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Introduced and read first time: January 22, 2004 Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning				
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2 Pu l	blic Health - Licensed Pharmacists - Emerge	ency Contraception
3	Dispensing Program	

4 FOR the purpose of establishing the Emergency Contraception Dispensing Program in the Department of Health and Mental Hygiene; providing for the purpose of 5 the Program; authorizing the Department to adopt certain regulations, collect 6 certain fees, issue and renew certificates to certain licensed pharmacists, and 7 8 conduct and approve certain educational training programs; requiring that 9 licensed pharmacists, to qualify for a certificate, complete certain educational training programs conducted by certain licensed physicians; requiring 10 applicants for certificates to submit certain applications and pay a certain 11 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 follow a certain procedure prior to dispensing emergency contraception; 20 requiring the Department to develop a certain fact sheet, in consultation with 21 certain entities, to distribute to certain individuals; requiring certain licensed 22 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 physicians from the protocol; providing that this Act does not affect, and may 27 28 not be construed as affecting, the requirements of existing law relating to

maintaining the confidentiality of medical records; prohibiting a cause of action

except under certain circumstances; providing that this Act does not affect, and

to arise against certain licensed pharmacists or certain licensed physicians

HOUSE BILL 204

1	may no	ot b	e construed	as	affecting,	certain	immunities	or	defense	s to	which
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- 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
- Section 13-2101 through 13-2109, inclusive, to be under the new subtitle
- "Subtitle 21. Emergency Contraception Dispensing Program"
- 12 Annotated Code of Maryland
- 13 (2000 Replacement Volume and 2003 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.

- 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;

1 13-2103.

- 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 \S 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.

HOUSE BILL 204

- 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.

HOUSE BILL 204

- 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, 2004.