

Department of Legislative Services
 Maryland General Assembly
 2005 Session

FISCAL AND POLICY NOTE

Senate Bill 541 (Senator Grosfeld, *et al.*)
 Education, Health, and Environmental Affairs

Public Health - Licensed Pharmacists - Emergency Contraception Dispensing Program

This bill creates an Emergency Contraception Dispensing Program within the Department of Health and Mental Hygiene (DHMH) to authorize licensed pharmacists to dispense emergency contraception.

Fiscal Summary

State Effect: General fund revenues could increase by \$3,800 in FY 2006 and general fund expenditures could increase by \$11,300. Future year revenues reflect a three-year renewal cycle. Future year expenditures reflect annualization and inflation.

(in dollars)	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
GF Revenue	\$3,800	\$5,000	\$1,300	\$5,000	\$6,300
GF Expenditure	11,300	15,200	15,300	15,500	15,600
Net Effect	(\$7,500)	(\$10,200)	(\$14,000)	(\$10,500)	(\$9,300)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect

Local Effect: None.

Small Business Effect: Meaningful to the extent that pharmacists dispense more emergency contraception as a result of this bill.

Analysis

Bill Summary: DHMH must adopt regulations to administer the program within six months of the bill's effective date, collect fees, issue and renew certificates to licensed

pharmacists, conduct training programs, and approve training programs conducted by other State agencies or private entities. Certificates to dispense emergency contraception are valid for three years. A public or private entity, other than DHMH, may be authorized to issue the certificates.

Certified licensed pharmacists may dispense emergency contraception without a licensed physician's prescription if the pharmacist follows a written protocol developed by the pharmacist and a licensed physician. The protocol must authorize the pharmacist to dispense emergency contraception to women who have recently had unprotected sex or contraceptive failure who wish to prevent pregnancy. The protocol also must define the maximum number of days after unprotected sex or contraceptive failure the pharmacist may dispense the emergency contraception.

Before dispensing emergency contraception, a pharmacist must screen the woman for the appropriateness of emergency contraception, provide the woman with any printed materials and package inserts that accompany the emergency contraception, and provide the woman with a fact sheet on when and how to use the drug and the need for follow-up medical care. DHMH must develop the fact sheet in consultation with the Board of Pharmacy, the American College of Obstetricians and Gynecologists, the Maryland Pharmacists Association, and other health care organizations.

Pharmacists must record the number of women receiving emergency contraception and forward that information quarterly to the physician. The physician must review the protocol annually, may revise the protocol as needed, and may withdraw from participating in the protocol at any time.

A cause of action may not arise against a certified licensed pharmacist or a physician who develops a protocol when they are acting in good faith, except when their conduct amounts to gross negligence, willful or wanton misconduct, or intentionally tortious conduct. This bill does not affect any immunities from civil liability or defenses established by other provisions of the Annotated Code or common law to which a licensed pharmacist or licensed physician may be entitled. It also does not affect existing law requirements for maintaining confidential medical records.

This bill does not require licensed pharmacists to obtain a certificate, nor does it require licensed physicians to develop a protocol, neither of whom may be held civilly liable for failing to do so. Licensed pharmacists may not be held civilly liable for any action arising from or in connection with dispensing emergency contraception solely because the licensed pharmacist did not possess a certificate.

Current Law: Pharmacists and physicians are not authorized under statute to enter into arrangements for the dispensing or provision of emergency contraceptives. Pharmacists can dispense drugs only on a health practitioner's written or oral prescription. A pharmacist may not dispense a drug on an oral prescription unless the pharmacist writes out and files the prescription. A pharmacist may not refill and dispense a prescription unless it is authorized by the health practitioner.

Background: Emergency contraception prevents pregnancy by stopping ovaries from releasing eggs, an egg from being fertilized by sperm, or a fertilized egg from attaching to the wall of the uterus, according to the National Women's Health Information Center. The two types of emergency contraception available in the U.S. are emergency contraception pills and intrauterine devices. Emergency contraception pills are taken in two doses, 12 hours apart and are most effective if taken within 72 hours of unprotected sex. An intrauterine device must be placed within a woman's uterus within seven days after unprotected sex to be effective.

Seven states – California, Hawaii, Illinois, Iowa, Maine, New Mexico, and Washington – currently have statutes related to emergency contraception. Four states – California, Hawaii, Maine, and New Mexico – allow pharmacists to initiate emergency contraception drug therapy after they have completed a training program in emergency contraception. Iowa's statute requires all pregnancy termination reports to include information about the method used to terminate a pregnancy, including the use of mifepristone.

Plan B emergency contraception that uses the synthetic hormone progestin to block ovulation and egg fertilization should be available without a doctor's prescription, according to testimonies from a panel of experts to the U.S. Food and Drug Administration (FDA). FDA rejected a proposal to make Plan B available without a prescription last year, saying there was a lack of information about how doing so would affect teenagers. The manufacturer applied again for FDA approval to sell Plan B without a prescription and proposed making the drug only available without a prescription to women age 16 and older. Under federal guidelines, FDA was supposed to make its decision by late January 2005. However, the pharmaceutical manufacturer reports FDA told the company it was unable to complete its review by then.

State Fiscal Effect: General fund revenues for DHMH's Family Health Administration (FHA) could increase by \$3,750 in fiscal 2006, which reflects the bill's October 1, 2005 effective date. The information and assumptions used in calculating the estimate are stated below:

- 150 pharmacist certifications in the first year, 200 certifications in the second year, and 50 additional certifications every year thereafter;

- each certification and renewal is subject to a \$25 fee paid for by the pharmacist; and
- certifications are renewed every three years.

General fund expenditures could increase by \$11,300 in fiscal 2006 (\$15,000 annually) for a contractor to hold educational training programs required under the bill. The Department of Legislative Services (DLS) assumes existing DHMH staff can issue the certifications.

Future year revenues assume: 200 new certifications in fiscal 2007, 50 new certifications in fiscal 2008, 150 recertifications and 50 new certifications in fiscal 2009, 200 recertifications and 50 new certifications in fiscal 2010.

Future year expenditures assume annualization and inflation.

The bill allows DHMH or a public or private entity to issue the certificates. DLS assumed that FHA would issue the certificates in its analysis, which resulted in the revenues and expenditures for this program going to or coming from the general fund. If the Board of Pharmacy were chosen instead to operate the program, the revenues and expenditures for this program would go to and come from the board's special fund.

If a private entity were chosen to operate this program, the revenues would go to that entity instead and the State would have to provide additional revenues for the educational training program.

Additional Information

Prior Introductions: SB 248 of 2004, an identical bill, had a hearing in the Education, Health, and Environmental Affairs Committee, but no further action was taken. Its cross file, HB 204, had a hearing in the Health and Government Operations Committee, but no further action was taken.

Cross File: HB 1145 (Delegate Hubbard, *et al.*) – Health and Government Operations.

Information Source(s): Department of Health and Mental Hygiene; National Women's Health Information Center; "OTC Morning After Pill Decision Delayed," *Baltimore Sun*, January 24, 2005; Department of Legislative Services

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