SB0394/733920/1

BY: Senator Cassilly

AMENDMENTS TO SENATE BILL 394, AS AMENDED
(First Reading File Bill)

AMENDMENT NO. 1

On page 1 of the bill, in lines 4, 7, 9, and 10, in each instance, strike "naloxone" and substitute "opioid overdose reversal drugs approved by the federal Food and Drug Administration"; in line 7, after "circumstances" insert "; altering the Overdose Response Program administered by the Maryland Department of Health to include the provision of all opioid overdose reversal drugs approved by the federal Food and Drug Administration"; and strike in their entirety lines 21 through 25, inclusive.

On page 1 of the Finance Committee Amendments (SB0394/223422/1), in line 3 of Amendment No. 1, strike "Maryland"; in line 4, strike "of Health"; in lines 4 and 5, in each instance, strike "naloxone" and substitute "opioid overdose reversal drugs approved by the federal Food and Drug Administration"; in line 7, strike "and 13–3103(d)"; and in line 8, strike "13–3108" and substitute "13–3101 through 13–3109".

AMENDMENT NO. 2

On page 2 of the bill, in line 18, strike "**NALOXONE**" and substitute "**AN OPIOID OVERDOSE REVERSAL DRUG APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION**".

On page 4 of the bill, in line 1, strike "**NALOXONE**" and substitute "**OPIOID OVERDOSE REVERSAL DRUGS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION**"; after line 6, insert:

"(b) "Pharmacist" has the meaning stated in § 12–101 of the Health Occupations Article.";

in line 9, after "addiction." insert:

"(d) "Program" means the Overdose Response Program.

(e) "Standing order" means a written instruction for the prescribing and dispensing of **[**naloxone**]** **AN OPIOID OVERDOSE REVERSAL DRUG APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION** in accordance with § 13–3106 of this subtitle.

13–3102.

The Overdose Response Program is a program administered by the Department for the purpose of providing a means of authorizing certain individuals to administer **[**naloxone**]** **AN OPIOID OVERDOSE REVERSAL DRUG APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION** to an individual experiencing, or believed to be experiencing, opioid overdose to help prevent a fatality when medical services are not immediately available.";

in lines 25 and 30, in each instance, strike "naloxone" and substitute "**AN OPIOID OVERDOSE REVERSAL DRUG APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION**"; and in line 31, strike "naloxone" and substitute "**THE OPIOID OVERDOSE REVERSAL DRUG APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION**".

On page 2 of the Finance Committee Amendments, in lines 1, 6, and 10 of Amendment No. 2, in each instance, strike "**NALOXONE**" and substitute "**AN OPIOID OVERDOSE REVERSAL DRUG APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION**".

On page 2 of the Finance Committee Amendments, after line 2 of Amendment No. 3, insert:

"(a) The Department shall adopt regulations necessary for the administration of the Program.

(b) The Department may:

(1) Collect fees necessary for the administration of the Program;

(2) Authorize private or public entities to conduct education and training on opioid overdose recognition and response that include:

(i) Education on recognizing the signs and symptoms of an opioid overdose;

(ii) Training on responding to an opioid overdose, including the administration of **[**naloxone**]** **OPIOID OVERDOSE REVERSAL DRUGS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION**; and

(iii) Access to **[**naloxone**]** **OPIOID OVERDOSE REVERSAL DRUGS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION** and the necessary supplies for the administration of the **[**naloxone**]** **OPIOID OVERDOSE REVERSAL DRUGS**;

(3) Develop guidance regarding the content of educational training programs conducted by private or public entities; and

(4) Collect and report data on the operation and results of the programs.

(c) An individual is not required to obtain training and education on opioid overdose recognition and response from a private or public entity under subsection (b) of this section in order for a pharmacist to dispense **[**naloxone**]** **AN OPIOID OVERDOSE REVERSAL DRUG APPROVED BY THE FEDERAL FOOD AND DRUG**

ADMINISTRATION to the individual."; and in lines 4 and 5, in each instance, strike "**NALOXONE**" and substitute "**OPIOID OVERDOSE REVERSAL DRUGS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION**".

On page 3 of the Finance Committee Amendments, in line 3 of Amendment No. 3, after "Department." insert:

"13–3104.

An authorized private or public entity shall enter into a written agreement with a licensed health care provider with prescribing authority to establish protocols for the prescribing and dispensing of **[**naloxone**] AN OPIOID OVERDOSE REVERSAL DRUG APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION** to any individual in accordance with this subtitle.

13–3105.

(a) An individual may receive from any licensed health care provider with prescribing authority a prescription for **[**naloxone**] AN OPIOID OVERDOSE REVERSAL DRUG APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION** and the necessary supplies for the administration of **[**naloxone**] THE OPIOID OVERDOSE REVERSAL DRUG**.

(b) An individual for whom **[**naloxone**] AN OPIOID OVERDOSE REVERSAL DRUG APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION** is prescribed and dispensed in accordance with this subtitle may:

(1) Possess **THE** prescribed **[**naloxone**] OPIOID OVERDOSE REVERSAL DRUG** and the necessary supplies for the administration of **[**naloxone**] THE OPIOID OVERDOSE REVERSAL DRUG**; and

(2) In an emergency situation when medical services are not immediately available, administer **[**naloxone**]** **THE OPIOID OVERDOSE REVERSAL DRUG** to an individual experiencing or believed by the individual to be experiencing an opioid overdose.

13–3106.

(a) A licensed health care provider with prescribing authority may prescribe and dispense **[**naloxone**]** **AN OPIOID OVERDOSE REVERSAL DRUG APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION** to an individual who:

(1) Is believed by the licensed health care provider to be at risk of experiencing an opioid overdose; or

(2) Is in a position to assist an individual at risk of experiencing an opioid overdose.

(b) (1) A licensed health care provider with prescribing authority may prescribe and dispense **[**naloxone**]** **OPIOID OVERDOSE REVERSAL DRUGS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION** by issuing a standing order if the licensed health care provider:

(i) Is employed by the Department or a local health department; or

(ii) Has a written agreement with an authorized private or public entity under § 13–3104 of this subtitle.

(2) A licensed health care provider with prescribing authority who issues a standing order under paragraph (1) of this subsection may delegate the dispensing of **[**naloxone**]** **OPIOID OVERDOSE REVERSAL DRUGS APPROVED BY THE**

FEDERAL FOOD AND DRUG ADMINISTRATION to an employee or a volunteer of an authorized private or public entity in accordance with a written agreement under § 13–3104 of this subtitle.

(3) Any licensed health care provider who has dispensing authority also may dispense **[**naloxone**] AN OPIOID OVERDOSE REVERSAL DRUG APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION** to any individual in accordance with a standing order issued by a licensed health care provider with prescribing authority in accordance with this subsection.

(c) A pharmacist may dispense **[**naloxone**] OPIOID OVERDOSE REVERSAL DRUGS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION** in accordance with a therapy management contract under Title 12, Subtitle 6A of the Health Occupations Article.

13–3107.

(a) An individual who, in accordance with this subtitle, is administering **[**naloxone**] AN OPIOID OVERDOSE REVERSAL DRUG APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION** to an individual experiencing or believed by the individual to be experiencing an opioid overdose may not be considered to be practicing:

(1) Medicine for the purposes of Title 14 of the Health Occupations Article; or

(2) Registered nursing for the purposes of Title 8 of the Health Occupations Article.

(b) An employee or volunteer of a private or public entity who, in accordance with this subtitle, provides **[**naloxone**] AN OPIOID OVERDOSE REVERSAL DRUG APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION** 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:

(1) Medicine for the purposes of Title 14 of the Health Occupations Article;

(2) Registered nursing for the purposes of Title 8 of the Health Occupations Article; or

(3) Pharmacy for the purposes of Title 12 of the Health Occupations Article.

(c) A licensed health care provider who prescribes or dispenses **[**naloxone**]** **OPIOID OVERDOSE REVERSAL DRUGS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION** in accordance with this subtitle may not be subject to any disciplinary action by the appropriate licensing health occupations board under the Health Occupations Article solely for the act of prescribing or dispensing **[**naloxone**]** **OPIOID OVERDOSE REVERSAL DRUGS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION**.";

in lines 1, 2, and 3 of Amendment No. 3, in each instance, strike "**NALOXONE**" and substitute "**AN OPIOID OVERDOSE REVERSAL DRUG APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION**".

On page 5 of the bill, in lines 3 and 26, in each instance, strike "**NALOXONE**" and substitute "**OPIOID OVERDOSE REVERSAL DRUGS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION**"; in line 5, strike "**NALOXONE**" and substitute "**THE OPIOID OVERDOSE REVERSAL DRUGS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION**"; in lines 13 and 24, in each instance, strike "naloxone" and substitute "**OPIOID OVERDOSE REVERSAL DRUGS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION**"; and after line 14, insert:

"13–3109.

A person who dispenses **[**naloxone**]** **AN OPIOID OVERDOSE REVERSAL DRUG APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION** in accordance with this subtitle is exempt from any laws that require a person to maintain a permit to dispense prescription drugs.".