

NICHOLAUS R. KIPKE
Legislative District 31
Anne Arundel County

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The Maryland House of Delegates
6 Bladen Street, Room 165
Annapolis, Maryland 21401
410-841-3421 · 301-858-3421
800-492-7122 Ext. 3421
Nicholaus.Kipke@house.state.md.us

The Maryland House of Delegates
ANNAPOLIS, MARYLAND 21401

HB 571 Overdose Response Program – Opioid Overdose Reversal Drugs – Choice of Formulation and Dosage

Chair Pena-Melnyk, Vice Chair Cullison, and members of the Committee, thank you for the opportunity to present HB 571. This bill requires the Department of Health to allow an entity provided with opioid reversal drugs through an opioid response program to choose the formulation or dosage of opioid overdose reversal drug approved the FDA with which the entity is to be provided.

This bill is simply about providing access and choice as we continue to combat the opioid epidemic in Maryland.

For returning members of the committee, you may recall that last year we passed legislation known as the STOP Act to expand community-based naloxone distribution. As part of this legislation, the definition of “Standing Order” for the prescribing and dispensing of naloxone was broadened and sections referring to opioid response programs were amended to refer to opioid overdose reversal drugs approved by the Federal Food and Drug Administration. This legislation and further conversations with the Administration resulted in the issuance of a new Statewide Standing Order for Opioid Overdose Reversal Drugs and a guidance document issued on July 21, 2022 which refers to 2 mg, 4 mg, and 8 mg formulations (intranasal and Intramuscular) of naloxone.

However, further amendments to the bill specified that opioid overdose reversal drugs approved by the FDA for broader distribution through the Maryland Department of Health’s Center for Harm Reduction opioid response programs could only be used if provided by the Department. This is the crux of the issue. Although the broader statewide standing order refers to all products currently approved by the FDA, a separate standing order has been issued specific to Opioid Response Program distribution dated October 24, 2022 to only allow for the use of NARCAN, a 4 mg nasal spray.

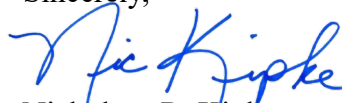
At this time, a 4 mg and 8 mg nasal formulation of naloxone have been approved by the FDA as well as intramuscular forms. I would contend our intent last session when amending the STOP Act to refer to all opioid overdose reversal medications approved by the FDA was to provide for access and a patient-centered approach when using these products. This would allow the treatment provider and/or individual providing access to opioid overdose reversal drugs to determine the medication best for the population they are serving. This is exactly what HB 571 would do, it would provide for choice when providing these medications through approved opioid response programs.

Although we have seen a decline in the overall number of fatal overdoses, the number of overall deaths involving fentanyl has increased significantly and data shows increases in overdose deaths for certain populations, particularly those older in age and Black Marylanders. Data also shows that most fatal overdoses occur in residences where a bystander is present. While this demonstrates a continued need for community-based naloxone distribution, the increased presence of fentanyl has also led to some instances when the need for two or more 4 mg nasal doses of naloxone were used to save a person's life. For these reasons specifically, thirteen states have already expanded their community-based harm reductions programs to include 4 mg and 8 mg nasal doses of naloxone in addition to the intramuscular forms. Six states are providing access to an 8 mg nasal dose of naloxone in addition to the 4 mg nasal dose outside of their department of health programs. The U.S. Veterans Administration does as well and includes specific guidance on populations who may benefit from higher dose naloxone products.

Our fight in this opioid crisis necessitates all resources be made available. I understand some medications may not be suited for certain populations we are trying to help. But, as we continue to combat this crisis, we need to ensure that programs have options available to them to best serve the populations they are trying to help. This bill seeks to achieve that goal and provide another tool in our toolbox to save the lives of Marylanders.

Madam Chair and members of the Committee, I urge you to give HB 571 a FAVORABLE report.

Sincerely,



Nicholaus R. Kipke

Attachments:

Statewide Standing Order and Guidance Document
Naloxone Standing Order for Opioid Response Program Dispensing
US Veterans Administration, Naloxone Recommendations for Use -
Kloxxodo One-Pager
MORE Study Postcard
AD Council Information on Naloxone