

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

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

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REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) <u>Health Standards (Sub)</u>	_____	<u>Chavis</u>	<u>Collins</u>
2) <u>Health Care</u>	_____	_____	_____
3) <u>Judiciary</u>	_____	_____	_____
4) _____	_____	_____	_____
5) _____	_____	_____	_____

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### SUMMARY ANALYSIS

HB 219 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 after the first trimester of pregnancy. The bill requires that such rules must not impose an unconstitutional burden on the woman's right to decide whether to have an abortion. Under current law, the agency'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 abortions during that particular trimester.

Currently, the agency has promulgated rules regulating the licensure of and setting clinical standards for hospitals (Chapter 59A-3, F.A.C.) and ambulatory surgical centers (Chapter 59A-5, 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.). The agency has also promulgated rules regulating abortion clinics (Chapter 59A-9, F.A.C.). The rules governing abortion clinics are more limited in scope (due to both federal and state case law) than the rules governing surgeries in a hospital, an ambulatory surgical center, or a physician's office.

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. Where an abortion is necessary to preserve the life or health of the mother, it must be permitted. 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 standard.

In *Florida Women's Medical Clinic, Inc. v. Smith*, the U.S. District Court, Southern District, ruled that the Florida Abortion Clinic Law and rules implementing its regulation of first trimester abortions, swept too broadly and were unconstitutional, based on federal constitutional analysis, as invading pregnant women's right of privacy; however, the clinic-licensing requirements contained in statute were not constitutionally objectionable. *Florida Women's Medical Clinic, Inc. v. Smith*, 478 F.Supp. 233, (S.D.Fla.1979), appeal dismissed, 620 F.2d 297. In 1990, the defendants moved for relief from judgment of 536 F.Supp. 1048, striking down Florida's statutes and rules governing first trimester abortions; however, among its other findings, the Court held that the Webster decision of the United States Supreme Court was not a significant change in the law that would warrant granting relief from judgment. *Florida Women's Medical Clinic, Inc. v. Smith*, 746 F.Supp. 89 (S.D.Fla. 1990). Finally, in *In re: T.W.*, 551 S.2d 1186 (Fla. 1989), the Supreme Court of Florida, held that under Florida's Constitution, the state's interest in the fetus become compelling upon viability and that prior to the end of the first trimester, the decision to abort must be left to the woman and may not be significantly restricted by the state.

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:** h0219.hc.doc  
**DATE:** March 3, 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:

#### Reduce government

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 expands the agency’s rulemaking authority relating to abortions performed in abortion clinics. The bill provides that abortions must be performed in accordance with current statutes that stipulate prohibited acts relating to abortions and must not impose an unconstitutional burden on the woman’s freedom to decide whether to have an abortion. Rules developed by the agency for clinics that perform first trimester abortions and those that perform post first trimester abortions must be comparable to rules that apply to all surgical procedures requiring approximately the same degree of skill and care as the performance of abortions during that particular trimester. The bill requires abortion clinics to develop policies to protect the health, care, and treatment of patients. In addition, the bill requires the rules to be in accordance with s. 797.03, F.S., which prohibits the following:

- 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.
- Any person or public body to establish, conduct, manage, or operate an abortion clinic without a valid current license.
- Any person to perform or assist in performing an abortion on a person in the third trimester other than in a hospital.

The bill provides penalties for willful violation of the section. The bill also deletes the requirement that such rules not impose “legally significant” burden on a woman’s freedom to decide whether to terminate her pregnancy and replaces it with the restriction that such rules “may not impose an unconstitutional” burden on such freedom.

## 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, thru 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.) is 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. DAFTING ISSUES OR OTHER COMMENTS for a comparison of the rules.]**

## Florida – 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." The rules of the agency must include such matters as minimum standards for the care and treatment of the clinic's clients; availability of aftercare services and emergency medical services administered by a hospital; transportation of patients requiring emergency care; cleanliness of the clinic consistent with surgical procedures; prompt and proper disposal of fetal remains and tissue in the interest of protecting the public health; and the making, protection and preservation of patient records. 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.<sup>1</sup>

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, abortion clinics that are members of the National Abortion Federation may choose to follow the "Clinical

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<sup>1</sup> 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/>]

Policy Guidelines” developed by the organization.<sup>2</sup> The rule also provides, in part, that the agency is required to conduct an annual licensure inspection of all facilities; however, while the agency has the right to enter the premises of any licensed facility or facility applying for a license, at any reasonable time in order to determine the state of compliance with the provisions of ch. 390, F.S., and rule 59A-9, F.A.C., that authority is very limited. Specifically, the agency is required to make such entry and inspection with the least possible disruption to the clinic activities and must conduct the entry and inspection in a manner considerate of the privacy and confidentiality of any patient who is present.

## **Right to Privacy**

The Supreme Court in *Griswold v. Connecticut*, 381 US 479 (1965), held that the Federal Constitution only contained an implicit right of privacy, the Court stated two years later in *Katz v. United States*, 389 US 347 (1967), that the states, and not the federal government, are "the final guarantors of personal privacy." *In re T.W.*, 551 So. 2d 1186, 1191 (Fla. 1989) (interpreting *Katz*). "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." *Katz*, 389 U.S. at 350-51. Accordingly, some states followed suit and began to add explicit privacy clauses to their own state constitutions. Today, Alaska, California, Florida, Hawaii, and Montana have explicit privacy clauses in their state constitutions.

## 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 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 his 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.

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<sup>2</sup>In Florida, 28 of the 68 licensed clinics are members of the National Abortion Federation. Source: National Abortion Federation.

## 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 a companion case, *Doe v. Bolton*, 410 U.S. 179 (1973), the Court held further that a state may not unduly burden a woman's fundamental right to an abortion by prohibition or substantially limiting access to the means of effectuating her decision.<sup>3</sup>

The Court shifted direction in *Webster v. Reproductive Health Services*, 492 U.S. 490 (1989), and was willing to apply a less stringent standard of review to state's restrictions relating to abortions. In addition, the court held, among other things, that states may require physicians, who determine that a woman desiring an abortion is at least 20 weeks pregnant, to perform tests to determine whether the child is viable. However, the Court in *Webster* splintered on the issue of whether viability should be the beginning point of a state's interest in regulating abortion decisions with only three of the five justices writing the majority opinion agreeing that the trimester structure should be overturned, thus, in effect, leaving the trimester hierarchy unchanged.

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 right to protect the potential of human life from conception and throughout the course of the pregnancy;
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); and
3. Doctors may not be held liable for violating a state's abortion restrictions if the abortion was performed to save the life of the mother.

In 2000, in *Stenberg v. Carhart*, 530 U.S. 914, 120 S.Ct. 2597 (2000), the Court narrowly struck down a Nebraska law that banned so called "partial-birth" abortion. The five-member majority found the law unconstitutional on two independent grounds: (1) it lacked a health exception; and (2) its broad language imposed an "undue burden" on a woman's right to choose abortion. The majority opinion reaffirmed that when a state restricts access to abortion, a woman's health must be the paramount consideration. As a result, every abortion restriction must contain a health exception that allows an

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<sup>3</sup> In *Doe*, the Court held that while the parent's right to an abortion is not absolute, it is incorrect to interpose an arbitrary committee in the decision, essentially leaving the choice to have an abortion up to the baby's parents and their doctor.

abortion when "necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." *Stenberg* at 914, 931. In addition, the court specifically rejected the state's argument that a health exception is unnecessary because the dilation and extraction ("D&X") abortion procedure is never necessary for a woman's health. It held that "a statute that altogether forbids D&X creates a significant health risk." *Stenberg* at 938.

However, also in 2001, the 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 burden a woman's right to an abortion. With one exception concerning privacy of records, the court upheld the constitutionality of the regulations. The court first found that there is no constitutional prohibition on special regulations on abortion clinics, in that they constitute a rational class to regulate, and that it is not unconstitutional for the state to regulate one potential public health issue without regulating all. According to the court, the regulations themselves appeared to be a good reflection of national standards for clinic sanitation and organization. Since this was a facial challenge, the court found the regulations were rationally related to a proper state concern with the health and safety of clinic patients and there was no evidence of improper enforcement. The opinion implicitly raises the issue of why all patients, and just abortion patients, get the benefit of these regulations, but this is not developed because it is not a constitutional bar to the regulations. *Greenville Women's Clinic v. Bryant*, 222 F.3d 157 (4th Cir. 2000), cert. denied, 531 U.S. 1191 (2001).<sup>4</sup>

### State Case Law

In 1982, 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 court 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. *Florida Women's Medical Clinic, Inc. v. Smith*, 478 F.Supp. 233, (S.D.Fla.1979), *appeal dismissed*, 620 F.2d 297.

In 1989, a pregnant minor sought waiver for parental consent for an abortion, in *In re T. W.*, 551 So.2d 1186 (Fla. 1989), the Court held, inter alia, that the privacy amendment to the Florida Constitution embraced more privacy interests and extended more protection to the individual than those of the Federal Constitution. In addition, the Court held that it was at the end of the first trimester when the state's interest in maternal health became compelling under Florida law and, following that point, the state could impose "significant restrictions only in the least intrusive manner designed to safeguard the health of the mother." *Id.* at 1193.

In 1990, the defendants moved for relief from judgment of 536 F.Supp. 1048, striking down Florida's statutes and rules governing first trimester abortions. However, among its other findings, the Court held that the *Webster* decision of the United States Supreme Court was not a significant change in the decision's law that would warrant granting relief from judgment. *Florida Women's Medical Clinic, Inc. v. Smith*, 746 F.Supp. 89 (S.D.Fla. 1990).

### C. SECTION DIRECTORY:

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

**Section 2.** Amends s. 390.123, 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.

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<sup>4</sup> In April 2001, the U.S. Court of Appeals for the Fifth Circuit, ruled in favor of Texas' abortion clinic regulations citing the *Greenville* case. *Women's Medical Center of Northwest Houston v. Bell*, 248 F.3d 411, 419 (5th Cir. 2001).

**Section 3.** 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:**

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:**

None.

## **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:

Florida's constitution, unlike the U.S. Constitution, contains an explicit right of privacy for individuals. The drafters of the amendment rejected the use of the words "unreasonable" or "unwarranted" before the phrase "governmental intrusion" in order to make the privacy right as strong as possible. Since the people of this state exercised their prerogative and enacted an amendment to the Florida Constitution which expressly and succinctly provides for a strong right of privacy not found in the United States Constitution. Subsequently, the court has consistently held that article I, section 23, Florida Constitution, was adopted in an effort to grant Floridians greater privacy protection than that available under the federal constitution. *See, In re T.W.*, 551 So.2d 1186 (Fla. 1989); however, at the end of the first trimester, the state may impose significant restrictions, in the least intrusive manner, which are designed to safeguard the health of the mother.

**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.

According to the Agency for Health Care Administration, the rule would also need to be expanded to include the content of a clinic’s policies to ensure protection of the patient’s health, care, treatment, right to informed consent, and post operative care of patients suffering complications from an abortion.

**C. DRAFTING ISSUES OR OTHER COMMENTS:**

Line 9: In the title there is a spelling error (heath) and on line 38, the word “for” should be deleted and placed on line 37.

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.  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, 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.
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#### IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES