J1, J2 7lr0133

By: Chair, Health and Government Operations Committee (By Request – Departmental – Health and Mental Hygiene)

Introduced and read first time: February 16, 2017 Assigned to: Rules and Executive Nominations

A BILL ENTITLED

1 AN ACT concerning

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Public Health - Drug Overdose Prevention Programs - Revisions

FOR the purpose of authorizing the Department of Health and Mental Hygiene to deny, suspend, revoke, or refuse to renew a certain registration if a certain applicant or a certain registrant has surrendered a certain federal registration or fails to meet certain requirements to obtain a certain registration; authorizing the Department to limit the scope of a certain initial registration or renewal of a certain registration; requiring a drug overdose fatality review team to review information on nonfatal overdoses at a certain meeting; requiring a certain local drug overdose fatality review team, at the request of the chair of the local team, to be provided access to certain information and records related to an individual whose near fatality is being reviewed by the local team; prohibiting the disclosure of identifying information of or of involvement of an agency with an individual who has experienced an overdose or of certain individuals related to an individual who has experienced an overdose during a public meeting of a certain local team; providing that the Overdose Response Program is to be administered by the Department for a certain purpose; repealing certain provisions of law relating to the qualifications for, application for, and issuance of a certificate for completion of a certain educational training program relating to an opioid overdose; altering the scope of the Program to include the prescribing and dispensing of other opioid antagonists in addition to naloxone; authorizing the Department to authorize certain entities to conduct certain education and training on opioid overdose recognition and response; authorizing an individual who has received certain education and training to receive from a certain health care provider a prescription for an opioid antagonist and certain related supplies; authorizing certain individuals to possess and administer an opioid antagonist under certain circumstances; authorizing a licensed health care provider with prescribing authority to prescribe and dispense an opioid antagonist by issuing a standing order under certain circumstances; authorizing a certain licensed health care provider who issues a certain standing order to delegate the dispensing of an opioid antagonist to a certain employee or a certain volunteer under certain



5-301.

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1	circumstances; prohibiting certain individuals who administer an opioid antagonist					
$\frac{2}{3}$	to a certain individual from being considered to be practicing medicine or registered nursing; prohibiting an employee or a volunteer of a certain entity who provides an					
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O	definitions, and generally relating to drug evertuous programs.					
7 BY repealing and reenacting, without amendments,						
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10	Annotated Code of Maryland					
11	(2012 Replacement Volume and 2016 Supplement)					
12	BY repealing and reenacting, with amendments,					
13	1 0					
14	Section 5–307					
15	Annotated Code of Maryland					
16	(2012 Replacement Volume and 2016 Supplement)					
17	BY repealing and reenacting, without amendments,					
18	8 Article – Health – General					
19	Section 5–901					
20	Annotated Code of Maryland					
21	(2015 Replacement Volume and 2016 Supplement)					
22	2 BY repealing and reenacting, with amendments,					
23	Article - Health - General					
24						
25	13–3111					
26	Annotated Code of Maryland					
27	(2015 Replacement Volume and 2016 Supplement)					
28	BY repealing					
29	29 Article – Health – General					
30	Section 13–3104 through 13–3106					
31	Annotated Code of Maryland					
32	(2015 Replacement Volume and 2016 Supplement)					
33	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,					
34	That the Laws of Maryland read as follows:					
35	Article - Criminal Law					

- 1 (a) (1) Except as otherwise provided in this section, a person shall be registered by the Department before the person manufactures, distributes, or dispenses a controlled dangerous substance in the State.
- 4 5–307.
- 5 (a) Subject to the notice and hearing provisions of § 5–308 of this subtitle, the 6 Department may deny a registration to any applicant, suspend or revoke a registration, or 7 refuse to renew a registration if the Department finds that the applicant or registrant:
- 8 (1) has materially falsified an application filed in accordance with or 9 required by this title;
- 10 (2) has been convicted of a crime under federal law or the law of any state relating to a controlled dangerous substance;
- 12 (3) has **SURRENDERED FEDERAL REGISTRATION OR** had federal 13 registration suspended or revoked and may no longer manufacture, distribute, or dispense 14 a controlled dangerous substance; [or]
- 15 (4) has violated this title; **OR**
- 16 (5) HAS FAILED TO MEET THE REQUIREMENTS FOR REGISTRATION UNDER THIS TITLE OR IN REGULATIONS ADOPTED BY THE DEPARTMENT.
- 18 (b) The Department may limit revocation or suspension of a registration to the particular controlled dangerous substance for which grounds for revocation or suspension exist.
- 21 (C) THE DEPARTMENT MAY LIMIT AN INITIAL REGISTRATION OR THE 22 RENEWAL OF A REGISTRATION TO THE PARTICULAR CONTROLLED DANGEROUS 23 SUBSTANCE FOR WHICH GROUNDS FOR DENIAL OR REFUSAL TO RENEW EXIST.
- 24 Article Health General
- 25 5-901.
- In this subtitle, "local team" means the multidisciplinary and multiagency drug overdose fatality review team established for a county.
- 28 5–903.
- 29 (a) The purpose of each local team is to prevent drug overdose deaths by:

- 1 (1) Promoting cooperation and coordination among agencies involved in 2 investigations of drug overdose deaths or in providing services to surviving family 3 members;

 4 (2) Developing an understanding of the causes and incidence of drug overdose deaths in the county;
- 6 (3) Developing plans for and recommending changes within the agencies 7 represented on the local team to prevent drug overdose deaths; and
- 8 (4) Advising the Department on changes to law, policy, or practice, 9 including the use of devices that are programmed to dispense medications on a schedule or 10 similar technology, to prevent drug overdose deaths.
- 11 (b) To achieve its purpose, each local team shall:
- 12 (1) In consultation with the Department, establish and implement a protocol for the local team;
- 14 (2) Set as its goal the investigation of drug overdose deaths in accordance 15 with national standards;
- 16 (3) Meet at least quarterly to review the status of drug overdose death 17 cases **AND INFORMATION ON NONFATAL OVERDOSES**, recommend actions to improve 18 coordination of services and investigations among member agencies, and recommend 19 actions within the member agencies to prevent drug overdose deaths;
- 20 (4) Collect and maintain data as required by the Department; and
- 21 (5) Provide requested reports to the Department, including:
- 22 (i) Discussion of individual cases;
- 23 (ii) Steps taken to improve coordination of services and 24 investigations;
- 25 (iii) Steps taken to implement changes recommended by the local 26 team within member agencies; and
- 27 (iv) Recommendations on needed changes to State and local laws, 28 policies, or practices to prevent drug overdose deaths.
- 29 (c) In addition to the duties specified in subsection (b) of this section, a local team 30 may investigate the information and records of an individual convicted of a crime or 31 adjudicated as having committed a delinquent act that caused a death or near fatality 32 described in § 5–904 of this subtitle.

1 5–904.

- 2 (a) On request of the chair of a local team and as necessary to carry out the 3 purpose and duties of the local team, the local team shall be immediately provided with:
- 4 (1) Access to information and records, including information about physical bealth, mental health, and treatment for substance abuse, maintained by a health care provider for:
- 7 (i) An individual whose death **OR NEAR FATALITY** is being 8 reviewed by the local team; or
- 9 (ii) An individual convicted of a crime or adjudicated as having 10 committed a delinquent act that caused a death or near fatality; and
- 12 government agency, including death certificates, law enforcement investigative information, medical examiner investigative information, parole and probation information and records, and information and records of a social services agency, if the agency provided services to:
- 16 (i) An individual whose death **OR NEAR FATALITY** is being 17 reviewed by the local team;
- 18 (ii) An individual convicted of a crime or adjudicated as having 19 committed a delinquent act that caused a death or near fatality; or
- 20 (iii) The family of an individual described in item (i) or (ii) of this 21 item.
- 22 (b) Substance abuse treatment records requested or provided under this section 23 are subject to any additional limitations on disclosure or redisclosure of a medical record 24 developed in connection with the provision of substance abuse treatment services under 25 State law or 42 U.S.C. § 290DD–2 and 42 C.F.R. Part 2.
- 26 5–905.
- 27 (a) Meetings of local teams shall be closed to the public and are not subject to 28 Title 3 of the General Provisions Article when the local teams are discussing individual 29 cases of **OVERDOSE OR** drug overdose deaths.
- 30 (b) Except as provided in subsection (c) of this section, meetings of local teams 31 shall be open to the public and are subject to Title 3 of the General Provisions Article when 32 the local team is not discussing individual cases of **OVERDOSE OR** drug overdose deaths.
- 33 (c) (1) During a public meeting, information may not be disclosed that 34 identifies:

(i) A deceased individual;				
(II) AN INDIVIDUAL WHO HAS EXPERIENCED AN OVERDOSE;				
[(ii)] (III) A family member, guardian, or caretaker of a deceased individual OR OF AN INDIVIDUAL WHO HAS EXPERIENCED AN OVERDOSE; or				
[(iii)] (IV) An individual convicted of a crime or adjudicated as having committed a delinquent act that caused a death or near fatality.				
(2) During a public meeting, information may not be disclosed about the involvement of any agency with:				
(i) A deceased individual;				
(II) AN INDIVIDUAL WHO HAS EXPERIENCED AN OVERDOSE;				
[(ii)] (III) A family member, guardian, or caretaker of a deceased individual OR OF AN INDIVIDUAL WHO HAS EXPERIENCED AN OVERDOSE; or				
[(iii)] (IV) An individual convicted of a crime or adjudicated as having committed a delinquent act that caused a death or near fatality.				
(d) This section does not prohibit a local team from requesting the attendance at a team meeting of a person who has information relevant to the team's exercise of its purpose and duties.				
(e) A person who violates this section is guilty of a misdemeanor and on conviction is subject to a fine not exceeding \$500 or imprisonment not exceeding 90 days or both.				
13–3101.				
(a) In this subtitle the following words have the meanings indicated.				
[(b) "Advanced practice nurse" has the meaning stated in § 8–101 of the Health Occupations Article.				
(c) "Certificate" means a certificate issued by a private or public entity to administer naloxone.				
(d) "Licensed physician" has the meaning stated in § 14–101 of the Health Occupations Article.]				

- 1 (B) "OPIOID ANTAGONIST" MEANS NALOXONE OR ANY OTHER MEDICATION
 2 APPROVED BY THE DEPARTMENT THAT IS USED TO COUNTER THE EFFECTS OF AN
 3 OPIOID OVERDOSE.
- 4 [(e)] (C) "Pharmacist" has the meaning stated in § 12–101 of the Health 5 Occupations Article.
- [(f)] (D) "Private or public entity" means a health care provider, local health department, community—based organization, substance abuse treatment organization, or other person that addresses medical or social issues related to drug addiction.
- 9 [(g)] (E) "Program" means an Overdose Response Program.
- [(h)] (F) "Standing order" means a written instruction for the prescribing and dispensing of [naloxone to a certificate holder] AN OPIOID ANTAGONIST in accordance with § [13–3108] 13–3105 of this subtitle.
- 13 13–3102.
- [An] THE Overdose Response Program is a program [overseen] ADMINISTERED by the Department for the purpose of providing a means of authorizing certain individuals to administer [naloxone] AN OPIOID ANTAGONIST to an individual experiencing, or believed to be experiencing, opioid overdose to help prevent a fatality when medical services are not immediately available.
- 19 13–3103.
- 20 (a) The Department shall adopt regulations necessary for the administration of 21 the Program.
- (b) The Department may:
- 23 (1) Collect fees necessary for the administration of the Program;
- 24 (2) [Authorize private or public entities to issue and renew certificates to 25 persons meeting the requirements of this subtitle;
- 26 (3) (i)] Authorize private or public entities to conduct [educational] 27 EDUCATION AND training [programs described in § 13–3104 of this subtitle] ON OPIOID 28 OVERDOSE RECOGNITION AND RESPONSE THAT INCLUDES:
- 29 (I) EDUCATION ON RECOGNIZING THE SIGNS AND SYMPTOMS 30 OF AN OPIOID OVERDOSE;

$1\\2$	(II) TRAINING ON RESPONDING TO AN OPIOID OVERDOSE, INCLUDING THE ADMINISTRATION OF AN OPIOID ANTAGONIST; AND					
3 4	(III) ACCESS TO AN OPIOID ANTAGONIST AND THE NECESSARY SUPPLIES FOR THE ADMINISTRATION OF THE OPIOID ANTAGONIST; [and]					
5 6	[(ii)] (3) Develop guidance regarding the content of educational training programs conducted by private or public entities; and					
7	(4) Collect and report data on the operation and results of the programs.					
8	[13–3104.					
9 10	(a) To qualify for a certificate, an individual shall meet the requirements of this section.					
11	(b) The applicant shall be at least 18 years old.					
12 13 14	(c) The applicant shall have, or reasonably expect to have, as a result of the individual's occupation or volunteer, family, or social status, the ability to assist an individual who is experiencing an opioid overdose.					
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17	(2) An educational training program required under this subsection shall:					
18	(i) Be conducted by:					
19	1. A licensed physician;					
20	2. An advanced practice nurse;					
21	3. A pharmacist; or					
22 23 24 25	who is supervised in accordance with a written agreement between the private or public entity and a supervisory licensed physician, advanced practice nurse, or pharmacist that					
26	A. Procedures for providing patient overdose information;					
27 28	B. Information as to how the employee or volunteer providing the information will be trained; and					

1 2	C. Standards for documenting the provision of patient overdose information to patients; and				
3	((ii) Include training in:			
4		1.	The recognition of the symptoms of opioid overdose;		
5		2.	The proper administration of naloxone;		
6		3.	The importance of contacting emergency medical services;		
7 8	naloxone; and	4.	The care of an individual after the administration of		
9		5.	Any other topics required by the Department.]		
0	[13–3105.				
$rac{1}{2}$	An applicant for a certificate shall submit an application to a private or public entity authorized by the Department on the form that the Department requires.]				
13	[13–3106.				
14 15	(a) A private or public entity authorized by the Department shall issue a certificate to any applicant who meets the requirements of this subtitle.				
16	(b) Each ce	ertificate sh	all include:		
17 18	(1) A statement that the holder is authorized to administer naloxone in accordance with this subtitle;				
19	$(2) \qquad 7$	The full name of the certificate holder; and			
20	(3) A	A serial nun	nber.		
21 22	(c) A replacement certificate may be issued to replace a lost, destroyed, or mutilated certificate.				
23	(d) (1) T	The certifica	ate shall be valid for 2 years and may be renewed.		
24	(2) I	n order to r	renew a certificate, the certificate holder shall:		
25 26	(i) Successfully complete a refresher training program conducted by an authorized private or public entity; or				
7	(ii) Damo	instrate proficiency to the private or public entity issuing		

certificates under this subtitle.]

1 [13–3107.] **13–3104.**

- 2 (A) An individual who [is certified] HAS RECEIVED EDUCATION AND TRAINING 3 IN OPIOID OVERDOSE RECOGNITION AND RESPONSE BY AN AUTHORIZED PRIVATE 4 OR PUBLIC ENTITY may [:
- On presentment of a certificate,] receive from any licensed [physician or advanced practice nurse] HEALTH CARE PROVIDER with prescribing authority a prescription for [naloxone] AN OPIOID ANTAGONIST and the necessary supplies for the administration of [naloxone;] THE OPIOID ANTAGONIST.
- 9 **(B)** AN INDIVIDUAL FOR WHOM AN OPIOID ANTAGONIST IS PRESCRIBED AND 10 DISPENSED TO IN ACCORDANCE WITH THIS SUBTITLE MAY:
- 11 **[(2)] (1)** Possess A prescribed [naloxone] OPIOID ANTAGONIST and the necessary supplies for the administration of [naloxone] THE OPIOID ANTAGONIST; and
- [(3)] (2) In an emergency situation when medical services are not immediately available, administer [naloxone] AN OPIOID ANTAGONIST to an individual experiencing or believed by the [certificate holder] INDIVIDUAL to be experiencing an opioid overdose.
- 17 **[**13–3108.**] 13–3105.**

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- [(a) A licensed physician or an advanced practice nurse with prescribing authority may prescribe and dispense naloxone to a certificate holder.
- 20 (b) A registered nurse may dispense naloxone to a certificate holder in a local 21 health department if the registered nurse complies with:
- 22 (1) The formulary developed and approved under § 3–403(b) of this article; 23 and
- 24 (2) The requirements established under § 8–512 of the Health Occupations 25 Article.]
- [(c)] (A) (1) A licensed [physician or an advanced practice nurse] HEALTH
 CARE PROVIDER with prescribing authority may prescribe and dispense [naloxone to a
 certificate holder] AN OPIOID ANTAGONIST by issuing a standing order if the licensed
 [physician or advanced practice nurse] HEALTH CARE PROVIDER:
 - (i) Is employed by the Department or a local health department; or

- 1 (ii) Supervises or conducts [an educational] EDUCATION AND 2 training [program under § 13–3104(d) of this subtitle] ON OPIOID OVERDOSE 3 RECOGNITION AND RESPONSE IN ACCORDANCE WITH A WRITTEN AGREEMENT WITH 4 AN AUTHORIZED PRIVATE OR PUBLIC ENTITY UNDER § 13–3103 OF THIS SUBTITLE.
- 5 (2) A licensed [physician or an advanced practice nurse] **HEALTH CARE**6 **PROVIDER** with prescribing authority who issues a standing order under paragraph (1) of
 7 this subsection may delegate **THE DISPENSING OF AN OPIOID ANTAGONIST** to [the
 8 following persons the authority for dispensing naloxone to a certificate holder:
- 9 (i) A licensed registered nurse who:
- 10 1. Is employed by a local health department; and
- 11 2. Completes a training program approved by the
- 12 Department; and
- 13 (ii) An] AN employee or a volunteer of [a] AN AUTHORIZED private 14 or public entity [who is authorized to conduct an educational training program in 15 accordance with § 13–3104(d) of this subtitle] IN ACCORDANCE WITH A WRITTEN 16 AGREEMENT BETWEEN THE DELEGATING LICENSED HEALTH CARE PROVIDER AND 17 THE AUTHORIZED PRIVATE OR PUBLIC ENTITY THAT EMPLOYS THE EMPLOYEE OR 18 VOLUNTEER.
- 19 (3) Any licensed health care provider who has dispensing authority also 20 may dispense [naloxone to a certificate holder] AN OPIOID ANTAGONIST TO ANY 21 INDIVIDUAL in accordance with a standing order issued by a licensed [physician] HEALTH 22 CARE PROVIDER WITH PRESCRIBING AUTHORITY IN ACCORDANCE WITH THIS 23 SUBSECTION.
- [(d)] (B) [(1)] Any licensed health care provider who has prescribing authority may prescribe [naloxone] AN OPIOID ANTAGONIST to a patient who is believed by the licensed health care provider to be at risk of experiencing an opioid overdose or in a position to assist an individual at risk of experiencing an opioid overdose.
- [(2) A patient who receives a naloxone prescription under paragraph (1) of this subsection is not subject to the training requirements under § 13–3104(d) of this subtitle.]
- 31 **[(e)] (C)** A pharmacist may dispense naloxone in accordance with a therapy 32 management contract under Title 12, Subtitle 6A of the Health Occupations Article.
- 33 **[**13–3109.**] 13–3106.**

- 1 (a) [(1) A certificate holder] AN INDIVIDUAL who, in accordance with this 2 subtitle, is administering [naloxone] AN OPIOID ANTAGONIST to an individual 3 experiencing or believed by the [certificate holder] INDIVIDUAL to be experiencing an opioid overdose may not be considered to be practicing:
- 5 [(i)] (1) Medicine for the purposes of Title 14 of the Health 6 Occupations Article; or
- 7 **[**(ii)**] (2)** Registered nursing for the purposes of Title 8 of the Health 8 Occupations Article.
- [(2)] (B) An employee or volunteer of a private or public entity who, in accordance with this subtitle, provides [naloxone to a certificate holder] AN OPIOID ANTAGONIST TO AN INDIVIDUAL WHO HAS RECEIVED EDUCATION AND TRAINING IN OPIOID OVERDOSE RECOGNITION AND RESPONSE in accordance with a standing order may not be considered to be practicing:
- 14 (i) Medicine for the purposes of Title 14 of the Health Occupations 15 Article;
- 16 (ii) Registered nursing for the purposes of Title 8 of the Health 17 Occupations Article; or
- 18 (iii) Pharmacy for the purposes of Title 12 of the Health Occupations 19 Article.
- 20 [(1)] A licensed [physician] HEALTH CARE PROVIDER WITH 21 PRESCRIBING AUTHORITY who prescribes or dispenses Inaloxone to a certificate holder 22in a manner consistent with the protocol established by the authorized private or public 23entity AN OPIOID ANTAGONIST IN ACCORDANCE WITH THIS SUBTITLE may not be 24subject to any disciplinary action BY THE APPROPRIATE LICENSING HEALTH 25 OCCUPATIONS BOARD under [Title 14 of] the Health Occupations Article solely for the 26 act of prescribing or dispensing [naloxone to the certificate holder] AN OPIOID 27 ANTAGONIST.
- [(2) An advanced practice nurse with prescribing authority who prescribes or dispenses naloxone to a certificate holder in a manner consistent with the protocol established by the authorized private or public entity may not be subject to any disciplinary action under Title 8 of the Health Occupations Article solely for the act of prescribing or dispensing naloxone to the certificate holder.]
- 33 **[**13–3110.**] 13–3107.**
- 34 (a) An individual who administers [naloxone] AN OPIOID ANTAGONIST to an individual who is or in good faith is believed to be experiencing an opioid overdose shall

- 1 have immunity from liability under §§ 5–603 and 5–629 of the Courts and Judicial Proceedings Article.
 - (b) A cause of action may not arise against any licensed [physician, advanced practice nurse] HEALTH CARE PROVIDER with prescribing authority[,] or pharmacist for any act or omission when the [physician, advanced practice nurse with] LICENSED HEALTH CARE PROVIDER WITH prescribing authority[,] or pharmacist in good faith prescribes or dispenses [naloxone] AN OPIOID ANTAGONIST and the necessary paraphernalia for the administration of [naloxone to a certificate holder] THE OPIOID ANTAGONIST TO AN INDIVIDUAL or patient under § [13–3108] 13–3105 of this subtitle.
- 10 (c) This subtitle may not be construed to create a duty on any individual to:
- 11 (1) Obtain [a certificate] EDUCATION AND TRAINING IN OPIOID
 12 OVERDOSE RECOGNITION AND RESPONSE under this subtitle, and an individual may
 13 not be held civilly liable for failing to obtain [a certificate] EDUCATION AND TRAINING IN
 14 OPIOID OVERDOSE RECOGNITION AND RESPONSE under this subtitle; or
- 15 (2) Administer [naloxone] AN OPIOID ANTAGONIST to an individual who 16 is experiencing or believed by the individual to be experiencing an opioid overdose.
- 17 [13–3111.] **13–3108.**

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- A person who dispenses [naloxone] AN OPIOID ANTAGONIST in accordance with this subtitle is exempt from any laws that require a person to maintain a permit to dispense prescription drugs.
- SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2017.