

**HOUSE OF REPRESENTATIVES STAFF ANALYSIS**

**BILL #:** HB 1041  
**SPONSOR(S):** Bean and others  
**TIED BILLS:**

Women's Health Care  
**IDEN./SIM. BILLS:** SB 1862

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<b>REFERENCE</b>	<b>ACTION</b>	<b>ANALYST</b>	<b>STAFF DIRECTOR</b>
1) Health Care Regulation Committee	9 Y, 2 N	Bell	Mitchell
2) Health & Families Council	8 Y, 3 N	Bell	Moore
3) _____	_____	_____	_____
4) _____	_____	_____	_____
5) _____	_____	_____	_____

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**SUMMARY ANALYSIS**

HB 1041 creates the, "Women's Health and Safety Act," which allows the Agency for Health Care Administration to regulate abortion clinics that perform abortions after the first trimester.

The bill requires separate rules for abortions performed in licensed abortion clinics during the first trimester of pregnancy, and for those performed 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 in this bill.

The bill prescribes a list of minimum 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. HB 1041 clarifies that rules promulgated may not impose an unconstitutional burden on a women's freedom to decide whether to terminate her pregnancy.

In compliance with AHCA's rulemaking authority mandated by this bill, licensed abortion clinics must develop and implement the proscribed policies.

The bill provides for a severability clause.

The effective date of the bill is July 1, 2005.

## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – The bill increases regulatory oversight of abortion clinics by the Agency for Health Care Administration (AHCA).

Safeguard Individual Liberty – Increased regulation of abortion clinics may lead to a higher degree of safety, care, and treatment of women seeking an abortion.

#### B. EFFECT OF PROPOSED CHANGES:

HB 1041 amends, s. 390.012, F.S., to create the Women's Health and Safety Act, which expands AHCA'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 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 bill.

The bill prescribes a list of minimum 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.

HB 1041 requires that the rules adopted comply with s. 797.03, F.S.,<sup>1</sup> and clarifies that such rules may not impose an unconstitutional burden on a women's freedom to decide whether to terminate her pregnancy.

In compliance with AHCA's rulemaking authority mandated by this bill, licensed abortion clinics must develop and implement the proscribed policies.

The bill provides for a severability clause.

#### CURRENT SITUATION

##### Regulation of Abortion Clinics in Florida

Regulation of abortion clinics is contained in chapter 390, F.S. The statutes and laws that govern abortion clinics in Florida are:

- Chapter 78-382, Laws of Florida, codified as chapter 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"; and

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<sup>1</sup> 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 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.

- Section 390.014(1), F.S., provides: "No abortion clinic shall operate in this state without a currently effective license issued by the [agency]."

AHCA currently licenses 68 abortion clinics. The Department of Health does not collect data to distinguish which of these clinics perform first trimester abortions and which perform second trimester abortions. However, some of the licensed abortion clinics perform abortions after the first trimester.

In addition, AHCA's current authority to protect patient health does not establish a different clinical standard for first trimester and post-first trimester abortions. The current rules governing abortion clinics<sup>2</sup> are far more limited in scope than the rules governing office surgery,<sup>3</sup> ambulatory surgical centers,<sup>4</sup> or hospitals.<sup>5</sup> Abortions performed must be reported monthly to the Department of Health, Office of Vital Statistics.<sup>6</sup>

Neither chapter 390, F.S., nor 59A-9, F.A.C., requires 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. Twenty-nine abortion clinics in Florida are members of the National Abortion Federation (NAF) and must follow the "Clinical Policy Guidelines"<sup>7</sup> developed by the organization.<sup>8</sup> The NAF inspects abortion clinic facilities before membership approval and does follow-up inspections every 5 years. Many of the regulations specified in HB 1041 are the same or similar to the recommendations in NAF's Clinical Policy Guidelines.

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.<sup>9</sup>

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 States District Court for the Southern District found that the State is precluded from regulating first trimester abortion facilities

<sup>2</sup> Chapter 59A-9, Florida Administrative Code.

<sup>3</sup> Chapter 64B8-9.009, Florida Administrative Code.

<sup>4</sup> Chapter 59A-5, Florida Administrative Code.

<sup>5</sup> Chapter 59-A-3.2, Florida Administrative Code.

<sup>6</sup> The Office of Vital Statistics compiles the data reported and makes it available to the public on their website. The latest comprehensive data reported is for 2003. The data indicate that a total of 89,995 abortions were performed in 2003 in hospitals, ambulatory surgical centers, doctor's offices, or abortion clinics. Of these, 81,188 were first trimester abortions (12 weeks gestation and under); 8,742 were second trimester abortions (13-24 weeks gestation); and 59 were third trimester abortions (25 weeks gestation and over). In 2004 there were 91,265 abortions performed. [<http://www.doh.state.fl.us/>]

<sup>7</sup> NAF develops its Clinical Policy Guidelines to provide quality patient-centered care. [<http://www.prochoice.org>]

<sup>8</sup> In Florida, 29 of the 68 licensed clinics are members of the National Abortion Federation. Source: National Abortion Federation.

<sup>9</sup> 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.

absent a compelling state interest; but that the State may, during the second trimester, regulate abortion procedures in ways that are reasonably related to maternal health.<sup>10</sup>

### **Abortion Regulation Nationwide**

There is no clear consensus on abortion regulation nationwide. Regulation varies greatly within the United States. Some states require that all abortions are performed in ambulatory surgical centers, thus bypassing abortion clinic regulation debates, while other states have extensive laws governing abortion facilities. Sixteen states have no health and safety standards imposed on abortion clinics but all the others regulate to some extent. A majority of the states have minimal regulation of first trimester abortion. Sixteen states require abortions after the first trimester to be performed in a hospital.<sup>11</sup> **[See, Section III COMMENTS, C. DRAFTING ISSUES OR OTHER COMMENTS for a nationwide comparison chart of abortion regulation]**

### **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.

AHCA has promulgated detailed rules regulating the licensure of and setting clinical standards for hospitals,<sup>12</sup> and ambulatory surgical centers.<sup>13</sup> The Department of Health, through the Board of Medicine, has promulgated detailed rules regulating office surgery.<sup>14</sup> The rules governing abortion clinics<sup>15</sup> are more limited in scope than the rules governing surgeries in hospitals, ambulatory surgical centers, or physicians' offices. **[See, Section III COMMENTS, C. DRAFTING ISSUES OR OTHER COMMENTS for comparison of regulations for abortion clinics, physician offices, ambulatory surgery centers, and hospitals]**

### **Abortion**

Abortion was legalized nationally on January 22, 1973, when the United States Supreme Court handing 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 legalized abortion nationwide for the first time. 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 made 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.

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<sup>10</sup> See *Florida Women's Medical Clinic, Inc. v. Smith*, 536 F.Supp. 1048 (S.D. Fla. 1982).

<sup>11</sup> New Jersey, Rhode Island, and Ohio require that abortions are performed in a hospital after the 14<sup>th</sup> week.

<sup>12</sup> Chapter 59A-3, Florida Administrative Code.

<sup>13</sup> Chapter 59A, Florida Administrative Code.

<sup>14</sup> Chapter 64B8-9,009, Florida Administrative Code.

<sup>15</sup> Chapter 59A-9, Florida Administrative Code.

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 *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. The lower court has twice upheld the constitutionality of the regulations on both due process and equal protection grounds.<sup>16</sup>

C. SECTION DIRECTORY:

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

**Section 2.** Amends s. 390.012, F.S., to increase the Agency's authority to develop rules for licensed abortion clinics that perform abortions after the first trimester. The rules must not impose an unconstitutional burden on the patient's freedom to choose an abortion. For first trimester abortions, the administrative rules 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. For facilities that administer post first trimester abortions the bill prescribes a list of minimum rules for: 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.

**Section 3.** Provides a severability clause.

**Section 4.** Provides an effective date of July 1, 2005.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:  
None.
2. Expenditures:  
None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:  
None.
2. Expenditures:

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<sup>16</sup> See *Greenville Women's Clinic v. Bryant*, 222 F.3d 157 (4th Cir. 2000).

None. [See, D. FISCAL COMMENTS]

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Indeterminate. [See, D. FISCAL COMMENTS]

D. FISCAL COMMENTS:

If enacted, it would take AHCA slightly more time to conduct the annual abortion clinic licensing survey. However, implementation of the bill can be accomplished, if necessary, within existing staff and resources.

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 a financial burden.<sup>17</sup>

Licensed abortion clinics could experience an increase in costs to revise and 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 regulation.

### III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or 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 revenue.

2. Other:

**Right to Privacy**

The United States Supreme Court has held that the Federal Constitution only contained an implicit right of privacy, and that the states, and not the federal government, are "the final guarantors of personal privacy...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."

**U. S. Constitution**

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:

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<sup>17</sup> *Akron v. Akron Ctr. For Reproductive Health*, 462 U.S. 416 (1983).

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 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.

**B. RULE-MAKING AUTHORITY:**

AHCA has the necessary authority to carry out the rulemaking provisions in the bill.

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

**Comparison of Florida Health Care Facilities Regulation**

*[Source: Information provided by AHCA & Governor's Office]*

<b>Abortion Clinics (Ch. 59A-9)</b>	<b>Abortion Clinics (Women's Health and Safety Act)</b>	<b>Physician Offices (Ch. 64B 8-9)</b>	<b>Ambulatory Surgery Centers (Ch. 59A-5)</b>	<b>Hospitals (Ch. 59A-3)</b>
<b>PHYSICAL FACILITIES</b>				
Lighting and ventilation as required by Florida Building Code for business occupancy.	Adequate private space for counseling and medical evaluation; dressing rooms for staff and patients; appropriate lavatory areas; areas for pre-procedure hand washing.  Procedure rooms must be private.  Adequate lighting and ventilation.  Surgical and gynecological tables and other fixed equipment are required.  Each recovery room must be supervised, staffed, and equipped to meet the patient's needs.	Physicians must provide their patients appropriate medical care under sanitary conditions.  Adequate operating room lighting must be provided.  Offices performing Level II & III surgery must be inspected by the Department of Health annually or maintain National Accreditation (Chapters 64B8-9.0091(2)(a) and 64B15-14.0076(2)(a)).  Equipment must meet current performance standards.  Office must have appropriate sterilization equipment and supplies.	Chapter 421 of the Florida Building Code and Chapter 9.5 of the 2001 Guidelines for the Design and Construction of Hospitals and Health Care Facilities provide additional extensive regulation of ambulatory surgery centers. The Building Code, in particular, establishes requirements for plumbing, electrical, heating and cooling, and nurses' calling system. Chapter 9.5 addresses a wide variety of issues, from required number of parking spaces to sterilizing facilities and clinical facilities.  Special Lighting and Ventilation as required by the Florida Building Code section 421.  Must have lockers, showers, and toilet rooms for doctors, nurses, and other personnel.  Each recovery room must be located in the surgical suite (or adjacent thereto).	The facilities must be designed to meet the needs of the age group of the patients served; indoor and outdoor areas must be provided for patient activities; individual and separate storage areas must be provided for each patient; laundry or dry-cleaning facilities must be provided; fire protection must meet NFPA guidelines.  Chapter 419 of the Florida Building Code and Chapter 7 of the 2001 Guidelines for the Design and Construction of Hospitals and Health Care Facilities provide additional extensive regulation of hospital facilities. Chapter 7, for example, requires storage areas, changing areas, report preparation areas, and minimum clear area for rooms based on the type of surgery.  Special lighting and ventilation as required by the Florida Building Code section 419.  Each general surgery area must have a minimum clear area of 400 sq. ft., and must include a phone and x-ray machine; other rooms vary in size depending on the procedure.  Ventilation varies depending on the type of service; for inpatient cardiac catheterization service, e.g., there are detailed air quantity and filtration requirements; there are also detailed requirements for lighting in operating rooms.  Each recovery room must have a medication administration station, hand washing facilities, nurse station, and storage space.
<b>CLINICAL EQUIPMENT AND SUPPLIES</b>				
None	Equipment and supplies necessary for any abortion procedure that anticipates performing,	There are different standards for each Surgery Level. Level I and II are briefly described below:  Level I: Oxygen, positive pressure ventilation device,	Chapter 421 of the Florida Building Code and Chapter 9.5 of the 2001 Guidelines for the Design and Construction of Hospitals	A central sterile supply department must be provided; a pharmacy must be provided within the hospital, and must be able to handle the pharmacy and medicine requirements of the hospital. Chapter 59-

Abortion Clinics (Ch. 59A-9)	Abortion Clinics (Women's Health and Safety Act)	Physician Offices (Ch. 64B 8-9)	Ambulatory Surgery Centers (Ch. 59A-5)	Hospitals (Ch. 59A-3)
	<p>including monitoring of each patient throughout the procedure and recovery period.</p> <p>Must have ultrasound equipment.</p> <p>All equipment must be safe for the patient and staff, must meet applicable federal standards, and must be checked annually.</p>	<p>Epinephrine, Corticoids, Antihistamine, and Atropine, if any anesthesia is used.</p> <p>Level II: Full and current crash cart at the location the anesthetizing is being carried out. The crash cart must include 21 resuscitative medications. In addition, the following supplies are required: suction devices, a positive pressure ventilation device, double tourniquet, monitors for blood pressure/EKG/Oxygen saturation; emergency power source able to produce adequate power to run required equipment for a minimum of two hours; appropriate sterilization equipment; IV solution and IV equipment. Benzodiazepine must be stocked but not on the crash cart.</p> <p>Level II standards include Level I requirements.</p>	<p>and Health Care Facilities provide additional extensive regulation of ambulatory surgery centers. Chapter 9.5, for example, requires a system for sterilizing equipment and supplies; in surgical service areas, the requirements include a drug distribution station, scrub facilities, soiled workroom, and fluid waste disposal facilities.</p>	<p>3.2085(3), Surgical Department, lists the minimal equipment to be located in each operating room or available.</p> <p>Chapter 419 of the Florida Building Code and Chapter 7 of the 2001 Guidelines for the Design and Construction of Hospitals and Health Care Facilities provide additional extensive regulation of hospitals. Chapter 7, for example, requires equipment storage areas, preparation areas, and clean workroom/clean supply room.</p>
<b>EMERGENCY EQUIPMENT, SUPPLIES, &amp; MEDICATIONS</b>				
None	<p>Equipment, supplies, and medications necessary for emergency use including written protocols and procedures to be followed by staff in an emergency (such as the loss of power).</p>	<p>See Clinical Equipment and supplies described above.</p> <p>Emergency Incubation Equipment required for Level II surgery.</p>	<p>Emergency equipment must be provided as needed, commensurate with the services of the facility including the surgical department, anesthesia services, and radiological services.</p>	<p>Chapter 59A-3.255, Emergency Care, provides a full description of the services and equipment which must be available for immediate use for the provision of emergency care and services.</p>
<b>MEDICAL HISTORY</b>				
None	<p>Must include reported allergies, past surgeries, and an obstetric and gynecological history.</p>	<p>Standards of care for allopathic and osteopathic physicians require a history, physical and maintenance of contemporary medical records.</p> <p>Must have a signed informed consent.</p>	<p>Part of a center's duty to maintain a current and complete medical record.</p> <p>Chapters 59A-5.0085, Departments and Services, and 59A-5.012, Medical Records, provide for patient medical history, physical exam and extensive medical records to be gathered, performed and maintained.</p>	<p>Part of a hospital's duty to maintain a current and complete medical record, i.e.: 59A-3.2085(3) Surgical Department requires an assessment of the patient's medical, anesthetic and drug history to determine appropriateness of the procedure to be performed; requires a complete history and physical workup in every patient's chart or if not yet transcribed a notation to that effect by the physician. Similar requirements are listed for other services and departments including ambulatory care.</p>
<b>PHYSICAL EXAMINATION &amp; TESTS</b>				

Abortion Clinics (Ch. 59A-9)	Abortion Clinics (Women's Health and Safety Act)	Physician Offices (Ch. 64B 8-9)	Ambulatory Surgery Centers (Ch. 59A-5)	Hospitals (Ch. 59A-3)
To perform laboratory tests onsite, a separate clinical laboratory license must be obtained under Chapter 483, Part I, F.S.	<p>Must include a bimanual examination estimating uterine size.</p> <p>Urine, blood, anemia, Rh typing, and other tests as indicated from the physical exam.</p> <p>Ultrasound evaluation, which a physician must use in estimating gestational age.</p> <p>To perform laboratory tests onsite, a separate clinical laboratory license must be obtained under Chapter 483, Part I, F.S.</p>	<p>The surgeon must examine the patient immediately before the surgery, to evaluate the risk of anesthesia and of the surgical procedure to be performed.</p> <p>To perform laboratory tests onsite, a separate clinical laboratory license must be obtained under Chapter 483, Part I, F.S.</p>	<p>To perform laboratory tests onsite, a separate clinical laboratory license must be obtained under Chapter 483, Part I, F.S.</p> <p>While not specifically listed, testing as necessary prior to procedures does occur.</p> <p>Chapter 59A-5.012, Medical Records, ensures that each medical record shall contain the original of the following as appropriate to the service provided:</p> <ul style="list-style-type: none"> <li>- Physical examination report;</li> <li>- Radiology, diagnostic imaging, and ancillary testing reports;</li> </ul>	<p>To perform laboratory tests onsite, a separate clinical laboratory license must be obtained under Chapter 483, Part I, F.S.</p> <p>While not specifically listed, testing as necessary prior to procedures does occur.</p> <p>Chapter 59A-3.2085 lists with respect to ambulatory care services that a patient's record must include and be updated as necessary to include reports of procedures and tests and their results, as well as diagnostic orders. The latter is also true for services provided through the Surgical Department, i.e., a determination of the appropriateness of a procedure for a patient is to be based on information including the patient's physical status, diagnostic data and pre-anesthesia evaluation prior to surgery if anesthesia is used. A complete physical workup is contained in the chart of every surgical services patient.</p>

**MEDICAL PERSONNEL**

Only licensed physicians may perform an abortion.	<p>Only licensed physicians may perform an abortion.</p> <p>An RN, LPN, ARNP, or PA must remain on the premises until all patients are discharged and must be trained in the managed of the recovery area, capable of providing basic CPR and related emergency procedures.</p> <p>Surgical assistants must receive training in counseling, patient advocacy, and specific responsibilities associated with the services the surgical assistants provide. Volunteers must undergo similar training if it is part of their responsibilities.</p> <p>A physician must sign the discharge order and be accessible and available until the last patient is discharged to facilitate the transfer of emergency cases if hospitalization is necessary.</p>	<p>Only licensed physicians may perform an abortion.</p> <p>Persons assisting in the delivery of medical care to their patients must be licensed, certified, or supervised as required by law.</p> <p>Qualified Anesthetist must be in the room for Level II and Level IIA surgeries.</p> <p>Surgeon and one assistant must be ACLS and BLS certified.</p> <p>Physicians doing Level II &amp; Level III procedures in their office must demonstrate compliance with the Office Surgery.</p> <p>Chapters 64B8-9 and 64B15-14.007 set specific standards for licensure, training and qualifications for the surgeon, anesthesiologist provider and the support staff.</p>	<p>Only licensed physicians may perform an abortion.</p> <p>There shall be a sufficient staffing pattern of registered professional nurses to provide quality nursing care to each surgical patient from admission through discharge.</p> <p>Chapter 59A-5.005 requires that all attending organized medical staff members, podiatrists and dentists who do not have admitting privileges at an acute care general hospital shall have a written agreement from a physician who has staff privileges with one or more acute care general hospitals to accept any patient who requires continuing care; or ensure that there is a written facility agreement with one or more acute care general hospitals for the same.</p>	<p>Only licensed physicians may perform an abortion.</p> <p>An unlicensed person may not assist or participate in any surgical procedure unless the hospital has authorized the person to do so following a competency assessment.</p> <p>Related to the surgical departments, each hospital shall ensure that immediately following each surgery, there is an operative report describing techniques and findings; the patient must be discharged by a qualified practitioner.</p> <p>Chapter 9A-3.2085, Department and Services, lists the staff required for departments and services including surgery, nursing and ambulatory care. For surgery each hospital shall designate a physician as medical advisor and a registered nurse to direct nursing services within the operating rooms; a roster of on-call physicians must be maintained/available, and an on-call surgeon must be promptly available. Regarding ambulatory care, such services must be under the direction of a licensed physician(s), supervised by a registered nurse, and staffed with appropriately trained and qualified individuals to provide the scope of services needed.</p>
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**MEDICAL DIRECTOR**

Abortion Clinics (Ch. 59A-9)	Abortion Clinics (Women's Health and Safety Act)	Physician Offices (Ch. 64B 8-9)	Ambulatory Surgery Centers (Ch. 59A-5)	Hospitals (Ch. 59A-3)
None	A medical director must be designated who is licensed to practice medicine and surgery in Florida, and has admitting privileges at an accredited hospital in Florida that is within 50 miles of the abortion clinic.	A Medical Director may be required by Chapter 400.990, F.S., if clinic or office is not wholly owned by healthcare licensees.	Pursuant to Chapter 59A-5.005, Governing Body, must have an effective governing authority responsible for the legal and ethical conduct of the ASC.  Pursuant to Chapter 59A-5.007, Organized Medical Staff, organized under written by laws and responsible for the quality of all medical care provided to patients in the center and for the ethical and professional practices of its members.  Chapter 59A-5.0085, Departments and Services, also provides for administrative and medical oversight.	Each hospital must have a governing body shall approve by-laws, rules and regulations of the organized medical staff; shall be under the direction of a chief executive officer; shall have an organized medical staff responsible for the quality of health care provided to patients. For surgery each hospital shall designate a physician as medical advisor and a registered nurse to direct nursing services within the operating rooms. Regarding ambulatory care, such services must be under the direction of a license physician(s), supervised by a registered nurse.

**ABORTION PROCEDURES**

Third trimester abortions may only be performed in a hospital (s. 797.03, F.S.).	Third trimester abortions may only be performed in a hospital (s. 797.03, F.S.).  A physician, RN, LPN, or PA must be available to all patients throughout the abortion procedure.  Appropriate use of general and local anesthesia, analgesia and sedation.  Appropriate precautions, including the establishment of IV access.  Appropriate monitoring of vital signs throughout the procedure.	Third trimester abortions may only be performed in a hospital (s. 797.03, F.S.).  Most abortions fall within the Level IIA surgery requirements. The surgeon must be assisted by a physician or PA, RN, or LPN during the procedure. Additional assistance may be required by specific procedure or patient circumstances.  Abortion procedures scheduled for more than five minutes or requiring a higher level of anesthesia must meet the requirements of Level II and Level III Office Surgery Registration Rule (Chapters 64B8-9.0091 and 64B15-14.0076).	Third trimester abortions may only be performed in a hospital (s. 797.03, F.S.).  A qualified person designated by the administrator shall be responsible for the daily functioning and maintenance of the surgical suite.  A registered nurse shall serve as O.R. Circulating Nurse.  There shall be a sufficient staffing pattern of registered professional nurses to provide quality nursing care to each surgical patient from admission through discharge.	Third trimester abortions may only be performed in a hospital (s. 797.03, F.S.).  Chapter 59A-3.2085 describes the organization, staffing and equipping of surgical, ambulatory care and nursing departments and services; procedures for patient assessments, records and safety.
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**POST-PROCEDURE CARE**

<b>Abortion Clinics (Ch. 59A-9)</b>	<b>Abortion Clinics (Women's Health and Safety Act)</b>	<b>Physician Offices (Ch. 64B 8-9)</b>	<b>Ambulatory Surgery Centers (Ch. 59A-5)</b>	<b>Hospitals (Ch. 59A-3)</b>
None	<p>Observation in a supervised and staffed recovery room, including monitoring of vital signs until the patient's condition is deemed to be stable.</p> <p>A specified minimum length of time by type of abortion procedure and duration of gestation.</p> <p>A physician ensures that an RN, LPN, ARNP, or PA make a good faith effort to contact the patient within 24 hours of surgery, with the patient's consent.</p>	<p>The surgeon must assure that the post-operative care arrangements made for the patient are adequate to the procedure being performed as set forth in Chapter 64B8-9.009.</p> <p>Following a Level IIA and Level II surgery, a physician, PA, or RN must be available to monitor the patient in the recovery room until the patient is recovered from anesthesia. The monitor must be certified in Advanced Cardiac Life Support.</p>	At least one RN must be in the recovery area during the patient's recovery period.	<p>A staff member may not attend to a patient in the recovery room unless that staff member is authorized and is in the company of at least one other person (s. 395.0197(1)(b)2., F.S.)</p> <p>Post procedure status of the patient is assessed on admission to and discharged from the recovery area; patient must be discharge by a qualified practitioner.</p>

### COMPLICATIONS

None	<p>Hospitalization must be arranged if complications arise, or are suspected, that are beyond the capability of the staff.</p> <p>Written instructions must be provided regarding possible problems and general aftercare.</p>	<p>The physician must have a transfer agreement with a licensed hospital within reasonable proximity if the physician does not have staff privileges to perform the same procedure as that being performed in the out-patient setting at a licensed hospital within reasonable proximity. "Reasonable proximity" is defined as not to exceed thirty (30) minutes transport time to the hospital.</p> <p>The surgeon must have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office setting or must be able to document satisfactory completion of training such as Board certification or Board eligibility or must be able to establish comparable background, training, and experience.</p>	<p>All attending organized medical staff members, podiatrists and dentists who do not have admitting privileges at an acute care general hospital, shall have a written agreement from a physician who has staff privileges with one or more acute care general hospitals licensed by the state to accept any patient who requires continuing care; or ensure that there is a written facility agreement, with one or more acute care general hospitals licensed by the state, which will admit any patient referred who requires continuing care.</p>	<p>Post procedure status of the patient is assessed on admission to and discharged from the recovery area; patient must be discharge by a qualified practitioner.</p>
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### MEDICAL RECORDS

A permanent clinical record must be kept for each patient	Original prints of each patient's ultrasound evaluation must be kept in the patient's medical history, along with a written estimate of the gestational age of the fetus.	<p>Medical records must be maintained pursuant to Chapters 64B8-9.003 and 64B15-15.004.</p> <p>Surgeons must maintain surgical logs of all level II and III surgical procedures.</p>	<p>Each center must have a medical records service. Each patient's record must contain a complete medical record for every admitted patient. In addition, the medical records service must maintain a system of identification and filing to ensure prompt location of a patient's record.</p>	<p>Each hospital must have a medical records department with administrative responsibility for medical records. Every hospital must also maintain a current and complete medical record for every patient seeking care, and must contain information required for completion of birth, death, and still birth certificates, as well as 24 other data items.</p>
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### ADVERSE INCIDENT REPORTING

Licensed practitioners have a duty to notify patients or their representatives about adverse incidents that	Abortion clinics must record each incident that results in "serious injury" to a patient or viable fetus at an abortion clinic. This incident must be reported to the Department of Health within 10 days	Each physician office must establish an incident reporting system for events that include those that result in the death of a patient, brain or spinal damage of a patient, performance of a surgical procedure on the wrong patient, or performance of a	<p>Adverse incident reporting to AHCA (Code 15) is required under s. 395.0197, F.S.</p> <p>Licensed practitioners have a duty to notify patients or their representatives about</p>	<p>Adverse incident reporting to AHCA (Code 15) is required under s. 395.0197, F.S.</p> <p>Licensed practitioners have a duty to notify patients or their representatives about adverse incidents that result in serious harm to the patient, pursuant to s. 456.0575, F.S.</p>
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<b>Abortion Clinics (Ch. 59A-9)</b>	<b>Abortion Clinics (Women's Health and Safety Act)</b>	<b>Physician Offices (Ch. 64B 8-9)</b>	<b>Ambulatory Surgery Centers (Ch. 59A-5)</b>	<b>Hospitals (Ch. 59A-3)</b>
result in serious harm to the patient, pursuant to s. 456.0575, F.S.	after the incident occurs. If a patient death occurs, the abortion clinic must report it to the Department of Health within the next working day.	wrong-site surgical procedure. Medical incidents that result in death must be reported immediately to the medical examiner pursuant to s. 406.12, F.S.  Licensed practitioners have a duty to notify patients or their representatives about adverse incidents that result in serious harm to the patient, pursuant to s. 456.0575, F.S.  Each physician must report any adverse incidents, including any incident requiring the transfer of the patient to the hospital, as the result of surgery performed in their office to the Department of Health (Chapters 64B8-9.001 (1) (a) and 64B15-14.007).	adverse incidents that result in serious harm to the patient, pursuant to s. 456.0575, F.S.	

### Comparison by State of Abortion Clinic Regulations

[Source: Information provided by AHCA & Governor's Office]

<b>State</b>	<b>Abortion Clinic Regulations</b>	<b>State Laws in brief regarding clinic regulations</b>
Alabama	Yes	Provider must obtain license if it performs more than 30 abortions per month during any given two months, or providers who advertise that it performs abortions regulation requires that physician must examine fetus by use of ultrasound to determine age and viability of the fetus. No abortion beyond first 19 weeks of pregnancy without first determining if the fetus is viable. 24-hour reflection period required.
Alaska	N/A	Regulations state that ambulatory surgical facilities (the only non-hospital facilities receiving state approval to perform abortions) may not perform abortions after the first trimester; resulting in post-first trimester abortions being performed in a hospital.
Arizona	Yes	Any provider, other than a hospital, who performs 5 or more 1 <sup>st</sup> trimester abortions per month, or any 2 <sup>nd</sup> or 3 <sup>rd</sup> trimester abortions, must be licensed as an abortion clinic. Clinics are subject to physical plant, recordkeeping, personnel, and patient care requirements. Ultrasound required after 12 weeks gestation.
Arkansas	Yes	Abortion facility license required if primary function is abortions. Regulations encompass administrative, physical plant, recordkeeping, personnel, and patient care requirements. Physical plant requirements address required number of rooms and minimum room dimensions.
California	No	No health and safety standards imposed on abortion clinics.
Colorado	No	No health and safety standards imposed on abortion clinics.
Connecticut	Yes	Requires that all abortions after the second trimester must be performed in a hospital. Outpatient clinics operated by corporations or municipalities are required to have a standard operating room. Clinics must hire counselors who have or who are supervised by a person with a graduate degree or training in social work, psychology, counseling, nursing, or ministry. Clinic regulations prescribe minimum standards for the building or facility, patient medical testing, and maintenance of patient records.
Delaware	No	Not required to license or regulate abortion clinics.
District of Columbia	No	No health and safety standards imposed on abortion clinics.
Florida	Yes (minimum requirements)	Any facility performing abortions must obtain an abortion clinic license. (FI Admin. Code 59A-9-020(1)) Clinics required to maintain personal medical records for a minimum of 5 years.
Georgia	Yes (minimum requirements)	Administrative requirements only on abortion clinics. 2 <sup>nd</sup> trimester or 3 <sup>rd</sup> trimester abortions must be performed in hospitals or ambulatory surgical centers.

Hawaii	N/A	All abortions are required to be performed in a licensed hospital.
Idaho	No	First trimester abortions may be done in physician's office or clinic with proper staff and equipment. All 2nd and 3rd trimester abortions must be performed in a licensed hospital.
Illinois	Yes (minimum requirements)	Outpatient abortion clinics are a subcategory of ambulatory surgical treatment centers. They are required to be licensed and regulated by the state, and are limited to performing abortions up to 18 weeks.
Indiana	Yes (minimum requirements)	Health and safety regulations are prescribed for abortions performed after the first trimester. 2nd and 3rd trimester abortions must be performed in a hospital or ambulatory outpatient surgical center.
Iowa	No	Does not require minimum health and safety standards for abortion clinics.
Kansas	No	Does not require minimum health and safety standards for abortion clinics.
Kentucky	Yes	All abortion providers, including private physicians, must comply with administrative, physical plant, and employee testing requirements. Every abortion facility must have written transfer agreement with a hospital and ambulance service. Comprehensive health and safety requirements for abortion clinics.
Louisiana	Yes	Required licensing of abortion clinics. Minimum health and safety standards including clinic administration, professional qualifications, patient testing, physical plant, and post-operative care. Regulations went into effect in 11/03. Outpatient abortion facilities are required to have segregated procedure rooms that are a minimum of 120 square feet, exclusive of vestibule, toilets, or closets.
Maine	N/A	Does not license abortion clinics or require that clinics meet minimum health and safety standards. Rules and regulations are proposed.
Maryland	No	Does not currently license abortion clinics or have regulatory criteria that require that clinics meet minimum health and safety standards related specifically to abortions.
Massachusetts	Yes (minimum requirements)	Abortions restricted to hospitals or other specialized facilities duly authorized to provide facilities for general surgery. No regulations regarding health and safety.
Michigan	Yes	Abortion clinics where more than 50% of the patients undergo abortions are regulated as "freestanding surgical outpatient facilities." (under 50% are exempt) The regulations provide for health and safety standards in such areas as clinic administration, professional qualifications, and physical plant.
Minnesota	Yes (minimum requirements)	Requires that abortions after the first trimester be performed in a hospital or abortion facility. Has a not mandated minimum health and safety standards for the state's abortion clinics.
Mississippi	Yes	Requires health and safety regulations for abortion clinics performing more than 10 abortions per month and/or more than 100 abortions per year. The regulations prescribe minimum health and safety standards for the building or facility, clinic administration, staffing, and pre-procedure medical evaluations. State inspections can be made as deemed necessary.
Missouri	Yes	Requires health and safety standards for clinics and facilities where abortions are performed on more than 50% of total patients treated or where more than 50% of the clinic or facility's revenue comes from the performance of abortions. Regulations prescribe health and safety standards for the building or facility, clinic administration, staffing, and patient medical evaluations.
Montana	N/A	Does not license abortion clinics or require that clinics meet minimum health and safety standards. Only state that allows physician assistants to perform abortions.
Nebraska	Yes	Requires health and safety standards for abortion clinics, which at any point during a calendar year, perform 10 or more abortions during one calendar week. The regulations prescribe minimum health and safety standards for the building or facility, staffing and medical testing of clinic employees.
Nevada	No	Does not license abortion clinics or require that clinics meet minimum health and safety standards.
New Hampshire	No	Does not license abortion clinics or require that clinics meet minimum health and safety standards.
New Jersey	Yes (minimum requirements)	Requires that abortions after the 14 <sup>th</sup> week of pregnancy be performed only in a licensed hospital or a licensed ambulatory care facility. There are no clinic regulations applicable to facilities performing first-trimester abortions.
New Mexico	No	Does not license abortion clinics or require that clinics meet minimum health and safety standards.
New York	No	Requirement that all abortions after the 12 <sup>th</sup> week be performed in a hospital and on an in-patient basis. Does not license abortion clinics or require that clinics meet minimum health and safety standards
North Carolina	Yes	Comprehensive regulations establishing minimum health and safety standards for abortion clinics. Among the areas regulated are clinic administration, staffing, patient medical evaluations, and post-operative care. A clinic must include at least 18 individual physical components, including its own lab and a "nourishment station" for serving means or snacks. Any non-hospital provider that performs abortions during the first 20 weeks of pregnancy must be "certified" as an abortion clinic. A clinic must hire a R.N. with experience in "post-operative or post-partum care" to be on duty in the clinic at all times when patients are in the facility. After 20 weeks all abortions must be performed in a licensed hospital.
North Dakota	No	Does not mandate minimum health and safety requirements for abortion clinics operating in the state. All abortions after 12 weeks of pregnancy must be performed in a licensed hospital.
Ohio	Yes (minimum requirements)	Does not mandate minimum health and safety requirements for abortion clinics operating in the

	requirements)	state. All abortions after the 14 <sup>th</sup> week after the first day of the woman's last menstrual period must be performed in a hospital. Requirement that abortion clinics have written transfer agreements with local hospitals to accept patients needing emergency care or to be admitted to a hospital following an abortion.
Oklahoma	Yes	Abortion clinics must meet minimal health and safety standards. The regulations prescribe minimum standards for the building or facility, clinic administration, and patient medical evaluations. An additional requirement that abortions after the first trimester be performed in a hospital has been ruled unconstitutional.
Oregon	No	Does not mandate minimum health and safety requirements for abortion clinics operating in the state.
Pennsylvania	Yes	Requires minimum health and safety standards for abortion clinics. The regulations prescribe requirements for the building or facility, staffing, clinic administration, patient medical evaluations and post-operative care. Requirement that all abortions after the first trimester be performed in a hospital that maintains an "obstetrical service" in compliance with state regulations.
Rhode Island	Yes	Providers of any abortion services, including private physicians, must comply with administrative and patient testing requirements, and providers of 1 <sup>st</sup> trimester surgical abortions must comply with additional physical plant requirements. Requires surgical abortions after the 14 <sup>th</sup> week through the end of the 18 <sup>th</sup> week of gestation in a hospital, a licensed freestanding ambulatory surgical center, physician office, or a freestanding surgical facility. After 18 weeks in a hospital. Does not mandate comprehensive health and safety protections for all abortions performed at state abortion clinics.
South Carolina	Yes	Requires comprehensive health and safety regulations for abortion clinics. These regulations are based on national abortion care standards and cover such areas as clinic administration, physical plant, sanitation standards, patient care, post-operative recovery, and proper maintenance of patient records. All licensed facilities are subject to inspection at any time.
South Dakota	No	Does not mandate comprehensive health and safety requirements for abortion clinics operating in the state.
Tennessee	No	Does not mandate comprehensive health and safety requirements for abortion clinics operating in the state. Any facility used to terminate a pregnancy at any stage is deemed an ambulatory surgical treatment center, and must comply with all requirements of ambulatory surgical treatment centers. Only those physicians' offices that do not perform a "substantial number" of abortions are exempt.
Texas	Yes	Requires comprehensive health and safety regulations for abortion clinics. These regulations cover such areas as clinic administration, sanitation standards, patient care, post-operative recovery, and proper maintenance of patient records. Providers, including private physicians, who perform more than 50 abortions per year, must become licensed as abortion facilities.
Utah	Yes	Does not require minimum health and safety requirements for clinics performing abortions during the first trimester. All providers that perform 2 <sup>nd</sup> trimester abortions must be licensed as "abortion clinics" and are subject to administrative, professional qualification, patient and employee testing, and physical plant requirements. Each clinic must be located within 15 minutes or less of a full-service hospital and transfer agreements and admitting privileges must be in place.
Vermont	N/A	Does not license and regulate abortion clinics.
Virginia	Yes (minimum requirements)	Does not require minimum health and safety requirements for clinics performing abortions during the first trimester. Requires all second trimester abortions be performed in a licensed general hospital or outpatient hospital.
Washington	N/A	Does not license and regulate abortion clinics.
West Virginia	No	Does not require minimum health and safety requirements for abortion clinics.
Wisconsin	Yes	Requires minimal health and safety requirements on abortion clinics. All abortions after the 1 <sup>st</sup> trimester must be performed in a hospital. Physicians may only perform 1 <sup>st</sup> trimester abortions within 30 minutes traveling time of a hospital.
Wyoming	No	Does not require minimum health and safety standards for abortion clinics.

#### IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES