J1 5lr2494 SB 248/04 - EHE CF 5lr2495

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By: Senators Grosfeld, Britt, Conway, Exum, Forehand, Frosh, Garagiola, Gladden, Hollinger, Jones, Kasemeyer, Kelley, Kramer, Lawlah, Pinsky, Ruben, and Teitelbaum

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CHAPTER

1 AN ACT concerning

Public Health - Licensed Pharmacists - Emergency Contraception
 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
- 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
- process of the certificates; authorizing licensed pharmacists who are certified to
- dispense emergency contraception without a certain prescription in accordance
- 17 with certain procedures; requiring certain licensed pharmacists and physicians
- 18 <u>the Department</u> to develop a written protocol authorizing certain licensed
- 19 pharmacists to dispense emergency contraception; requiring certain licensed
- 20 pharmacists to follow a certain procedure prior to dispensing emergency
- 21 contraception; requiring the Department to develop a certain fact sheet sheets,
- in consultation with certain entities, to distribute to certain individuals;
- 23 requiring certain licensed pharmacists to record the number of individuals
- 24 receiving emergency contraception and to report the number at certain times to
- 25 certain physicians the Department; requiring review and modification of the
- 26 protocol by certain physicians the Department at certain times; providing

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1	certain procedures for the withdrawal of certain physicians from the protocol;
2	providing that this Act does not affect, and may not be construed as affecting,
3	the requirements of existing law relating to maintaining the confidentiality of
4	medical records; prohibiting a cause of action to arise against certain licensed
5	pharmacists or certain licensed physicians except under certain circumstances;
6	providing that this Act does not affect, and may not be construed as affecting,
7	certain immunities or defenses to which licensed pharmacists or licensed
8	physicians may be entitled; providing that this Act may not be construed to
9	create a certain duty and that licensed pharmacists or licensed physicians may
10	
11	certain certificate or participate in a certain program; establishing that a
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1 /	and the Emergency Contraception Dispensing Program.
10	DV adding to
	BY adding to Article - Health - General
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21	"Subtitle 21. Emergency Contraception Dispensing Program"
22	
23	(2000 Replacement Volume and 2004 Supplement)
24 25	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:
26	Article - Health - General
27	SUBTITLE 21. EMERGENCY CONTRACEPTION DISPENSING PROGRAM.
28	13-2101.
29 30	(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.
31 32	(B) "CERTIFICATE" MEANS A CERTIFICATE ISSUED BY THE DEPARTMENT OR A PRIVATE OR PUBLIC ENTITY TO DISPENSE EMERGENCY CONTRACEPTION.
	(C) (1) "EMERGENCY CONTRACEPTION" MEANS MEDICATION THAT PREVENTS PREGNANCY AFTER SEXUAL INTERCOURSE.
35 36	(2) "EMERGENCY CONTRACEPTION" DOES NOT INCLUDE ABORTIFACIENTS.
	(D) "PROGRAM" MEANS THE EMERGENCY CONTRACEPTION DISPENSING PROGRAM.

- 1 13-2102.
- 2 (A) THERE IS AN EMERGENCY CONTRACEPTION DISPENSING PROGRAM IN 3 THE DEPARTMENT.
- 4 (B) THE PURPOSE OF THE PROGRAM IS TO PROVIDE A MEANS OF
- 5 AUTHORIZING LICENSED PHARMACISTS TO DISPENSE EMERGENCY
- 6 CONTRACEPTION.
- 7 13-2103.
- 8 THE DEPARTMENT SHALL:
- 9 (1) ADOPT REGULATIONS FOR THE ADMINISTRATION OF THE PROGRAM;
- 10 (2) COLLECT FEES NECESSARY FOR THE ADMINISTRATION OF THE
- 11 PROGRAM;
- 12 (3) ISSUE AND RENEW CERTIFICATES TO LICENSED PHARMACISTS WHO
- 13 MEET THE REQUIREMENTS OF THIS SUBTITLE; AND
- 14 (4) (I) CONDUCT EDUCATIONAL TRAINING PROGRAMS DESCRIBED
- 15 UNDER § 13-2104 OF THIS SUBTITLE; AND
- 16 (II) APPROVE EDUCATIONAL TRAINING PROGRAMS CONDUCTED BY
- 17 OTHER STATE AGENCIES OR PRIVATE ENTITIES.
- 18 13-2104.
- 19 (A) TO QUALIFY FOR A CERTIFICATE, A LICENSED PHARMACIST SHALL
- 20 SUCCESSFULLY COMPLETE AN EDUCATIONAL TRAINING PROGRAM APPROVED BY
- 21 THE DEPARTMENT.
- 22 (B) EDUCATIONAL TRAINING PROGRAMS REQUIRED UNDER THIS SECTION
- 23 SHALL BE CONDUCTED BY A PHYSICIAN LICENSED TO PRACTICE MEDICINE UNDER
- 24 TITLE 14 OF THE HEALTH OCCUPATIONS ARTICLE.
- 25 (C) (B) EDUCATIONAL TRAINING PROGRAMS REQUIRED UNDER THIS
- 26 SECTION SHALL INCLUDE:
- 27 (1) CONDUCT OF SENSITIVE COMMUNICATIONS;
- 28 (2) QUALITY ASSURANCE;
- 29 (3) REFERRAL TO ADDITIONAL SERVICES; AND
- 30 (4) DOCUMENTATION.

- 1 13-2105.
- 2 AN APPLICANT FOR A CERTIFICATE SHALL:
- 3 (1) SUBMIT AN APPLICATION TO THE DEPARTMENT OR A PRIVATE OR 4 PUBLIC ENTITY ON THE FORM THAT THE DEPARTMENT REQUIRES; AND
- 5 (2) PAY TO THE DEPARTMENT OR A PRIVATE OR PUBLIC ENTITY THE 6 APPLICATION FEE SET BY THE DEPARTMENT.
- 7 13-2106.
- 8 (A) THE DEPARTMENT OR A PRIVATE OR PUBLIC ENTITY SHALL ISSUE A 9 CERTIFICATE TO ANY LICENSED PHARMACIST WHO MEETS THE REQUIREMENTS OF 10 THIS SUBTITLE.
- 11 (B) EACH CERTIFICATE SHALL INCLUDE:
- 12 (1) THE FULL NAME OF THE CERTIFICATE HOLDER; AND
- 13 (2) A SERIAL NUMBER.
- 14 (C) A REPLACEMENT CERTIFICATE MAY BE ISSUED TO REPLACE A LOST,
- 15 DESTROYED, OR MUTILATED CERTIFICATE IF THE CERTIFICATE HOLDER PAYS THE
- 16 CERTIFICATE REPLACEMENT FEE.
- 17 (D) (1) THE CERTIFICATE SHALL BE VALID FOR 3 YEARS.
- 18 (2) IN ORDER TO RENEW THE CERTIFICATE FOR AN ADDITIONAL 3 19 YEARS. THE APPLICANT SHALL:
- 20 (I) SUCCESSFULLY COMPLETE A REFRESHER TRAINING PROGRAM
- 21 APPROVED BY THE DEPARTMENT; OR
- 22 (II) DEMONSTRATE PROFICIENCY TO THE DEPARTMENT OR A
- 23 PRIVATE OR PUBLIC ENTITY ISSUING CERTIFICATES UNDER THIS SUBTITLE.
- 24 13-2107.
- 25 (A) A LICENSED PHARMACIST WHO IS CERTIFIED MAY DISPENSE EMERGENCY
- 26 CONTRACEPTION WITHOUT A PRESCRIPTION FROM A LICENSED PHYSICIAN, IF THE
- 27 PHARMACIST FOLLOWS A WRITTEN PROTOCOL DEVELOPED BY THE PHARMACIST
- 28 AND A LICENSED PHYSICIAN WHO IS ACTING WITHIN THE PHYSICIAN'S SCOPE OF
- 29 PRACTICE DEPARTMENT.
- 30 (B) THE PROTOCOL DEVELOPED UNDER SUBSECTION (A) OF THIS SECTION
- 31 SHALL:
- 32 (1) AUTHORIZE THE PHARMACIST TO DISPENSE EMERGENCY
- 33 CONTRACEPTION TO WOMEN WHO HAVE RECENTLY HAD UNPROTECTED SEXUAL

- 1 INTERCOURSE OR CONTRACEPTIVE FAILURE, AND WHO WISH TO PREVENT 2 PREGNANCY; AND
- 3 (2) DEFINE, ON THE BASIS OF THE PHYSICIAN'S MEDICAL JUDGMENT
- 4 AND THE AVAILABLE SCIENTIFIC EVIDENCE, THE MAXIMUM NUMBER OF DAYS
- 5 AFTER UNPROTECTED SEXUAL INTERCOURSE OR CONTRACEPTIVE FAILURE THAT
- 6 THE PHARMACIST MAY DISPENSE EMERGENCY CONTRACEPTION.
- 7 (C) THE PHARMACIST AND PHYSICIAN SHALL EACH MAINTAIN A COPY OF THE 8 WRITTEN PROTOCOL IN THEIR THE PHARMACIST'S OFFICE FILES.
- 9 (D) PRIOR TO DISPENSING EMERGENCY CONTRACEPTION, THE PHARMACIST 10 SHALL:
- 11 (1) SCREEN THE WOMAN FOR APPROPRIATENESS OF EMERGENCY
- 12 CONTRACEPTION IN ACCORDANCE WITH THE WRITTEN PROTOCOL;
- 13 (2) PROVIDE THE WOMAN WITH ANY PRINTED MATERIALS AND
- 14 PACKAGE INSERTS THAT ACCOMPANY THE EMERGENCY CONTRACEPTION; AND
- 15 (3) PROVIDE THE WOMAN WITH A STANDARDIZED FACT SHEET THAT 16 INCLUDES:
- 17 (I) INFORMATION ON:
- 18 $\frac{\text{(I)}}{\text{1.}}$ INDICATIONS FOR USE OF THE DRUG;
- 19 <u>(II)</u> <u>2.</u> APPROPRIATE METHODS FOR USING THE DRUG; AND
- 20 (III) 3. THE NEED FOR MEDICAL FOLLOW-UP; AND
- 21 (II) TO THE EXTENT PRACTICABLE, A LIST, PROVIDED BY THE
- 22 STATE BOARD OF PHYSICIANS, OF THE NAMES OF THE PRACTICING GYNECOLOGISTS
- 23 IN THE COUNTY IN WHICH THE WOMAN IS RECEIVING THE EMERGENCY
- 24 CONTRACEPTION; AND
- 25 (4) PROVIDE THE WOMAN WITH A STANDARDIZED FACT SHEET THAT
- 26 INCLUDES INFORMATION ON THE RISKS AND EFFECTS OF SEXUALLY TRANSMITTED
- 27 DISEASES.
- 28 (E) (1) THE DEPARTMENT SHALL DEVELOP THE FACT SHEETS
- 29 REQUIRED UNDER SUBSECTION (D)(3) AND (4) OF THIS SECTION IN CONSULTATION
- 30 WITH THE STATE BOARD OF PHARMACY, THE AMERICAN COLLEGE OF
- 31 OBSTETRICIANS AND GYNECOLOGISTS, THE MARYLAND PHARMACISTS
- 32 ASSOCIATION, AND OTHER HEALTH CARE ORGANIZATIONS.
- 33 (2) THIS SUBSECTION DOES NOT PRECLUDE THE USE OF EXISTING
- 34 PUBLICATIONS DEVELOPED BY NATIONALLY RECOGNIZED MEDICAL
- 35 ORGANIZATIONS.

- 1 (F) THE PHARMACIST SHALL RECORD THE NUMBER OF WOMEN RECEIVING
- 2 EMERGENCY CONTRACEPTION FROM THE PHARMACIST, AND SHALL FORWARD
- 3 THOSE NUMBERS QUARTERLY TO THE PHYSICIAN DEPARTMENT.
- 4 (G) (1) THE PHYSICIAN DEPARTMENT SHALL MODIFY THE PROTOCOL AS
- 5 NEEDED IN ACCORDANCE WITH THE PHYSICIAN'S MEDICAL JUDGMENT.
- 6 (2) THE <u>PHYSICIAN DEPARTMENT</u> SHALL REVIEW THE PROTOCOL AT 7 LEAST ANNUALLY TO DETERMINE WHETHER MODIFICATIONS ARE APPROPRIATE.
- 8 (H) THE PHYSICIAN MAY WITHDRAW FROM PARTICIPATION IN THE PROTOCOL.
- 9 AT ANY TIME BY PROVIDING WRITTEN NOTICE TO THE PHARMACIST.
- 10 13-2108.
- 11 (A) A CAUSE OF ACTION MAY NOT ARISE AGAINST A LICENSED PHARMACIST
- 12 CERTIFIED UNDER THIS SUBTITLE FOR ANY ACT OR OMISSION WHEN THE LICENSED
- 13 PHARMACIST IS ACTING IN GOOD FAITH WHILE DISPENSING EMERGENCY
- 14 CONTRACEPTION, EXCEPT WHERE THE CONDUCT OF THE CERTIFIED LICENSED
- 15 PHARMACIST AMOUNTS TO GROSS NEGLIGENCE, WILLFUL OR WANTON
- 16 MISCONDUCT, OR INTENTIONALLY TORTIOUS CONDUCT.
- 17 (B) A CAUSE OF ACTION MAY NOT ARISE AGAINST A LICENSED PHYSICIAN
- 18 WHO DEVELOPS A PROTOCOL UNDER THIS SUBTITLE FOR ANY ACT OR OMISSION
- 19 WHEN THE LICENSED PHYSICIAN IS ACTING IN GOOD FAITH, EXCEPT WHERE THE
- 20 CONDUCT OF THE LICENSED PHYSICIAN AMOUNTS TO GROSS NEGLIGENCE.
- 21 WILLFUL OR WANTON MISCONDUCT, OR INTENTIONALLY TORTIOUS CONDUCT.
- 22 (C) (B) THIS SUBTITLE DOES NOT AFFECT, AND MAY NOT BE CONSTRUED AS
- 23 AFFECTING, ANY IMMUNITIES FROM CIVIL LIABILITY OR DEFENSES ESTABLISHED
- 24 BY ANY OTHER PROVISIONS OF THE CODE OR BY COMMON LAW TO WHICH A
- 25 LICENSED PHARMACIST OR LICENSED PHYSICIAN MAY BE ENTITLED.
- 26 (D) (C) THIS SUBTITLE DOES NOT AFFECT, AND MAY NOT BE CONSTRUED AS
- 27 AFFECTING, THE REOUIREMENTS OF EXISTING LAW RELATING TO MAINTAINING
- 28 THE CONFIDENTIALITY OF MEDICAL RECORDS.
- 29 13-2109.
- 30 (A) (A) THIS SUBTITLE MAY NOT BE CONSTRUED TO CREATE A DUTY FOR
- 31 REQUIRE ANY LICENSED PHARMACIST TO OBTAIN A CERTIFICATE UNDER THIS
- 32 SUBTITLE, AND A LICENSED PHARMACIST MAY NOT BE HELD CIVILLY LIABLE FOR
- 33 FAILING TO OBTAIN A CERTIFICATE UNDER THIS SUBTITLE OR PARTICIPATE IN THE
- 34 PROGRAM.
- 35 (B) THIS SUBTITLE MAY NOT BE CONSTRUED TO CREATE A DUTY FOR ANY
- 36 LICENSED PHYSICIAN TO DEVELOP A PROTOCOL UNDER THIS SUBTITLE. AND A
- 37 LICENSED PHYSICIAN MAY NOT BE HELD CIVILLY LIABLE FOR FAILING TO DEVELOP
- 38 A PROTOCOL UNDER THIS SUBTITLE.

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- 1 (C) A LICENSED PHARMACIST MAY NOT BE HELD CIVILLY LIABLE IN ANY
- 2 ACTION ARISING FROM OR IN CONNECTION WITH THE DISPENSING OF EMERGENCY
- 3 CONTRACEPTION BY THE LICENSED PHARMACIST SOLELY BECAUSE THE LICENSED
- 4 PHARMACIST DID NOT POSSESS A CERTIFICATE UNDER THIS SUBTITLE.
- 5 (B) (1) A LICENSED PHARMACIST MAY NOT BE REQUIRED TO DISPENSE
- 6 EMERGENCY CONTRACEPTION, OR REFER A PERSON TO ANY SOURCE FOR
- 7 EMERGENCY CONTRACEPTION.
- 8 (2) THE REFUSAL OF A LICENSED PHARMACIST TO DISPENSE
- 9 EMERGENCY CONTRACEPTION OR TO REFER A PERSON TO ANY SOURCE FOR
- 10 EMERGENCY CONTRACEPTION MAY NOT BE A BASIS FOR:
- 11 <u>(I) CIVIL LIABILITY TO ANOTHER PERSON; OR</u>
- 12 (II) DISCIPLINARY OR OTHER RECRIMINATORY ACTION AGAINST
- 13 THE LICENSED PHARMACIST.
- 14 SECTION 2. AND BE IT FURTHER ENACTED, That the regulations
- 15 required by this Act shall be adopted within 6 months of the effective date of this Act.
- 16 SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take
- 17 effect October 1, 2005.