

# SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

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Prepared By: Judiciary Committee

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BILL: CS/SB 1862

SPONSOR: Judiciary Committee, Senator Dockery and others

SUBJECT: Women's Health Care

DATE: April 26, 2005

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Harkey</u>	<u>Wilson</u>	<u>HE</u>	<b>Favorable</b>
2.	<u>Brown</u>	<u>Maclure</u>	<u>JU</u>	<b>Fav/CS</b>
3.	_____	_____	<u>HA</u>	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

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## I. Summary:

The committee substitute creates the "Women's Health and Safety Act," amending s. 390.012, F.S., to require separate rules for licensed abortion clinics that perform abortions only during the first trimester of pregnancy, and for those licensed abortion clinics that perform abortions after the first trimester of pregnancy. The rules may not impose an unconstitutional burden on a woman's freedom to decide whether to terminate her pregnancy.

The committee substitute requires the Agency for Health Care Administration (AHCA) to adopt rules for an abortion clinic's physical facilities, clinic supplies and equipment standards, clinic personnel, medical screening and evaluation of each abortion clinic patient, abortion procedure, recovery room standards, follow-up care, and incident reporting.

This committee substitute amends s. 390.012, Florida Statutes, and creates two undesignated sections of law.

## II. Present Situation:

### Case Law on Abortion Restrictions

The landmark case of *Roe v. Wade*, decided in 1973, established that a woman's right to have an abortion is part of the fundamental right to privacy.<sup>1</sup> The decision in *Roe v. Wade* established a "trimester framework" in which the balance between privacy of an individual woman's medical decision and a state's interest in protecting maternal health and the potential life of the fetus changed according to the trimester of the pregnancy. In the first trimester of pregnancy, abortion

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<sup>1</sup> 410 U.S. 113 (1973)

is viewed as a private medical decision. During the second trimester of pregnancy, the state's interest in protecting maternal health by regulating abortion becomes compelling. In the third trimester of pregnancy, when a fetus could survive outside the mother's body the state could ban abortions except in cases where abortion was necessary to save the life or health of the mother.

In 1992, in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, the Court relaxed the standard of review in abortion cases involving adult women from strict scrutiny to unduly burdensome, while still recognizing that the right to an abortion emanates from the constitutional penumbra of privacy rights.<sup>2</sup> In *Planned Parenthood*, the Court determined that prior to fetal viability, a woman has the right to an abortion without being unduly burdened by government interference.<sup>3</sup>

The unduly burdensome standard, generally considered to be a hybrid between strict scrutiny and intermediate level scrutiny, shifted the Court's focus to whether a restriction creates a substantial obstacle to access. This is the prevailing standard today applied in cases in which abortion access is statutorily restricted.

However, the undue burden standard was held to be inapplicable in Florida. The 1999 Legislature passed a parental notification law, the Parental Notice of Abortion Act, requiring a physician to give at least 48 hours of actual notice to one parent or to the legal guardian of a pregnant minor before terminating the pregnancy of the minor. Although a judicial waiver procedure was included, the act was never enforced.<sup>4</sup> In 2003, the Florida Supreme Court<sup>5</sup> ruled this legislation unconstitutional on the grounds that it violated a minor's right to privacy, as expressly protected under Article I, s. 23 of the State Constitution.<sup>6</sup> Citing the principle holding of *In re T.W.*,<sup>7</sup> the court reiterated that, as the privacy right is a fundamental right in Florida, any restrictions on privacy warrant a strict scrutiny review, rather than that of an undue burden. Here, the court held that the state failed to show a compelling state interest.<sup>8</sup>

The Women's Right to Know Act, an abortion informed-consent statute, was challenged in 2004.<sup>9</sup> In applying the strict scrutiny standard, the court held the statute unconstitutional for the following reasons:

- Application was not limited to the second and third trimesters of pregnancy, when the state is lawfully authorized to restrict abortions;
- Creating categories of physicians authorized to provide informed consent information were impermissibly restrictive and did not meet the least intrusive means required; and

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<sup>2</sup> 505 U.S. 833, 834 (1992).

<sup>3</sup> *Id.* at 837.

<sup>4</sup> See s. 390.01115, F.S.

<sup>5</sup> *North Florida Women's Health and Counseling Services, Inc., et al., v. State of Florida*, 866 So.2d 612, 619 (Fla. 2003)

<sup>6</sup> The constitutional right of privacy provision reads: "Every natural person has the right to be let alone and free from governmental intrusion into the person's private life except as otherwise provided herein. This section shall not be construed to limit the public's right of access to public records and meetings as provided by law."

<sup>7</sup> 551 So.2d 1186, 1192 (Fla. 1989).

<sup>8</sup> *North Florida Women's Health and Counseling Services*, *supra* note 8, at 642.

<sup>9</sup> *State v. Presidential Women's Center*, 884 So.2d 526 (Fla. 4<sup>th</sup> DCA 2004).

- The information to be provided to a patient was based on what a “reasonable patient would consider material” and not what that specific patient would need.<sup>10</sup>

### **Regulation of Abortion Clinics**

The Agency for Health Care Administration and the Department of Health (DOH) have promulgated detailed rules regulating the licensure of and setting clinical standards for surgical facilities, including physicians’ offices (Chapter 64B8-9.009, F.A.C.) and ambulatory surgical centers (Chapter 59A-5, F.A.C.). AHCA has also promulgated rules regulating abortion clinics (Chapter 59A-9, F.A.C.).

In 1990 Florida’s rules governing first trimester abortions were challenged in the U.S. District Court, in a class action lawsuit that resulted in a permanent injunction against those rules.<sup>11</sup> The rules required that a nurse and other personnel be employed to assist the physician performing the abortion. Rules have since been adopted (Chapter 59A-9, F.A.C) that do not include the requirements that were found to impermissibly regulate first trimester abortions.

Under s. 390.012(1), F.S., AHCA’s rulemaking authority for abortion clinics is limited to the promulgation of rules that are “comparable to rules which apply to all surgical procedures requiring approximately the same degree of skill and care as the performance of first trimester abortions.” There are 65 licensed abortion clinics. AHCA does not collect data that would allow it to know which of these clinics perform post-first trimester abortions.

AHCA’s surveyors examine records in the front office of an abortion clinic; they do not inspect facilities. The local Fire Marshall would be responsible for inspecting the buildings.

Surveyors check for the following:

- That the license is current and posted in a conspicuous place.
- That abortions are performed only by a licensed physician.
- That fetal remains are disposed of in a sanitary and appropriate manner (inspector reviews the contract for biohazard disposal).
- That a complete, accurately documented clinical record is maintained on each patient.
- That clinical records are kept on file for at least 5 years.
- That the number of terminations of pregnancy is reported to the Office of Vital Statistics within the timeframe established in law.

### **Prohibited Acts**

Under s. 797.03, F.S., it is unlawful for any person to perform or assist in performing an abortion except in an emergency care situation, other than in a licensed abortion clinic, licensed hospital, or physician’s office. It is unlawful for anyone to operate an abortion clinic without a license or to perform a third trimester abortion in any setting other than a hospital. A violation of these provisions is a second-degree misdemeanor punishable under ss. 775.082 or 775.083, F.S.

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<sup>10</sup> *Id.* at 532-533.

<sup>11</sup> *Florida Women’s Medical Clinic v. Smith*, 746 F.Supp. 89 (S.D. Fla. 1990).

## Reports of Induced Termination of Pregnancy in Florida

The Office of Vital Statistics, DOH, collects all statistical data and analysis on termination of pregnancies. Section 390.0112(1), F.S., requires the report to be filed with AHCA; however, it is the practice of the agencies (DOH and AHCA) to direct the medical directors and physicians to file the report with DOH. Chapter 59A-9.034, F.A.C., requires that an abortion clinic must submit a cumulative report each month to the Office of Vital Statistics. AHCA licenses and inspects abortion clinics, but all reporting from physicians or medical directors regarding termination of pregnancies is sent directly to the Office of Vital Statistics, DOH, where the data is entered and reports are prepared.

Reports are confidential and will not be revealed except under court order. Statutorily, such reports include the following information:

- Number of procedures performed;
- Reason for pregnancy termination (personal choice, physical condition, mental condition, abnormal fetus, or other reason) which must be specified; and
- Period of gestation at the time such procedure was performed.

According to the Office of Vital Statistics, 91,265 abortions were performed in Florida in 2004. Of these, 82,358 were performed during the first trimester (at or under 12 weeks of gestation); 8,897 were performed in the second trimester (13-24 weeks of gestation); and 10 were performed in the third trimester (at or after 25 weeks of gestation).

### III. Effect of Proposed Changes:

**Section 1.** Provides a popular title for the committee substitute—"The Women's Health and Safety Act."

**Section 2.** Amends s. 390.012, F.S., to increase AHCA's authority to develop rules for licensed abortion clinics, particularly for those that perform abortions after the first trimester. The committee substitute requires AHCA to develop rules that would be in compliance with s. 797.03, F.S., which requires that all third trimester abortions be performed only in a hospital, and to specify that the rules may not impose *an unconstitutional* burden, rather than "a legally significant" burden, on a woman's freedom to decide whether to terminate her pregnancy.

For clinics that perform, or claim to perform, abortions after the first trimester, the rules must be adopted according to the provisions of ss. 120.536(1) and 120.54, F.S., and must include the following:

**Rules for an abortion clinic's physical facilities.** At a minimum, these rules must prescribe standards for:

- Adequate private space that is specifically designated for interviewing, counseling, and medical evaluations.
- Dressing rooms for staff and patients.
- Appropriate lavatory areas.
- Areas for preprocedure hand washing.
- Private procedure rooms.
- Adequate lighting and ventilation for abortion procedures.
- Surgical or gynecological examination tables and other fixed equipment.
- Postprocedure recovery rooms that are equipped to meet the patients' needs.
- Emergency exits to accommodate a stretcher or gurney.
- Areas for cleaning and sterilizing instruments.
- Adequate areas for the secure storage of medical records and necessary equipment and supplies.
- The display in the abortion clinic, in a place that is conspicuous to all patients, of the clinic's current license issued by the agency.

**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 must:

- Prescribe required clean and sterilized 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.
- 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.
- Prescribe equipment and supplies for required laboratory tests and requirements for protocols to calibrate and maintain laboratory equipment or equipment operated by clinic staff at the abortion clinic.
- Require ultrasound equipment in those facilities that provide abortions.
- 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.

**Rules relating to abortion clinic personnel.** At a minimum, these rules must require that:

- The abortion clinic designate a medical director who is licensed to practice medicine and surgery in the state and who has admitting privileges at an accredited hospital in the state that is within 50 miles of the abortion clinic.
- If a physician is not present after an abortion is performed, a registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant shall be present and remain at the clinic to provide postoperative monitoring and care until the patient is discharged.
- Surgical assistants receive training in counseling, patient advocacy, and the specific responsibilities associated with the services the surgical assistants provide.
- Volunteers receive training in the specific responsibilities associated with 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.

**Rules relating to the medical screening and evaluation of each abortion clinic patient.** At a minimum, these rules must require:

- A medical history including reported allergies to medications, antiseptic solutions, or latex; past surgeries; and an obstetric and gynecological history.
- A physical examination, including a bimanual examination estimating uterine size and palpation of the adnexa.
- The appropriate laboratory tests, including:
  - 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.
  - A test for anemia.
  - Rh typing, unless reliable written documentation of blood type is available.
  - Other tests as indicated from the physical examination.
- An ultrasound evaluation for all patients who elect to have an abortion after the first trimester. The rules shall require that if a person who is not a physician performs an ultrasound examination, that person shall have documented evidence that he or she has completed a course in the operation of ultrasound equipment as prescribed in rule. The physician, registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant shall review, at the request of the patient, the ultrasound evaluation results, including an estimate of the probable gestational age of the fetus, with the patient before the abortion procedure is performed.
- 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.

**Rules relating to the abortion procedure.** At a minimum, these rules must require:

- That a physician, registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant is available to all patients throughout the abortion procedure.
- 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.
- Appropriate use of general and local anesthesia, analgesia, and sedation if ordered by the physician.
- Appropriate precautions, such as the establishment of intravenous access at least for patients undergoing post-first trimester abortions.
- 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.

**Rules that prescribe minimum recovery room standards.** At a minimum, these rules must require that:

- Postprocedure recovery rooms are supervised and staffed to meet the patient's needs.
- Immediate postprocedure care consists of observation in a supervised recovery room for as long as the patient's condition warrants.
- The clinic arranges hospitalization if any complication beyond the medical capability of the staff occurs or is suspected.
- A registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant 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.
- A physician shall sign the discharge order and be readily accessible and available until the last patient is discharged to facilitate the transfer of emergency cases if hospitalization of the patient or viable fetus is necessary.
- A physician discusses Rho(D) immune globulin with each patient for whom it is indicated and ensures that it is offered to the patient in the immediate postoperative period or that it will be available to her within 72 hours after completion of the abortion procedure. If the patient refuses the Rho(D) immune globulin, a refusal form approved by AHCA shall be signed by the patient and a witness and included in the medical record.
- Written instructions with regard to postabortion coitus, signs of possible problems, and general aftercare are given to each patient. Each patient shall have specific written instructions regarding access to medical care for complications, including a telephone number to call for medical emergencies.
- 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.
- The physician ensures that a registered nurse, licensed practical nurse, advanced registered nurse practitioner, or physician assistant from the abortion clinic makes a

good faith effort to contact the patient by telephone, with the patient's consent, within 24 hours after surgery to assess the patient's recovery.

- Equipment and services are physically located in a place that is readily accessible to provide appropriate emergency resuscitative and life support procedures pending the transfer of the patient or viable fetus to the hospital.

**Rules that prescribe standards for follow-up care.** At a minimum, these rules must require that:

- A postabortion medical visit that includes a medical examination and a review of the results of all laboratory tests is offered and, if requested, scheduled for 2 to 3 weeks after the abortion.
- 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.

**Rules to prescribe minimum abortion clinic incident reporting.** At a minimum, these rules must require that:

- The abortion clinic records each incident that results in serious injury to a patient or a viable fetus at an abortion clinic and shall report an incident in writing to AHCA within 10 days after the incident occurs. 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 bodily organ.
- 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 workday.
- Incident reports are filed with the department and appropriate professional regulatory boards.
- The rules adopted pursuant to this section shall not limit the ability of a physician to advise a patient on any health issue.

The rules adopted under this committee substitute will be in addition to any other laws, rules, and regulations, which are applicable to facilities defined as abortion clinics under s. 390.012, F.S.

**Section 3.** Provides for severability of the provisions of the act, and states that if certain provisions are held to be invalid, the invalidity of those provisions will not affect the validity of other provisions in the committee substitute.

**Section 4.** Provides that the committee substitute takes effect July 1, 2005.



**IV. Constitutional Issues:**

## A. Municipality/County Mandates Restrictions:

None.

## B. Public Records/Open Meetings Issues:

None.

## C. Trust Funds Restrictions:

None.

## D. Other Constitutional Issues:

**Right of Privacy**

The *Roe v. Wade* trimester framework is still valid law. Additionally, it appears well established that although *Planned Parenthood of Southeastern Pennsylvania v. Casey* reduced the standard of review to that of whether a woman is unduly burdened by a governmental restriction on abortion, the express right of privacy provided in the state constitution requires a strict scrutiny standard to apply in analyzing these cases. It is unclear if a court would find a compelling state interest in preserving health or whether the requirements for abortion clinics under this committee substitute would be considered to unconstitutionally restrict access. Additionally, this committee substitute provides for more restrictive regulations on those clinics that provide abortions after the first trimester. However, if an abortion clinic provides abortions to both women in their first trimester and after, thereby required to abide by the enhanced standards, a court may find the extra restrictions to impede the right of privacy of those patients going to that clinic who are in their first trimester.

Additionally, the committee substitute does not address confidentiality of an abortion patient's identifying information furnished to the department. Section 456.057, F.S., does provide for confidentiality and limited disclosure of patient records and information in delineated circumstances. To the extent that an abortion patient's information may still be disclosed, an additional constitutional challenge based on right of privacy may be made.

**V. Economic Impact and Fiscal Note:**

## A. Tax/Fee Issues:

None.

## B. Private Sector Impact:

Licensed abortion clinics might incur a cost to implement the requirements of the new rules, which most likely would be passed on to the women receiving abortion clinic services.

C. Government Sector Impact:

Licensing surveys by AHCA would be more extensive and would take more time. The agency indicates that the surveys could be accomplished within existing resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

On page 5, line 2, the committee substitute specifies that the rules relating to abortion clinic personnel must require each abortion clinic to designate a medical director “who is licensed to practice medicine and surgery” in the state. The State of Florida does not license physicians by specialty or treatment modality such as surgery. As part of their scope of practice, medical physicians, osteopathic physicians, and podiatric physicians may perform surgery. Many physicians perform surgical procedures in their offices without being specifically licensed to practice surgery.

The committee substitute recognizes a distinction between abortions in the first trimester and after the first trimester. However, the bifurcated regulatory scheme in the committee substitute applies to the clinics, not the procedures. If a clinic performed one or more abortions in the second trimester, the enhanced regulatory requirements would apply to that clinic. That is, if almost all of the abortions performed at a clinic were during the first trimester, but the clinic performed one or more abortions during the second trimester, the clinic would have to meet the enhanced regulatory standards established in this bill. Since the lesser standard would apply exclusively to clinics that perform abortions *only* during the first trimester, and the enhanced regulatory requirements would apply to abortion clinics that perform *any* abortions after the first trimester, an abortion clinic would face the choice of only performing abortions during the first 12 weeks of pregnancy or complying with the enhanced standards.

## **VIII. Summary of Amendments:**

None.

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This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.

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