

COMMONWEALTH of VIRGINIA

Karen Shelton, MD State Health Commissioner Department of Health
P O BOX 2448
RICHMOND, VA 23218

TTY 7-1-1 OR 1-800-828-1120

January 19, 2024

MEMORANDUM

TO: The Honorable L. Louise Lucas

Chair, Senate Finance and Appropriations Committee

The Honorable Luke E. Torian

Chair, House Appropriations Committee

The Honorable Mark D. Sickles

Vice Chair, House Appropriations Committee

FROM: Karen Shelton, MD

State Health Commissioner, Virginia Department of Health

SUBJECT: Virginia Plan for Distribution and Saturation of Naloxone

This report is submitted in compliance with the 2023 Virginia Acts of the Assembly – Chapter 631, the second enactment clause of which states:

That the Department of Health, the Department of Behavioral Health and Developmental Services, and the Department of Corrections shall review existing naloxone distribution programs and collaborate to develop a comprehensive statewide plan for the distribution of naloxone throughout the Commonwealth. The plan shall provide guidance to emergency medical services agencies on the distribution of naloxone in high-risk areas and shall ensure that every pharmacy that carries naloxone is provided with a supply of fentanyl test strips to include with every order of naloxone provided to consumers. The plan shall also provide guidance to localities for the implementation of local naloxone distribution plans. The respective departments are authorized to begin implementation of the plan, to the extent the agencies have existing resources to do so. The Department of Health shall provide a report on the statewide naloxone plan, including the resources needed to fully implement the plan, to the Chairs of the House Committee on Appropriations and the Senate Committee on Finance and Appropriations by September 1, 2023.



Should you have any questions or need additional information, please feel free to contact me at (804) 864-7002.

KS/AJ Enclosure

Pc: The Honorable John Littel, Secretary of Health and Human Resources



VIRGINIA PLAN FOR DISTRIBUTION AND SATURATION OF NALOXONE

REPORT TO THE GENERAL ASSEMBLY

2023



VIRGINIA DEPARTMENT OF HEALTH

PREFACE

On March 26, 2023, Virginia's General Assembly approved Chapter 631, which focuses on reducing the impact of the opioid epidemic. One provision in the bill relates to the development of a comprehensive, statewide plan for naloxone distribution. The Department of Health (VDH), Department of Behavioral Health and Developmental Services (DBHDS), and Department of Corrections (DOC) collaborated to review existing distribution processes and seek input from stakeholders to assess current naloxone distribution, naloxone demand, barriers to access, and to present the concept of naloxone saturation. This document reflects the collaboration between VDH, DBHDS, and DOC, and comments from stakeholders including Virginia state agencies and organizations and community leaders working in opioid response.

WORKGROUP MEMBERS

Department of Behavioral Health and Developmental Services (DBHDS)

Candace Roney, Director of Substance Use Services

Tiffani Wells, Harm Reduction Coordinator, Office of Substance Use Services

Department of Corrections (DOC)

Michael Fatula, Statewide Substance Use Disorder Program Manager

Department of Health Professions (DHP)

Ellen Shinaberry, Deputy Executive Director, Virginia Board of Pharmacy

Department of Criminal Justice Services (DCJS)

Leslie Egen, Criminal Justice Behavioral Health and Substance Use Disorder Response Coordinator, FAACT Project Manager, Division of Programs and Services / Adult Justice Programs

Department of Medical Assistance Services (DMAS)

John Morgan, Chief Clinical Innovation Officer

Jason Lowe, Behavioral Health Integration Advisor, Division of Behavioral Health

Department of Juvenile Justice (DJJ)

Ashaki McNeil, Deputy Director of Interventions, Education and Reentry

Department of Education (DOE)

Karen Mask, School Health Special Projects Coordinator, Department of Special Education and Student Services Office

Tracey White, School Health Specialist, Office of Special Education and Student Services, Office of Student Services

Department of Social Services (DSS)

Stephen Wade, Health Equity Project Manager

Virginia Department of Health (VDH)

Dr. Laurie Forlano, State Epidemiologist, Office of Epidemiology

Dr. Stephanie Wheawill, Director of Division of Pharmacy Services, Office of Epidemiology

Dr. Alexis Page, Deputy Director of Division of Pharmacy Services, Office of Epidemiology Heather Board, Director of Division of Prevention and Health Promotion, Office of Family Health Services

Carolyn Lamere, Program Manager for Naloxone Distribution, Office of Epidemiology Ashley Matthews, Program Manager for Operations and Process Improvement, Office of Epidemiology

TABLE OF CONTENTS

Preface	i
Workgroup Members	i
Table of Contents	
Executive Summary	iv
Recommendations	iv
Introduction	1
Workgroup Mandate	1
Workgroup Activities	
June 6, 2023 Meeting	
June 20, 2023 Meeting	
Report Outline	
Background and context	
Virginia's Opioid Crisis	
Current Naloxone Access	
Barriers to access	
Prescribing and Co-Prescribing	
Standing order	
Direct purchase and dispensing	
VDH Distribution – Current State	
Future considerations	
Naloxone Saturation	
Background and Definition of Saturation	8
Limitations and Considerations for Saturation Models	8
Saturation Recommendations	9
High-Priority Individuals	9
High-Priority Settings	
Recommended targets for saturation and maintenance of undesignated stock	10
Recommended targets for saturation and maintenance of undesignated stock	11
VDH Distribution of Naloxone - Recommendations for Future State	
High impact	13
\$Distribution to partner organizations	13
Mail-order	
Expanded access	14
Partner Guidance	15
Pharmacies	15
Emergency Medical Service Agencies	16
Localities - Implementation of Local Distribution Plans	16
Additional support	17
Data & Reporting	17
Virginia Department of Health	17
Individuals	18
Partner Organizations	18
Additional data	
Department of Behavioral Health and Developmental Services	
Department of Corrections	
Recommendations	
Appendix A - Chapter 631 of the 2023 Acts of Assembly	

Appendix B	- Acronyms and Abbreviations	31
	- Works Cited	
Appendix D -	- Methodology for Indicator Selection and Determination of Need for Drug Over	dose-
Related Surve	eillance, Prevention, and Intervention Strategies: Right Help, Right Now Initiative	33

EXECUTIVE SUMMARY

Chapter 631 directs the Virginia Department of Health (VDH), Department of Behavioral Health and Developmental Services (DBHDS) and Department of Corrections (DOC) to develop a statewide plan for the distribution of naloxone throughout the Commonwealth. VDH is required to provide a report on the development of the plan, including the resources needed to fully implement the plan, to the Chairs of the House Committee on Appropriations and the Senate Committee on Finance and Appropriations by September 1, 2023. To develop the plan and report, VDH conducted additional outreach to solicit feedback from stakeholders, including holding focus groups with local health districts, community service boards, and authorized comprehensive harm reduction sites. VDH also discussed naloxone in depth in small-group or one-on-one sessions with the DOC, Department of Juvenile Justice (DJJ), DBHDS, and the Department of Social Services (DSS). Recommendations from the workgroup are listed below. If sufficient funding is made available, Virginia anticipates implementing key activities from the plan within SFY 24.

RECOMMENDATIONS

By engaging with stakeholders, VDH, DBHDS, and DOC developed the following shared recommendations; further detail is provided on page 20.

- 1. Virginia should leverage all available fund sources (local, state and federal) to assure sufficient naloxone saturation in the Commonwealth.
- 2. Engage with local jurisdictions.
- 3. Distribute no-cost naloxone to high-impact partners.
- 4. VDH should develop naloxone distribution portal.
- 5. Engage with community-level partners.
- 6. Escalate budget needs and submit budget requests as required, including for a minimum of \$5,519,145 for FY 2025 and for \$5,464,145 for FY 2026.
- 7. Assess Virginia's naloxone distribution and saturation annually.

INTRODUCTION

WORKGROUP MANDATE

On March 26, 2023, Virginia's General Assembly approved Chapter 631, which focuses on reducing the impact of the opioid epidemic. One provision in Chapter 631 relates to the development of a comprehensive, statewide plan for naloxone distribution. The Department of Health (VDH), Department of Behavioral Health and Developmental Services (DBHDS), and Department of Corrections (DOC) collaborated to review existing distribution and seek input from stakeholders to assess current naloxone distribution, naloxone demand, barriers to access, and to present the concept of naloxone saturation. The full text of Chapter 631 can be found in Appendix A.

WORKGROUP ACTIVITIES

The Virginia Department of Health (VDH), along with the Department of Behavioral Health and Developmental Services (DBHDS) and the Department of Corrections (DOC), has developed a plan to distribute naloxone or other opioid reversal agents and test strips across Virginia, with a goal to saturate communities with naloxone, ultimately reducing injury and death associated with opioid overdose. VDH solicited input from work group agencies, including specific feedback related to naloxone distribution and saturation, as well as additional stakeholders working in opioid response.

JUNE 6, 2023 MEETING

The purpose of the meeting was to gather input from stakeholders working on opioid response to better allow VDH to incorporate this feedback into Virginia's Naloxone Distribution & Saturation Plan. VDH shared about current naloxone distribution, some potential future plans, and led a discussion within the interagency work group. Each agency sent a representative to attend the meeting in-person. Outcomes from this meeting included comments on the prospective pilot mail-to-home distribution of naloxone; recommendations for focus groups with local health districts, community service boards, and comprehensive harm reduction sites; and recommendations for future one-on-one meetings between workgroup attendees to share additional information.

JUNE 20, 2023 MEETING

The meeting took place virtually. Interagency attendees shared feedback on the proposed naloxone distribution and saturation plan, including comments on barriers to access for naloxone. Attendees also provided comments on finding the balance for saturation, e.g., providing sufficient naloxone to avert overdose injury and death, but avoiding wastage and expiry of unused doses. Attendees also provided suggestions for one-on-one conversations with community-based organizations working within opioid response.

REPORT OUTLINE

This document summarizes the current state of the opioid crisis in Virginia, as well as barriers to naloxone access, current ways individuals can access naloxone, and points to consider in the

future like the forthcoming availability of over-the-counter naloxone. The report then provides a definition for naloxone saturation, describes literature and limitations related to naloxone saturation, and identifies targets for naloxone saturation in Virginia. Following this discussion, this document describes changes to Virginia's naloxone distribution that will be necessary to meet saturation targets and outlines the budget needed to do so. The document finally includes guidance for specific entities, e.g., pharmacies, emergency medical service agencies, local jurisdictions; provides a timeline for activities; and concludes with recommendations.

BACKGROUND AND CONTEXT

Opioids are a class of drugs prescribed by licensed healthcare providers to treat moderate to severe pain. Examples of opioids include prescription opioids, such as oxycodone (OxyContin), hydrocodone (Vicodin), and morphine, as well as illicit opioids, such as heroin. While effective at relieving pain, opioids have serious risks and side effects. Opioids can produce a sense of euphoria and can cause the individual taking opioids to develop tolerance and physical dependency, resulting in a high potential of abuse, addiction, and overdose.

Fentanyl is a highly potent synthetic opioid, commonly prescribed for severe pain. It is more powerful than other opioids and illicit fentanyl distribution is on the rise across the United States. Fatal drug overdoses have been the most common method of unnatural death in the Commonwealth of Virginia since 2013, largely driven by the rise of illicit fentanyl. In 2022, 2,204 Virginians lost their lives to opioid overdose (Office of the Chief Medical Examiner, 2022). Eighty-nine percent of these fatal overdoses were caused by fentanyl.

As opioid use and overdoses continue to trend upwards across the country, including Virginia, several developments are underway to help reverse this trend. One such development is the formation of a naloxone distribution and saturation plan for the Commonwealth of Virginia. Naloxone is a critical resource to help reduce deaths due to opioid overdose. When used appropriately, naloxone can reverse the impacts of an opioid overdose and can prevent death, potentially saving the life of an individual.

Stakeholders from across the Commonwealth have expressed interest in responding to the opioid crisis and aiding in the promotion and access to resources and services, including naloxone. Sufficient funding will be necessary to support Virginia's opioid response. Federal grants (e.g., Overdose Data to Action) and funds available at the state and local level, such as those paid by pharmaceutical companies to the Opioid Abatement Authority, will help support resources and action at multiple levels across the Commonwealth. These funds are limited which will warrant strategic programmatic implementation. Notably, some federal fund sources do not allow the purchase and distribution of naloxone.

Naloxone saturation and distribution supports access to life-saving medication for at-risk individuals. However, naloxone access is one component of a larger opioid response. Support for increased access to treatment, harm reduction and prevention services are necessary to combat the opioid epidemic and improve the lives of Virginians.

VIRGINIA'S OPIOID CRISIS

In June 2023, VDH began developing a prioritization model that considers data related to the opioid crisis in Virginia. The model includes indicators that quantify drug overdoses, opioid prescription volume, naloxone administrations by EMS providers and others. A full list of indicators included in this analysis are attached in Appendix D.

Together with other information, this model can be used to prioritize localities according to risk, which can help inform program planning efforts and optimal use of available resources in communities of greatest need. Importantly, even localities deemed lower priority according to

these criteria will still have access to opioid response services, including naloxone; however, local jurisdictions deemed high priority may receive additional outreach.

This model should be considered along with other available data and key information, such as community's readiness, locality capacity, and existing available resources. Virginia continues to explore additional data that may help inform its response to the opioid crisis. For example, an interagency work group has been established to explore the ability to test wastewater for fentanyl, which might also be considered when determining which communities could be targeted for enhanced efforts. Virginia will be able to use available data at the locality level to cross-reference risk for overdose injury and death against naloxone distributed by VDH to identify communities where additional naloxone may be needed.

CURRENT NALOXONE ACCESS

Virginia residents have many ways to access naloxone, including through prescription from healthcare providers, pharmacist-initiated models (e.g., statewide standing order or statewide protocol), local health districts and community service boards, emergency responders, or community-based organizations. Entities obtain naloxone by directly purchasing it from a manufacturer or pharmaceutical wholesaler, or at no cost through VDH. Despite the current channels to access naloxone, barriers to access may still exist for some individuals.

BARRIERS TO ACCESS

Barriers to naloxone access may include:

- Administrative barriers of dispensing entities interested in dispensing must comply with administrative requirements, e.g., affixing a label to the naloxone kit, collecting the name of the recipient, and maintaining records for two years. This may also represent a barrier to individual recipients who may not wish to provide their name.
- Awareness of naloxone individuals may be unaware of naloxone and its effectiveness as an opioid antagonist. They may also not be aware of ways to access naloxone within their communities.
- Awareness of opioid overdose risk individuals, particularly people who use drugs (PWUD), may not be aware that they are at risk for opioid overdose. This is particularly true for users of illicit drugs that are not opioids, e.g., individuals who use cocaine. While cocaine is not an opioid and thus cannot cause an opioid overdose, illicit drugs may be adulterated with other substances, including fentanyl and other opioids. Individuals may thus not realize they are at risk of exposure to opioids through illicit drug use.

Individuals who are prescribed opioids may also not believe they are at risk for opioid overdose. However, all opioids carry a risk of overdose, including those that are prescribed to individuals. This is particularly true for individuals who are prescribed high dosages of opioids, multiple types of opioids, and/or individuals who are prescribed opioids alongside benzodiazepines and other respiratory suppressants.

- *Cost* individuals seeking naloxone from pharmacies may not be able to cover the cost of naloxone out of pocket. This can disproportionately impact those who are uninsured, underinsured, or those with copays. Anecdotal reports also indicate that some individuals avoid using insurance to access naloxone for fear of stigma and unforeseen negative consequences, which would lead them to pay the full cost out-of-pocket.
- Lack of availability while naloxone should be accessible from all pharmacies under the standing order, stakeholders report that some pharmacies indicate that they are not aware of the standing order and do not keep naloxone in stock.
- Lack of connection to the medical system/lack of medical home lack of connection to the medical system could prevent an individual from realizing that they may benefit from naloxone. Health care providers can counsel patients, including those legally prescribed opioids and those illegally accessing opioids, about the potential dangers of opioid use and the benefits of naloxone.
- Language barriers REVIVE! Trainings educating individuals in how to administer
 naloxone are generally available in English and Spanish. It may be more challenging for
 individuals who are not proficient in either English or Spanish to learn about and access
 naloxone.
- Stigma naloxone is associated with illicit drug use and substance use disorders in general; stigma of opioid disorder is common and pervasive. For example, individuals prescribed opioids may be concerned that accessing naloxone may imply illicit use of their legal prescriptions. Individuals without prescriptions may be concerned that accessing naloxone could lead others to believe that they are illicit drug users, which may or may not be the case. Rural communities report stigma as a particular growing concern.
- *Transportation* in some parts of rural Virginia, the nearest pharmacy may be an hour's drive away. Other naloxone access points like comprehensive harm reduction sites, community service boards, and local health districts may also be challenging to access, particularly for those that lack a reliable means of transportation.
- Unwitnessed overdose in the event of an overdose, individuals cannot self-administer naloxone. Unwitnessed overdoses therefore are a higher risk for death as the life-saving medication cannot be administered to reverse the overdose. During engagement sessions, stakeholders expressed concern that unwitnessed overdoses may have increased as a result of COVID-19 isolation. They also report that some PWUD express concerns and confusion about potential liability due to recently passed legislation (SB1188) that categorizes substances containing detectable levels of fentanyl as weapons of terrorism and outlines associated penalties for fentanyl distribution. Misunderstanding of these statutes might make PWUD less likely to practice harm reduction strategies like using drugs in the presence of others.

PRESCRIBING AND CO-PRESCRIBING

Individuals interested in receiving naloxone can discuss prescribing and co-prescribing with their healthcare provider. Authorized prescribers may issue a prescription to the individual, upon request, if deemed medically appropriate. This is assuming the individual has a medical home and access to a prescriber.

Physicians and dentists are required to prescribe naloxone to individuals who are prescribed high doses of opioids (>120 MME/day), who have a history of prior substance use or overdose, and/or when benzodiazepines are also prescribed. Co-prescribing requirements increase access to naloxone, and prompt prescribers to discuss the potential risk of opioid overdose with patients. Some health insurance payers may cover the cost of naloxone when co-prescribed.

STANDING ORDER

VDH maintains a statewide standing order for naloxone, which allows individuals to access naloxone directly from a pharmacy, even if they do not have a personal prescription. Some health insurance providers may cover the cost of naloxone accessed via a standing order.

DIRECT PURCHASE AND DISPENSING

Entities can purchase naloxone directly from the manufacturer or through a pharmaceutical wholesaler. Examples include healthcare institutions (e.g., hospitals, pharmacies, urgent care) and community-based organizations. All settings acquiring naloxone are required to follow the Board of Pharmacy regulations with regards to controlled medication storage, handling and record keeping.

VDH DISTRIBUTION - CURRENT STATE

In SFY 2022 and SFY 2023, VDH distributed 205,001 naloxone kits to partners across Virginia. Each kit contains two 4 milligram (mg) doses of naloxone in the form of a nasal spray. Partners were also able to request auxiliary materials, e.g., gloves and masks. VDH shipped naloxone to partners upon request on a first come, first served basis. Eligible partners included:

- Authorized comprehensive harm reduction sites (CHRs)
- Community Services Boards (CSBs)
- Department of Behavioral Health and Developmental Services (DBHDS)
- Department of Corrections (DOC) facilities
- Department of Juvenile Justice (DJJ) facilities
- Law enforcement (e.g., police departments)
- Licensed Emergency Medical Services (EMS) (e.g., non-volunteer fire departments)
- Local health departments
- Public K-12 school divisions
- VA Department of Veteran's Services

VDH also shipped naloxone to:

- Organizations that did not fall into one of the above categories (e.g., rehabilitation facilities and community organizations serving people who use drugs) that applied and were approved as a "Naloxone Partner."
- Individuals receiving at-home test kits for HIV who requested naloxone kits in partnership with VDH's existing Division of Disease Prevention program.

Table 1 describes the number of kits shipped to partners in SFY 2022 (July 1, 2021 – June 30, 2022) and 2023 (July 1, 2022 – June 30, 2023), the cost of shipped kits, and other programmatic costs like masks, gloves, shipping expenses, and staffing expenses. (Note that VDH continues to negotiate naloxone prices with suppliers, resulting in a lower cost per kit for SFY 2023 compared to SFY 2022.)

Table 1. Quantit	v and Cost of	f Naloxone S	Shipped to	Partners by	VDH.	SFY 2022 and SFY 2023.
Toole I. Quentiti	, control Cost of	1 1 COU COU COU C	Ji i i p p c ci i c	1 0010101000	, ,	

	Number of naloxone kits distributed to partners	naloxone	Other expenses incurred (staffing, additional PPE supplies, shipping, administrative expenses)	Total cost of naloxone distribution
SFY 2022	87,121	\$6.00 million	\$640,000	\$6.64 million
SFY 2023	117,880	\$4.71 million	\$680,000	\$5.39 million

FUTURE CONSIDERATIONS

Program eligibility criteria: In SFY 2024, VDH will revise eligibility criteria to better target no-cost naloxone distribution to high-impact partners, i.e., partners more likely to interact with PWUD and their friends and family. This will allow VDH to continue providing no-cost naloxone to partners that have the most interaction with PWUD and therefore are likely to have greater impact on reducing overdose deaths. This may result in entities that previously received no-cost naloxone not receiving future no-cost distribution or may necessitate limitations on the size of orders. VDH will continue to evaluate demand for naloxone, trends in opioid overdose, and feedback from community partners in its consideration of additional entity types that are eligible for naloxone receipt, as necessary and as resources allow.

Over the Counter Product: Narcan, the name-brand form of naloxone 4mg intranasal spray, received the first approval for over-the-counter (non-prescription) distribution in March 2023. Distribution of over-the-counter (OTC) naloxone began in September 2023, but it is not currently available in all settings. Individuals will not need a prescription to access OTC naloxone, and the administrative requirements for prescription naloxone will not apply to OTC naloxone. Even after OTC naloxone becomes widely available, it will be necessary to maintain the standing order, as it allows individuals to purchase prescription naloxone via their insurance. When non-prescription Narcan is available to VDH, VDH anticipates providing non-prescription Narcan to partners

whenever possible to ease some of the restrictions and documentation burdens that are required for prescription products. Due to anticipated high demand, VDH may not be able to fill all requests for non-prescription Narcan; prescription naloxone (including Narcan and generic) will therefore continue to play an important role in meeting demand for naloxone in Virginia.

Other opioid antagonists: VDH continues to monitor the availability of opioid reversal agents, including other forms of OTC naloxone and other types of opioid antagonists like nalmefene (brand name Opvee, which received FDA approval in May 2023). VDH will consider how these agents align with Virginia's needs for opioid reversal agents and will pursue according to this need.

NALOXONE SATURATION

BACKGROUND AND DEFINITION OF SATURATION

Research data on naloxone saturation are limited. While there is no formal or official definition, naloxone saturation can be defined for the purposes of this plan as the point at which additional naloxone in a community does not reduce overdose deaths, i.e., opioid deaths do not result from a lack of access to naloxone. As the conditions of the opioid epidemic change, the amount of naloxone needed to saturate a community may also change. In "Estimating naloxone need in the USA across fentanyl, heroin, and prescription opioid epidemics: a modelling study," Michael Irvine (2022) et al. developed a mathematical model to determine how many doses a state needs to saturate their communities with naloxone. Irvine et al. define saturation as the point at which there is at least a 95% probability that naloxone will be used at 80% of witnessed overdoses. In addition to the mathematical model, the paper presents several observations that must be considered when planning for naloxone saturation. Irvine et al. find that distributing via a community-based program, rather than a provider-based or pharmacy-based, resulted in a greater probability of naloxone use and greater probably of reductions in overdose deaths, for the same amount of naloxone distributed. This finding demonstrates that it is not sufficient to only consider the quantity of naloxone distributed to the community, but that the mode of distribution is also critical. In addition to prioritizing highly effective community-based distribution, plans must also prioritize distribution to target populations who are more likely to witness overdoses and consider barriers to access for these high priority individuals.

LIMITATIONS AND CONSIDERATIONS FOR SATURATION MODELS

The naloxone saturation model described above has some limitations, including:

- We do not have full knowledge of all naloxone doses available and dispensed in Virginia; therefore, planning assumptions about baseline distribution in the Commonwealth would need to be utilized to apply a saturation model.
- The model only contemplates witnessed overdoses. It is not possible for an individual to self-administer naloxone during an overdose; therefore, any saturation target must consider the percentage of overdoses that are witnessed. In many communities, the majority of overdoses are unwitnessed. For example, a 2017 study of Massachusetts overdose deaths found that 91% of overdose deaths took place in private (e.g., a hotel room or private

residence) rather than a public space, and in 76% of cases there was no bystander present, or any additional individuals were in another room (Somerville et al., 2017). Therefore, it is important to consider and implement additional efforts to increase use of harm reduction practices like encouraging PWUD not to use alone.

Saturation models do not account for the differential likelihood of use for a given dose depending on the naloxone recipient. For example, PWUD and their friends, family, and caregivers are generally more likely to use a dose of naloxone than an individual who does not have a close relationship with a person who uses drugs. Therefore, it is necessary to consider not only the amount of naloxone to be distributed to reach saturation goals, but also how to target to the highest impact recipients who are most likely to be able to use doses to reverse the effects of overdose.

SATURATION RECOMMENDATIONS

While there will continue to be a role for prescriber-based and pharmacy-initiated naloxone distribution, Irvine et al. (2022) demonstrate that community-based programs generally lead to greater reductions in overdose death. VDH will focus on supporting community-based distribution and dispensing to individuals at highest risk, while continuing to collaborate and provide guidance to on naloxone distribution and overdose education for people seen within in primary care, hospital, emergency room, and pharmacy settings. Saturation targets thus include the number of high-risk individuals receiving naloxone, either directly from VDH or indirectly via organizational partners within Virginia communities.

VDH will also consider targets for the maintenance of undesignated stock of naloxone, i.e., naloxone maintained within a community location for use in the event of suspected overdose. It can be reasonable to distribute naloxone for emergency use to a location like a school, library, or other community location—even if there is a low likelihood of use—similar to the provision of emergency response tools like fire extinguishers and AED devices.

HIGH-PRIORITY INDIVIDUALS

Naloxone saturation means that those individuals who are mostly likely to experience and/or witness overdose have sufficient access to naloxone. Highest priority individual recipients include:

- People who use drugs (PWUD)
- Friends, family, and caregivers of PWUD
- People who work with or frequently serve PWUD

To ensure high-priority individuals have ready access to naloxone, programmatic components should include a range of access options, such as dispensing at no-cost from community partners like CSBs and CHRs. VDH is also exploring a new mail-to-home pilot program allowing high-priority individuals to request no-cost naloxone to be shipped directly to their homes. Program implementation is subject to available resources. These program components would collectively address barriers to access including cost, transportation challenges and stigma. Individuals would also continue to be able to access naloxone outside of VDH-supported doses, including via the

standing order, or by receiving a prescription. These are anticipated to continue to be important avenues of accessing naloxone for community members. Currently, VDH has limited visibility into these methods of naloxone access but intends to pursue access to this additional data.

HIGH-PRIORITY SETTINGS

It is important to prioritize distribution of no-cost naloxone to high-priority settings in order to increase the chance that individuals who overdose in those places are able to receive naloxone in a timely manner. This includes institutions with a higher likelihood of on-site overdose, either due to high levels of interaction with PWUD and/or high levels of interaction with the public. Examples of high priority settings include comprehensive harm reduction sites, DOC facilities, Community Service Boards, and local health departments. While some of these high-priority settings may also dispense naloxone to individuals, targets for high-priority locations relate to the maintenance of undesignated stock on-site for use in a suspected overdose. VDH intends to consult with key partners and stakeholders to develop targets for the maintenance of undesignated stock within key, prioritized community locations. Examples of settings that may be targeted for maintenance of undesignated stock include local health districts, community service boards, DOC facilities, DJJ facilities, law enforcement facilities, local/regional jails, and public middle and high schools.

VDH has also received expressions of interest from community partners to supply naloxone to other types of entities, e.g., restaurants, Departments of Motor Vehicles, rest stops, and other community locations. VDH intends to explore the feasibility and impact of supplying naloxone to these locations during SFY 2024 and/or providing these locations with technical assistance to allow them to secure their own naloxone, as appropriate.

RECOMMENDED TARGETS FOR SATURATION AND MAINTENANCE OF UNDESIGNATED STOCK

Table 2 describes the recommended saturation target for naloxone dispensed to high-risk individuals, as well as the recommended targeted allocation of naloxone kits for undesignated stock in priority locations. Note that VDH currently does not differentiate between naloxone distributed to partner organizations for dispensing or for maintenance as undesignated stock but intends to collect this information when the new distribution portal is built.

Table 2. Recommended Minimum Targets for Saturation and Maintenance of Undesignated Stock in Virginia.

	Minimum number of kits
	needed for SFY 24
Saturation for high-risk individuals	111,677
Maintenance of undesignated stock in high priority locations	60,134
Total	171,811

An interagency work group is also exploring the ability to test wastewater for fentanyl and target response, including naloxone, accordingly. This work is ongoing but may inform naloxone prioritization in the future.

RESOURCES NEEDED

Sufficient funding is needed to implement this naloxone distribution plan, including support for the cost of purchasing naloxone, program staff, and administrative costs associated with storing naloxone and processing and shipping orders. Number and cost of naloxone purchased may vary as it is determined based on actual demand in SFY 24 and cost of drug at time of purchase. Staff costs include personnel who will conduct outreach to partner organizations, assess the risk of overdose for communities, and implement and operationalize program strategy for naloxone distribution and saturation. Table 3 describes the estimated costs for SFY 24.

Table 3. Costs Associated with the Naloxone Distribution Program for SFY 24. (July 1, 2023 – June 30, 2024).

Projected Maximum Number of naloxone kits purchased in SFY24	205,516
Naloxone (estimated cost of drug purchased in SFY24)	\$7,969,900
Staff /Supplies/Travel	\$651,354
VDH Admin Cost	\$796,990
Shipping	\$164,413
Test Strips	\$256,102
Software	\$447,881
Total	\$10,286,640

It is important to note that several of the sources previously used to support naloxone distribution are no longer available to support the program. For example, VDH received \$3,000,000 in American Rescue Plan Act funds to support naloxone purchase; this grant is not ongoing to future fiscal years. Another funding source, Overdose Data to Action, no longer allows for the purchase of naloxone as an allowable expense (though support for some expenses like staffing is permitted). Table 4 describes available resources for SFY 24.

Table 4. Existing Resources Available to Support Naloxone Distribution for SFY 24.

Resources supporting purchase of naloxone			
Value of inventory rolled over from SFY23	\$920,109		
Value of purchases made with OD2A funding	\$1,943,391		
General Fund appropriation	\$1,300,000		
OAA award	\$1,000,000		
SOR III Year II Fund	\$2,000,000		
SAMHSA First Responder	\$480,000		
DBHDS – Non-general funds	\$1,366,398		
Total resources supporting naloxone purchase	\$9,009,898		
Resources supporting distribution infrastructure			
OD2A	\$447,881		

OAA*	\$491,322
OD2A-S	\$191,526
CDC Workforce Grant	\$146,013
Total resources supporting naloxone infrastructure	\$1,276,742
Total funds available (purchase + infrastructure)	\$10,286,640
Outstanding need	\$0

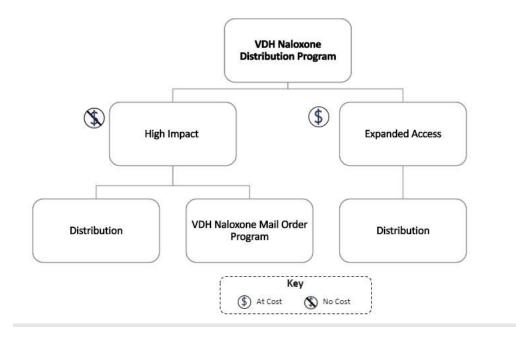
^{*} The OAA Award amount is for a one-time amount of \$603,843 for October 2023-September 2024. The figure in the table represents the amount that will be utilized in SFY24. The majority will be spent in FY24 with a small amount for personnel that will hit in FY25.

VDH DISTRIBUTION OF NALOXONE - RECOMMENDATIONS FOR FUTURE STATE

VDH recommends that distribution of naloxone focus on meeting saturation goals. Distribution to high-priority locations for both dispensing to high-priority individuals as well as maintenance of undesignated stock and the exploration of VDH's mail-to-home pilot program will assist in meeting saturation goals.

VDH anticipates distributing to high-impact settings, i.e., locations and individuals deemed high-risk and/or high-priority, as well as expanding naloxone access beyond these high priority populations and locations (Figure 1). High impact and expanded access settings are described in more detail below.

Figure 1. VDH Naloxone Distribution Program Distributes Via Two Branches, High Impact and Expanded Access.



Pending funding availability, Virginia also intends to develop a new distribution portal to streamline the ordering process for partners and better allow VDH to track key information like inventory shipped to each partner. This portal will allow VDH to support high-impact distribution to partners, exploration of a high-impact mail-to-home pilot program and expanded access naloxone distribution.

HIGH IMPACT

DISTRIBUTION TO PARTNER ORGANIZATIONS

VDH proposes to assess entities for eligibility based upon expected levels of interaction with high-priority individuals, risk of on-site overdose, and/or status as a state facility with a duty of care. VDH can then distribute naloxone to eligible partners, who can use their supply to maintain undesignated stock, dispense naloxone to high-priority individuals, or both. First responders (law enforcement, fire services, and emergency medical services) will also continue to be permitted to dispense by "leave behind," i.e., leaving doses behind after responding to a suspected overdose. Table 5 describes allowable use for naloxone for each partner organization type.

Table 5. High-Impact Partner Organizations Eligible to Receive No-Cost Naloxone From VDH, Including Allowable Use for Naloxone Distributed.

Partner organization type	Maintain undesignated stock	Dispense	Leave behind
Authorized Comprehensive Harm Reduction Site	X	X	
Community Services Board	X	X	
Department of Behavioral Health and Developmental	X	X	
Services			
Department of Corrections	X	X	
Department of Juvenile Justice	X	X	
Law enforcement	X		X
Local Health Department	X	X	
Fire services (non-EMS)	X		X
EMS			X
Institute of higher education		X	
Public K-12 school	X		
Public library	X	X	
Recovery/treatment program		X	

Partner organizations can order naloxone kits, which VDH will be able to directly distribute to provided addresses. VDH does not anticipate setting a maximum quantity of kits that partners can order, but partners will likely be asked to provide justification for orders above 100 kits due to the fact that naloxone does expire. Partners should request no more than a 4-week supply of naloxone and provide estimated weeks of supply of current on hand order upon ordering naloxone.

VDH will continue to assess demand for naloxone and will be able to identify additional high-priority entities as needed.

MAIL-ORDER PILOT PROGRAM

VDH is exploring a new programmatic component that would permit high-priority individuals that live in Virginia to request naloxone be shipped directly to their homes via a new mail-to-home pilot program. Currently, the Division of Pharmacy Services (DPS) has partnered internally with the Division of Disease Prevention (DDP) to mail naloxone kits to individuals upon request when requesting at-home HIV test kits. DPS has shipped over 1,400 naloxone kits directly to individual homes since 2019. Through this collaboration, DPS has determined mail order for naloxone is a successful model to increase access to at-risk individuals in a private, discreet manner. The program is particularly tailored to address several barriers to access, including cost, lack of availability, stigma, and transportation. This program is herein called the High Impact Naloxone Mail Order Program.

The High Impact Naloxone Mail Order Pilot Program would require the individual to attest that they are a high-priority individual eligible to receive no-cost naloxone through the program. Individuals can also view a training video demonstrating how and when to use naloxone.

If the individual is not eligible to receive no-cost naloxone through this program, (e.g., the person cannot attest that they fit the eligibility criteria) they would be directed to alternative sources to obtain naloxone, such as local pharmacies, community service boards, local health departments, REVIVE! training events, etc. If an individual is not eligible because they are under age 18, they would be directed to the DSS Helpline to seek further assistance.

VDH secured funding from the CDC to support development of the infrastructure for this expanded mail-to-home pilot program. The anticipated new distribution portal will facilitate receipt of mail-to-home orders and will allow VDH to better track orders by region and locality.

VDH anticipates shipping a total of 30,000 kits via mail-to-home during the first year the pilot program is active, provided funding is available. VDH intends to adjust allocation pending demand from other organizational partners, and it will consider limiting orders to high-priority communities if needed (e.g., if demand is higher than anticipated).

EXPANDED ACCESS

VDH recognizes that responding to the opioid crisis is a whole community effort and is committed to promoting naloxone access while reserving state resources for the highest priority and highest impact settings. Expanded access would allow VDH to support individuals and entities that are not deemed high priority and may not align with VDH's goals, but that nonetheless express a need or desire to access naloxone. This could allow VDH to concentrate resources on the highest impact partners while allowing other entities to offset costs for naloxone incurred by VDH and eliminating the need for local jurisdictions or other entities to enter into individual contracts with manufacturers or other suppliers.

Under the Expanded Access program, local jurisdictions could reimburse VDH for naloxone to be distributed to entities not meeting VDH's criteria for high-priority partner organizations. VDH intends to explore appropriate funding mechanisms, including development of a cost-sharing or match model for local jurisdictions interested in expanding access within their community. Local jurisdictions may consider expanding distribution to private K-12 schools, public higher

education institutions wishing to dispense to the general student body, recreational centers and/or other entities as the locality deems appropriate.

VDH also intends to explore additional ways to expand access, including providing access directly to entities and shipping to individuals not qualifying as high-priority. At this time, VDH contracts with suppliers preclude providing naloxone at cost to non-governmental entities.

PARTNER GUIDANCE

PHARMACIES

Pharmacies are not eligible to receive naloxone from VDH at no cost. Pharmacies have the ability to purchase naloxone directly from their wholesaler and also have the ability to recoup the cost of naloxone via payment from the consumer or insurance claim. Pharmacies providing naloxone to individuals via the Health Commissioner's standing order may bill naloxone to the patient's insurance or the patient may purchase naloxone and pay out-of-pocket. While pharmacies may also initiate treatment with and dispense naloxone via the Board of Pharmacy statewide protocol, reimbursement challenges may exist if the insurance does not recognize the pharmacist as the provider.

Irvine et al. (2022) demonstrate that community-based distribution programs out-perform pharmacy-based models in reducing overdose deaths, as naloxone is more likely to reach higher risk individuals through community-based distribution programs. Therefore, Virginia does not intend to distribute no-cost naloxone to pharmacies for disbursement as a major distribution strategy.

Pharmacies will remain an important naloxone access point for communities across Virginia. VDH will conduct outreach to pharmacies, through state and national pharmacy associations, to ensure they are aware of the standing order, maintain a supply of naloxone, and will provide information designed to reduce stigma around naloxone access in Virginia. The Board of Pharmacy will also continue to maintain protocols related to pharmacist dispensing and/or administration of naloxone.

Fentanyl test strips are another tool that can help reduce harm associated with illicit drug use. A proportion of people to whom naloxone is dispensed might benefit from concurrent receipt of fentanyl test strips. Fentanyl test strips do not require a prescription. Individuals can purchase fentanyl test strips from retailers; the average cost is \$1-2 per strip. To address potential barriers related to cost for the people in most need, VDH currently distributes fentanyl test strips to authorized comprehensive harm reduction sites and local health departments. Available literature indicates that community-based distribution of naloxone yields higher impact than pharmacy-based dispensing; we assume this would be the same for the provision of fentanyl test strips. Currently, pharmacies can purchase fentanyl test strips from manufacturers and medical suppliers, which may be provided at a cost to the patient. VDH is exploring a mechanism that could allow pharmacies to purchase fentanyl test strips to provide to consumers accessing naloxone. Virginia will conduct proactive outreach to pharmacies through state and national pharmacy associations to ensure all pharmacies are aware of how to obtain a supply of fentanyl test strips if they want

this resource. The ability for state government to provide a supply of test strips to all pharmacies in Virginia that dispense naloxone is limited by available resources, as well as purchasing agreements for public entities, and would likely be difficult to sustain.

EMERGENCY MEDICAL SERVICE AGENCIES

Emergency Medical Service (EMS) agencies are able to access naloxone for use on patients experiencing suspected overdose via their normal procurement processes.

As first responders, EMS agencies are well positioned to dispense naloxone to individuals at high risk for future overdose, including those who have recently overdosed as well as other individuals present who may be present for future overdoses. Using this "leave-behind" strategy, EMS agencies can leave doses of naloxone after responding to a call of suspected overdose. EMS agencies are currently able to access prescription naloxone for this purpose, but due to regulations from the Virginia Board of Pharmacy, they are required to collect personal information from recipients, which may serve as a deterrent for individuals who might benefit from accessing naloxone. It is anticipated that the availability of non-prescription naloxone increases EMS agencies' ability to leave behind naloxone doses.

EMS agencies in high-risk areas – e.g., those with high numbers and/or rates of individuals at high-risk for opioid overdose – are particularly good candidates for this leave-behind model. VDH will be able to use the prioritization model and real-time dashboard data to conduct proactive outreach to EMS agencies.

LOCALITIES - IMPLEMENTATION OF LOCAL DISTRIBUTION PLANS

Localities are encouraged to develop and implement local naloxone distribution plans that take local context and circumstances into account.

Local jurisdictions can begin by assessing the nature of the opioid epidemic within their community. This may include:

- Reviewing the prioritization model available in Appendix D.
- Conducting fatality reviews of recent opioid fatalities to determine what common factors, if any, can be addressed by a naloxone distribution plan. Local jurisdictions may consider contacting the Office of the Chief Medical Examiner for assistance.
- Consulting with overdose survivors, particularly those who had naloxone administered by lay witnesses, as well as witnesses who administered naloxone.
- Consulting with those working in opioid response, e.g., local health departments, community service boards, authorized comprehensive harm reduction sites, nonprofits, and other stakeholders. Consultations should include collection of observations from partners, including whom partners feel is most at-risk for overdose within the community, who struggles to access naloxone, and what some of the barriers to naloxone access are.
- Considering how naloxone distribution fits into the broader opioid response efforts within
 the community and consider whether there are additional activities that need additional
 attention.

Following this assessment, local jurisdictions can develop a distribution plan. The plan should:

- Target high-risk populations and locations within the community.
- Address barriers to opioid access for high-risk populations and locations.
- Include community partners to receive and dispense naloxone, as appropriate.
- Consider how the community may respond to changes in the landscape, e.g., changes in overdose trends or the availability of over-the-counter Narcan or other opioid reversal agents.

When the distribution plan is finalized, the local jurisdiction should review available resources to support its naloxone needs. These may include opioid abatement funds obtained by the locality and other funds obtained by community partners to support opioid response activities. Local jurisdictions and/or community-based organizations may also consider applying for federal and/or private funding to support the purchase of naloxone.

As localities implement their naloxone distribution plans, they should continue to engage with community partners and seek input from high-risk individuals and locations identified during the assessment process. Localities should also be prepared to adjust their plans as needed as conditions change.

ADDITIONAL SUPPORT

Entities not eligible to receive no-cost naloxone from VDH can purchase naloxone. VDH is available to assist with identifying vendors with available supply of naloxone.

Virginia can also provide additional support to specific entities as needed. This may include:

- *Technical assistance* for high-priority recipients, e.g., public K-12 schools and law enforcement agencies.
- Connection to purchasing for entities who wish to purchase their own naloxone, e.g., private universities.

VDH may also explore collaboration with other entities as appropriate, e.g., hospitals and veteran's administrations.

DATA & REPORTING

Agencies distributing naloxone collect various data related to naloxone distribution.

VIRGINIA DEPARTMENT OF HEALTH

Individuals and organizations requesting naloxone do not need to provide extensive justification or documentation when requesting naloxone; such requirements could represent a barrier to naloxone access. However, certain information is routinely requested, and can be used to help inform future naloxone distribution and other elements of the response to the opioid crisis.

VDH intends to develop a new inventory management portal which will allow VDH to better track data after distributing to partners, including inventory at sites and expiration dates. Development will take place pending identification and availability of funding.

INDIVIDUALS

Individuals receiving mail-to-home naloxone via the pilot program will share the following information:

- Attestation that the individual is high-risk (a person who uses drugs; friend, family, or caregiver of PWUD, or someone who works with PWUD);
- Name:
- Date of birth; and
- Mailing address.

VDH will be able to use the zip code provided in the shipping address to analyze receipt of naloxone by individuals. Personal identifying information, including names, dates of birth, and addresses of individuals requesting naloxone, will not be shared or used for analysis unless it is deidentified (except to determine that recipients are ages 18 and older).

PARTNER ORGANIZATIONS

Requesting partner organizations will share the following information each time they request naloxone:

- Partner organization type (e.g., K-12 school division, Department of Corrections facility, etc.);
- Partner organization address;
- Shipping address, if partner organization has multiple locations;
- Total amount of naloxone requested;
 - o Total amount requested for undesignated stock;
 - o Total amount requested for dispensing to individuals;
- Number of doses previously used to reverse suspected overdose;
- Number of kits disposed of due to expiry; and
- Total inventory of naloxone kits.

These data will allow Virginia to monitor distribution, identify local jurisdictions that may benefit from additional naloxone address, and track progress towards saturation targets. It is important to note that these addresses provide only a partial picture of naloxone distribution. For example, organizations serving PWUD may request that naloxone be shipped to one address but may serve individuals in multiple localities; Virginia's data may not capture this distribution.

ADDITIONAL DATA

VDH will also explore how additional data may be useful in identifying localities that would benefit from additional naloxone. For example, Virginia's Prescription Monitoring Program (PMP) tracks naloxone prescriptions across Virginia. VDH can solicit this data from the PMP to determine whether this data about additional naloxone access will assist VDH in allocating naloxone. Currently, all naloxone dispensed via pharmacies is included in the PMP, but when overthe-counter naloxone becomes available, over-the-counter sales will not be included in the PMP.

DEPARTMENT OF BEHAVIORAL HEALTH AND DEVELOPMENTAL SERVICES

DBHDS supervises REVIVE! trainings, which educate community members how to use naloxone. Often, participants receive a naloxone kit following completion of the training and demonstration that the participant has retained key information. DBHDS also supervises "training of trainer" events which help to increase the number of REVIVE! trainers, and ultimately REVIVE! trainings that can take place in a particular community.

The agency collects data from REVIVE! trainings on a monthly basis and circulates reports to key stakeholders, including VDH. Data reported each month is disaggregated by date and by location, as displayed in Table 6.

Data type	Disaggregated by date	Disaggregated by local jurisdiction
Number of trainings	X	X
Number of individuals trained	X	
Number of "training of trainer" events held	X	
Number of paloxone kits dispensed	X	Y

Table 6. Data Collected By DBHDS, Disaggregated by Date and/or Local Jurisdiction.

DBHDS analyzes these data to identify areas where naloxone access may be limited. For example, if a local jurisdiction has held one or more mass events but reports limited or no naloxone dispensed, this may indicate a shortage of naloxone in that community. DBHDS also calculates the percentage of REVIVE! training attendees that receive naloxone.

DEPARTMENT OF CORRECTIONS

Naloxone dispensing from DOC is currently in a pilot phase, with 15 facilities dispensing naloxone to all released inmates. DOC collects and reports the total naloxone kits dispensed, disaggregated by which facility the kits were dispensed from.

RECOMMENDATIONS

1. Virginia should leverage all available fund sources (local, state, and federal) to assure sufficient naloxone saturation in the Commonwealth. Funds available to support naloxone distribution from VDH are currently limited. To enable wider access to naloxone, funds available at the local level can be used to supplement federal and state-funded naloxone. VDH is developing a cost-matching program with local jurisdictions which could stretch limited state resources and allow local jurisdictions to use available funds to direct local access to no-cost naloxone according to their assessment of local needs. Other entities not designated as high-impact partners can identify funding sources to support naloxone purchase, either via reimbursement to VDH or directly from vendors, as appropriate and allowable.

- 2. *Engage with local jurisdictions*. State agencies, including VDH, should disseminate the Prioritization Model to localities as a starting point to identify communities experiencing higher levels and/or risk of overdose. This will help ensure strategic deployment of resources.
- 3. Distribute no-cost naloxone to high-impact partners. Maximizing VDH provision of no-cost naloxone to high impact partners is more likely to reduce overdose injury and death and will make the best use of public funding. High-impact partners will also be best positioned to maintain naloxone as undesignated stock, dispense naloxone to high-risk individuals, and/or leave behind naloxone following overdose response.
- 4. *VDH should a develop naloxone distribution portal*. The distribution portal will allow VDH to more efficiently process requests for naloxone, as well as track key data like distribution by locality, amount distributed to specific partner organizations, and inventory by expiration date for recipients.
- 5. Engage with community-level partners. Community-level partners, including LHDs, CSBs, CHRs, and other community-based organizations, are critical to the effective distribution of naloxone and other activities related to opioid response. Virginia will continue to engage with community-level partners, including sharing distribution data and seeking feedback about community-level observations related to demand for naloxone, fentanyl test strips, and other opioid-related activities.
- 6. Escalate budget needs and submit budget requests as required, including for \$5,519,145 for FY 2025 and for \$5,464,145 for FY 2026.
- 7. Assess Virginia's naloxone distribution and saturation annually. The nature of the opioid epidemic continues to evolve; so too must Virginia's response. By reviewing naloxone distribution, factors like overdose deaths, and achievement of saturation targets, Virginia can assess ways in which naloxone distribution may need to be adapted to better saturate communities with naloxone.

APPENDIX A - CHAPTER 631 OF THE 2023 ACTS OF ASSEMBLY

Be it enacted by the General Assembly of Virginia:

- 1. That § **54.1-3408** of the Code of Virginia is amended and reenacted as follows:
- § <u>54.1-3408</u>. Professional use by practitioners.
- A. A practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine, a licensed nurse practitioner pursuant to § <u>54.1-2957.01</u>, a licensed certified midwife pursuant to § <u>54.1-2957.04</u>, a licensed physician assistant pursuant to § <u>54.1-2952.1</u>, or a TPA-certified optometrist pursuant to Article 5 (§ <u>54.1-3222</u> et seq.) of Chapter 32 shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice.
- B. The prescribing practitioner's order may be on a written prescription or pursuant to an oral prescription as authorized by this chapter. The prescriber may administer drugs and devices, or he may cause drugs or devices to be administered by:
- 1. A nurse, physician assistant, or intern under his direction and supervision;
- 2. Persons trained to administer drugs and devices to patients in state-owned or state-operated hospitals or facilities licensed as hospitals by the Board of Health or psychiatric hospitals licensed by the Department of Behavioral Health and Developmental Services who administer drugs under the control and supervision of the prescriber or a pharmacist;
- 3. Emergency medical services personnel certified and authorized to administer drugs and devices pursuant to regulations of the Board of Health who act within the scope of such certification and pursuant to an oral or written order or standing protocol; or
- 4. A licensed respiratory therapist as defined in § <u>54.1-2954</u> who administers by inhalation controlled substances used in inhalation or respiratory therapy.
- C. Pursuant to an oral or written order or standing protocol, the prescriber, who is authorized by state or federal law to possess and administer radiopharmaceuticals in the scope of his practice, may authorize a nuclear medicine technologist to administer, under his supervision, radiopharmaceuticals used in the diagnosis or treatment of disease.
- D. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered nurses and licensed practical nurses to possess (i) epinephrine and oxygen for administration in treatment of emergency medical conditions and (ii) heparin and sterile normal saline to use for the maintenance of intravenous access lines.

Pursuant to the regulations of the Board of Health, certain emergency medical services technicians may possess and administer epinephrine in emergency cases of anaphylactic shock.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any school nurse, school board employee, employee of a local governing body, or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or standing protocol that shall be issued by the local health director within the course of his professional practice, any school nurse, school board employee, employee of a local governing body, or employee of a local health department who is authorized by the local health director and trained in the administration of albuterol inhalers and valved holding chambers or nebulized albuterol may possess or administer an albuterol inhaler and a valved holding chamber or nebulized albuterol to a student diagnosed with a condition requiring an albuterol inhaler or nebulized albuterol when the student is believed to be experiencing or about to experience an asthmatic crisis.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education, or any employee of a private school that is accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is authorized by a prescriber and trained in the administration of (a) epinephrine may possess and administer epinephrine and (b) albuterol inhalers or nebulized albuterol may possess or administer an albuterol inhaler or nebulized albuterol to a student diagnosed with a condition requiring an albuterol inhaler or nebulized albuterol when the student is believed to be experiencing or about to experience an asthmatic crisis.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any nurse at an early childhood care and education entity, employee at the entity, or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a public institution of higher education or a private institution of higher education who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of an organization providing outdoor educational experiences or programs for youth who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health, such prescriber may authorize any employee of a restaurant licensed pursuant to Chapter 3 (§ 35.1-18 et seq.) of Title 35.1 to possess and administer epinephrine on

the premises of the restaurant at which the employee is employed, provided that such person is trained in the administration of epinephrine.

Pursuant to an order issued by the prescriber within the course of his professional practice, an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services may possess and administer epinephrine, provided such person is authorized and trained in the administration of epinephrine.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any employee of a public place, as defined in § 15.2-2820, who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize pharmacists to possess epinephrine and oxygen for administration in treatment of emergency medical conditions.

- E. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed physical therapists to possess and administer topical corticosteroids, topical lidocaine, and any other Schedule VI topical drug.
- F. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed athletic trainers to possess and administer topical corticosteroids, topical lidocaine, or other Schedule VI topical drugs; oxygen for use in emergency situations; epinephrine for use in emergency cases of anaphylactic shock; and naloxone or other opioid antagonist for overdose reversal.
- G. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health pursuant to § 32.1-50.2, such prescriber may authorize registered nurses or licensed practical nurses under the supervision of a registered nurse to possess and administer tuberculin purified protein derivative (PPD) in the absence of a prescriber. The Department of Health's policies and guidelines shall be consistent with applicable guidelines developed by the Centers for Disease Control and Prevention for preventing transmission of mycobacterium tuberculosis and shall be updated to incorporate any subsequently implemented standards of the Occupational Safety and Health Administration and the Department of Labor and Industry to the extent that they are inconsistent with the Department of Health's policies and guidelines. Such standing protocols shall explicitly describe the categories of persons to whom the tuberculin test is to be administered and shall provide for appropriate medical evaluation of those in whom the test is positive. The prescriber shall ensure that the nurse implementing such standing protocols has received adequate training in the practice and principles underlying tuberculin screening.

The Health Commissioner or his designee may authorize registered nurses, acting as agents of the Department of Health, to possess and administer, at the nurse's discretion, tuberculin purified protein derivative (PPD) to those persons in whom tuberculin skin testing is indicated based on protocols and policies established by the Department of Health.

H. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administer glucagon to a student diagnosed as having diabetes and who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, nurse practitioner, physician, or physician assistant is not present to perform the administration of the medication.

Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a public institution of higher education or a private institution of higher education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administration of glucagon to a student diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, nurse practitioner, physician, or physician assistant is not present to perform the administration of the medication.

Pursuant to a written order issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services to assist with the administration of insulin or to administer glucagon to a person diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia, provided such employee or person providing services has been trained in the administration of insulin and glucagon.

I. A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present, by (i) licensed pharmacists, (ii) registered nurses, or (iii) licensed practical nurses under the supervision of a registered nurse. A prescriber acting on behalf of and in accordance with established protocols of the Department of Health may authorize the administration of vaccines to any person by a pharmacist, nurse, or designated emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health under the direction of an operational medical director when the prescriber is not physically present. The emergency medical services provider shall provide documentation of the vaccines to be recorded in the Virginia Immunization Information System.

J. A dentist may cause Schedule VI topical drugs to be administered under his direction and supervision by either a dental hygienist or by an authorized agent of the dentist.

Further, pursuant to a written order and in accordance with a standing protocol issued by the dentist in the course of his professional practice, a dentist may authorize a dental hygienist under his general supervision, as defined in § 54.1-2722, or his remote supervision, as defined in subsection E or F of § 54.1-2722, to possess and administer topical oral fluorides, topical oral anesthetics, topical and directly applied antimicrobial agents for treatment of periodontal pocket lesions, and any other Schedule VI topical drug approved by the Board of Dentistry.

In addition, a dentist may authorize a dental hygienist under his direction to administer Schedule VI nitrous oxide and oxygen inhalation analgesia and, to persons 18 years of age or older, Schedule VI local anesthesia.

K. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered professional nurses certified as sexual assault nurse examiners-A (SANE-A) under his supervision and when he is not physically present to possess and administer preventive medications for victims of sexual assault as recommended by the Centers for Disease Control and Prevention.

L. This section shall not prevent the administration of drugs by a person who has satisfactorily completed a training program for this purpose approved by the Board of Nursing and who administers such drugs in accordance with a prescriber's instructions pertaining to dosage, frequency, and manner of administration, and in accordance with regulations promulgated by the Board of Pharmacy relating to security and record keeping, when the drugs administered would be normally self-administered by (i) an individual receiving services in a program licensed by the Department of Behavioral Health and Developmental Services; (ii) a resident of the Virginia Rehabilitation Center for the Blind and Vision Impaired; (iii) a resident of a facility approved by the Board or Department of Juvenile Justice for the placement of children in need of services or delinquent or alleged delinquent youth; (iv) a program participant of an adult day-care center licensed by the Department of Social Services; (v) a resident of any facility authorized or operated by a state or local government whose primary purpose is not to provide health care services; (vi) a resident of a private children's residential facility, as defined in § 63.2-100 and licensed by the Department of Social Services, Department of Education, or Department of Behavioral Health and Developmental Services; or (vii) a student in a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education.

In addition, this section shall not prevent a person who has successfully completed a training program for the administration of drugs via percutaneous gastrostomy tube approved by the Board of Nursing and been evaluated by a registered nurse as having demonstrated competency in administration of drugs via percutaneous gastrostomy tube from administering drugs to a person receiving services from a program licensed by the Department of Behavioral Health and Developmental Services to such person via percutaneous gastrostomy tube. The continued competency of a person to administer drugs via percutaneous gastrostomy tube shall be evaluated semiannually by a registered nurse.

M. Medication aides registered by the Board of Nursing pursuant to Article 7 (§ 54.1-3041 et seq.) of Chapter 30 may administer drugs that would otherwise be self-administered to residents of any assisted living facility licensed by the Department of Social Services. A registered medication aide shall administer drugs pursuant to this section in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; in accordance with regulations promulgated by the Board of Pharmacy relating to security and recordkeeping; in accordance with the assisted living facility's Medication Management Plan; and in accordance with such other regulations governing their practice promulgated by the Board of Nursing.

N. In addition, this section shall not prevent the administration of drugs by a person who administers such drugs in accordance with a physician's instructions pertaining to dosage, frequency, and manner of administration and with written authorization of a parent, and in accordance with school board regulations relating to training, security and record keeping, when the drugs administered would be normally self-administered by a student of a Virginia public school. Training for such persons shall be accomplished through a program approved by the local school boards, in consultation with the local departments of health.

O. In addition, this section shall not prevent the administration of drugs by a person to (i) a child in a child day program as defined in § 22.1-289.02 and regulated by the Board of Education or a local government pursuant to § 15.2-914, or (ii) a student of a private school that is accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education, provided such person (a) has satisfactorily completed a training program for this purpose approved by the Board of Nursing and taught by a registered nurse, licensed practical nurse, nurse practitioner, physician assistant, doctor of medicine or osteopathic medicine, or pharmacist; (b) has obtained written authorization from a parent or guardian; (c) administers drugs only to the child identified on the prescription label in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; and (d) administers only those drugs that were dispensed from a pharmacy and maintained in the original, labeled container that would normally be self-administered by the child or student, or administered by a parent or guardian to the child or student.

P. In addition, this section shall not prevent the administration or dispensing of drugs and devices by persons if they are authorized by the State Health Commissioner in accordance with protocols established by the State Health Commissioner pursuant to § 32.1-42.1 when (i) the Governor has declared a disaster or a state of emergency, the United States Secretary of Health and Human Services has issued a declaration of an actual or potential bioterrorism incident or other actual or potential public health emergency, or the Board of Health has made an emergency order pursuant to § 32.1-13 for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious, and infectious diseases and other dangers to the public life and health and for the limited purpose of administering vaccines as an approved countermeasure for such communicable, contagious, and infectious diseases; (ii) it is necessary to permit the provision of needed drugs or devices; and (iii) such persons have received the training necessary to safely administer or dispense the needed drugs or devices. Such persons shall administer or dispense all drugs or devices under the direction, control, and supervision of the State Health Commissioner.

- Q. Nothing in this title shall prohibit the administration of normally self-administered drugs by unlicensed individuals to a person in his private residence.
- R. This section shall not interfere with any prescriber issuing prescriptions in compliance with his authority and scope of practice and the provisions of this section to a Board agent for use pursuant to subsection G of § 18.2-258.1. Such prescriptions issued by such prescriber shall be deemed to be valid prescriptions.
- S. Nothing in this title shall prevent or interfere with dialysis care technicians or dialysis patient care technicians who are certified by an organization approved by the Board of Health Professions or persons authorized for provisional practice pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.), in the ordinary course of their duties in a Medicare-certified renal dialysis facility, from administering heparin, topical needle site anesthetics, dialysis solutions, sterile normal saline solution, and blood volumizers, for the purpose of facilitating renal dialysis treatment, when such administration of medications occurs under the orders of a licensed physician, nurse practitioner, or physician assistant and under the immediate and direct supervision of a licensed registered nurse. Nothing in this chapter shall be construed to prohibit a patient care dialysis technician trainee from performing dialysis care as part of and within the scope of the clinical skills instruction segment of a supervised dialysis technician training program, provided such trainee is identified as a "trainee" while working in a renal dialysis facility.

The dialysis care technician or dialysis patient care technician administering the medications shall have demonstrated competency as evidenced by holding current valid certification from an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ <u>54.1-2729.1</u> et seq.).

- T. Persons who are otherwise authorized to administer controlled substances in hospitals shall be authorized to administer influenza or pneumococcal vaccines pursuant to § <u>32.1-126.4</u>.
- U. Pursuant to a specific order for a patient and under his direct and immediate supervision, a prescriber may authorize the administration of controlled substances by personnel who have been properly trained to assist a doctor of medicine or osteopathic medicine, provided the method does not include intravenous, intrathecal, or epidural administration and the prescriber remains responsible for such administration.
- V. A physician assistant, nurse, dental hygienist, or authorized agent of a doctor of medicine, osteopathic medicine, or dentistry may possess and administer topical fluoride varnish pursuant to an oral or written order or a standing protocol issued by a doctor of medicine, osteopathic medicine, or dentistry.
- W. A prescriber, acting in accordance with guidelines developed pursuant to § <u>32.1-46.02</u>, may authorize the administration of influenza vaccine to minors by a licensed pharmacist, registered nurse, licensed practical nurse under the direction and immediate supervision of a registered nurse, or emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health when the prescriber is not physically present.

X. Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, a pharmacist, a health care provider providing services in a hospital emergency department, and emergency medical services personnel, as that term is defined in § 32.1-111.1, may dispense naloxone or other opioid antagonist used for overdose reversal and a person to whom naloxone or other opioid antagonist has been dispensed pursuant to this subsection may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose. Law-enforcement officers as defined in § 9.1-101, employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, employees of the Department of General Services Division of Consolidated Laboratory Services, employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1, employees of the Department of Juvenile Justice designated as probation and parole officers or as juvenile correctional officers, employees of regional jails, school nurses, local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board, other school board employees or individuals contracted by a school board to provide school health services, and firefighters who have completed a training program may also possess and administer naloxone or other opioid antagonist used for overdose reversal and may dispense naloxone or other opioid antagonist used for overdose reversal pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, an employee or other person acting on behalf of a public place who has completed a training program any person may also possess and administer naloxone or other opioid antagonist used for overdose reversal, other than naloxone in an injectable formulation with a hypodermic needle or syringe, in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Notwithstanding any other law or regulation to the contrary, an employee or other person acting on behalf of a public place may possess and administer naloxone or other opioid antagonist, other than naloxone in an injectable formulation with a hypodermic needle or syringe, to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose if he has completed a training program on the administration of such naloxone and administers naloxone in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

For the purposes of this subsection, "public place" means any enclosed area that is used or held out for use by the public, whether owned or operated by a public or private interest.

Y. Notwithstanding any other law or regulation to the contrary, a person who is acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal may dispense naloxone to a person who has received instruction on the administration of naloxone for opioid overdose reversal, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber and (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. If the person acting on behalf of an organization dispenses naloxone in an injectable formulation with a hypodermic needle or syringe, he shall first obtain authorization from the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe, and he shall obtain a controlled substance registration from the Board of Pharmacy. The Board of Pharmacy shall not charge a fee for the issuance of such controlled substance registration. The dispensing may occur at a site other than that of the controlled substance registration provided the entity possessing the controlled substances registration maintains records in accordance with regulations of the Board of Pharmacy. No person who dispenses naloxone on behalf of an organization pursuant to this subsection shall charge a fee for the dispensing of naloxone that is greater than the cost to the organization of obtaining the naloxone dispensed. A person to whom naloxone has been dispensed pursuant to this subsection may possess naloxone and may administer naloxone to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

Z. A person who is not otherwise authorized to administer naloxone or other opioid antagonist used for overdose reversal may administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

AA. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is trained in the administration of injected medications for the treatment of adrenal crisis resulting from a condition causing adrenal insufficiency to administer such medication to a student diagnosed with a condition causing adrenal insufficiency when the student is believed to be experiencing or about to experience an adrenal crisis. Such authorization shall be effective only when a licensed nurse, nurse practitioner, physician, or physician assistant is not present to perform the administration of the medication.

2. That the Department of Health, the Department of Behavioral Health and Developmental Services, and the Department of Corrections shall review existing naloxone distribution programs and collaborate to develop a comprehensive statewide plan for the distribution of naloxone throughout the Commonwealth. The plan shall provide guidance to emergency medical

services agencies on the distribution of naloxone in high-risk areas and shall ensure that every pharmacy that carries naloxone is provided with a supply of fentanyl test strips to include with every order of naloxone provided to consumers. The plan shall also provide guidance to localities for the implementation of local naloxone distribution plans. The respective departments are authorized to begin implementation of the plan, to the extent the agencies have existing resources to do so. The Department of Health shall provide a report on the statewide naloxone plan, including the resources needed to fully implement the plan, to the Chairs of the House Committee on Appropriations and the Senate Committee on Finance and Appropriations by September 1, 2023.

- 3. That the Department of Health (the Department) shall begin development of a Commonwealth opioid impact reduction registry. The registry shall include a list of nonprofit organizations that work to reduce the impact of opioids in the Commonwealth and shall list the services provided by each such organization and contact information for each such organization to be published on the Department's website. The Department shall develop a process to determine which organizations that work to reduce the impact of opioids in the Commonwealth to include in such registry and what criteria and metrics should be utilized to determine their inclusion in such registry. The Department shall examine administrative burdens on local governments in procuring the services of nonprofit organizations on the registry in a timely manner. The Department, within existing resources, may publish an initial list of known nonprofit organizations that work to reduce the impact of opioids on the Department's website that is searchable by zip code. The Department shall report on the process, criteria, and metrics for the registry, including the verification process to ensure an organization meets the criteria to be listed on the registry, and recommendations on reducing administrative burdens on local governments to contract with organizations on the registry to the Chairs of the House Committee on Appropriations and the Senate Committee on Finance and Appropriations by September 1, 2023.
- 4. That the Department of Corrections shall amend its regulations to require that training in the administration of naloxone be provided to every inmate prior to release.

APPENDIX B - ACRONYMS AND ABBREVIATIONS

This is a listing of the acronyms and abbreviations appearing throughout the report and its appendices.

AED – automated external defibrillator

CHR – comprehensive harm reduction site

CSB – Community Service Board

DBHDS – Department of Behavioral Health and Developmental Services

DCJS – Department of Criminal Justice Services

DDP – Division of Disease Prevention

DHP – Department of Health Professions

DJJ – Department of Juvenile Justice

DMAS – Department of Medical Assistance Services

DOC – Department of Corrections

DOE – Department of Education

DPS – Division of Pharmacy Services

EMS – Emergency Medical Services

LHD – Local Health District

OTC – over-the-counter

PMP – Prescription Monitoring Program

PWUD – people who use drugs

REVIVE! – lay training in how to administer naloxone in response to suspected opioid overdose

VDH – Virginia Department of Health

APPENDIX C - WORKS CITED

Irvine, MA, D Oller, J Boggis, B Bishop, D Coombs, E Wheeler, M Doe-Simkins, AY Walley, BDL Marshall, J Bratberg, TC Green (2022). Estimating Naloxone Need in the United States Across Fentanyl, Heroin, and Prescription Opioid Epidemics: A Modelling Study. *Lancet Public Health*. https://doi.org/10.1016/S2468-2667(21)00304-2

Somerville, N. J., O'Donnell, J., Gladden, R. M., Zibbell, J. E., Green, T. C., Younkin, M., Ruiz, S., Babakhanlou-Chase, H., Chan, M., Callis, B. P., Kuramoto-Crawford, J., Nields, H., & Walley, A. Y. (2017). Characteristics of Fentanyl Overdose — Massachusetts, 2014—2016. *Morbidity and Mortality Weekly Report*, 66(14), 382–386. https://doi.org/10.15585/mmwr.mm6614a2

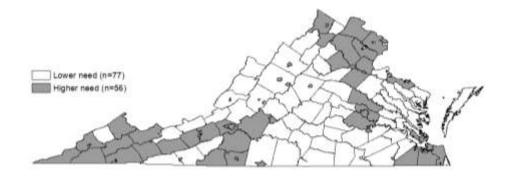
Office of the Chief Medical Examiner. (2023). Fatal Drug Overdose Quarterly Report: Fourth Quarter 2022. (Edition 2022.4). Retrieved from https://www.vdh.virginia.gov/content/uploads/sites/18/2023/05/Quarterly-Drug-Death-Report-FINAL-Q4-2022.pdf

REMAINDER OF PAGE LEFT INTENTIONALLY BLANK

APPENDIX D - METHODOLOGY FOR INDICATOR SELECTION AND DETERMINATION OF NEED FOR DRUG OVERDOSE-RELATED SURVEILLANCE, PREVENTION, AND INTERVENTION STRATEGIES: RIGHT HELP, RIGHT NOW INITIATIVE

Figures 1 and 2 display the identification of Virginia localities at higher need for drug overdose-related surveillance, prevention, and intervention strategies, considering indicators described below. The needs assessment tool in Figure 1 was developed in June 2023.

Figure 1. Determination of Need for Drug Overdose-Related Surveillance, Prevention, and Intervention Strategies: Right Help, Right Now Initiative



Data presented hore were account and analyzed by inputy and violence provention epithesistopy stuff, Office of Family Health Services, Devices of Population Health Data, Ages 1, 2421.

The below indicators were included in the Methodology for Indicator Selection and Determination of Need for Drug Overdose-Related Surveillance, Prevention, and Intervention Strategies: Right Help, Right Now Initiative document.

Methodology for Indicator Selection and Determination of Need for Drug Overdose-Related Surveillance, Prevention, and Intervention Strategies: Right Help, Right Now Initiative

I. Indicator selection and data source documentation

The methodology below can be used to determine Virginia localities at higher need for drug overdose-related surveillance, prevention, and intervention strategies, such as comprehensive harm reduction program expansion, naloxone distribution, and fentanyl wastewater surveillance piloting through the *Right Help, Right Now* initiative. Indicators are used to assess whether a locality may be at a higher burden for drug overdose and misuse and other infectious disease outcomes associated with drug use (i.e., hepatitis C and HIV) in their communities. Socioeconomic indicators (i.e., poverty and unemployment) are also included because these factors are related with a locality being at higher risk for drug overdose and misuse. These indicators are listed below:

- 1. Counts and crude rates per 100,000 population of all-drug overdose deaths
- 2. Counts and crude rates per 10,000 emergency department visits of all-drug overdose emergency department visits
- 3. Counts and crude rates per 100,000 population of nonfatal all-drug overdose inpatient hospitalizations
- 4. Percent of population in poverty
- 5. Percent of population unemployed
- 6. Counts and crude rates per 100,000 population of people prescribed opioids (i.e., prescription opioid volume)
- 7. Counts and crude rates per 100,000 population of people prescribed buprenorphine (i.e., buprenorphine prescription volume; potential to provide medication-assisted treatment)
- 8. Counts and crude rates per 100,000 population of newly reported hepatitis C cases among people aged 18-30 years
- 9. Counts and crude rates per 100,000 population of newly diagnosed HIV cases
- 10. Counts and crude rates per 100,000 population of new drug treatment admissions to publicly funded community service boards
- 11. Counts and crude rates per 100,000 population of arrestees for drug/narcotic-related arrests
- 12. Counts and crude rates per 10,000 emergency medical services incidents of patients receiving naloxone with positive responses

Table 1 includes the list of indicators with accompanying data sources and relevant notes.

Table 1. Selected Indicators and Relevant Notes

Indicator	Indicator	Data Source	Notes
Variable Name	Description		
IND_1_ODDEA	Indicator 1: All-	Death certificate	Drug overdose deaths include all
THS	drug overdose	data from the	drugs and all intents (unintentional,
	deaths by	VDH Vital Event	suicide, homicide, or undetermined).

	locality in calendar year 2021 (counts and rates per 100,000 population)	Statistics Program	Deaths are of Virginia residents only, including Virginia residents who died out of state. All-drug overdose deaths follow the World Health Organization and Centers for Disease Control and Prevention definition using the following underlying
			cause-of-death ICD-10 codes: X40-X44 (unintentional), X60-X64 (suicide), X85 (homicide), Y10-Y14 (undetermined).
			Data are maintained by VDH Office of Information Management and analyzed by Injury and Violence Prevention epidemiology staff, VDH Division of Population Health Data, Office of Family Health Services. Data are produced and processed from sources believed to be reliable
IND_2_OD_ED VISITS	Indicator 2: Emergency department visits due to all-drug overdoses by locality in calendar year 2021 (counts and rates per 10,000 emergency department visits)	Syndromic surveillance emergency department visit data from CDC ESSENCE	and accurate at that point of time. Syndromic surveillance data reporting to VDH by hospitals and freestanding emergency departments in Virginia of count and rate statistics for emergency department visits for unintentional drug overdose among Virginia residents. One hundred percent (100%) of hospital-based emergency departments report to ESSENCE. The all drug case definition was updated in June 2022 and can be found here: https://www.vdh.virginia.gov/surveillance-and-investigation/syndromic-surveillance/drug-overdose-case-definition/. Data come from the 2015-2023 Statistics file (published on May 10, 2023) here: https://www.vdh.virginia.gov/surveillance-and-investigation/syndromic-surveillance/drug-overdose-surveillance/drug-overdose-surveillance/drug-overdose-surveillance/drug-overdose-surveillance/. Geographic location is assigned based on patient's residential zip code provided. A single zip code may span multiple

			localities in Virginia. If a patient resides in a spanning zip code, the visit is assigned to the locality where most of the population lives. Some localities were combined to calculate an overdose visit count and rate due to zip counts spanning multiple localities. Those localities are indicated in the above report. Rates per 10,000 emergency department visits: total number of
			emergency department visits among Virginia residents of a defined geographic area each month. The 2021 rate per 10,000 emergency department visits is based on the monthly average rate for calendar year 2021. This metric provides a consistent rate calculation across time when reporting by emergency departments change (increases or decreases) as compared to the rate per 100,000 population.
			Data are maintained and analyzed by the VDH Enhanced Surveillance team, Division of Surveillance and Investigation, Office of Epidemiology.
IND_3_NF_OD_ HOSPS	Indicator 3: Nonfatal inpatient hospitalizations due to all-drug overdoses by locality in calendar year 2021 (counts and rates per 100,000 population)	Virginia Health Information (VHI) inpatient hospitalization data	Data are of nonfatal inpatient hospitalizations only and represent Virginia resident hospitalizations within Virginia. Virginia residents hospitalized outside of Virginia are excluded, which may cause potential underreporting of Virginia residents from bordering areas of the state who go out of state for care. Hospitalization data are from 100% of Virginia-licensed hospitals and do not include federal entities, rehabilitative hospitals, or state psychiatric hospitals. Indicator definitions come from the Drug Overdose Indicator from the Council

IND_4_POVER TY	Indicator 4 (used in variation 1 only): Poverty estimates by locality in	United States Census Bureau: Small Area Income and Poverty Estimates	of State and Territorial Epidemiologists (CSTE) Injury Surveillance toolkit. Data are produced and processed from sources believed to be reliable and accurate at that point of time. The city/county is based on the zip code of the patient's residence at time of hospitalization. Some Virginia zip codes may cross city/county boundaries. This may cause under- or over-reporting of hospitalizations at the city/county level for those localities with zip codes that cross boundaries. Data are maintained by VDH Office of Information Management (OIM) and analyzed by Injury and Violence Prevention (IVP) epidemiology staff, VDH Division of Population Health Data, Office of Family Health Services. Poverty percentage estimates are based on all ages by locality in Virginia; see Methodology page for additional details on the model used to estimate poverty:
	calendar year 2021; percentage of persons living in the locality below the poverty threshold (percentages)		https://www.census.gov/programs-surveys/saipe/technical-documentation/methodology.html. Data pulled on April 6, 2023 from the US Census Bureau Small Area Income and Poverty Estimates (SAIPE) data dashboard: https://www.census.gov/data-tools/demo/saipe/#/?s_state=51&s_c_ounty=&s_district=&s_geography=c_ounty
IND_5_UNEMP LOY	Indicator 5 (used in variation 1 only: Unemployment estimates by locality in calendar year	United States Bureau of Labor Statistics Labor Force Data by County, 2021 Annual Averages: Local Area	Data are as of March 1, 2023; labor force data by county, 2021 annual averages are from: https://www.bls.gov/lau/tables.htm#c ntyaa . See Methodology page for additional details on the model used to estimate labor force and

	2021 (percentages)	Unemployment Statistics	unemployment: https://www.bls.gov/lau/laumthd.htm
IND_6_RXOPIO ID_VOL	Indicator 6: Persons prescribed prescription opioids by locality in calendar year 2021 (prescription opioid volume) (counts and rates per 100,000 population)	Virginia All- Payer Claims Database (APCD)	Opioid prescription claims are calculated using the All-Payer Claims Database and subset to the individual count of persons receiving prescription opioids in calendar year 2021. The Virginia APCD currently contains 100% Medicare, 100% Medicaid, and about 45-60% of the commercial population. The APCD collects paid medical and pharmacy claims for roughly 4-4.5 million Virginia residents. The majority of individuals not included are: federal employees, those that are active duty or have TRICARE, and the uninsured. The largest missing population are individuals with ERISA self-insured plans (big private employers), since those plans are not required to submit data to the APCD. Data are based on the patient's residence at time of pharmacy claim. More information can be found here: https://www.vhi.org/apcd/ .
IND_7_BUP_TR EAT	Indicator 7: Persons prescribed buprenorphine by locality in calendar year 2021 (potential to treat opioid use disorder) (counts and rates per 100,000 population)	Virginia All- Payer Claims Database (APCD)	Buprenorphine prescription claims are calculated using the All-Payer Claims Database (APCD) for the individual count of persons receiving a prescription for buprenorphine in calendar year 2021. Claims for prescription drugs included were: Belbuca, Buprenex, buprenorphine, buprenorphine buccal, buprenorphine HCL, buprenorphine HCL/naloxone, buprenorphine hydrochloride, Butrans, Sublocade, Subutex, Suboxone, and Zubsolv. Virginia APCD currently contains 100% Medicare, 100% Medicaid, and about 45-60% of the commercial population. The APCD collects paid medical and pharmacy claims for

IND_8_HCV_18 _30	Indicator 8: Newly reported hepatitis C cases among persons aged 18-30 years in calendar year 2021 (counts and rates per 100,000 population)	Virginia Electronic Disease Surveillance System (VEDSS)	roughly 4-4.5 million Virginia residents. The majority of individuals not included are: federal employees, those that are active duty or have TRICARE, and the uninsured. The largest missing population are individuals with ERISA self-insured plans (big private employers), since those plans are not required to submit data to the APCD. Data are based on the patient's residence at time of pharmacy claim. More information can be found here: https://www.vhi.org/apcd/. Data included are probable and confirmed hepatitis C cases among Virginia residents aged 18-30 years. Data also include people who were incarcerated so localities containing correctional facilities which may show higher rates of newly identified cases. Injection drug use is the most common risk factor reported among newly identified confirmed-acute hepatitis C cases, and particularly among those aged 18-30 years. The denominator used to calculate rates per 100,000 population only include persons aged 18-30 years. Data are maintained and analyzed by the VDH Division of Surveillance and Investigation, Office of Epidemiology.
IND_9_HIV	Indicator 9: Newly diagnosed HIV cases in calendar year 2021 (counts and rates per 100,000 population)	Enhanced HIV/AIDS Reporting System (eHARS)	New HIV diagnoses are based on the date of diagnosis and the locality where the HIV case was residing at time of diagnosis. Data come from the Annual HIV Report 2021 and were accessed in April 2023. The COVID-19 pandemic impacted access to HIV testing, HIV care services, and HIV case surveillance activities. Data in 2021 should be

IND_10_ADMI T	Indicator 10: New all substance use disorder admissions to publicly funded community service boards in calendar year 2021 (counts and rates per 100,000 population)	Department of Behavioral Health and Developmental Services (DBHDS)	interpreted with caution, as 2021 totals are lower than expected. Data are maintained and analyzed by the VDH Division of Disease Prevention, Office of Epidemiology. Data are of new admissions, not number of people, and based on patient's residence at time of admission. Some people may have more than one admission. Counts do not include new admissions from out-of-state residents or residents who are unhoused.
IND_11_ARRES TS	Indicator 11: Arrestees for drug/narcotic violations by locality in calendar year 2021 (counts and rates per 100,000 population)	Virginia State Police Virginia Crime Repository	Data were accessed in May 2023 and come from the Arrests by Jurisdiction report on the Virginia Crime Repository. Arrests include local agencies and Virginia State Police arrests. Arrests are a count by persons and not by charges lauded.
IND_12_NAL_ ADMINS	Indicator 12: Naloxone administrations with positive responses in calendar year 2021 (counts and rates per 10,000 emergency medical services incidents)	VDH Office of Emergency Medical Services ESO Pre-Hospital Data System	Data are as of April 17, 2023. Inclusion Criteria: • Unit Notified by Dispatch Date is between January 1, 2021 and December 31, 2021, • Medication Given includes "Naloxone" or "Narcan", and • Response to Medication is equal to "Improved". Exclusion Criteria: • Records that did not have a submission status of "passed" (for records with a date unit notified by dispatch between 5/18/2021 and 12/31/2022; historical records prior to 5/18/21 do not contain a value in the submission status

field and therefore are
unaffected by this exclusion
criteria),
**
Records with a Type of
Service Requested equal to
Mutual Aid, Public
Assistance, or Standby, and
Records with an
Incident/Patient Disposition
of Assist, Canceled, Standby,
Non-Patient Transport, or
Patient Treated, Transferred
Care to Another EMS Unit.
The total doses of naloxone
administered is more than the
number of patients who received
naloxone, as the same patient can
receive multiple doses. Numbers do
not reflect total number of naloxone
administrations given in Virginia, as
naloxone can be administered in
other healthcare encounters.
Accuracy of the data within ESO is
limited by system performance and
accuracy of data submissions from
hospitals.
Data are maintained and analyzed by
the VDH Office of Emergency
Medical Services.
Wiedieur Berviees.