

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 219 w/CS Women's Health & Safety Act
SPONSOR(S): Bean and others
TIED BILLS: None **IDEN./SIM. BILLS:** SB 212

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) <u>Health Standards (Sub)</u>	<u>6 Y, 3 N</u>	<u>Chavis</u>	<u>Collins</u>
2) <u>Health Care</u>	<u>8 Y, 7 N w/CS</u>	<u>Chavis</u>	<u>Collins</u>
3) <u>Judiciary</u>	<u></u>	<u>Birtman</u>	<u>Havlicak</u>
4) <u></u>	<u></u>	<u></u>	<u></u>
5) <u></u>	<u></u>	<u></u>	<u></u>

SUMMARY ANALYSIS

HB 219/CS expands the Agency for Health Care Administration's (agency) authority to promulgate rules regulating abortion clinics. The bill requires separate rules for abortions performed in licensed abortion clinics during the first trimester of pregnancy, and for those performed in licensed abortion clinics thereafter. The bill specifies that for clinics that perform abortions after the first trimester of pregnancy, the agency must adopt rules to implement the provisions of this section. The bill requires the rules to be in accordance with s. 797.03, F.S., and specifies that such rules may not impose a constitutional burden on a woman's freedom to decide whether to terminate her pregnancy. Currently, the agency's rulemaking authority for abortion clinics performing first trimester abortions is limited, by court order, to clinic-licensing requirements. The agency has promulgated rules regulating the licensure of and setting clinical standards for hospitals (Chapter 59A-3, F.A.C.), ambulatory surgical centers (Chapter 59A-5, F.A.C.), and abortion clinics (Chapter 59A-9, F.A.C.). The Department of Health, through the Board of Medicine has promulgated detailed rules regulating office surgeries (Chapter 64B8-9.009, F.A.C.). Comparatively speaking, the rules regulating abortion clinics are considerably less in both number and detail. In addition, while no other medical facility's regulation is specified in such detail in statute as provided for in this bill, no other medical procedure has been and continues to be as scrutinized by both state and federal courts as abortion has been.

Under U.S. Constitutional analysis, a woman's right of privacy is a fundamental right under the liberty component of the due process clause of the fourteenth amendment. When fundamental rights are at stake, the state regulations of those rights must be narrowly drawn to achieve a compelling government interest. During the first trimester of pregnancy, a state may not ban, or even closely regulate abortion. During the second trimester, the state may protect its interest in the mother's health by regulating abortion in ways that are reasonably related to the mother's health. At the beginning of the third trimester, the state has a compelling interest in protecting the fetus and it may regulate or even proscribe abortion. Laws affecting "fundamental rights" must meet the threshold test of "strict scrutiny," which provides that a state act is constitutional if and only if it is necessary to achieve a compelling state interest.

The bill requires clinics to: develop, promulgate, and enforce policies for obtaining the informed consent of the patient and for postoperative care of patients suffering from complications from abortions; and expands the applicability of standards relating to the making, protection, and preservation of patient records. The bill provides an effective date of July 1, 2003.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h0219c.ju.doc
DATE: April 21, 2003

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

- | | | | |
|--------------------------------------|------------------------------|--|---|
| 1. Reduce government? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. Lower taxes? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 3. Expand individual freedom? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 4. Increase personal responsibility? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 5. Empower families? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |

For any principle that received a “no” above, please explain:

The bill requires revisions to the current administrative rule regulating licensed abortion clinics. The result would be to increase the regulatory oversight of abortion clinics by the agency. Some clinics may have to develop or expand their policies as a result. Clinics that provide post-first trimester abortions will likely experience increased regulations when the administrative rule is revised to ensure compliance with reasonable standards for the level of services provided. These increased regulations may be comparable to those that regulate surgical procedures in hospitals, ambulatory surgical centers, or doctors’ offices requiring approximately the same degree of skill and care as the performance of abortions after the first trimester.

B. EFFECT OF PROPOSED CHANGES:

HB 219/CS expands the agency’s rulemaking authority relating to abortions performed in abortion clinics. The bill requires separate rules for abortions performed in licensed abortion clinics during the first trimester of pregnancy, and for those performed in licensed abortion clinics after the first trimester of pregnancy. The bill specifies that for clinics that perform abortions after the first trimester of pregnancy, the agency must adopt rules to implement the provisions of this section, and must include reasonable and fair minimum standards for insuring:

- Sufficient numbers and qualified types of personnel are on duty and available at all times to provide necessary and adequate patient care and safety;
- Appropriate medical screening and evaluation of each abortion clinic patient takes place;
- Appropriate supplies and equipment are available, including supplies and equipment that are required to be immediately available for use in an emergency;
- Appropriate standards for follow-up care are established and followed;
- Adequate private space that is specifically designated for interviewing, counseling, and medical evaluations;
- Appropriate lavatory areas;
- Areas for pre-procedure hand washing;
- Private procedure rooms;
- Adequate lighting and ventilation for abortion procedures;
- Surgical or gynecologic examination tables and other fixed equipment;
- Post-procedure recovery rooms;
- Emergency exits to accommodate a stretcher or gurney;
- Areas for cleaning and sterilizing instruments; and
- Adequate areas for the secure storage of medical records and necessary equipment and supplies.

The bill requires that the rules adopted be in accordance with s. 797.03, F.S.,¹ and clarifies that such rules may not impose an unconstitutional burden on a woman's freedom to decide whether to terminate her pregnancy.

The bill requires each abortion clinic to develop, promulgate, and enforce policies to protect the health, care, and treatment of patients, including policies for obtaining the informed consent of the patient and for postoperative care of patients suffering complications from an abortion.

The bill expands the requirements for making, protecting, and preserving of patient records to be treated as medical records to include those required under chapter 459, F.S., relating to osteopathic medicine.

The bill provides for a severability clause.

Abortion

Abortion was legalized nationally in the United States on January 22, 1973, when the United States Supreme Court handed down the *Roe v. Wade*, 410 U.S. 113 (1973), and *Doe v. Bolton*, 410 U.S. 179 (1973) decisions. Prior to 1973, the abortion issue was almost exclusively dealt with by state legislatures.

Federal Case Law

In *Roe vs. Wade*, 410 U.S. 113 (1973), the Supreme Court for the first time legalized abortion nationwide. The court based its 7-2 ruling on a woman's constitutional right to privacy. The court said a woman's decision to have an abortion during the first three months of pregnancy must be left to her and her doctor. The Court held that the right of privacy extends to the decision of a woman, in consultation with her physician, to terminate her pregnancy. During the first trimester of pregnancy, this decision may be effectuated free of state interference. After the first trimester, the state has a compelling interest in protecting the woman's health and may reasonably regulate abortion to promote that interest. At the point of fetal viability (capacity for sustained survival outside the uterus), the state has a compelling interest in protecting potential life and may ban abortion, except when necessary to preserve the woman's life or health.

In 1992, in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992), the Court specifically rejected *Roe's* strict scrutiny standard and adopted the undue burden analysis. In *Casey*, the Court reaffirmed its position in *Roe* of a constitutional right to have an elective abortion; however, it officially overturned the trimester hierarchy which controlled the timing of the state's interest in an abortion decision. Instead, the Court stipulated that:

1. The government has a legitimate interest in protecting the potential of human life from conception and throughout the course of the pregnancy; and
2. States may not impose an "undue burden" on a woman's right to obtain an abortion (placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable human).

In 2001, the United State Supreme Court declined to review a challenge to South Carolina's abortion clinic regulations. In *Greenville Women's Clinic v. Bryant*, the clinic alleged that the South Carolina abortion clinic regulations were unconstitutional, and that complying with such regulations would unduly

¹ Section 797.03, F.S., makes it unlawful for any person to perform or assist in performing an abortion on a person, except in an emergency care situation, other than in a validly licensed hospital or abortion clinic or in a physician's office; to establish, conduct, manage, or operate an abortion clinic without a valid current license; and to perform or assist in performing an abortion on a person in the third trimester other than in a hospital. Willful violation of this section is a misdemeanor of the second degree.

burden a woman's right to an abortion. The lower court upheld the constitutionality of the regulations on both due process and equal protection grounds.²

Florida – surgical settings

In Florida there are four types of surgical settings:

- A hospital;
- An ambulatory surgical center;
- A physician's office; and
- An abortion clinic.

The Agency for Health Care Administration has promulgated detailed rules regulating the licensure of and setting clinical standards for hospitals (Chapter 59A-3, F.A.C.), and ambulatory surgical centers (Chapter 59A, F.A.C.). The Department of Health, through the Board of Medicine, has promulgated detailed rules regulating office surgery (Chapter 64B8-9.009, F.A.C.). The rules governing abortion clinics (Chapter 59A-9, F.A.C.) are more limited in scope (due to both federal and state case law) than the rules governing surgeries in hospitals, ambulatory surgical centers, or physicians' offices. **[See, Section III COMMENTS, C. DRAFTING ISSUES OR OTHER COMMENTS for a comparison of the rules.]**

Regulation of Abortion Clinics

Regulation of abortion clinics is contained in ch. 390, F.S. The title to ch. 78-382, Laws of Florida, codified as ch. 390, F.S., provides that the law was enacted for purposes of "providing for licensing, inspection, and regulation [of abortion clinics]; prescribing license fees; providing for department's powers and rulemaking authority; providing for renewal, denial, suspension and revocation of licenses; providing administrative penalties; prohibiting certain acts and providing penalties..." Section 390.012, F.S., in part, provides that the Agency for Health Care Administration "shall have the authority to develop and enforce rules for the health, care, and treatment of persons in abortion clinics and for the safe operation of such clinics." Section 390.014(1), F.S., provides: "No abortion clinic shall operate in this state without a currently effective license issued by the [agency]."

The agency currently licenses 68 abortion clinics. The agency does not collect data that would indicate which of these clinics perform first trimester abortions and which perform second trimester abortions. However, it is known that some of the licensed abortion clinics do perform second trimester abortions. In addition, the agency's current authority to protect patient health does not establish a different clinical standard for first trimester and post-first trimester abortions. Moreover, the rule governing abortion clinics (Ch. 59A-9, F.A.C.), is far more limited in scope than rules governing office surgery (ch. 64B8-9.009, F.A.C.), ambulatory surgical centers (ch. 59A-5, F.A.C.), or hospitals (ch. 59A-3.2, F.A.C.). Abortions performed must be reported monthly to the Department of Health, Office of Vital Statistics.³

Neither ch. 390, F.S., nor ch. 59A-9, F.A.C., require abortion clinics to develop and implement operational policies or procedures; although some insurance companies providing liability coverage to the clinics may require operational policies as part of their risk management program. In addition,

² See *Greenville Women's Clinic v. Bryant*, 222 F.3d 157 (4th Cir. 2000), cert. denied, 531 U.S. 1191 (2001).

³ The Office of Vital Statistics compiles the data reported and makes it available to the public on their website. The latest data reported is for 2001. The data indicate that a total of 85,589 abortions were performed in 2001 in hospitals, ambulatory surgical centers, doctor's offices, or abortion clinics. Of these, 77,985 were first trimester abortions (12 weeks gestation and under); 7,572 were second trimester abortions (13-24 weeks gestation); and 32 were third trimester abortions (25 weeks gestation and over). [<http://www.doh.state.fl.us/>]

abortion clinics that are members of the National Abortion Federation may choose to follow the "Clinical Policy Guidelines" developed by the organization.⁴

In 1979, a class action suit was brought challenging Florida statutes and regulations governing first trimester abortions. In *Florida Women's Medical Clinic, Inc. v. Smith*, the United States District Court for the Southern District ruled that the Florida Abortion Clinic Law and rules implementing its regulation of first trimester abortions, swept too broadly and were unconstitutional, as invading pregnant women's right of privacy; however, the clinic-licensing requirements contained in statute were not constitutionally objectionable.⁵

Subsequent to the 1979 case, the Florida Abortion Clinic Law was amended, granting broader rule-making authority to promulgate rules which provide for the establishment of minimum standards for the care and treatment of clients of an abortion clinic; the availability of after care services and emergency medical services to be administered by a hospital; and the transportation of patients requiring emergency care from an abortion clinic to a licensed hospital. The same plaintiffs moved to amend their complaint in order to challenge the law as amended. Again the United State District Court for the Southern District found that the State is precluded from regulating first trimester abortion facilities absent a compelling state interest; but that the State may, during the second trimester, regulate abortion procedure in ways that are reasonably related to maternal health.⁶

C. SECTION DIRECTORY:

Section 1. Creates the "Women's Health and Safety Act."

Section 2. Amends s. 390.012, F.S., expanding the rulemaking authority of the Agency for Health Care Administration to regulate abortion clinics; and requires each clinic to develop, promulgate, and enforce certain policies.

Section 3. Provides a severability clause.

Section 4. Provides an effective date of July 1, 2003.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

According to the Agency for Health Care Administration, the agency would, after the adoption of the expanded rules, spend "slightly more time" in conducting the annual abortion clinic licensing survey.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

⁴In Florida, 28 of the 68 licensed clinics are members of the National Abortion Federation. Source: National Abortion Federation.

⁵ See *Florida Women's Medical Clinic, Inc. v. Smith*, 478 F.Supp. 233, (S.D.Fla.1979), appeal dismissed, 620 F.2d 297, wherein the United States District Court for the Southern District of Florida found that the rules implementing the regulation of first trimester abortions were unconstitutional as invasive of the right to privacy. The rules at question addressed surgical services, nursing services, laboratory services and facilities, and sanitation, housekeeping and maintenance. These rules have since been repealed.

⁶ See *Florida Women's Medical Clinic, Inc. v. Smith*, 536 F.Supp. 1048 (S.D. Fla. 1982).

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Licensed abortion clinics could experience a modest increase in costs to revise or develop written policies. Women who receive abortions in licensed abortion clinics may be assured a higher degree of safety, care, treatment, and information regarding the health impacts of the procedure as a result of increased regulations.

D. FISCAL COMMENTS:

The United States Supreme Court has held that only when the increased cost of abortion is prohibitive, essentially depriving women of the choice to have an abortion, has the Court invalidated regulations because they impose financial burdens.⁷

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

Right to Privacy

The United States Supreme Court has held that the Federal Constitution only contained an implicit right of privacy,⁸ and that the states, and not the federal government, are "the final guarantors of personal privacy."⁹ "But the protection of a person's general right to privacy--his right to be let alone by other people--is, like the protection of his property and of his very life, left largely to the law of the individual States."¹⁰

U. S. Constitution

Imprinted on the U.S. Constitution and the Bill of Rights is the conviction of the Founding Fathers that government interference in the lives of Americans must be restricted; yet nowhere in either document does the word "privacy" appear, nor is it directly addressed in the Federalist Papers. However, the U.S. Supreme Court while acknowledging that there is no explicit right to privacy in the Constitution, discovered that the First Amendment's right of association; the Third Amendment's prohibition against quartering soldiers in citizens' homes; the Fourth Amendment's protection against illegal searches of homes; the Fifth Amendment's protection against self-incrimination; and the Ninth Amendment's

⁷ See *Akron v. Akron Ctr. for Reproductive Health*, 462 U.S. 416 (1983).

⁸ See *Griswold v. Connecticut*, 381 US 479 (1965).

⁹ See *Katz v. United States*, 389 US 347 (1967).

¹⁰ See *Katz*, 389 U.S. at 350-51.

statement that individuals may enjoy rights not specifically defined in the Constitution, in combination, has created the "penumbra" -- or shadows -- of a right to privacy.

Florida Constitution

In 1980, the citizens of Florida approved an amendment to Florida's Constitution, which grants Florida citizens an explicit right of privacy. Contained in article I, section 23, the Constitution provides as follows:

Right of privacy.--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.

This right to privacy protects Florida's citizens from the government's uninvited observation of or interference in those areas that fall within the ambit of the zone of privacy afforded under this provision. Unlike the penumbra or "implicit" privacy right of the federal constitution, Florida's privacy provision is, in and of itself, a fundamental one that, once implicated, demands evaluation under a compelling state interest standard. The federal privacy provision, on the other hand, extends only to such fundamental interests as marriage, procreation, contraception, family relationships, and the rearing and educating of children. Government intrusions into fundamental privacy rights may only be justified by a compelling state interest and by a legislative enactment that is the least intrusive means to further that interest.¹¹

While case law has made it clear that that the State may not regulate first trimester abortion facilities absent a compelling state interest,¹² it is less clear whether the regulation of post-first trimester abortion facilities as permitted by this bill will be found by the courts to be reasonably related to maternal health and will likely be subject to litigation challenging its constitutionality.

B. RULE-MAKING AUTHORITY:

The bill requires the agency to adopt rules applicable to clinics that perform abortions after the first trimester in contrast to the current rules which are applicable to clinics that perform first trimester abortions.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Comparison of rules regulating surgeries performed by location:

Activity	Abortion Clinics	Physician Offices	Ambulatory Surgery Centers	Hospitals
Inspections	The Agency shall conduct an annual licensure inspection of all facilities.	Unless accredited by AAAASF, AAAHC or JCAHO, the physician shall submit to an annual inspection by the Department of Health.	AmSurg Centers which are not accredited by JCAHO or AAAHC shall be subject to a scheduled annual licensure inspection survey by the Agency. The Agency shall conduct a scheduled annual life-safety inspection to ensure physical plant compliance with the life safety codes.	Hospitals that are not accredited by a hospital accrediting organization are subject to a scheduled annual licensure inspection survey. The Agency shall conduct periodic inspections of hospitals in order to ensure compliance with all licensure requirements.

¹¹ See *In re T.W., a minor*, 551 So.2d 1186 (Fla. 1989), in which the Florida Supreme Court struck down a statute which placed restrictions upon a minor's right to obtain an abortion.

¹² See *Florida Women's Medical Clinic, Inc. v. Smith*, 536 F.Supp. 1048 (S.D. Fla. 1982).

				The Agency shall conduct a scheduled life-safety inspection to ensure physical plant compliance with life safety codes and requirements for disaster preparedness.
Governing Body			The AmSurg Center shall have an effective governing authority responsible for the legal and ethical conduct of the center.	The licensee shall have a governing body responsible for the conduct of the hospital as a functioning institution.
Policies & Procedures		The Board of Medicine adopts the "Standards of the American Society of Anesthesiologists for Basic Anesthetic Monitoring," as the standards for anesthetic monitoring by any qualified anesthesia provider. A policy and procedure manual must be maintained in the office, updated annually and implemented.	The surgical department, anesthesia service, nursing service and housekeeping service shall be organized under written policies and procedures. Each AmSurg Center shall develop and adopt written policies and procedures to ensure the protection of patient rights.	Each hospital providing operative and other invasive procedures shall be organized under written policies and procedures regarding surgical privileges, maintenance of the operating rooms and evaluation and recording of treatment of the patient. All surgical department policies and procedures shall be available to the Agency, reviewed annually and enforced.
Organized Medical Staff			Each AmSurg Center shall have an organized medical staff organized under written by-laws.	Each hospital shall have an organized medical staff organized under written by-laws.
Infection Control		The policies and procedures manual must address responsibilities for cleaning, sterilization and infection control.	Each AmSurg Center shall establish an Infection Control Program that provides for the surveillance, prevention and control of infection; identification, reporting, evaluating and maintaining records of infection; ongoing review and evaluation of sanitation techniques; and development of training programs.	Each hospital shall establish an Infection Control Program that provides for the surveillance, prevention and control of infection; identification, reporting, evaluating and maintaining records of infection; ongoing review and evaluation of sanitation techniques; and development of training programs. Each hospital shall have written policies and procedures reflecting the scope of the infection control program.
Medical Records	A permanent individual clinical record shall be kept on each clinic patient.	The surgeon must maintain complete records of each surgical procedure, including written informed consent.	Each center shall have a medical records service with administrative responsibility of medical records.	All licensed hospitals shall have a current and complete medical record for each patient admitted to the hospital.
Risk Management			Shall establish an internal risk management program.	The chief executive officer shall provide for an internal risk management program which meets the requirements of Section 395.0197, F.S. and

				Chapter 59A-10, F.A.C.
Plans Submission			Must obtain written approval from the Office of Plans and Construction prior to construction. All design and construction shall comply with the requirements contained in applicable codes and standards.	No construction work, including demolition, shall be started until prior written approval has been given by the Office of Plans and Construction.
Physical Plant Requirements		Standards of care and standards of practice require that Florida licensed physicians provide appropriate medical care under sanitary conditions.	Minimum standards of construction and specified minimum essential facilities shall be met regarding: surgical suites (operating rooms, operating service areas, recovery area, recovery service area, laundry, central stores, etc.), elevators where required, water supply and sewage disposal, incinerators, air conditioning, heating and ventilating systems, plumbing fixtures, electrical requirements, nurses' calling system, fire alarm system and emergency electric system.	All construction of new hospitals and all constructions of additions, alterations, refurbishing, renovations to and reconstruction of existing facilities shall be in compliance with current codes and standards (building codes, fire code, and handicapped accessibility). Minimum standards of construction and specified minimum essential facilities shall be met regarding number of operating rooms, size of operating rooms, recovery rooms, service areas, clean and soiled workrooms, storage facilities, etc.
Quality Assessment & Improvement		The policy and procedures manual must contain quality assessment and improvement systems comparable to those required by Rule 59A-5.019 (AmSurg Centers).	Each AmSurg Center shall have an ongoing quality assessment and improvement system to monitor and evaluate the quality and appropriateness of patient care, and opportunities to improve its performance.	Each hospital shall have a planned, systematic, hospital wide approach to the assessment and improvement of its performance to enhance and improve the quality of health care provided to the public.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On April 10, 2003, the Heath Standards Subcommittee adopted a "strike everything" amendment and reported the bill favorably to the Health Care Committee.

Amendment #1 clarifies that the existing rulemaking authority applies to clinics that perform first trimester abortions only. In addition, the amendment authorizes the agency to adopt rules for clinics that provide post first trimester abortions and specifies that such rules should include specified criteria. The amendment also requires each abortion clinic to develop, promulgate, and enforce policies to protect the "health, care, and treatment of patients, including policies for obtaining the informed consent of the patient and for postoperative care of patients suffering complications from an abortion" and expanded the existing reference to medical records to include both chapters 458 and 459, F.S.

The amendment includes a severability clause and provides an effective date of July 1, 2003.

On April 15, the Health Care Committee adopted the amendment recommended by the Health Standards Subcommittee and reported the bill favorably with a CS.