

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.)

Prepared By: Health Care Committee

BILL: SB 1862

SPONSOR: Senator Dockery and others

SUBJECT: Women's Health Care

DATE: April 4, 2005

REVISED: _____

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

I. Summary:

The bill 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, rather than a legally significant burden, on a woman's freedom to decide whether to terminate her pregnancy.

The bill 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 bill amends s. 390.012, F.S., and creates two unnumbered sections of law.

II. Present Situation:

The Trimester Framework for State Regulation of Abortion

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 privacy¹. 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 is viewed as a private medical decision. During the second trimester of pregnancy, the state's

¹ 410 U.S. 113 (1973)

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.

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 the 1980s 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.² 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.

²*Florida Women's Medical Clinic v. Smith*, (746 F.Supp. 89)

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 the order of a court. 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 bill—"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 rules for clinics that perform only first-trimester abortions must be comparable to those that apply to surgical procedures requiring approximately the same degree of skill and care as the performance of abortions during the first trimester. The bill 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 department.

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 after 12 weeks' gestation.
- 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 12 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 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 patients' 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 the department 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 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.

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 the department 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 department shall not release personally identifiable patient or physician information.
- 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 bill 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 bill.

Section 4. Provides that the bill will take effect July 1, 2005.

IV. Constitutional Issues:**A. Municipality/County Mandates Restrictions:**

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

D. Other Constitutional Issues:**Right of Privacy under the Federal Constitution**

The United States Supreme Court's decision in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992) sets forth the limits that the 14th Amendment Due Process Clause of the United States Constitution imposes on the states' ability to interfere with abortion procedures. 505 U.S. at 874. In *Casey*, the Court held that a state has legitimate interests in protecting the life of the fetus; however, the Court held that the following two principles are paramount:

1. A woman has a right to an abortion before viability and to obtain it without undue interference from the state. *Id.* at 846.
2. Subsequent to viability, the state in promoting its interest in the potentiality of human life may ... proscribe abortion, except where it is necessary in appropriate medical judgment, for the preservation of the life or health of the mother. *Id.* at 879, quoting *Roe v. Wade*, 410 U.S. at 164-165.

Under *Casey*, state legislation that does not comply with these two principles may raise constitutional concerns.

Right of Privacy under the Florida Constitution

The Florida Supreme Court has held that the express right of privacy in section 23 of article I of the Florida Constitution provides broader protection than that afforded by the U.S. Constitution. See *Winfield v. Division of Pari-Mutual Wagering*, 477 So.2d 544 (Fla. 1985). Therefore, any state regulation of a fundamental right is subject to the higher standard of review, i.e., strict scrutiny. The Florida Supreme Court has held that the right of privacy is "clearly implicated in a woman's decision of whether or not to continue her pregnancy." *In re T.W.*, 551 So.2d 1186, 1192 (1989) (statute for parental consent for a minor's abortion declared unconstitutional). Therefore, any regulation regarding

termination of pregnancy must be analyzed against whether the state has a compelling state interest and whether the state has satisfied its burden to justify its regulatory goal through the use of the least intrusive means. *Id.*, citing to *Winfield*, 447 So.2d at 547.

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:

On page 4, line 6, the bill refers to the license issued by the “department.” Abortion clinic licenses are issued by the Agency for Health Care Administration. On page 8, line 14; page 9, lines 28, 29, and 30; and page 10, line 1, the bill also refers to the “department.” The word “department” should be replaced with the word “agency.”

VII. Related Issues:

On page 5, line 4, the bill 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 bill recognizes a distinction between abortions in the first trimester and after the first trimester. However, the bifurcated regulatory scheme in the bill 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.

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

VIII. Summary of Amendments:

None.

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