The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Health Regulation Committee

BILL:	CS/SB 780
INTRODUCER:	Health Regulation Committee, Senator Rich and others
SUBJECT:	Reproductive health services and family planning
DATE:	April 16, 2008 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson	HR	**Fav/CS**
2.			JU	
3.			HA	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

The committee substitute provides Legislative findings and creates the "Prevention First Act" for the treatment of female rape survivors and for access to contraception in a pharmacy. Specifically, the committee substitute requires health care practitioners and health care facilities to inform a female rape survivor about emergency contraceptives and, if requested, provide a complete regimen of emergency contraceptives to her, unless contraindicated because she is pregnant. It requires the Department of Health (department) to produce informational materials relating to emergency contraception for distribution to and use in health care facilities providing care to rape survivors and for posting on the department's website relating to the duty of licensed health care practitioners and health care facilities to provide emergency contraception to female rape survivors. The Agency for Health Care Administration (agency), with input from stakeholders, is required to adopt a protocol to implement these requirements in health care facilities.

Licensed pharmacies must provide oral contraceptives that are in stock to patients who request them, with certain limited exceptions. A pharmacy must ensure that its employees do not mistreat patients seeking contraceptives.

Penalties are provided for health care facilities and pharmacies that violate the provisions in this committee substitute. The Attorney General is authorized to bring an action against a pharmacy that fails to comply with the requirements of this law.

This committee substitute amends the following sections of the Florida Statutes: 390.011, 465.016, and 465.023; creates two new sections: 390.027 and 465.190, Florida Statutes; and creates three undesignated sections of law.

II. Present Situation:

Health Care Practitioner, Health Care Facility, and Pharmacy Regulation

Health care practitioners are required to be licensed and are regulated under the general provisions for the regulation of health professions and occupations in ch. 456, F.S., the specific provisions for the applicable discipline through the professional boards under the Department of Health /Medical Quality Assurance, and rules adopted for the health care professions. The practice of medicine is regulated under ch. 458, F.S., the practice of osteopathic medicine is regulated under ch. 459, F.S., and the practice of nursing is regulated under ch. 464, F.S.

Chapter 465, F.S., governs the practice of pharmacy. The Board of Pharmacy within the department regulates the practice of pharmacy. Pharmacists are also subject to the general provisions for the regulation of health professions and occupations in ch. 456, F.S.

Health care facilities: hospitals, ambulatory surgical centers, and mobile surgical facilities, are licensed and regulated under ch. 395, F.S., and ch. 408, F.S., by the agency. Hospitals are not required to provide emergency services; however, according to the agency's inventory, as of April 2, 2008, 224 out of the 288 hospitals in the state have an emergency department.[1] Hospitals with an emergency department and that receive Medicare funding are required by the federal Emergency Medical Treatment and Labor Act (EMTALA) and Florida's Access to Emergency Services and Care Law[2] to provide any person who presents at the emergency department with stabilizing treatment and care to relieve or treat the emergency condition.

Section 395.1021, F.S., requires any licensed facility which provides emergency room services to arrange for the rendering of appropriate medical attention and treatment of victims of sexual assault through:

- Such gynecological, psychological, and medical services as are needed by the victim;
- The administration of medical examinations, tests, and analyses required by law enforcement personnel in the gathering of evidence required for investigation and prosecution; and
- The training of medical support personnel competent to provide the medical services and treatment as described in the preceding bullets.

[1] See *Hospital ER Services as of 04/02/2008, Listed Alphabetically by County*. Found at: <http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/forms/HospitalERServicesInventory.pdf > (Last visited on April 10, 2008).
[2] Section 395.1041, Florida Statutes.

Hospital regulatory provisions do not address the standard of practice for the treatment of rape survivors.

Public Health Family Planning Program[3]

The department's Family Planning Program provides information to reduce unplanned pregnancies, to improve pregnancy outcomes, and to lower rates of sexually transmitted diseases, including HIV.

The department has implemented policies regarding emergency contraceptive services. Emergency contraception is offered to all women of reproductive age who desire emergency contraception and are at risk for unintended pregnancy. It is available to clients, who are screened as a precautionary measure and counseled on usage, in accordance with department technical assistance guidelines and county health department protocols. Federal regulations require that each client is furnished with patient information in the form of patient package inserts for oral contraceptives or estrogens.[4] This information is supplied by the pill manufacturer and is provided with each cycle of pills. The client is prescribed or issued a progestin-only or combined estrogen-progestin method of emergency contraception. The client receives method specific counseling by the "BRAIDED" method, including: benefits, risks, alternatives, time for inquiry, decision, explanation of method, and documentation of counseling. Informed consent is obtained and must be documented in the health record. Written method-specific information is provided to the client at the time of consent.

County health departments not equipped to provide forensic examinations onsite, refer rape victims to a rape crisis center or an emergency department to perform forensic examinations of rape victims. Rape Crisis Centers provide information and referral, crisis intervention, advocacy and support, therapy, medical intervention and system coordination to the rape survivor. County health departments may also provide information to rape survivors about pregnancy prevention, prophylaxis options, and medical services.

Emergency Contraception

Emergency contraception prevents pregnancy after unprotected sexual intercourse. Emergency contraceptives available in the United States include emergency contraceptive pills, sometimes referred to as "the morning after pill," and the Copper T intrauterine contraceptive (IUC).[5] Emergency contraception can keep a woman from *becoming* pregnant. It works one of three ways:

- By keeping the egg from leaving the ovary
- By keeping the sperm from meeting the egg
- By keeping the fertilized egg from attaching to the uterus (womb) any time up to 120 hours after unprotected intercourse.

[3] Department of Health Bill Analysis for SB 780, dated December 31, 2007.
[4] 21 Code of Federal Regulations 310.501 and 310.515.
[5] *Emergency Contraception: A Last Chance to Prevent Unintended Pregnancy* by James Trussell, PhD and Elizabeth G. Raymond, MD, MPH, March 2008, found at: <http://ec.princeton.edu/questions/ec-review.pdf> (Last visited April 10, 2008).

Emergency contraceptive pills
Currently, two types of emergency contraceptive pills (ECPs) are available in the United States: combined ECPs containing both estrogen and progestin and progestin-only ECPs. The newer progestin-only ECPs have largely replaced the other combined ECPs because they are more effective and cause fewer side effects. Treatment with the ECPs may be initiated immediately after unprotected intercourse or at any time up to 120 hours after unprotected intercourse.[6]

The only progestin-only product available in the United States is Plan B®, which was approved by the federal Food and Drug Administration (FDA) as an ECP in July 1999. On August 24, 2006, Plan B® was approved by the FDA for nonprescription sales (over-the-counter) to women and men 18 years of age and older in the United States. A prescription is required for women 17 years of age and younger. In order to verify the age requirement to purchase Plan B®, it is required to be sold behind the counter in licensed pharmacies, and it can only be sold when a pharmacist is on duty. Recent studies indicate that a stronger one-dose regimen is as effective as the two-dose regimen. The first dose must be taken within 72 hours after unprotected intercourse. However, Plan B® is more effective the sooner it is taken, especially within the first 24 hours of unprotected intercourse.[7]

Combined ECPs contain the hormones estrogen and progestin. The regimen is one dose followed by a second dose 12 hours later, where each dose consists of from 1 to 6 pills depending on the brand. Currently, 23 brands of combined oral contraceptives are approved in the United States for use as emergency contraception.[8]

Newer research has demonstrated the safety and efficacy of alternative substances.

Copper-bearing IUDs
Copper IUDs can be inserted up to the time of implantation – 5 to 7 days after ovulation – to prevent pregnancy. Because of the difficulty in determining the day of ovulation, many protocols allow insertion up to only five days after unprotected intercourse.[9]

Safety
No deaths or serious complications have been causally linked to emergency contraception. According to the latest World Health Organization medical eligibility criteria, there are no situations in which the risks of using ECPs outweigh the benefits.[10]

How Emergency Contraceptives Work[11]
The ECPs can prevent ovaries from releasing an egg, can prevent an egg from being fertilized by sperm, or can prevent a fertilized egg from attaching itself to the wall of the uterus. The ECPs are

[6] *Supra*, 5
[7] See <http://www.go2planb.com/ForConsumers/Index.aspx> and <http://www.go2planb.com/ForPharmacists/Index.aspx> (Last visited on April 10, 2008)
[8] *Supra*, 5
[9] *Supra*, 5
[10] *Supra*, 5.
[11] See Family Doctor.org at : <http://familydoctor.org/online/famdocen/home/women/contraceptive/805.html> and see also The Emergency Contraception Website found at: <http://ec.princeton.edu/questions/ecwork.html> (Last visited on April 10, 2008).

not the same as the medicine known as the "abortion pill." This medicine is taken in the early weeks of pregnancy to end the pregnancy. Pills used as emergency contraception can't end a pregnancy once a fertilized egg has attached itself to the wall of the uterus. Although absolute proof about Plan B's mechanisms of action is currently unavailable, the best available evidence is consistent with the hypothesis that Plan B's ability to prevent pregnancy can be fully accounted for by mechanisms that do not involve interference with post-fertilization events.[12]

Unlike the morning-after pill, an IUD doesn't stop ovaries from releasing an egg. The IUD can prevent an egg from being fertilized and it can stop a fertilized egg from attaching itself to the wall of the uterus.

The abortion pill (Mifeprex, also called RU-486) is not emergency contraception since it works after a woman becomes pregnant (after a fertilized egg has attached to the uterus). The abortion pill makes the uterus force out the egg, ending the pregnancy.

Efficacy[13]
The ECPs can be very effective if they are used in time. If used within 72 hours of unprotected sex, they can reduce the risk of pregnancy by 75 to 89 percent. These pills work best when taken as soon as possible after unprotected sex.

Emergency IUD insertion can reduce the risk of pregnancy by 99.9 percent if inserted within 7 days after unprotected sex.

ACLU Study[14]

A study conducted by the American Civil Liberties Union (ACLU) in 2005 found that most emergency care facilities in Florida failed to ensure that victims of sexual assault receive emergency contraception. The ACLU conducted a telephone survey of 139 hospital emergency rooms (88 responded) and 35 sexual assault treatment centers (25 responded) with which many hospitals partner. The study assessed whether sexual assault patients received emergency contraception. The survey revealed that 47 percent of the hospital emergency departments and sexual assault treatment centers provided patients with inconsistent care, failing to ensure that sexual assault patients left the facility with emergency contraception. At these facilities, provision often depended on an individual physician's discretion, the patient's age or whether the facility had emergency contraception in stock, factors that put sexual assault patients at a higher risk of getting pregnant because they are less likely to take emergency contraception within the 120-hour time frame when it's most effective. Another 6 percent of the emergency care facilities surveyed never informed patients about this effective form of pregnancy prevention or assisted them in obtaining it. Only 35 percent of emergency care facilities surveyed ensured that all rape victims received emergency contraception on-site.

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[12] *Supra*, 5 and *Plan B and the Politics of Doubt*, JAMA, October 11, 2006, Vol 296, No. 14.
[13] See Family Doctor.org at : <http://familydoctor.org/online/famdocen/home/women/contraceptive/805.html> (Last visited on April 10, 2008).
[14] *ACLU* Study Shows Most Emergency Care Facilities in Florida Fail to Ensure Victims of Sexual Assault Receive Emergency Contraception, released June 20, 2005, found at:
<http://www.aclufl.org/news_events/index.cfm?action=viewRelease&emailAlertID=1153> (Last visited on April 10, 2008).

The Florida Civil Rights Act of 1992

The general purposes of the Florida Civil Rights Act of 1992 are to secure for all individuals within the state freedom from discrimination because of race, color, religion, sex, national origin, age, handicap, or marital status and thereby to protect their interest in personal dignity, to make available to the state their full productive capacities, to secure the state against domestic strife and unrest, to preserve the public safety, health, and general welfare, and to promote the interests, rights, and privileges of individuals within the state.[15]

III. Effect of Proposed Changes:

Section 1. Creates the "Prevention First Act."

Section 2. Creates an undesignated section of law related to the treatment for survivors of rape.

Subsection 1. Provides definitions of terms used for the treatment for survivors of rape as follows:

- "Agency" means the Agency for Health Care Administration;
- "Care to a rape survivor" means medical examinations, procedures, and services provided to a rape survivor;
- "Department" means the Department of Health;
- "Emergency contraception" means one or more prescription or over-the-counter drugs used separately or in combination to be administered to or self-administered by a patient to prevent pregnancy within a medically recommended amount of time after sexual intercourse and dispensed for that purpose, in accordance with professional standards of practice, and determined to be safe by the FDA;
- "Health care facility" means a facility licensed under ch. 395, F.S. (a hospital, ambulatory surgical center, or a mobile surgical facility);
- "Incest" means a sexual offense described in s. 826.04, F.S., (marrying or having sexual intercourse with a person to whom a person is related by lineal consanguinity, or a sibling, uncle, aunt, nephew, or niece);
- "Medically and factually accurate" means information that is supported by the weight of research conducted in compliance with accepted scientific methods and that is recognized as accurate and objective by leading professional organizations and agencies having relevant expertise in the field;
- "Rape" means sexual battery as described in ss. 794.011 and 827.071, F.S., (oral, anal, or vaginal penetration by, or union with, the sexual organ of another or the anal or vaginal penetration of another by any other object; however sexual battery does not include an act done for a bona fide medical purpose); and
- "Rape survivor" means a person who alleges or is alleged to have been raped or who is the victim of alleged incest and because of the alleged offense seeks treatment as a patient.

Subsection 2. Requires a health care practitioner licensed under ch. 458, F.S., related to the practice of medicine, ch. 459, F.S., related to the practice of osteopathic medicine, or ch. 464,

[15] S. 760.01, F.S.

F.S., related to the practice of nursing, or a licensed hospital, ambulatory surgical center or mobile surgical facility providing care to a female rape survivor to:

- Provide her with medically and factually accurate, clear, and concise information about emergency contraception, including its indications and contraindications and the risks associated with its use;
- Inform her of her medical option to receive emergency contraception; and
- Provide her with a complete regimen of emergency contraception immediately if she so requests, unless she is already pregnant as determined by a pregnancy test.

The agency, with input from the Florida Hospital Association and the Florida Council Against Sexual Violence, must adopt a protocol to implement these requirements.

Subsection 3. Requires the department, in consultation with community stakeholders, to develop information for female rape survivors or female victims of sexual assault that is medically and factually accurate and objective, clearly written, readily comprehensible, and culturally appropriate to explain the use, safety, efficacy, and availability of emergency contraception; and:

- Produce a sufficient quantity of this informational material for distribution to and use in all health care facilities in the state that provide care to rape survivors, based on funding availability, and
- Post information on the department's website relating to the duty of licensed health care practitioners and health care facilities to provide emergency contraception to female rape survivors.

Subsection 4. Requires the agency to respond to complaints and periodically determine whether health care facilities are complying with their statutory responsibilities for the treatment of survivors of rape. If the agency finds that a health care facility is not complying, the agency must impose a fine of $5,000 per woman who is denied the required information about emergency contraception or who is not offered or provided with emergency contraception and impose an additional fine of $5,000 for every 30 days that a health care facility does not comply with these requirements.

The agency is required to adopt rules as necessary to administer these provisions.

Section 3. Amends s. 390.011, F.S., to define contraception to mean any drug or device approved by the FDA to prevent pregnancy.

Section 4. Amends s. 390.027, F.S., to specify that the provision of contraception is not subject to or governed by ch. 390, F.S., related to abortion.

Section 5. Creates s. 465.190, F.S., related to patient contraceptive protection.

Subsection 1. Provides definitions of terms used in this new section of law as follows:

- "Contraception" or "contraceptive" means any prescription or over-the-counter oral contraceptive approved by the FDA to prevent pregnancy;

- "Employee" means a person hired, by contract or any other form of agreement, by a pharmacy;
- "Product" means a drug or device approved by the FDA;
- "Professional clinical judgment" means the use of professional knowledge and skills to form a clinical judgment in accordance with prevailing medical standards; and
- "Without delay," with respect to a pharmacy providing, providing a referral for, or ordering contraception, or transferring a prescription for contraception, means within the pharmacy's customary timeframe for providing, providing a referral for, or ordering other products, or transferring the prescription for other products.

Subsection 2. Requires licensed pharmacies to:

- Provide to a patient or patient representative a contraceptive that has been requested and is in stock without delay; and
- Ensure that employees do not:
  - Intimidate, threaten, or harass a patient in the delivery of services relating to a request for contraception;
  - Interfere with or obstruct the delivery of services relating to a request for contraception;
  - Intentionally misrepresent or deceive a patient about the availability of contraception or its mechanism of action;
  - Breach medical confidentiality with respect to a request for contraception or threaten to breach such confidentiality; or
  - Refuse to return a valid, lawful prescription for contraception upon a patient's request.

However, a pharmacy may refuse to provide a contraceptive to a patient if a valid, lawful prescription is not presented for a contraceptive that requires a prescription; the customer is unable to pay for the contraceptive; or the employee of the pharmacy refuses to provide the contraceptive on the basis of a professional clinical judgment. In addition, a pharmacist or other person may refuse to furnish any contraceptive for religious reasons so long as the pharmacy ensures that the patient receives the contraceptive without delay and in compliance with these provisions.

The bill provides that this section does not alter any standard established under the Florida Civil Rights Act of 1992.

Any person who believes that a violation of these requirements has occurred may file a complaint with the department. If the department finds that a violation occurred, it may take disciplinary action under s. 465.016, F.S., or s. 465.023, F.S., related to the practice of pharmacy.

The Attorney General may bring a civil action if he or she has reasonable cause to believe that any person or group of persons is being, has been, or may be injured by conduct constituting a violation of the provisions related to patient contraceptive protection.

Section 6. Amends s. 465.016, F.S., to include the violation of the patient contraceptive protection in s. 465.190, F.S., as an action for which the Board of Pharmacy may take disciplinary action against a licensee.

Section 7. Amends s. 465.023, F.S., to include the violation of the patient contraceptive protection in s. 465.190, F.S., as an action for which the Board of Pharmacy may take disciplinary action against a pharmacy permittee.

Section 8. Provides a severability provision.

Section 9. Provides that the act will take effect upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

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

B. Public Records/Open Meetings Issues:

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

C. Trust Funds Restrictions:

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

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

As a part of the standard of practice, a female rape survivor will be informed about emergency contraceptives and the bill is intended to ensure she has ready access to the contraceptive, if she is not already pregnant and desires the emergency contraceptive. Patients will have easy access to oral contraceptives at pharmacies.

Health care facilities and health care practitioners have a specified duty to provide certain information and emergency contraception to female rape survivors. Health care facilities that fail to comply with these requirements are subject to administrative fines. Health care facilities will also be subject to a medical protocol developed by the agency.

Pharmacies are required to provide patients with oral contraceptives. A pharmacy that fails to comply with these requirements is subject to administrative discipline.

C. Government Sector Impact:

The department, agency, and Attorney General may have additional investigation and enforcement responsibilities based on the provisions in this bill. The agency indicated that three additional full-time equivalent positions would be needed to implement the bill as originally filed to perform the survey and monitoring responsibilities imposed on the licensed health care facilities at a cost of $207,991 for the first year and $229,551 thereafter, which would need to come from General Revenue funding or an assessment to the facilities. The agency did not quantify additional legal support that may be necessary if enforcement action is required. However, with the changes in the committee substitute, the fiscal impact to the agency may be reduced. The department anticipates the increase in complaint, investigation, and prosecution workload to be minimal and no fiscal impact is provided for this aspect of the bill. However, the department projects a fiscal impact of $28,500 in the first year and $7,463 thereafter for the cost of producing and distributing the informational materials.

VI. Technical Deficiencies:

The sentence beginning on line 161 appears redundant to the provisions on lines 154 – 160.

VII. Related Issues:

None.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Regulation on April 15, 2008:
The committee substitute:

- Changes the terminology in the bill from “emergency birth control” to “emergency contraception”. Emergency contraception is defined to include one or more prescription or over-the-counter drugs used to prevent pregnancy. A pregnancy test must be performed prior to the survivor of rape receiving emergency contraception from a health care facility subject to regulation under this bill.
- Requires the agency, with input from other stakeholders, to develop a protocol to implement the provisions related to treatment for survivors of rape.
- Limits the responsibilities for pharmacies to providing oral contraceptives that are in stock as opposed to addressing drugs and devices and procedures for items not in stock.
- Modifies the administrative sanctions that may be imposed against health care facilities and pharmacies to more closely track existing administrative discipline and not subject these licensed entities to permit suspension or revocation after a couple of violations.

B. Amendments:

None.