - Journal of Reproductive Toxicology, Pergamon Press July 1987-2000.

Rarick, Lisa D, Heard in Audio-Digest OB/GYN, vol. 42, no. 6, 1995 "Revising the FDA package insert."

Rarick, Lisa D, Idea to Product: The Process. Chapters, Understanding the Organization and Function of the FDA, and What is Involved in a New Drug Application? Editors, N. Alexander, A. Wentz, et al., Springer-Verlag New York, Inc., 1996.

Rarick, Lisa D, Proceedings of The Third International Conference on Harmonisation, Data To Support Inclusion of Special Populations, pp. 345-347. Editors, P.F. D Arcy and D.W.G. Harron, International Federation of Pharmaceutical Manufacturers, IFPMA, 1996.

L Potter, J Trussell, L Rarick, New England Journal of Medicine, Letter to the Editor, Emergency Postcoital Contraception, vol 338, no. 7., February 12, 1998.

Rarick, Lisa, Building Quality Measure into the Regulatory Review Process: Assessing the Needs of Industry and Regulators. Chapter, The Prescription Drug User Fee Act, The Food and Drug Administration Modernization Act and Good Review Practice: Impact on the Quality of the Review Process and Approval of New Medicines, pp.17-20. Editors, C Hynes, et al., Centre for Medicines Research International, 2001.

Review and Presenter—New Frontiers in Contraceptive Research: A Blueprint for Action. Institute of Medicine of the National Academy of Sciences, The National Academics Press, 2004.

Reviewer – Review of the HIVNET 012 Perinatal HIV Prevention Study. Institute of Medicine of the National Academy of Sciences, The National Academies Press, 2005.

Rarick, L, Contraception, United States regulatory considerations for intrauterine progestins for hormone replacement therapy, vol. 5, issue 6 (supplement), S140-S143, June 2007.

Exhibit B

DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration, HFI-22
Rockville, Maryland 20857

Official Business

THIRD CLASS BULK RATE
Postage & Fees Paid
PHS
Permit No. G29

Third Class Bulk Rate

April 1982

Volume 12 Number 1

FDA Drug Bulletin

New Angina Drugs

Two calcium channel blockers, nifedipine and verapamil, have been approved for treatment of vasospastic and classical effort-associated angina. These drugs are also referred to as "calcium entry blockers" or "calcium antagonists."

Drugs of this pharmacologic class have some common properties but also some important differences in clinical effects. These agents inhibit transmembrane movement of extracellular calcium into cardiovascular smooth muscle, and in isolated tissues, negative inotropic effects, depressed sino-atrial (SA) node and atrio-ventricular (AV) node conduction, and vasodilation. At clinical doses in humans, however, the vascular effects are usually predominant, causing reduced peripheral vascular resistance and lower blood pressure and preventing or reversing coronary spasm. The effects on cardiac tissues are usually less prominent, probably because of afterload reduction and reflex sympathetic responses to vasodilation. In patients with normal cardiac function not on other negatively inotropic drugs, the negative inotropic effects of the drugs are not usually manifested.

In some cases, however, heart failure can be induced or worsened, and particular care must be paid to concomitant use of calcium channel blockers with beta blockers and to use in patients with aortic stenosis, where vasodilation would not be expected to produce significant afterload reduction.

Effects on AV and SA node function are also not prominent *in vivo* with nifedipine, although they can occur with verapamil.

Effectiveness

Verapamil, but not nifedipine, is an effective agent intravenously in interrupting supraventricular tachycardia and slowing the heart rate in atrial fibrillation.

Both drugs are effective in angina due to vasospasm and in chronic stable angina. Current labeling for nifedipine recommends it for use in stable angina only in patients "who remain symptomatic despite adequate doses of beta blockers and/or organic nitrates or who cannot tolerate those agents." This reservation is based on the limited long-term evidence of safety and effective-

more than 1 of every 330 patients were diarrhea, nausea, gastric discomfort, indigestion, dry mouth, rash, pruritus, back pain, dizziness, sleepiness, and vertigo.

No long-term studies have been carried out and there is no recognized reason for long-term use of sucralfate. Specifically, it is not known whether sucralfate can prevent ulcer recurrence. Long-term studies will be needed to assess the possibility of adverse effects associated with long-term use, e.g., effects on absorption of fat-soluble vitamins.

The recommended adult dosage is 1 g four times a day on an empty stomach. Antacids may be prescribed as needed for relief of pain but should not be taken within 30 minutes before or after administration of sucralfate.

While healing with sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been confirmed by X-ray or endoscopy.

Ritodrine Update

Since the approval of ritodrine (Yutopar) for use in premature labor (see November 1980 and July 1981 *Drug Bulletins*), FDA has been monitoring several areas of concern about the drug's known cardiovascular effects. In light of a number of adverse reaction reports, the labeling of ritodrine has been updated to warn about:

- the need to monitor the patient's state of hydration;
- the possibility of pulmonary edema with or without the concomitant use of corticosteroids, many cases of which seem to be related to overhydration;
- the possible unmasking of occult cardiac disease, the first sign of which may be chest pain.

Ritodrine, a beta₂-sympathomimetic drug, may be useful in preterm labor in pregnancies of at least 20 weeks gestation when contraindications have been ruled out.

However, in pregnancies of more than 32 weeks, physicians should carefully weigh the risks and benefits before administering the drug.

When gestational age is in doubt, intrauterine growth retardation should be considered in the differential diagnosis of preterm labor. Among low birth weight infants, about 9 percent may be growth retarded for gestational age. Prolongation of labor beyond term will not correct the growth retardation of these babies.

Initial administration of ritodrine is intravenous. To minimize the risk of hypotension, the patient should be maintained in the left lateral position during infusion and careful attention should be given to her state of hydration. The amount of i.v. fluids administered should be monitored to avoid either circulatory fluid overload (overhydration) or inadequate hydration. An excess sodium load should be avoided in hydrating the patient.[1]

The boxed warning for ritodrine has been amended to read:

> Maternal pulmonary edema has been reported in patients treated with Yutopar, sometimes after delivery. While occurring infrequently, it has occurred more often when patients were treated concomitantly with corticosteroids. Maternal death from this condition has been reported with or without corticosteroids given concomitantly with drugs of this class.
>
> Patients so treated must be closely monitored in the hospital. The patient's state of hydration should be carefully monitored. (See Dosage and Administration.) If pulmonary edema develops during administration, the drug should be discontinued. Edema should be managed by conventional means.
>
> Because cardiovascular responses are common and more pronounced during intravenous administration of Yutopar, cardiovascular effects, including maternal pulse rate and blood pressure and fetal heart rate, should be closely monitored. Observe for premonitory or actual maternal signs and symptoms of pulmonary edema. A persistent high tachycardia (over 140 beats per minute) and/or persistent tachypnea (respiratory rate over 20 per minute) may be signs of impending pulmonary edema with drugs of this class.
>
> Occult cardiac disease may be unmasked with the use of Yutopar. If the patient complains of chest pain or tightness of chest, the drug should be temporarily discontinued and an ECG should be done as soon as possible.
>
> The drug should not be administered to patients with mild to moderate preeclampsia, hypertension, or diabetes unless the attending physician considers that the benefits clearly outweigh the risks.

Reference:

1. Philipson T, et al.: Pulmonary edema following ritodrine-ritin infusion in premature labor. *Ob Gyn* 1981; 58(3): 304-7.

Use of Approved Drugs for Unlabeled Indications

The appropriateness or the legality of prescribing approved drugs for uses not included in their official labeling is sometimes a cause of concern and confusion among practitioners.

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, a drug approved for marketing may be labeled, promoted, and advertised by the manufacturer only for those uses for which the drug's safety and effectiveness have been established and which FDA has approved. These are commonly referred to as "approved uses." This means that adequate and well-controlled clinical trials have documented these uses, and the results of the trials have been reviewed and approved by FDA.

The FD&C Act does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such "unapproved" or, more precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.

The term "unapproved uses" is, to some extent, misleading. It includes a variety of situations ranging from unstudied to thoroughly investigated drug uses. Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigations. Before such advances can be added to the approved labeling, however, data substantiating the effectiveness of a new use or regimen must be submitted by the manufacturer to FDA for evaluation. This may take time and, without the initiative of the drug manufacturer whose product is involved, may never occur. For that reason, accepted medical practice often includes drug use that is not reflected in approved drug labeling.

With respect to its role in medical practice, the package insert is informational only. FDA tries to assure that prescription drug information in the package insert accurately and fully reflects the data on safety and effectiveness on which drug approval is based.

Hepatitis B Vaccine for Use in Selected Populations

An inactivated hepatitis B vaccine (Recombivax-B) has been licensed for use in the United States. It is intended for selected populations at high risk of acquiring hepatitis B, one of three known types of viral hepatitis. (The others are hepatitis A and non-A non-B hepatitis.)

The vaccine is the first to be made from human blood. Noninfectious antigen is purified from the plasma of asymptomatic human carriers of hepatitis B. After a series of chemical treatments, followed by the addition of alum adjuvant, the vaccine is administered in three intramuscular injections over a 6-month period.

Vaccination is not intended for the general population, but is recommended for persons older than 3 months of age who are at increased risk of hepatitis B virus infection. These persons will include health care workers, institutionalized patients, laboratory workers, hemodialysis staff and patients, family contacts of carriers, some military personnel, and persons with numerous sexual partners.

There continues to be a dialogue among government agencies, industry, and the medical community about use of the vaccine in selected high-risk groups. The Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control (CDC), with assistance from representatives of FDA, the National Institutes of Health, and the medical community, has met several times to discuss specifically which population groups should receive this vaccine. The ACIP will meet once more in May of this year to draft final guidelines for use of this vaccine.

Efficacy

In clinical trials, 85 to 96 percent of persons receiving three doses of either 20 mg or 40 mg of vaccine were immune to infection. The duration of protection is presently unknown. However, in clinical trials, vaccine-induced antibodies, shown to provide protection against infection, persisted for at least 24 months in those receiving all three doses and will probably last for at least 5 years. After this time, a booster may be necessary to maintain immunity.

Side effects have been mainly local, mild, and transitory.

Availability

Due to the complexity of the methods used for producing the vaccine, it will be summer or fall of 1982 before the product is generally available from Merck, Sharp & Dohme. This manufacturer can supply complete physician information.

Advice on Limiting Intake of Bonemeal

Due to the unknown but often substantial lead content of individual samples of bonemeal and dolomite, FDA advises practitioners that these substances should be used as little as possible in infants, young children, and pregnant or lactating women.

Bonemeal is used primarily as calcium and/or phosphorus supplements. Bonemeal supplements are usually composed of finely crushed, processed bone and are packaged in powder, capsule, tablet, or wafer form. The source of bone is usually cattle but sometimes also horses. Bone marrow may also be added to this product. All bonemeal products contain lead which originates primarily from the diet of the animals from which the bone is taken. Bone serves as a repository for lead in the body and, in general, the older the animal the more lead in its bones.

Dolomite is a mineral deposit, consisting of calcium-magnesium carbonate with traces of other elements, including lead. Dolomite is used as a calcium and magnesium supplement and, like bonemeal, may be purchased in powder, capsule, tablet, or wafer form.

While a large portion of the small amounts of dietary lead ingested by humans is excreted, some is deposited in the mineral fabric of bone and some goes into soft tissue. Infants and children tend to absorb lead more efficiently than adults. When it is consumed in excess, lead may produce toxic reactions including central nervous system damage, anemia, and abdominal pain. As in animals, the accumulation of lead in human bone increases with age. Additionally, studies with