
By: **Delegates Hubbard, Anderson, Barkley, Barve, Benson, Bobo, Bronrott, Cardin, D. Davis, Feldman, Franchot, Goldwater, Gutierrez, Kaiser, King, Madaleno, Mandel, Marriott, McIntosh, Menes, Montgomery, Murray, Nathan-Pulliam, Niemann, Oaks, Pendergrass, Quinter, Rosenberg, Ross, V. Turner, and Vaughn**

Introduced and read first time: February 11, 2005

Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **Public Health - Licensed Pharmacists - Emergency Contraception**
3 **Dispensing Program**

4 FOR the purpose of establishing the Emergency Contraception Dispensing Program
5 in the Department of Health and Mental Hygiene; providing for the purpose of
6 the Program; authorizing the Department to adopt certain regulations, collect
7 certain fees, issue and renew certificates to certain licensed pharmacists, and
8 conduct and approve certain educational training programs; requiring that
9 licensed pharmacists, to qualify for a certificate, complete certain educational
10 training programs conducted by certain licensed physicians; requiring
11 applicants for certificates to submit certain applications and pay a certain
12 application fee; requiring the Department or certain entities to issue a
13 certificate to certain licensed pharmacists; requiring the certificates to include
14 certain information; providing for the replacement, duration, and renewal
15 process of the certificates; authorizing licensed pharmacists who are certified to
16 dispense emergency contraception without a certain prescription in accordance
17 with certain procedures; requiring certain licensed pharmacists and physicians
18 to develop a written protocol authorizing certain licensed pharmacists to
19 dispense emergency contraception; requiring certain licensed pharmacists to
20 follow a certain procedure prior to dispensing emergency contraception;
21 requiring the Department to develop a certain fact sheet, in consultation with
22 certain entities, to distribute to certain individuals; requiring certain licensed
23 pharmacists to record the number of individuals receiving emergency
24 contraception and to report the number at certain times to certain physicians;
25 requiring review and modification of the protocol by certain physicians at
26 certain times; providing certain procedures for the withdrawal of certain
27 physicians from the protocol; providing that this Act does not affect, and may
28 not be construed as affecting, the requirements of existing law relating to
29 maintaining the confidentiality of medical records; prohibiting a cause of action
30 to arise against certain licensed pharmacists or certain licensed physicians
31 except under certain circumstances; providing that this Act does not affect, and

1 may not be construed as affecting, certain immunities or defenses to which
2 licensed pharmacists or licensed physicians may be entitled; providing that this
3 Act may not be construed to create a certain duty and that licensed pharmacists
4 or licensed physicians may not be held liable for certain reasons; requiring
5 certain regulations be adopted within a certain period of time; defining certain
6 terms; and generally relating to licensed pharmacists and the Emergency
7 Contraception Dispensing Program.

8 BY adding to
9 Article - Health - General
10 Section 13-2101 through 13-2109, inclusive, to be under the new subtitle
11 "Subtitle 21. Emergency Contraception Dispensing Program"
12 Annotated Code of Maryland
13 (2000 Replacement Volume and 2004 Supplement)

14 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
15 MARYLAND, That the Laws of Maryland read as follows:

16 **Article - Health - General**

17 **SUBTITLE 21. EMERGENCY CONTRACEPTION DISPENSING PROGRAM.**

18 13-2101.

19 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
20 INDICATED.

21 (B) "CERTIFICATE" MEANS A CERTIFICATE ISSUED BY THE DEPARTMENT OR A
22 PRIVATE OR PUBLIC ENTITY TO DISPENSE EMERGENCY CONTRACEPTION.

23 (C) (1) "EMERGENCY CONTRACEPTION" MEANS MEDICATION THAT
24 PREVENTS PREGNANCY AFTER SEXUAL INTERCOURSE.

25 (2) "EMERGENCY CONTRACEPTION" DOES NOT INCLUDE
26 ABORTIFACIENTS.

27 (D) "PROGRAM" MEANS THE EMERGENCY CONTRACEPTION DISPENSING
28 PROGRAM.

29 13-2102.

30 (A) THERE IS AN EMERGENCY CONTRACEPTION DISPENSING PROGRAM IN
31 THE DEPARTMENT.

32 (B) THE PURPOSE OF THE PROGRAM IS TO PROVIDE A MEANS OF
33 AUTHORIZING LICENSED PHARMACISTS TO DISPENSE EMERGENCY
34 CONTRACEPTION.

1 13-2103.

2 THE DEPARTMENT SHALL:

3 (1) ADOPT REGULATIONS FOR THE ADMINISTRATION OF THE PROGRAM;

4 (2) COLLECT FEES NECESSARY FOR THE ADMINISTRATION OF THE
5 PROGRAM;

6 (3) ISSUE AND RENEW CERTIFICATES TO LICENSED PHARMACISTS WHO
7 MEET THE REQUIREMENTS OF THIS SUBTITLE; AND

8 (4) (I) CONDUCT EDUCATIONAL TRAINING PROGRAMS DESCRIBED
9 UNDER § 13-2104 OF THIS SUBTITLE; AND

10 (II) APPROVE EDUCATIONAL TRAINING PROGRAMS CONDUCTED BY
11 OTHER STATE AGENCIES OR PRIVATE ENTITIES.

12 13-2104.

13 (A) TO QUALIFY FOR A CERTIFICATE, A LICENSED PHARMACIST SHALL
14 SUCCESSFULLY COMPLETE AN EDUCATIONAL TRAINING PROGRAM APPROVED BY
15 THE DEPARTMENT.

16 (B) EDUCATIONAL TRAINING PROGRAMS REQUIRED UNDER THIS SECTION
17 SHALL BE CONDUCTED BY A PHYSICIAN LICENSED TO PRACTICE MEDICINE UNDER
18 TITLE 14 OF THE HEALTH OCCUPATIONS ARTICLE.

19 (C) EDUCATIONAL TRAINING PROGRAMS REQUIRED UNDER THIS SECTION
20 SHALL INCLUDE:

21 (1) CONDUCT OF SENSITIVE COMMUNICATIONS;

22 (2) QUALITY ASSURANCE;

23 (3) REFERRAL TO ADDITIONAL SERVICES; AND

24 (4) DOCUMENTATION.

25 13-2105.

26 AN APPLICANT FOR A CERTIFICATE SHALL:

27 (1) SUBMIT AN APPLICATION TO THE DEPARTMENT OR A PRIVATE OR
28 PUBLIC ENTITY ON THE FORM THAT THE DEPARTMENT REQUIRES; AND

29 (2) PAY TO THE DEPARTMENT OR A PRIVATE OR PUBLIC ENTITY THE
30 APPLICATION FEE SET BY THE DEPARTMENT.

1 13-2106.

2 (A) THE DEPARTMENT OR A PRIVATE OR PUBLIC ENTITY SHALL ISSUE A
3 CERTIFICATE TO ANY LICENSED PHARMACIST WHO MEETS THE REQUIREMENTS OF
4 THIS SUBTITLE.

5 (B) EACH CERTIFICATE SHALL INCLUDE:

6 (1) THE FULL NAME OF THE CERTIFICATE HOLDER; AND

7 (2) A SERIAL NUMBER.

8 (C) A REPLACEMENT CERTIFICATE MAY BE ISSUED TO REPLACE A LOST,
9 DESTROYED, OR MUTILATED CERTIFICATE IF THE CERTIFICATE HOLDER PAYS THE
10 CERTIFICATE REPLACEMENT FEE.

11 (D) (1) THE CERTIFICATE SHALL BE VALID FOR 3 YEARS.

12 (2) IN ORDER TO RENEW THE CERTIFICATE FOR AN ADDITIONAL 3
13 YEARS, THE APPLICANT SHALL:

14 (I) SUCCESSFULLY COMPLETE A REFRESHER TRAINING PROGRAM
15 APPROVED BY THE DEPARTMENT; OR

16 (II) DEMONSTRATE PROFICIENCY TO THE DEPARTMENT OR A
17 PRIVATE OR PUBLIC ENTITY ISSUING CERTIFICATES UNDER THIS SUBTITLE.

18 13-2107.

19 (A) A LICENSED PHARMACIST WHO IS CERTIFIED MAY DISPENSE EMERGENCY
20 CONTRACEPTION WITHOUT A PRESCRIPTION FROM A LICENSED PHYSICIAN, IF THE
21 PHARMACIST FOLLOWS A WRITTEN PROTOCOL DEVELOPED BY THE PHARMACIST
22 AND A LICENSED PHYSICIAN WHO IS ACTING WITHIN THE PHYSICIAN'S SCOPE OF
23 PRACTICE.

24 (B) THE PROTOCOL DEVELOPED UNDER SUBSECTION (A) OF THIS SECTION
25 SHALL:

26 (1) AUTHORIZE THE PHARMACIST TO DISPENSE EMERGENCY
27 CONTRACEPTION TO WOMEN WHO HAVE RECENTLY HAD UNPROTECTED SEXUAL
28 INTERCOURSE OR CONTRACEPTIVE FAILURE, AND WHO WISH TO PREVENT
29 PREGNANCY; AND

30 (2) DEFINE, ON THE BASIS OF THE PHYSICIAN'S MEDICAL JUDGMENT
31 AND THE AVAILABLE SCIENTIFIC EVIDENCE, THE MAXIMUM NUMBER OF DAYS
32 AFTER UNPROTECTED SEXUAL INTERCOURSE OR CONTRACEPTIVE FAILURE THAT
33 THE PHARMACIST MAY DISPENSE EMERGENCY CONTRACEPTION.

34 (C) THE PHARMACIST AND PHYSICIAN SHALL EACH MAINTAIN A COPY OF THE
35 WRITTEN PROTOCOL IN THEIR OFFICE FILES.

1 (D) PRIOR TO DISPENSING EMERGENCY CONTRACEPTION, THE PHARMACIST
2 SHALL:

3 (1) SCREEN THE WOMAN FOR APPROPRIATENESS OF EMERGENCY
4 CONTRACEPTION IN ACCORDANCE WITH THE WRITTEN PROTOCOL;

5 (2) PROVIDE THE WOMAN WITH ANY PRINTED MATERIALS AND
6 PACKAGE INSERTS THAT ACCOMPANY THE EMERGENCY CONTRACEPTION; AND

7 (3) PROVIDE THE WOMAN WITH A STANDARDIZED FACT SHEET THAT
8 INCLUDES INFORMATION ON:

9 (I) INDICATIONS FOR USE OF THE DRUG;

10 (II) APPROPRIATE METHODS FOR USING THE DRUG; AND

11 (III) THE NEED FOR MEDICAL FOLLOW-UP.

12 (E) (1) THE DEPARTMENT SHALL DEVELOP THE FACT SHEET REQUIRED
13 UNDER SUBSECTION (D)(3) OF THIS SECTION IN CONSULTATION WITH THE STATE
14 BOARD OF PHARMACY, THE AMERICAN COLLEGE OF OBSTETRICIANS AND
15 GYNECOLOGISTS, THE MARYLAND PHARMACISTS ASSOCIATION, AND OTHER HEALTH
16 CARE ORGANIZATIONS.

17 (2) THIS SUBSECTION DOES NOT PRECLUDE THE USE OF EXISTING
18 PUBLICATIONS DEVELOPED BY NATIONALLY RECOGNIZED MEDICAL
19 ORGANIZATIONS.

20 (F) THE PHARMACIST SHALL RECORD THE NUMBER OF WOMEN RECEIVING
21 EMERGENCY CONTRACEPTION FROM THE PHARMACIST, AND SHALL FORWARD
22 THOSE NUMBERS QUARTERLY TO THE PHYSICIAN.

23 (G) (1) THE PHYSICIAN SHALL MODIFY THE PROTOCOL AS NEEDED IN
24 ACCORDANCE WITH THE PHYSICIAN'S MEDICAL JUDGMENT.

25 (2) THE PHYSICIAN SHALL REVIEW THE PROTOCOL AT LEAST
26 ANNUALLY TO DETERMINE WHETHER MODIFICATIONS ARE APPROPRIATE.

27 (H) THE PHYSICIAN MAY WITHDRAW FROM PARTICIPATION IN THE PROTOCOL
28 AT ANY TIME BY PROVIDING WRITTEN NOTICE TO THE PHARMACIST.

29 13-2108.

30 (A) A CAUSE OF ACTION MAY NOT ARISE AGAINST A LICENSED PHARMACIST
31 CERTIFIED UNDER THIS SUBTITLE FOR ANY ACT OR OMISSION WHEN THE LICENSED
32 PHARMACIST IS ACTING IN GOOD FAITH WHILE DISPENSING EMERGENCY
33 CONTRACEPTION, EXCEPT WHERE THE CONDUCT OF THE CERTIFIED LICENSED
34 PHARMACIST AMOUNTS TO GROSS NEGLIGENCE, WILLFUL OR WANTON
35 MISCONDUCT, OR INTENTIONALLY TORTIOUS CONDUCT.

1 (B) A CAUSE OF ACTION MAY NOT ARISE AGAINST A LICENSED PHYSICIAN
2 WHO DEVELOPS A PROTOCOL UNDER THIS SUBTITLE FOR ANY ACT OR OMISSION
3 WHEN THE LICENSED PHYSICIAN IS ACTING IN GOOD FAITH, EXCEPT WHERE THE
4 CONDUCT OF THE LICENSED PHYSICIAN AMOUNTS TO GROSS NEGLIGENCE,
5 WILLFUL OR WANTON MISCONDUCT, OR INTENTIONALLY TORTIOUS CONDUCT.

6 (C) THIS SUBTITLE DOES NOT AFFECT, AND MAY NOT BE CONSTRUED AS
7 AFFECTING, ANY IMMUNITIES FROM CIVIL LIABILITY OR DEFENSES ESTABLISHED
8 BY ANY OTHER PROVISIONS OF THE CODE OR BY COMMON LAW TO WHICH A
9 LICENSED PHARMACIST OR LICENSED PHYSICIAN MAY BE ENTITLED.

10 (D) THIS SUBTITLE DOES NOT AFFECT, AND MAY NOT BE CONSTRUED AS
11 AFFECTING, THE REQUIREMENTS OF EXISTING LAW RELATING TO MAINTAINING
12 THE CONFIDENTIALITY OF MEDICAL RECORDS.

13 13-2109.

14 (A) THIS SUBTITLE MAY NOT BE CONSTRUED TO CREATE A DUTY FOR ANY
15 LICENSED PHARMACIST TO OBTAIN A CERTIFICATE UNDER THIS SUBTITLE, AND A
16 LICENSED PHARMACIST MAY NOT BE HELD CIVILLY LIABLE FOR FAILING TO OBTAIN
17 A CERTIFICATE UNDER THIS SUBTITLE.

18 (B) THIS SUBTITLE MAY NOT BE CONSTRUED TO CREATE A DUTY FOR ANY
19 LICENSED PHYSICIAN TO DEVELOP A PROTOCOL UNDER THIS SUBTITLE, AND A
20 LICENSED PHYSICIAN MAY NOT BE HELD CIVILLY LIABLE FOR FAILING TO DEVELOP
21 A PROTOCOL UNDER THIS SUBTITLE.

22 (C) A LICENSED PHARMACIST MAY NOT BE HELD CIVILLY LIABLE IN ANY
23 ACTION ARISING FROM OR IN CONNECTION WITH THE DISPENSING OF EMERGENCY
24 CONTRACEPTION BY THE LICENSED PHARMACIST SOLELY BECAUSE THE LICENSED
25 PHARMACIST DID NOT POSSESS A CERTIFICATE UNDER THIS SUBTITLE.

26 SECTION 2. AND BE IT FURTHER ENACTED, That the regulations
27 required by this Act shall be adopted within 6 months of the effective date of this Act.

28 SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take
29 effect October 1, 2005.