TestimonySB954 Overdose Response Program – Opioid

Uploaded by: AmandaLynn Reese

Position: FAV

TestimonySB954 Overdose Response Program – Opioid Overdose Reversal Drugs – Choice of Formulation and Dosage

Ohio was the first state to allow access to all forms of naloxone in August of 2021. We did our best to learn about all forms, concerns raised and inform our community members and partners about all options available. In preparation for expanding access to all forms we began surveying naloxone use in both our online orders and community distribution programs. We learned how many doses were being used based on the type of administration and we were able to consider the circumstances of the overdose event in these instances. We saw a gradual increase in orders for higher dose naloxone as it became known to partners and those we serve. It is still premature to call this a trend, but it continues to be clear that nasal delivery is the preferred method of administration overall. Nonetheless, a substantial minority of people preferred IM. This suggests that the continued availability of all forms of naloxone is important. **We promote total autonomy of choice to all forms of FDA approved naloxone**. We also learned most people used naloxone as per the directions. However, from our two surveys prior to the introduction of higher dose we learned about 1⁄4 of the online respondents and 1⁄3 of the HRO community distribution respondents **reported using 3 or more doses**. Due to the adulterated drug supply. It is not just those who intentionally use opioids experiencing opioid overdoses. Across the board we have seen a decrease in cost for ALL forms of naloxone since the market expanded. The price of naloxone has fallen by half in less than a year. Ohio plans to use these savings and regulatory changes to improve getting this life-saving drug to people who need it most. In 2022 we distributed over 42k naloxone kits. Less than a year ago a box of 4mg NS was $75. At current prices, the cost of the 42k naloxone kits shipped by Harm Reduction Ohio is about $1.4 million, down from $2.7 million under the old prices.

Finally, almost all of the people receiving naloxone in the two surveys survived their overdose. While this may be partly due to sample selection bias, it also makes it clear that widespread distribution of and training about administering naloxone **of any form** at a lower cost is an important tool in reducing deaths from accidental drug overdoses.

Naloxone does not seem to create life-threatening side effects, even at higher doses.

Thank you

AmandaLynn Reese

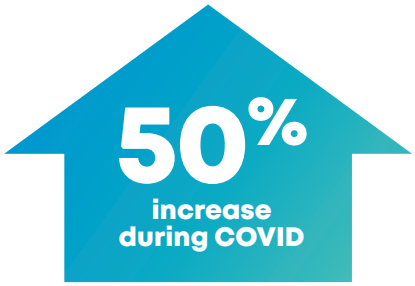
Kloxxado_One-Pager - v1.pdf
Uploaded by: Andrea Mansfield
Position: FAV

Our Communities Need Access to All Forms of Naloxone

Kloxxado® (naloxone HCl) nasal spray 8 mg

Enable the provision and use of KLOXXADO® (naloxone HCl) Nasal Spray 8 mg

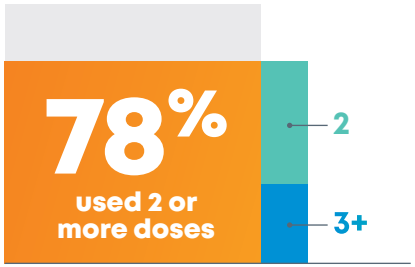
100,000+ people died of drug overdose in 2021, largely attributed to illicitly manufactured fentanyl.[1,2]



During COVID, annual **overdose deaths surged 50%.**[1]

Illicit fentanyl is 50x stronger than heroin.[4]

Within 4 minutes of no oxygen, permanent brain damage can occur, causing death.[5]



78% of opioid overdose reversals involved 2 or more doses of naloxone, while 30% involved 3+ doses, according to the 2021 MORE study, a survey of people who administered NARCAN® (naloxone HCl) Nasal Spray 4 mg.[6]

77% of respondents in the 2021 MORE study would prefer a naloxone dose of 8 mg over 4 mg in the nasal spray.[6]

KLOXXADO® 8 mg contains **twice as much** naloxone per dose as Narcan® 4 mg.[7,8]

- Only KLOXXADO® contains 8 mg per spray upfront in a single dose.[7]
- KLOXXADO® is made in the USA.
- Community Health pricing is available.

About Hikma Pharmaceuticals

- Hikma is a longstanding US provider of high-quality, affordable medicines.
- Hikma offers >220 medicines in the US, most made in the US, with ~1900 US employees and 3 large manufacturing/R&D sites.[9]
- Hikma is a strong public health partner, providing critical medicines involved in the treatment of COVID-19 patients (including dexamethasone), as well as substance use disorder (including buprenorphine).[9]

KLOXXADO® (naloxone HCl) Nasal Spray 8 mg Important Safety Information

CONTRAINDICATIONS

- Hypersensitivity to naloxone hydrochloride or to any of the other ingredients in KLOXXADO®

WARNINGS AND PRECAUTIONS

- **Risk of Recurrent Respiratory and Central Nervous System Depression**
  Seek emergency assistance immediately after administration of the first dose and keep the patient under continued surveillance. The duration of action of most opioids may exceed that of KLOXXADO®, resulting in a return of respiratory and/or central nervous system depression after an initial improvement in symptoms. Administer additional doses as necessary if the patient is not adequately responding or responds and then relapses back into respiratory depression.

- **Risk of Limited Efficacy With Partial Agonists or Mixed Agonist/Agonists**
  Reversal of respiratory depression by partial agonists or mixed agonist/antagonists may be incomplete. Larger or repeat doses of naloxone hydrochloride may be required.

- **Precipitation of Severe Opioid Withdrawal**
  Use in patients who are opioid-dependent may precipitate opioid withdrawal characterized by body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness and increased blood pressure. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated and may include convulsion, excessive crying and hyperactive reflexes. Monitor the patient for the development of the signs and symptoms of opioid withdrawal. For more information about management of opioid withdrawal, see the full Prescribing Information.

  Abrupt reversal of opioid effects in persons who were physically dependent on opioids has precipitated an acute withdrawal syndrome. In some patients, there was aggressive behavior upon abrupt reversal of an opioid overdose.

  Abrupt postoperative reversal of opioid depression after using naloxone hydrochloride may result in nausea, vomiting, sweating, tremulousness, tachycardia, hypotension, hypertension, seizures, ventricular tachycardia and fibrillation, pulmonary edema and cardiac arrest. Death, coma and encephalopathy have been reported as sequelae of these events. These events have primarily occurred in patients who had pre-existing cardiovascular disorders or received other drugs that may have similar adverse cardiovascular effects. Monitor these patients closely in an appropriate healthcare setting.

ADVERSE REACTIONS

In two pharmacokinetic studies, a total of 47 healthy adult volunteers were exposed to a single dose of KLOXXADO®, one spray in one nostril.

- Adverse reactions were reported in two subjects for each of the following: abdominal pain, asthenia, dizziness, headache, nasal discomfort, and presyncope.
- Signs of nasal inflammation and nasal congestion were observed
- Serious adverse reactions reported: none

The following most frequently reported events (in decreasing frequency) have been identified primarily during post-approval use of naloxone hydrochloride: withdrawal syndrome, vomiting, nonresponsiveness to stimuli, drug ineffective, agitation, somnolence, and loss of consciousness.

USE IN SPECIFIC POPULATIONS

- **Pregnancy**
  Naloxone may precipitate opioid withdrawal in the pregnant woman and fetus. Careful monitoring is needed until the fetus and mother are stabilized.
- **Infants**
  In situations where the primary concern is for infants at risk for opioid overdose, consider the availability of alternate naloxone-containing products.

For more information, please see the full Prescribing Information and Patient Information, which you can find on our website at www.kloxxado.com.

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit https://www.fda.gov/medwatch or call 1-800-FDA-1088.

Distr. by: Hikma Specialty USA Inc. Columbus, OH 43228

1. Ahmad FB, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2021. Accessed August 4, 2022. **2.** Prescription Behavior Surveillance System (PBSS): Issue Brief. National Center for Injury Prevention and Control/Centers for Disease Control and Prevention. Accessed August 4, 2022. **3.** Facts about Fentanyl. United States Drug Enforcement Administration. https://www.dea.gov/resources/facts-about-fentanyl. Accessed August 4, 2022. **4.** Stop Overdose, 2022, "The Facts About Fentanyl," CDC, https://www.cdc.gov/stopoverdose/fentanyl, Accessed 2022 0819. **5.** Zibbell J, et al. Non-fatal opioid overdose and associated health outcomes: final summary report. US Department of Health and Human Services. https://aspe.hhs.gov/basic-report/non-fatal-opioid-overdose-and-associated-health-outcomes-final-summary-report. Accessed August 4, 2022. **6.** Abdelal, R., Raja Banerjee, A., Carlberg-Racich, S. et al. Real-world study of multiple naloxone administration for opioid overdose reversal among bystanders. *Harm Reduct J* 19, 49 (2022). **7.** KLOXXADO® (Naloxone HCl) Nasal Spray [prescribing information]. Columbus, OH: Hikma Specialty USA Inc.; 2021. **8.** NARCAN® (Naloxone HCl) Nasal Spray [prescribing information]. Plymouth Meeting, PA: Adapt Pharma, Inc.; 2020. **9.** Hikma Internal Information.

MORE STUDY_postcard -v1.pdf
Uploaded by: Andrea Mansfield
Position: FAV

It Can Take MORE Than Four.[1]

learn more at morenaloxone.com

78% of opioid overdose reversals involved MORE than 4 mg of naloxone.[1]

According to the MORE study, a survey of 125 adult bystanders who have administered Narcan® (naloxone HCl) Nasal Spray 4 mg.[1]

The MORE study answers these questions:[1]

- How many doses of Narcan® Nasal Spray 4 mg were administered?
- Do people with experience giving naloxone" think one box of Narcan® is enough?
- Do people with experience giving naloxone prefer a 4mg or an 8mg dose?

Do your patients know that it often takes at least 8 mg of naloxone to reverse an opioid overdose?[1]

> **"Now with fentanyl, it's getting trickier. People aren't coming responsive like they used to. It takes more than just one [spray of naloxone nasal spray 4 mg]."** - Patient Participant, MORE study[1]

Scan the QR code to read the full study

Thank you for being a leader in your community. Naloxone champions like you help keep our communities safe.[2]

Brought to you by Hikma Community Health™, Connecting Patient Health and Community Wellness.

Reference

1 Abdelal, R., Raja Banerjee, A., Carlberg-Racich, S. et al. Real-world study of multiple naloxone administration for opioid overdose reversal among bystanders. Harm Reduct J 19, 49 (2022). https://doi.org/10.1186/s12954-022-00627-3 .

2 US Department of Health and Human Services, Office of the Surgeon General. Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health. Washington, DC: HHS, 2016.

HK-1727

hikma.

SB954 - Johns Hopkins - Support.pdf
Uploaded by: Annie Coble
Position: FAV

JOHNS HOPKINS
UNIVERSITY & MEDICINE
Government and Community Affairs

SB954
Favorable

TO: The Honorable Melony Griffith, Chair
Senate Finance Committee

FROM: Annie Coble
Assistant Director, State Affairs

DATE: March21,2023

RE: SB954 OVERDOSE RESPONSE PROGRAM – OPIOID OVERDOSE REVERSAL DRUGS – CHOICE OF FORMULATION AND DOSAGE

Johns Hopkins **supports SB954 Overdose Response Program – Opioid Overdose Reversal Drugs – Choice of Formulation and Dosage.** This bill allows providers that receive naloxone from the Maryland Department of Health to choose the formulation or dosage of the drug.

As the Committee is aware, naloxone is an important tool in the fight against the opioid epidemic and should be widely available. Johns Hopkins is the only health system in the state that is designated as an Overdose Response Program (ORP). This allows all of the hospitals in our health system to dispense naloxone at no cost to patients at risk for an opioid overdose at the point of discharge from the emergency departments. In 2021, across all the hospitals, Johns Hopkins distributed 382 naloxone kits. Important to the success of this program is the fact that the naloxone supply is provided by the State at no cost.

Providing options on the formulation and dosage of naloxone allows for flexibility in providing different care for different patient needs. We appreciate that this bill just provides a choice, and not a mandate, that allows us to continue to treat our patients by prioritizing their safety.

For these reasons and more, Johns Hopkins urges a **favorable** report on **SB954**.

BrightView - HB 571 Letter of Support (1).pdf
Uploaded by: Emily schwarz-Harsh
Position: FAV

BrightView
PATIENT-FOCUSED ADDICTION TREATMENT

BrightView
446 Morgan St.
Cincinnati, OH 45206

March 1, 2023

Dear Chair Pena-Melnyk, Vice Chair Cullison, and members of the Committee:

I'm writing today to voice strong support for HB 571 on behalf of BrightView Health. BrightView is a new kind of addiction treatment center, founded on the philosophy of same day access to care for individuals experiencing substance use disorders. Since opening our doors in 2015, BrightView has served over 50,000 individuals experiencing substance use disorders across 85 centers in Ohio, Kentucky, Virginia, Delaware, Connecticut, Massachusetts, North Carolina, Arizona, and most recently, Maryland.

With our experience treating individuals with substance use disorders, we have worked with countless individuals who have achieved stability and remission from opioid use disorder following an overdose experience. To put it frankly, ***individuals cannot move on to a life after of addiction and recover from opioid use disorders if they do not survive the medical emergency of an opioid overdose - these medications must be widely available and accessible to all individuals.*** Access to all forms of FDA approved medications for opioid overdose and reversal should be a vital component of every communities strategy to providing individuals with the tools they need to survive an overdose experience and recover. We strongly support increasing accessibility to all forms of FDA approved opioid overdose reversal medications.

Sincerely,

Emily Harsh, LPC, LICDC

Director of Justice System Outreach

SB 954-MCPA-MSA-ORPs-Choice of Formulation and Dos

Uploaded by: Natasha Mehu

Position: FAV

Maryland Chiefs of Police Association
Maryland Sheriffs' Association

MEMORANDUM

TO: The Honorable Melony Griffith, Chair and
Members of the Finance Committee

FROM: Darren Popkin, Executive Director, MCPA-MSA Joint Legislative Committee
Andrea Mansfield, Representative, MCPA-MSA Joint Legislative Committee
Natasha Mehu, Representative, MCPA-MSA Joint Legislative Committee

DATE: March 21, 2023

RE: **SB 954 Overdose Response Program – Opioid Overdose Reversal Drugs – Choice of Formulation and Dosage**

POSITION: SUPPORT

The Maryland Chiefs of Police Association (MCPA) and the Maryland Sheriffs' Association (MSA) SUPPORT SB 954. This bill requires the Maryland Department of Health to provide choice in the selection of formulation or dosage of opioid overdose reversal drugs approved by the Federal Food and Drug Administration (FDA).

MCPA and MSA are composed of leadership from local law enforcement agencies who protect the safety and well-being of more than 16,000 officers across the state. Our officers are often the first to respond to overdose situations. Officers need the tools to save the lives of those who may be overdosing, but also need to protect themselves from substances that may be laced with fentanyl. Just recently, a deputy sheriff in Indiana collapsed after coming into contact with fentanyl while patting down a suspect. This could easily occur right here in Maryland.

Currently, officers carry two 4 mg nasal doses of naloxone. These doses are distributed to law enforcement agencies by the local health departments through the Maryland Department of Health's Center for Harm Reduction. Oftentimes, officers administer both doses to reverse an overdose, leaving officers out in the field without additional doses for another overdose victim or for themselves should they encounter a harmful substance.

MCPA and MSA are aware of higher dose forms of naloxone approved by the FDA and believe access to this option could benefit officers in the field. However, the Maryland Department of Health's Center for Harm Reduction only provides access to 4 mg nasal doses of naloxone. Law enforcement agencies are not able to access higher dose formulations of naloxone through distribution mechanisms. MCPA and MSA believe access should be provided to ALL tools to keep Marylanders and officers alive.

For these reasons, MCPA and MSA strongly SUPPORT SB 954 and urge a favorable committee report.

532 Baltimore Boulevard, Suite 308
Westminster, Maryland 21157
667-314-3216 / 667-314-3236

SB0954-FIN_MACo_SUP.pdf
Uploaded by: Sarah Sample
Position: FAV

MARYLAND Association of COUNTIES

Senate Bill 954

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

MACo Position: **SUPPORT**

To: Finance Committee

Date: March 21, 2023

From: Sarah Sample

The Maryland Association of Counties (MACo) **SUPPORTS** SB 954. This bill would require the Maryland Department of Health to authorize local programs to treat and reverse overdoses to choose their preferred formulation of medication for these purposes.

Local health departments are at the forefront of mitigation and remediation efforts to restore communities that continue to be harmed by the opioid epidemic. With the surge in fentanyl usage, which is a particularly potent opioid, previous overdose reversal medications can be rendered ineffective depending on the use case. As challenges like this continue to evolve, it is vital that treatment methods keep up, and this legislation would certainly further that cause.

With a stronger tool for overdose reversal programs, local health departments will be better equipped to manage the deadly and unprecedented flood of fentanyl cases especially where locals teams are finding that the current single dosage amounts are not sufficient to reverse an overdose. While a free option for reversal drugs through the existing Opioid Overdose Response Program is beneficial, counties want to make sure the treatment methods are keeping pace with the problem. This legislation ensures counties can respond to the new challenges with new solutions.

Overdose prevention programs are a key strategy for ensuring as few lives as possible will be lost to this ongoing crisis. Allowing local health departments and community programs the ability to specify the drugs, dosage, and formulations that are seen to be effective in their communities will bolster their ability to save lives. Accordingly, MACo requests a **FAVORABLE** report on SB 954.

8 - X - SB 954 - FIN - MDH - LOO.pdf
Uploaded by: State of Maryland (MD)
Position: UNF

Maryland
DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

March 21, 2023

The Honorable Melony Griffith
Chair, Senate Finance Committee
3 East Miller Senate Office Building
Annapolis, MD 21401

RE: SB 954 – Overdose Response Program - Opioid Overdose Reversal Drugs - Choice of Formulation and Dosage – Letter of Opposition

Dear Chair Griffith and Committee Members:

The Maryland Department of Health (MDH) respectfully submits this letter of opposition for Senate Bill 954(SB 954) – Overdose Response Program - Opioid Overdose Reversal Drugs - Choice of Formulation and Dosage. This bill requires that MDH provide Overdose Response Programs (ORPs) with the formulation and dosage of opioid overdose reversal drugs of the ORP's choosing.

MDH's Center for Harm Reduction Services currently purchases and provides local ORPs with opioid overdose reversal drugs, specifically naloxone, at no charge. Presently, ORPs can request any type of opioid overdose reversal drug from MDH. It should be noted that MDH conducts due diligence to obtain the best price for naloxone and pursue the most efficient procurement mechanism, in accordance with state procurement laws. MDH has a fixed budget for naloxone drug procurement, which is calculated based on cost and availability of the drugs. In addition, MDH has not received any feedback from ORPs about unmet community need for requested supplies.

For reference, current overdose reversal drugs (per two-dose kit) supplied through the ORPs are:

- Narcan nasal spray (4 mg);
- Kloxxado nasal spray (8 mg); and
- Naloxone injectable intramuscular (0.4 mg/mL).

MDH experiences the highest volume of requests for the Narcan nasal spray. If SB 954 is enacted, MDH will be required to honor ORP requests for higher priced naloxone formulations. Purchasing naloxone products without consideration of cost, will result in an unknown fiscal impact and may impact MDH's compliance with the STOP Act of 2022. In turn, this could limit MDH's goal to maximize naloxone access statewide.

If you would like to discuss this topic further, please do not hesitate to contact Megan Peters, Acting Director of Governmental Affairs at megan.peters@maryland.gov or (410) 260-3190.

Sincerely,

Laura Herrera Scott, M.D., M.P.H.
Secretary