

Department of Legislative Services
 Maryland General Assembly
 2006 Session

FISCAL AND POLICY NOTE

House Bill 828 (Delegate Hubbard, *et al.*)
 Health and Government Operations

Public Health - Licensed Pharmacists - Contraception Dispensing Program

This bill creates a Contraception Dispensing Program within the Department of Health and Mental Hygiene (DHMH) to authorize licensed pharmacists to dispense emergency contraception without a prescription.

Fiscal Summary

State Effect: Special fund revenues could increase by \$10,000 in FY 2007 and special 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 2007	FY 2008	FY 2009	FY 2010	FY 2011
SF Revenue	\$10,000	\$2,000	\$2,000	\$10,000	\$4,000
SF Expenditure	11,300	15,200	15,300	15,500	15,600
Net Effect	(\$1,300)	(\$13,200)	(\$13,300)	(\$5,500)	(\$11,600)

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 department. 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 including information on when and how to use the drug and the need for follow-up medical care, along with a fact sheet on the risks and effects of sexually transmitted diseases. DHMH must develop the fact sheets 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 department must review the protocol annually and may revise the protocol as needed.

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.

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: There are 5,331 licensed pharmacists in Maryland. The State Board of Pharmacy assumes 5% of licensed pharmacists (266 pharmacists) will initially seek certification.

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.

Fourteen states – Alaska, California, Hawaii, Illinois, Iowa, Maine, Massachusetts, New Hampshire, New Jersey, New Mexico, New York, Oregon, South Carolina, 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. Alaska allows a pharmacist to dispense emergency contraception without a physician's prescription under a collaborative practice agreement. New Hampshire allows a pharmacist to initiate emergency contraception drug therapy according to procedures established by the state's pharmacy board and a physician or other authorized prescriber. Massachusetts requires timely access to 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.

Seven states – Illinois, Massachusetts, New Jersey, New Mexico, Oregon, South Carolina, and Washington – have emergency contraception statutes related to women who have been sexually assaulted. Four states – Illinois, Massachusetts, New Mexico, and Washington – require facilities treating sexual assault victims to provide accurate emergency contraception information upon request. South Carolina and Washington require available medical treatment for sexual assault victims to include emergency contraception. Oregon authorizes state payment for emergency contraception when it is dispensed to women who have been assaulted, although it does not mandate treatment or providing information about emergency contraception.

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). The FDA has twice rejected a proposal to make Plan B available without a prescription. Most recently, the FDA issued a statement August 26, 2005 indicating that they are delaying a decision on a request to make Plan B available over-the-counter without a prescription for women ages 16 and older. Instead, the FDA published an advance notice of proposed rulemaking to address the regulatory and policy issues raised by the request.

State Fiscal Effect: This fiscal estimate reflects the State Board of Pharmacy within DHMH operating the Contraception Dispensing Program. There are 5,331 licensed pharmacists in Maryland. The State Board of Pharmacy assumes 5% of licensed pharmacists (266 pharmacists) will initially seek certification.

Special fund revenues for the State Board of Pharmacy could increase by \$10,000 in fiscal 2007, which reflects the bill's October 1, 2006 effective date. The information and assumptions used in calculating the estimate are stated below:

- 250 pharmacist certifications in fiscal 2007;
- each certification and renewal is subject to a \$40 fee paid by the pharmacist; and
- certifications are renewed every three years.

Special fund expenditures could increase by an estimated \$11,250 in fiscal 2007 (\$15,000 annually) for a contractor to hold educational training programs required under the bill. The Department of Legislative Services (DLS) assumes existing board staff can issue the certifications.

Future year revenues assume: 50 new certifications each in fiscal 2008 and 2009, 200 recertifications and 50 new certifications in fiscal 2010, and 50 recertifications and 50 new certifications in fiscal 2011.

Future year expenditures assume annualization and inflation.

DLS assumed that the State Board of Pharmacy would issue the certificates in its analysis, which resulted in the revenues and expenditures for this program going to or coming from the special fund.

If a public or 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 education program.

Additional Information

Prior Introductions: A similar bill, SB 541 of 2005, received a favorable report with amendments by the Education, Health, and Environmental Affairs Committee but did not pass in the Senate.

Cross File: SB 297 (Senator Grosfeld, *et al.*) – Education, Health, and Environmental Affairs.

Information Source(s): Department of Health and Mental Hygiene, U.S. Food and Drug Administration, National Conference of State Legislatures, Department of Legislative Services

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