REPORT OF THE VIRGINIA
DEPARTMENT OF BEHAVIORAL HEALTH
AND DEVELOPMENTAL SERVICES

Report on the Pilot Program for Opioid Overdose Reversal (REVIVE!)

TO THE GENERAL ASSEMBLY OF VIRGINIA

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To: Members, Virginia General Assembly

Pursuant to House Bill 1672 from the 2013 Legislative Session, please find enclosed the *Report on the Pilot Program for Opioid Overdose Reversal (REVIVE!).*

Staff at the department are available should you wish to discuss this report.

Sincerely,

Debra Ferguson, Ph.D.

Cc: William A. Hazel, Jr., M.D.
Joe Flores
Delegate John M. O'Bannon, III

Report on HB 1672 (2013)

Pilot Program for Opioid Overdose Reversal (REVIVE!)

to the

2015 Session of the General Assembly

TABLE OF CONTENTS

Report on HB 1672 (2013) to the
2015 Session of the General Assembly:
Pilot Program for Opioid Overdose Reversal (REVIVE!)

EXECUTIVE SUMMARY

Overview

House Bill 1672 enacted by the 2013 Session of the Virginia General Assembly amended §§ 8.01-225 and 54.1-3408 of the *Code of Virginia* (COV) to authorize the Virginia Department of Behavioral Health and Developmental Services (DBHDS) to implement pilot programs on the administration of naloxone to counteract the effects of opiate overdose. The legislation allowed prescribers to issue nonpatient specific prescriptions to a friend or family member (a "lay rescuer") so that they could administer naloxone to an individual experiencing an opioid overdose. The legislation also provided civil immunity to these lay rescuers. individuals. The legislation called for DBHDS to work in cooperation with the Department of Health, the Department of Health Professions, substance abuse recovery support organizations and other stakeholders. The project, named REVIVE!, was funded with $10,000 in General Funds. This report provides information about how this pilot was implemented, its outcomes and recommendations for going forward.

Epidemiology of Opioid Overdose in the Commonwealth

The Commonwealth of Virginia has been severely impacted by opioid abuse, including heroin, as well as prescription analgesics such as codeine, desomorphone, fentanyl, hydrocodone, methadone, oxycodone, oxymorphone, and tramadol. In 1999, the first year for which such data is available, approximately 23 Virginians died from abuse (due to limitations in available data, this figure is approximate) of fentanyl, hydrocodone, methadone and oxycodone (FHMO). By 2012, the numbers of deaths from these drugs increased to 354, an increase of 1,439%. From 1999 to 2006, the number of fatal heroin overdoses never surpassed 19 per year, but by 2012 that figure was 135, an increase of more than 611%. Treatment data from DBHDS shows more Virginians identifying opioids as their primary drug of abuse as well.

Opioid Overdose Emergencies and Naloxone

An opioid overdose emergency occurs when an individual administers too much opioid into their system, resulting in the inhibition of the central nervous system, limiting the body's ability to control heart rate and respiration. Opioid overdose emergencies are rarely instantaneous as the central nervous system slowly loses its ability to control heart rate and respiration, which can take anywhere from one to three hours to occur. When naloxone is administered, it binds to opioid receptors in the brain, removing the opioid, allowing the central nervous system to regain control of heart rate and respiration. Naloxone is a proven public health response to the opioid overdose epidemic, and has saved the lives of more than 10,000 individuals in the United Sates.

Initial Implementation

DBHDS worked in cooperation with the Department of Health and the Department of Health Professions to make initial decisions about how to implement a naloxone program that would utilize family and friends by allowing prescribers to issue nonpatient specific prescriptions for

naloxone to these individuals to have available for use should an individual overdose as a result of opioid use. This state agency workgroup selected the metropolitan Richmond area (city of Richmond and counties of Chesterfield, Henrico, and Charles City) and the far Southwest Virginia area (the cities of Bristol and Norton and the counties of Buchanan, Dickenson, Lee, Russell, Scott, Tazewell, Washington and Wise) to implement pilot programs. These areas were chosen based on opioid treatment and mortality data. DBHDS worked with its state agency partners as well as stakeholder groups in both communities to determine the most effective strategies to implement the pilot program for each area. While the metropolitan Richmond area is primarily urban with heroin as the primary opioid of abuse, the far Southwest Virginia area is rural and prescription opioids are the primary opioids of abuse. When the project began, the formulations of naloxone available were for intramuscular injection, intravenous injection, or intranasal injection. Most naloxone programs that utilize Lay Rescuers use the intranasal method to avoid having to train individuals how to inject medication using a hypodermic needle. Initial implementation included determining that intranasal administration of naloxone was the most effective for use by the friends and family members. In addition, considerable attention was given to preparing materials to train Lay Rescuers, and producing the kit bags that contain the equipment, minus the naloxone, necessary to administer naloxone.

Public Implementation

Public implementation of REVIVE! began with the first series of Training of Trainer events in June 2014. Six events were held across the two pilot areas, and an initial cadre of 61 trainers participated. Those 61 trainers were provided with all the information, knowledge, and materials needed to perform Lay Rescuer training events in the pilot areas. In addition to leading Training of Trainer events, DBHDS also made presentations and participated in other activities to provide public education about naloxone and why it was being distributed in selected communities. This included meeting with first responder and law enforcement groups about the purpose and scope of the pilot so that they would understand the implications for their own rescue protocols.

Successes and Challenges

REVIVE! has trained 187 trainers who have gone on to train 339 Lay Rescuers in the two pilot areas. To date, DBHDS is not aware of any successful opioid overdose emergency reversals as a result of REVIVE! Lay rescuers report having difficulty obtaining prescriptions for naloxone, finding pharmacies to fill those prescriptions, and being able to afford naloxone. A recent price increase from approximately $30 per dose to as high as $60 per (two doses are required for each Lay Rescuer because the effects of naloxone only last 30-45 minutes, and in some cases a single administration may not be sufficient to reverse an overdose before medical help arrives.) has made the cost barrier an even more difficult hurdle. REVIVE! has provided an opportunity for state agencies to work collaboratively in the implementation of the pilot, which has increased inter-agency discussion about the overall problem of opioid abuse. The primary challenges facing REVIVE! in the future are funding of the infrastructure (training and REVIVE! kits bags), stigma about addiction (particularly opioid addiction), engaging the level of community involvement necessary for success, the diversity of the pilot locations, poor access to prescriptions due to lack of physician understanding, pharmacy stocking practices, and manufacturer pricing and availability of naloxone.

The Future of Naloxone in Virginia and in the United States

Since the project began another formulation of naloxone, Evzio®, an auto-injector formulation, has been approved by the U.S. Food and Drug Administration (FDA), but it is very expensive, at about $500 per dose. Produced by Kaléo, Evzio® is a small, handheld device that contains the medication (administered through a retractable needle to help prevent accidental exposure) and provides automated voice instructions for administration. Reckitt-Benckiser Pharmaceuticals has recently begun development of an intranasal formulation that provides a pre-dosed, pre-filled, disposable delivery system that is already assembled with the mucosal atomizer device.

The U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) has recently announced that states may use their allocations from the Substance Abuse Prevention and Treatment Block Grant to support naloxone distribution. However, the block grant allocation has been stable for more than 10 years and is not likely to increase; funds spent for this purpose would not be available to support community-based prevention and treatment activities. Meanwhile, agencies as diverse as the Office of the U.S. Attorney General, the World Health Organization and the Office of National Drug Control Policy are promoting naloxone as an opioid overdose emergency strategy.

Recommendations

Interest in REVIVE! has been widespread and DBHDS has received several requests to be included in an expanded pilot. In addition, DBHDS has received interest from several law enforcement agencies about officers carrying naloxone as part of their official duties. DBHDS therefore recommends that the pilot format be discontinued and that REVIVE! be available statewide, including nonpatient specific prescribing and civil immunity to lay rescuers.

We also recommend that, in addition to civil immunity, some form of criminal immunity be extended to naloxone rescue situations. This would remove barriers to Lay Rescuers calling 911 who fear that either they or the overdose victim will be criminally charged if illegal drugs are present at the rescue site.

Finally, we recommend that additional funding be made available to continue this project, which has been largely funded by other sources beyond the initial appropriation of $10,000.

Report on HB 1672 (2013) to the
2015 Session of the General Assembly:
Pilot Program for Opioid Overdose Reversal (REVIVE!)

I. Introduction

REVIVE! is a pilot program of the Commonwealth of Virginia which makes naloxone (Narcan ®) available to Lay Rescuers to reverse opioid overdoses. A collaborative effort with the Virginia Department of Behavioral Health and Developmental Services (DBHDS) taking the lead, the project includes the Virginia Department of Health, the Virginia Department of Health Professions, recovery community organizations such as the McShin Foundation, OneCare of Southwest Virginia, the Substance Abuse and Addiction Recovery Alliance of Virginia (SAARA), and other stakeholders. Enacted as HB 1672 by the 2013 Session of the General Assembly, the legislation required a report evaluating the pilot program established in the legislation. This document is the response to that requirement. This report explains the legislation, its implementation, provides lessons learned and makes recommendations for consideration by the 2015 Session of the General Assembly.

II. Legislation

House Bill 1672 of the 2013 Virginia General Assembly directed DBHDS to oversee the implementation of a pilot project to distribute naloxone in Virginia. The legislation made the following changes to sections §§ **8.01-225** and **54.1-3408** of the *Code* of Virginia:

§ **8.01-225**

- Any person who…in good faith and without compensation, administers naloxone in an emergency to an individual who is experiencing or is about to experience a life-threatening opiate overdose shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment if such administering person is a participant in a pilot program conducted by the Department of Behavioral Health and Developmental Services on the administration of naloxone for the purpose of counteracting the effects of opiate overdose.

and

§ **54.1-3408**

- Notwithstanding the provisions of § **54.1-3303** and only for the purpose of participation in pilot programs conducted by the Department of Behavioral Health and Developmental Services, a person may obtain a prescription for a family member or a friend and may possess and administer naloxone for the purpose of counteracting the effects of opiate overdose.

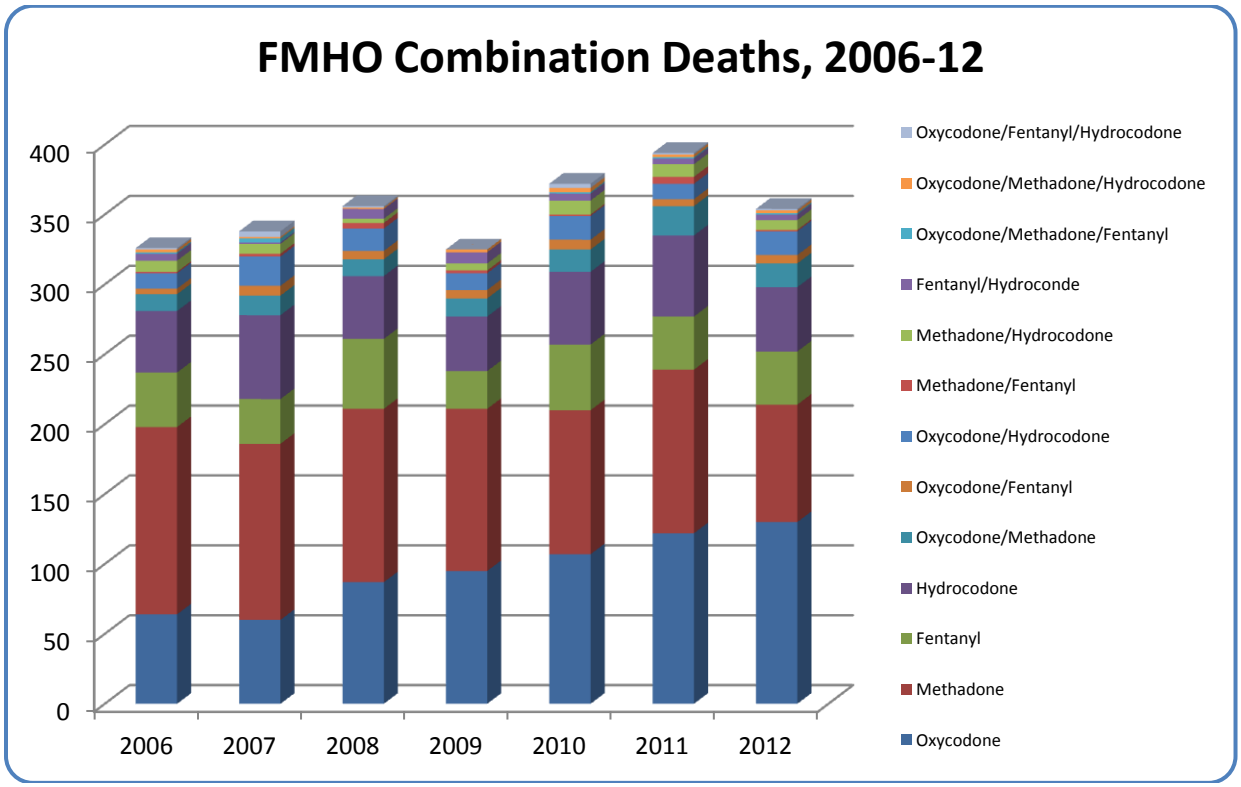
The amendment to § **8.01-225** provides what is commonly referred to as "Good Samaritan" protection which allows individuals to administer naloxone to an individual suffering an opioid

overdose emergency (OOE) without fear of civil litigation that could potentially occur as the result of an adverse reaction to the administration of naloxone.

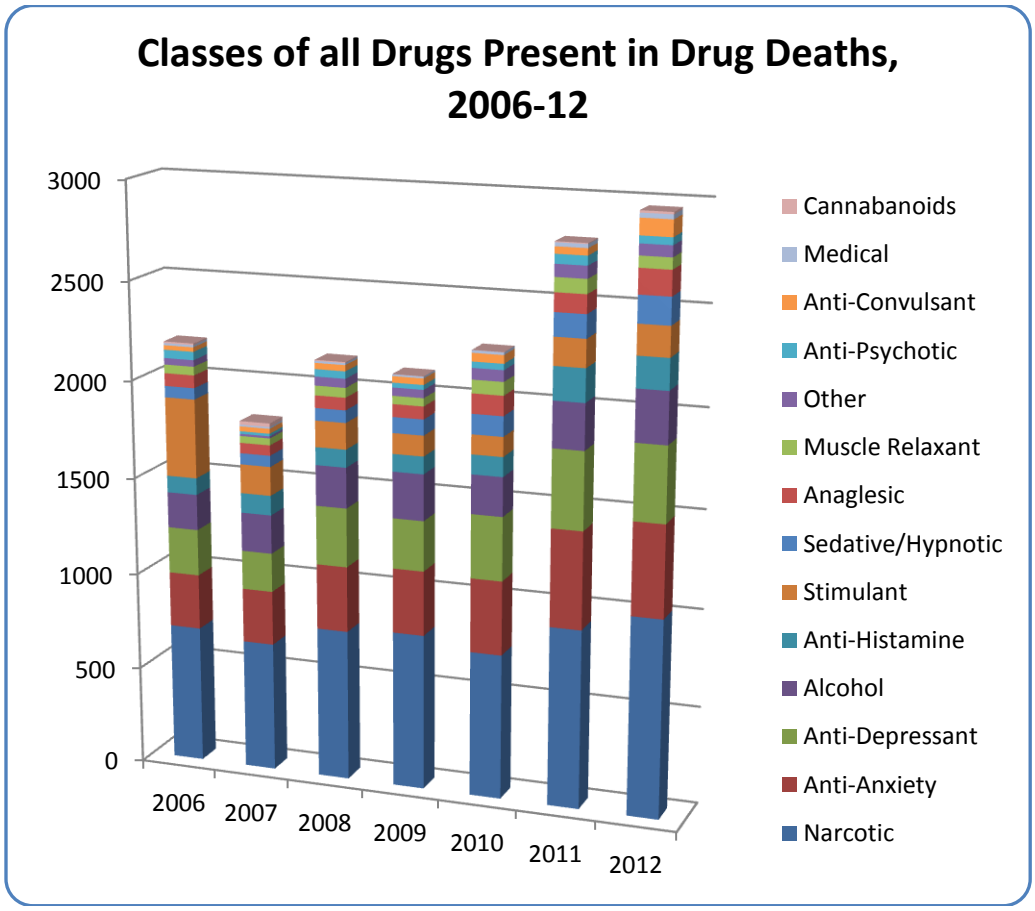
The second amendment allows for "nonpatient specific prescribing" which allows prescribers to prescribe naloxone to an individual with whom they do not have a *bona fide* patient relationship (as defined in § **54.1-3303**). This allows a friend or family member to obtain a prescription for naloxone that they would administer to an opioid user. Naloxone is the only prescription medication in the Commonwealth for which nonpatient specific prescribing is permitted.

III. Epidemiology of Opioid Overdose in Virginia

Virginia has been severely impacted by opioid abuse. Opioids have been prescribed by physicians for decades to treat acute and chronic pain, but the past ten to 15 years have seen an increasing amount of these medications diverted into the community for non-medical use. In 1999, the first year for which such data are available, approximately 23 people died from overdose as a result of abuse of fentanyl, hydrocodone, methadone, and oxycodone (the leading prescription opioids abused, commonly referred to as FHMO). By 2012, the most recent year for which complete data are available, 354 individuals died from the abuse of FMHO, an increase of 1,439%.



The issue of opioid abuse in Virginia is not limited to prescription analgesics. The use of heroin follows a similar trend. From 1999 to 2006, there were never more than 19 deaths attributed to heroin in Virginia. In 2012, 135 people died from overdose as a result of heroin abuse, an increase of more than 611%. The chart below depicts the increase of drug-related deaths where narcotics (a category that is primarily composed of opioids) were present as a portion of all drug-related deaths, from 706 in 2006 to 1,017 in 2012. This upward trend in opioid-related deaths continues, as recently finalized data from the Virginia Office of the Chief Medical Examiner indicates that opioids were directly responsible for 648 deaths in 2013 (Virginia Office of the Chief Medical Examiner, 2013).[1]



A 2011 statistic provides the true scope of the impact of opioids in Virginia. That year, for the first time ever, drug-related deaths occurred at a higher per capita rate than motor vehicle crashes -- 9.6 deaths per 100,000 for drug-related deaths versus 9.4 deaths per 100,000 for motor vehicle crashes (Virginia Office of the Chief Medical Examiner, 2012).

[1] Data for drug related deaths prior to 2004 is unpublished, but was obtained from the Office of the Chief Medical Examiner. Due to limitations with this data, figures prior to 2006 are considered approximate.

Statewide, identification of opioids as the primary drug of choice for individuals seeking publicly-funded substance abuse treatment services has increased in recent years.

Individuals Identifying Opioids as Primary Drug of Choice in Virginia

	SFY*2011	SFY*2012	SFY*2013
Heroin	3330	3322	3366
Percentage of all Individuals	9.81%	9.73%	10.45%
Other Opiates/Synthetics	3694	3997	3754
Percentage of all Individuals	10.88%	11.70%	11.65%

**State Fiscal Year*

This increase in opioid abuse and related deaths is most evident in two regions of the Commonwealth: the Richmond metropolitan area, where heroin is the primary opioid being abused, and far Southwest Virginia, where prescription analgesic medications are primarily abused. In FY 2013, of the 7,120 individuals seeking publicly-funded treatment services in Virginia who identified opioids as their primary drug of choice, 1,946 (27.33%) sought those services in the Richmond metropolitan region and 1,851 (25.99%) sought those services in the far Southwest Virginia region.

In addition, cause of death data from the Office of the Chief Medical Examiner indicated that these regions were especially affected by opioid abuse. Some localities in Southwest Virginia had death rates due to specific prescription pain medications that were consistently three times the state average rate, and preliminary data in the metropolitan Richmond area as this project was being implemented indicated a significant increase in deaths from heroin.

Because of these data, the Richmond metropolitan and far Southwest Virginia regions were selected as pilot areas for REVIVE! These pilot areas included the city of Richmond and counties of Chesterfield, Henrico, and Charles City for the Richmond metropolitan region. In the far Southwestern region, the pilot area included the cities of Bristol and Norton and the counties of Buchanan, Dickenson, Lee, Russell, Scott, Tazewell, Washington and Wise. These jurisdictions were chosen because they comprise the jurisdictions covered by the community services board catchment areas for those regions.

The selection of these regions also provided an opportunity to study differences in implementation. The Richmond metropolitan region is, relatively speaking, densely populated, and primarily urban, and heroin is the primary opioid of abuse. The far Southwest Virginia region is sparsely populated and extremely rural, and prescription analgesics are the primary opioids of abuse. Due to its rural and mountainous terrain, wait times for first responders in the far Southwest Virginia region can often be significantly longer than in the Richmond metropolitan region.

IV. Opioid Overdose Emergencies and Naloxone

Opioids are analgesics that reduce perception and reaction as well as increase tolerance to pain. Opioids include substances naturally produced from the resin of the opium poppy as well as synthetic substances. The opioid group includes heroin as well as prescription medications, including codeine, desomorphone, fentanyl, hydrocodone, methadone, oxycodone, oxymorphone, and tramadol.

Opioids attach to receptors that are found in the brain and other parts of the body to reduce the perception of pain. They also produce other effects such as drowsiness and confusion and, since they also impact the reward areas of the brain, they can cause the person to feel euphoric. Individuals who use opioids over a period of time, whether to legitimately control pain or to abuse them to achieve euphoria, develop tolerance, which requires that they use more of the opioid to achieve the same effect. If a person suddenly increases the amount of opioid, either by volume or strength, he is at risk of overdose. If the person ceases to use the opioid for a period of time, his tolerance decreases; the next time the person uses the opioid, less will be required to achieve the same effect.

An opioid overdose emergency (OOE) occurs when an individual administers too much opioid into their system, resulting in the inhibition of the central nervous system. In excessive quantities, opioids bind to receptors in the brain stem, which interrupts communication between neurotransmitters. This limits the body's ability to control heart rate and respiration. Opioid overdose emergencies are rarely instantaneous, and can often develop over one to three hours as the central nervous system slowly loses its ability to control heart rate and respiration.

Naloxone is an opioid antagonist, meaning that its molecules have a higher affinity for the receptors in the brain than opioid molecules. When naloxone is administered, it binds to those receptors, removing the opioid molecules. Once this has occurred, neurotransmitter communication resumes, and the central nervous system can regain control of heart rate and respiration. Naloxone is a proven public health response to the epidemic of opioid overdose. A 2012 Morbidity and Mortality Weekly Report indicates that there were 48 naloxone distribution programs in the United States that had trained 53,032 individuals in the administration of naloxone. Those individuals saved the lives of 10,171 individuals who were experiencing an OOE (Centers for Disease Control and Prevention, 2012).

In addition to saving lives, studies suggest that naloxone reduces the economic cost of OOEs and deaths in the United States. It is estimated that in 2009 the economic burden due to opioid-related poisoning in the U.S. was $20.4 billion, including $2.2 billion in medical costs with mortality accounting for the majority of costs (Inocencio, Carroll, Read & Holdford, 2013). Another study, in 2009, estimated the societal costs of prescription opioid abuse, dependence and misuse in the U.S. were $55.7 billion, including $25.0 billion in health care costs, $5.1 billion in criminal justice costs, and $11.2 billion in workplace costs due to loss of earnings from premature death (Birnbaum, White, Schiller, Waldman, Cleveland & Roland, 2011).

Another study indicated that training heroin users to administer naloxone would reduce overdose deaths by six percent. The study also suggested that quality-adjusted life-years would be

increased, and that even in a "'worst-case scenario' where overdose was rarely witnessed and naloxone was rarely used, minimally effective, and expensive," there was still a significant increase in cost-effectiveness, concluding that even under conservative assumptions naloxone distribution is likely to reduce overdose deaths and is cost-effective (Coffin & Sullivan, 2013).

Naloxone is a Schedule VI drug in Virginia, meaning it has no potential for abuse, and no impact if accidentally administered. The dosage to administer is the same for an adult as it is for a child. Naloxone is included on the World Health Organization's List of Essential Medicines (World Health Organization, 2013). Naloxone has been used for years by emergency medical technicians and emergency room doctors in response to OOEs.

V. Initial Implementation

A. State-level Coordination

A team of DBHDS staff held a number of internal meetings to make the initial decisions about how REVIVE! should be implemented. Having determined what areas of the Commonwealth would be served, DBHDS created the REVIVE! Workgroup (RW) to help advise the development of REVIVE! In addition to DBHDS staff, this workgroup included David Trump, M.D., M.P.H., M.P.A., Chief Deputy Commissioner for Public Health and Preparedness at the Virginia Department of Health (VDH), JoAnne Wells, Injury Prevention Outreach Coordinator at VDH, and Caroline Juran, R.Ph., Executive Director of the Board of Pharmacy at the Virginia Department of Health Professions (DHP).

B. Pilot Area Stakeholder Meetings

DBHDS began the process of implementation by performing outreach in the community to identify stakeholders willing to work with DBHDS to implement REVIVE! These stakeholders serve a vital role, providing community-specific knowledge about logistics, resources and other elements vital to REVIVE! In the Richmond metropolitan pilot area, the McShin Foundation and SAFE of Chesterfield County were identified as stakeholder organizations that could provide organizational assistance. In the far Southwest Virginia region, One Care of Southwest Virginia, the Substance Abuse Task Force in Rural Appalachia (SATIRA), and the Appalachian Substance Abuse Coalition (ASAC) were the stakeholder organizations identified. In addition to these organizations, DBHDS and the REVIVE! Workgroup reached out to public health officials, law enforcement officials, emergency medical treatment providers, public and private substance abuse treatment providers, hospitals, pharmacists, members of the faith-based community, and friends and family members of those who abuse opioids. The initial stakeholder event for the Richmond metropolitan region was held on August 2, 2013, with 29 attendees. The initial stakeholder event for the far Southwest Virginia region was held on December 16, 2013, with 46 attendees. At these meetings, DBHDS discussed the preliminary plans for implementation of REVIVE! and requested feedback. These meetings both lasted two to three hours, and during these meetings stakeholders identified the following issues as some of the most important to implementation of REVIVE!:

- Involving medical professionals, first responders, schools, the faith-based community, and law enforcement;
- Treatment as an important part of the response to an OOE;
- Importance of educating public to reduce stigma; and

- Reducing barriers to naloxone access, specifically the requirement for a prescription and cost of medication.

C. Method of Administration

The first issue the RW addressed was the method of naloxone administration for REVIVE! There are three possible methods for the administration of naloxone: intramuscular (IM), intravenous (IV) and intranasal (IN). IM and IV administration require syringes and hypodermic needles to administer the naloxone, either into the outer thigh (IM), or a vein (IV). Intranasal (IN) administration requires a specific type of vial and syringe (known as a Luer Lock syringe) that can accommodate a mucosal atomizer device (MAD), which atomizes the liquid naloxone as it is administered into an individual's nostrils. A standard vial of naloxone costs considerably less than a vial used in a Luer Lock syringe. However, the implementation of REVIVE! using IM or IV administration of naloxone would necessitate the distribution of syringes and needles as part of an effective program, which would potentially violate state laws concerning the distribution and possession of drug paraphernalia, especially in situations in which the trainers had the syringe and the needles without medication. In addition, the RW was concerned about the difficulty of training Lay Rescuers to inject the medication. As a result, the RW determined that IN administration would be the most effective method to utilize for REVIVE! This method offers other advantages as well. The vial that comes with the Luer Lock syringe has a pre-measured dose and no exposed needle. Studies have shown that intranasal administration of naloxone is a viable alternative to IM/IV administration, showing the same overall response time for IN versus IM administration (Robertson, Hendey, Stroh & Shalit, 2009) as well as similar levels of bioavailability (Hussein, Kimura, Chong-Heng & Kashihara, 1984), while also providing an increased margin of safety, especially in emergency situations with regard to infection risks associated with puncture (Loimer, Hofmann & Chaudhry, 1994).

D. Training

Having determined the most appropriate method of administration, the next issue for the RW to address was training. The legislation enacted by the General Assembly did not indicate that training was a requirement for pilot implementation but the RW, by reviewing relevant literature and examining successful naloxone distribution programs around the country, determined that a strong, two-pronged training component was vital to successful implementation of REVIVE! DBHDS would train trainers in the proper methods to lead REVIVE! trainings, and then those trainers would lead REVIVE! training events in their communities.

A number of studies have examined the effectiveness of Lay Rescuer administration of naloxone. These studies have concluded that not only *can* individuals with no medical background or training be trained to effectively administer naloxone, but that they can do so effectively, and thereby improve outcomes for the individual experiencing the OOE.

Pilot studies as far back as 2001 indicated that Lay Rescuer use of naloxone could be effective. No unexpected or adverse consequences were reported (Dettmer, Saunders & Strang, 2001). Further studies indicated that not only can individuals be trained on the administration of naloxone, but that once trained they are willing to administer in the case of an OOE. These findings support those of other studies that recommend distribution of naloxone to heroin users to prevent overdose deaths (Seal, Thawley, Gee, Bamberger, Kral, Ciccarone, Downing & Edlin,

2005). Other studies have shown that naloxone is so easy to use that even individuals trained by other peers, family members, or through social networks can be as effective in administration to an individual experiencing an OOE as a person who has received formal training (Doe-Simkins, Quinn, Xuan, Sorensen-Alawad, Hackman, Ozonoff, & Walley, 2014). Subsequent studies have verified these findings (Doe- Simkins, Walley, Epstein & Moyer, 2009; Hedin, Fondario, & Friedrichs, 2014).

Studies have also shown that trained individuals are as effective as emergency medical personnel, not only in recognizing an OOE, but in responding with the administration of IN naloxone. Finally, studies also suggest that administration of naloxone in the community before arriving at the hospital can lead to better outcomes and fewer post-overdose inpatient hospital admissions. An overdose patient who received naloxone before arriving at the hospital was two and a half times more likely to be discharged home than admitted (Hedin, Fondario, & Friedrichs, 2014).

E. Curriculum Development

Having established the clear advantages provided by training Lay Rescuers in the administration of naloxone, DBHDS began the process of developing its own training curricula for trainers and for Lay Rescuers. Although many programs around the country already had developed curricula of their own, the RW decided that the pilot needed to develop its own specific curricula. DBHDS began this process by reviewing curricula from around the United States and beyond, including curricula developed in California, Illinois, Massachusetts, Oregon, Washington, Canada, and the United Kingdom. While tailored to their specific needs, these curricula were similar in that they all proposed training Lay Rescuers in a naloxone administration protocol that included the following steps:

1. Check for Responsiveness
2. Call 911
3. Administer rescue breathing
4. Administer naloxone
5. Resume rescue breathing
6. Follow-up as needed

With these basic steps, DBHDS developed its Training Guide to be distributed to Lay Rescuers who attend a training event. DBHDS utilized, with permission, curricula and other media from the Multnomah County (OR) Health Department, the Massachusetts Department of Public Health, the San Francisco Department of Health, the University of Washington Alcohol and Drug Abuse Institute, the Chicago Recovery Alliance, the Boston Public Health Commission, Project Lazarus, the New York City Department of Mental Health and Hygiene, and the Harm Reduction Coalition in the preparation the Guide, which discusses:

- How an OOE occurs and how naloxone works;
- How to recognize the difference between someone who is just high versus someone who is experiencing an OOE;
- Risk factors that may make someone more susceptible to an OOE;
- Dispelling myths and urban legends about how to respond to an OOE; and

- The effective administration of naloxone, including the six steps above

The training includes interactive elements, including videos on opioid overdose emergencies and naloxone distribution, question and answer sessions, and opportunities for Lay Rescuers to practice rescue breathing, naloxone administration, and responding to an individual who may respond to the administration of naloxone in an agitated fashion.

The protocol for naloxone distribution includes the administration of rescue breathing to the person experiencing the OOE. This is contrary to the American Heart Association's "Hands Only" cardiopulmonary resuscitation that is currently recommended, which eliminates administering rescue breaths when performing CPR as a response to cardiac arrest. Rescue breathing is still appropriate when responding to an OOE. In CPR, the primary goal is to help the heart resume beating. However, during an OOE, the primary issue is respiratory depression, not cardiac arrest (Harm Reduction Coalition, undated). Therefore, rescue breathing is an essential part of the naloxone administration protocol.

Once drafted and reviewed internally, DBHDS distributed the Training Guide to the RW as well as other medical and healthcare professionals and other stakeholders. Their feedback was incorporated into the final version of the Training Guide, which was finalized in early 2014. Once the Training Guide was finalized, a Training Curriculum for use by those providing the training to the Lay Rescuers was developed. Building upon the foundation of the Training Guide, the Training Curriculum added extensive information for the trainers to help them successfully lead their Lay Rescuer trainings. The Training Curriculum included:

- How to effectively schedule and prepare for the training event, including selecting an appropriate location and time;
- Suggested scripts for the trainer to use, including ways to generate discussion;
- Points of emphasis, including the importance of calling 911 and staying with the person until first responders arrive; and
- Instructions for leading role play scenarios of rescue breathing and naloxone administration.

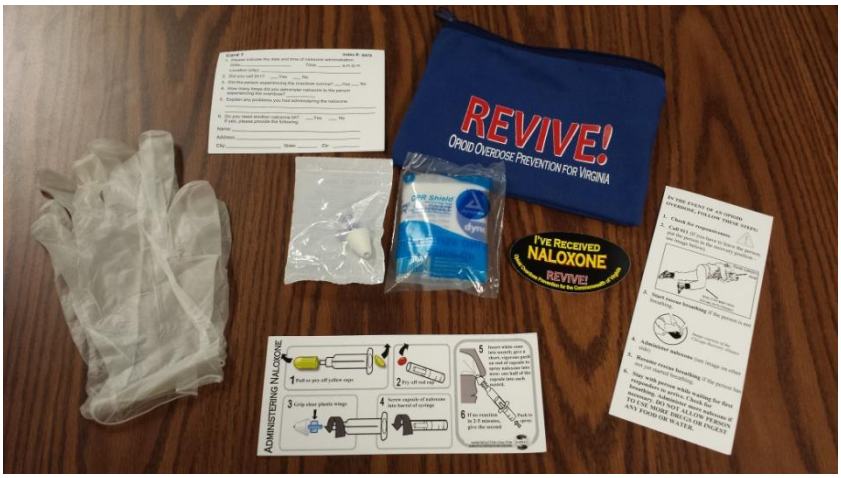
The Training Curriculum was reviewed by the same healthcare professionals and stakeholders that reviewed the Training Guide, but additional review was performed by training experts to ensure that the curriculum was as comprehensive and helpful as possible. Like the Training Guide, the Training Curriculum was finalized in early 2014.

F. Kit Bags

Once the training materials were prepared, DBHDS and the RW moved onto the planning and production of the kit bag. Because the protocol for naloxone administration requires access to specific equipment, a bag containing these items is necessary to ensure that the Lay Rescuer has all the supplies needed (with the exception of the prescription for naloxone) to carry out all those steps. The kit bag includes:

- Latex-free gloves
- Rescue breathing face shields

- Mucosal atomizer devices (MADs)
- An information card
- Two Incident Report cards
- Two "I've Received Naloxone" stickers



The latex-free gloves and face shields are included to allow the Lay Rescuer to administer rescue breaths in a sanitary fashion, protecting both the Lay Rescuer and the person experiencing the OOE. The MADs fit onto the Luer-Lock syringe to allow for nasal administration of naloxone. The information card has the six steps of the naloxone administration protocol listed, as well as an image reminding the Lay Rescuer of the steps needed to prepare the Luer Lock syringe. The two Incident Report cards are to inform DBHDS of a reversal (more about these cards in the Evaluation section below), and the stickers allow the Lay Rescuer to indicate to first responders that naloxone has been administered in case they cannot or are not willing to wait for them to arrive.[2]

DBHDS initially looked to procure standard size kit bags that could be screen printed with the REVIVE! logos and prefilled with some of the necessary supplies (gloves and face shields). However, difficulties finding an appropriately sized bag and a suitable vendor led DBHDS to work with Mount Rogers Industrial and Developmental Center (IDC). A division of Mount Rogers Community Services Board, Mount Rogers IDC was able to provide DBHDS not only with custom size bags, but also the screen printing and filling of the bags with all the supplies listed above. Mount Rogers IDC prepared an initial order of 1,000 kit bags for REVIVE! that were delivered in June 2014.

G. Funding

From its inception, DBHDS has asserted that accessibility and availability of naloxone are the hallmarks of REVIVE! To that end, DBHDS has done everything possible to minimize costs for Lay Rescuers. In passing the legislation for REVIVE!, the General Assembly appropriated $10,000 for program implementation. The preparation and production of the kit bags spent all of these funds, with DBHDS ordering 1,000 bags at an overall per unit cost of $10.49 for a total of

[2] The Training Guide stresses to Lay Rescuers the importance of waiting until first responders arrive before leaving due to the potential for OOE relapse, but some do not stay due to potential interaction with law enforcement.

$10,490. DBHDS was able to identify additional funds, including funds from the Purdue Pharma Settlement as well as other sources. The success of the program, described in more detail below, has led DBHDS to order a second production of 1,000 prefilled bags from Mount Rogers. When this order is completed, DBHDS will have expended nearly $25,000 on the implementation of REVIVE! DBHDS provides all trainings as well as all kit bags to trainers and Lay Rescuers at no cost to them.

While IN naloxone is the formulation best suited for use in REVIVE!, it is also the most expensive, with a single vial costing between $20.00 and $40.00. A vial of IM formulation naloxone can be purchased for less than $5.00. Due to this high cost, REVIVE! would be more successful if funds were available to subsidize the purchase of the medication. However, the limited funding provided meant that DBHDS did not have the resources necessary to assist Lay Rescuers in purchasing naloxone. Another barrier to obtaining naloxone is the fact that a prescription is required, meaning a Lay Rescuer must visit his primary care provider and pay a co-pay in order to obtain the prescription. DBHDS is working on ways to address these barriers, but finding solutions that have minimal cost impact has been challenging.

H. Evaluation

DBHDS and the RW looked at a number of methods for evaluating the effectiveness of REVIVE!, but in the end it was determined that three primary measures would be used for evaluation purposes: the number of trainers and Lay Rescuers trained, the number and location of kit bags distributed, and the number of OOE reversals performed by REVIVE! Lay Rescuers. A database has been developed by DBHDS which tracks all trainers and Lay Rescuers for REVIVE! After any Training of the Trainer or Lay Rescuer training event is conducted, registration forms from that training are submitted to DBHDS, where the information is entered into a database. DBHDS developed a novel method for tracking the second and third measures. Inside each kit bag there are two pre-addressed postage-paid post cards. When a Lay Rescuer performs an OOE reversal, they are asked to submit the following information about that reversal:

- Date, time and city where reversal took place;
- Whether the Lay Rescuer called 911;
- Whether the person experiencing the OOE survived;
- The number of times the Lay Rescuer administered naloxone to the person experiencing the OOE; and
- Any problems the Lay Rescuer had with administering naloxone or the rest of the protocol.

The Lay Rescuer is then given the opportunity to submit his or her name and address in case all of the supplies in the kit bag have been used; in this case, the kit bag is replaced at no cost. These cards are printed with an index number which corresponds to that specific bag. When bags are distributed to training events, DBHDS tracks which index number is distributed to which training. This allows DBHDS to not only track usage, but to measure effectiveness in the pilot areas. DBHDS is not aware of any other naloxone distribution program in the country that is evaluating its project on this level.

VI. Public Implementation

A. Preparation

The process of designing, reviewing, and preparing the Training Guide and Curriculum as well as the kit bag took several months. During this time, DBHDS was distributing REVIVE! newsletters to keep its stakeholders up to date on DBHDS' progress towards initial training events. DBHDS was also working with the RW to determine the most appropriate venues to hold the initial training events for trainers and Lay Rescuers. Initially, it was determined that the first training events would be held in "pre-pilot" locations, primarily at opioid treatment programs. This "pre-pilot" implementation would allow for DBHDS to closely and efficiently monitor the initial implementation .. However, the logistical issues related to the design and production of the kit bags took much longer than expected. By the time the kit bags were ready, DBHDS decided that REVIVE! needed to move forward throughout the pilot areas instead of limiting locations for trainings.

B. Training of Trainers (TOTs)

With the assistance of community stakeholders and DBHDS staff, six Training of Trainer (TOT) events were scheduled for the two pilot regions. They were:

Far Southwest Virginia Pilot Area TOTs
Thursday June 19, 1:00 PM – Dickenson County Behavioral Health Services – Clintwood, VA
Thursday June 19, 7:00 PM – Mountain Empire Community College – Big Stone Gap, VA
Friday, June 20, 8:00 AM – Southwest Virginia Community College – Cedar Bluff, VA
Friday, June 20, 2:00 PM – Southwest Virginia Higher Education Center, Abingdon, VA

Richmond Metropolitan Pilot Area TOTs
Thursday, June 26, 7:00 PM – Henrico Area Mental Health & Developmental Services, Henrico, VA
Friday, June 27, 1:00 PM – Richmond Ambulance Authority, Richmond, VA

Invitations for Training of Trainer (TOT) events were targeted to substance abuse treatment professionals and community members concerned about a friend, family member, or significant other who is abusing opioids. Between these six events, REVIVE! trained an initial cadre of 61 trainers. One immediate issue for these trainers was obtaining a prescription for naloxone, necessary as a demonstration tool when leading training event. DBHDS was able to partner with doctors in both pilot areas to write these prescriptions so there would be no delay in these trainers being able to hold their own Lay Rescuer training events in their communities.

C. Training of Lay Rescuers

The first Lay Rescuer training event was held on July 10, 2014, 21 days after that trainer attended a TOT event. It was held at the nurses' meeting for the Cumberland Plateau Health District, where the first 19 Lay Rescuers for REVIVE! were trained. Since that first training, 23 more training events have been held and 339 Lay Rescuers have been trained, including United States Senator Tim Kaine, who attended a training event held in Lebanon, VA on August 21, 2014. These training events were publicized in the community through newspapers, television

stations, and social media. All REVIVE! Lay Rescuer training events are free and open to the public.

D. Presentations and Public Education

The work of REVIVE! has extended beyond training of Lay Rescuers and distributing naloxone in the pilot areas. DBHDS is also working to educate the general public as well as health care and substance abuse treatment professionals about naloxone and its importance to individuals who abuse opioids. Stories about naloxone training events have appeared in the Richmond Times-Dispatch, the Bristol Herald Courier, The Virginian Pilot, and other publications. DBHDS staff have provided presentations on REVIVE! to the Virginia Rural Health Association, the Mountain Empire Public Health Emergency Coordination Council Summer Conference, the Old Dominion EMS Council, and Atlantic Outreach Group. Interest in REVIVE! has been expressed by Virginia's U.S. Senators Mark Warner and Tim Kaine. DBHDS staff has provided technical assistance to individuals developing naloxone distribution programs in Tennessee, and are members of the Emerging Opioid Overdose Strategic Group (EOOSG) and the Opioid Safety and Naloxone Network (OSNN), nationwide groups of professionals sharing information about emerging trends in opioid abuse and naloxone distribution programs.

On September 26, 2014, Governor Terry McAuliffe signed Executive Order 29, establishing the Governor's Task Force on Prescription Drug and Heroin Abuse. The task force will recommend immediate steps to address a growing and dangerous epidemic of prescription opioid and heroin abuse in the Commonwealth. Of the five workgroups of the Task Force, naloxone is a topic of discussion in at least three of them.

VII. Successes and Challenges

A. Success – Number of Individuals Trained

REVIVE! has trained 187 individuals who are able to provide training in the pilot areas. Those individuals have trained 339 Lay Rescuers. To date, DBHDS has not received any return cards that would indicate the administration of naloxone as part of the REVIVE! pilot project.

B. Success – Collaboration

REVIVE! has demonstrated the ability of state agencies and community stakeholders to come together and work collectively towards a common goal. While DBHDS has been the lead agency for implementation of REVIVE!, the assistance provided by the Virginia Department of Health and the Virginia Department of Health Professions has been invaluable. REVIVE! has also strengthened ties between DBHDS and stakeholder groups in the community. While DBHDS has been responsible for state-level implementation, organizations such as the McShin Foundation, SAARA of Virginia, and One Care of Southwest Virginia have provided community-level information and resources that have helped to make REVIVE! a success. DBHDS has also had success working with community-level entities of other state agencies, specifically local health departments in the far Southwest Virginia pilot area. The opportunities for collaboration have strengthened these relationships and improved DBHDS' ability to meet the needs of the individuals it serves, not only in the pilot areas, but throughout the Commonwealth.

C. Challenge – Funding

In passing House Bill 1672, the Virginia General Assembly appropriated $10,000 in funding to support REVIVE. As previously reported, these funds were exhausted by the first production run of kit bags. DBHDS has identified other sources of funding, including monies awarded to DBHDS as part of the Purdue Pharma Settlement Agreement. Since its inception, REVIVE! has distributed more than 900 kit bags, nearly exhausting the first production run. A second production was ordered in October 2014 at the same costs listed above. SAMHSA has authorized the use of Block Grant funds for naloxone distribution, but funding, which has remained level for more than ten years, does not have any excess that could be reappropriated towards REVIVE! Additional funds would also support subsidizing the costs of IN naloxone, which typically costs around $25 per box, with two boxes required for every kit.

D. Challenge – Stigma

Stigma continues to be a major obstacle in the implementation of REVIVE! Opioid abuse, like other forms of drug abuse, is stigmatized in many ways by members of the community who believe that addiction is a choice an individual has made as opposed a brain disease. Some Lay Rescuer training attendees have commented that they do not believe current opioid abusers should be allowed to attend REVIVE! trainings. This is fueled by the belief that the availability of naloxone somehow enables or promotes opioid abuse, an opinion held not only by some in the general public but some medical professionals as well. However, multiple studies have indicated that there is no scientific basis for this belief (Maxwell, Bigg, Stanczykiewicz, & Carlberg-Racich, 2006; Seal. Thawley, Gee, Bamberger, Kral, Ciccarone, Downing, & Edlin, 2005; Wagner, Valente, Casanova, et. al., 2010). Lay Rescuers have encountered difficulty in obtaining a prescription from their Primary Care Provider for naloxone in both pilot areas. There is also concern about community members being capable of administering naloxone in an OOE. As detailed above, these concerns are unfounded. The unfortunate reality is that some people who are addicted to, or dependent on, prescription opioids started taking them as a legitimate treatment for acute and/or chronic pain, and eventually became addicted to them. Others may be more susceptible to addiction due to genetics or co-occurring mental illness.

E. Challenge - Community Involvement

While REVIVE! has provided outstanding opportunities for collaboration, it has also faced challenges in getting the community at large involved. In addition to the stigma described above, there is a "Not in My Back Yard" (NIMBY) attitude towards naloxone distribution specifically, as well as substance abuse treatment in general. Additionally, some community members seek to minimize the issue of opioid abuse in their community by simply ignoring the fact that the problem exists.

F. Challenge – Diversity of Pilot Locations

The choice of the pilot areas was based on identified need as described above, but the choice of the two areas offered other advantages as well. The far Southwest Virginia area is rural and widely dispersed, where prescription opioids are typically abused more than heroin, and where the time between a 911 call and the arrival of first responders can exceed 45 minutes. The Richmond metropolitan area is mostly dense and urban, where heroin is typically abused more than prescription opioids. The differences go beyond geographic and demographic as well. The far Southwest Virginia has a stronger network of stakeholder and recovery-based organizations

that have provided connections to resources, including meeting locations and, courtesy of the Appalachian Substance Abuse Coalition, funds to offset the cost of naloxone. As a result, trainings in the far Southwest Virginia region have been led in more locations by more providers. In Richmond, there are two main stakeholder organizations assisting with REVIVE! – the McShin Foundation and SAARA of Virginia. McShin has been very active in REVIVE!, providing the majority of trainings for the Richmond pilot area. The diversity of the regions has also required the adjustment of protocols for training, writing of prescriptions, and access to naloxone at pharmacies.

G. Challenge – Medication access – Pharmacy Stocking and Cost

The cost and availability of naloxone has provided significant challenges for REVIVE! While most small and independent pharmacies have been willing to stock naloxone, DBHDS has been unable to secure agreements with any nationwide retail pharmacies, including CVS, Walgreens, and Rite-Aid. The retail pharmacies have concerns about demand for the medication, which leads to concerns about the cost-effectiveness of using up shelf space to stock naloxone as opposed to other more commonly prescribed medications.

The cost of a vial of naloxone for IM administration is very low, typically two to three dollars. However, the vial used in the Luer-Lock syringe is only available with the syringe itself. Lay Rescuers have indicated to us that a single box of this formulation typically costs between $20 and $35 from their pharmacy. Evzio®, an auto-injector formulation of naloxone, is now available for purchase at pharmacies, but cost for a single dose has been said to be between $300 and $500 (Rosenthal, 2014), with many insurance policies not covering the cost.

Currently, only one company, International Medication Systems (IMS), sells naloxone in the Luer-Lock syringe. Recently, some pharmacies in the pilot areas were indicating that they could not purchase naloxone from their wholesale distributors due to what they were told were "delays with the manufacturer."

To date, reports DBHDS has received indicate that the IMS price increase has increased the cost of naloxone at retail locations from 80-120 percent. The intranasal use of this product is technically off-label because the FDA has not approved any naloxone product for intranasal use. As a result, IMS refuses to discuss any shortage or price issues with any naloxone programs using their product intranasally, including REVIVE! National advocacy groups involved in improving access to naloxone are working with naloxone distribution programs around the country to strategize effective ways to respond to this price increase.

VIII. The Future of Naloxone in Virginia and the United States

A. New Formulations of Naloxone

Two new formulations of naloxone have the potential to change the landscape for naloxone distribution as it currently exists. The first is an auto-injector formulation of naloxone called Evzio®. Evzio® is the first hand-held auto-injector formulation of naloxone approved for use in community settings by the Food and Drug Administration (FDA). Evzio® administers naloxone intramuscularly, and provides automated voice instructions for administration similar to those on automatic defibrillators. Evzio® provides significant advantages over the IN form of naloxone

but, as previously stated, early indications are that the cost of a single dose of Evzio will be prohibitive.

In May 2014, Reckitt Benckiser Pharmaceuticals entered into an agreement with AntiOp to develop the first FDA-approved IN naloxone formulation. (The IN formulation currently used in Virginia and other states is effective, but is not approved by the FDA.) This formulation is a pre-filled, unit-dose, disposable delivery system for IN administration of naloxone. Unlike current syringes used for IN administration of naloxone, this formulation will come prepackaged with the MAD, making administration even simpler and easier than before. The FDA recently announced that they were fast-tracking approval of this formulation of naloxone. These two new formulations offer exciting new opportunities for the continued distribution of naloxone, not only in Virginia but nationwide as well.

B. Action at Federal Level

A number of federal agencies either have taken or are considering taking action to make naloxone more available nationwide. On April 2, 2014 the Substance Abuse and Mental Health Services Administration (SAMHSA) issued a letter advising that Substance Abuse Block Grant funds could be used "to purchase naloxone and the necessary materials to assemble overdose kits and to cover the costs associated with the dissemination of such kits." This was preceded by SAMHSA's distribution of the Opioid Overdose Toolkit, a series of documents targeted towards community members, first responders, patients, prescribers, and overdose survivors and family members. The Toolkit equips communities and local governments with material to develop policies and practices to help prevent opioid-related overdoses and deaths.

Federal agencies including the United States Office of the Attorney General, the Office of National Drug Control Policy, the National Association of State Alcohol and Drug Abuse Directors, SAMHSA, the Centers for Disease Control and Prevention, the National Institute of Drug Abuse, the World Health Organization and others have promoted naloxone as an opioid overdose prevention strategy.

IX. Recommendations

A. Pilot Expansion

From the early stages of implementation, DBHDS has received numerous inquiries from organizations around the Commonwealth seeking to be included in REVIVE! Interest has been greatest from the Winchester, Roanoke, and Hampton Roads areas. DBHDS has also received numerous inquiries from law enforcement officials, emergency medical technicians, and other public safety officials who have expressed interest in carrying naloxone as part of their official duties.

It is vital to note that as the Commonwealth continues to address the issue of diversion of prescription opioids, therefore reducing their availability, users will not simply quit using opioids. The majority of these users will likely switch to heroin which is cheaper and more readily available. In other words, the Commonwealth will still have a major opioid abuse problem. The only difference will be which opioid is being abused. In making this transition, the person will not know the purity of the heroin and it may exceed their tolerance level. Naloxone

can save the life of someone regardless of what kind of opioid they are using. Therefore, DBHDS recommends that the General Assembly consider discontinuing the pilot program and making REVIVE! a statewide effort, so that the benefits of the pilot, including nonpatient specific prescribing and civil immunity are available to everyone in the Commonwealth.

B. Criminal Immunity

While REVIVE! offers Good Samaritan protection guarding Lay Rescuers against civil lawsuits in the case of adverse consequences as the result of naloxone administration, it does not allow criminal immunity for Lay Rescuers from prosecution that may result from law enforcement responding to the 911 call that is a vital part of the naloxone administration protocol. In fact, studies suggest that individuals who witness an OOE are less likely to call 911 if criminal immunity is not available (Wakeman, Bowman, McKenzie, Jeronimo, & Rich, 2009). Even if a Lay Rescuer calls 911, they may not remain with the individual suffering the OOE due to fear of arrest or probation violation.

Calling 911 as part of a naloxone administration protocol is vital for three reasons. First, the individual may suffer adverse medical consequences (such as brain damage due to the lack of oxygen) from the OOE that may require medical attention and hospital admission,. Second, depending on which opioid the person used, the amount used, and the potency, the individual may relapse into an OOE. The effects of naloxone only last 30-45 minutes, and in some cases a single administration may not be sufficient to reverse an OOE. If the Lay Rescuer is not willing to stay with the individual long enough for emergency medical personnel arrive, the individual could fall back into an OOE and expire. Third, the Lay Rescuer can provide valuable information to the emergency medical professional, including what substances, opioids and otherwise, were being used, how long the individual may have been without oxygen, and more information that could inform the care the individual needs. Therefore, DBHDS recommends that the General Assembly consider adding criminal immunity against arrest for Lay Rescuers who call 911 as part of the naloxone administration protocol.

C. Expanded Funding

The success of REVIVE! to date has been made possible in part by other funds made available by DBHDS to augment the $10,000 provided by the General Assembly. Use of naloxone is a cost-effective way to save lives and minimize the physiological damage of opioid overdose. The General Assembly may want to consider appropriating additional funds to implement REVIVE! statewide, allowing DBHDS to distribute more of this life-saving medication to citizens of the Commonwealth, reducing the number of needless deaths caused every day by the epidemic of opioid abuse that is devastating the Commonwealth of Virginia.

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VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 8.01-225 and 54.1-3408 of the Code of Virginia, relating to naloxone; administration in cases of opiate overdose.

[H 1672]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 8.01-225 and 54.1-3408 of the Code of Virginia are amended and reenacted as follows:

§ 8.01-225. Persons rendering emergency care, obstetrical services exempt from liability.

A. Any person who:

1. In good faith, renders emergency care or assistance, without compensation, to any ill or injured person (i) at the scene of an accident, fire, or any life-threatening emergency; (ii) at a location for screening or stabilization of an emergency medical condition arising from an accident, fire, or any life-threatening emergency; or (iii) en route to any hospital, medical clinic or doctor's office, shall not be liable for any civil damages for acts or omissions resulting from the rendering of such care or assistance.

2. In the absence of gross negligence, renders emergency obstetrical care or assistance to a female in active labor who has not previously been cared for in connection with the pregnancy by such person or by another professionally associated with such person and whose medical records are not reasonably available to such person shall not be liable for any civil damages for acts or omissions resulting from the rendering of such emergency care or assistance. The immunity herein granted shall apply only to the emergency medical care provided.

3. In good faith and without compensation, including any emergency medical services technician certified by the Board of Health, administers epinephrine in an emergency to an individual shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment if such person has reason to believe that the individual receiving the injection is suffering or is about to suffer a life-threatening anaphylactic reaction.

4. Provides assistance upon request of any police agency, fire department, rescue or emergency squad, or any governmental agency in the event of an accident or other emergency involving the use, handling, transportation, transmission or storage of liquefied petroleum gas, liquefied natural gas, hazardous material or hazardous waste as defined in § 10.1-1400 or regulations of the Virginia Waste Management Board shall not be liable for any civil damages resulting from any act of commission or omission on his part in the course of his rendering such assistance in good faith.

5. Is an emergency medical care attendant or technician possessing a valid certificate issued by authority of the State Board of Health who in good faith renders emergency care or assistance whether in person or by telephone or other means of communication, without compensation, to any injured or ill person, whether at the scene of an accident, fire or any other place, or while transporting such injured or ill person to, from or between any hospital, medical facility, medical clinic, doctor's office or other similar or related medical facility, shall not be liable for any civil damages for acts or omissions resulting from the rendering of such emergency care, treatment or assistance, including but in no way limited to acts or omissions which involve violations of State Department of Health regulations or any other state regulations in the rendering of such emergency care or assistance.

6. In good faith and without compensation, renders or administers emergency cardiopulmonary resuscitation, cardiac defibrillation, including, but not limited to, the use of an automated external defibrillator, or other emergency life-sustaining or resuscitative treatments or procedures which have been approved by the State Board of Health to any sick or injured person, whether at the scene of a fire, an accident or any other place, or while transporting such person to or from any hospital, clinic, doctor's office or other medical facility, shall be deemed qualified to administer such emergency treatments and procedures and shall not be liable for acts or omissions resulting from the rendering of such emergency resuscitative treatments or procedures.

7. Operates an automated external defibrillator at the scene of an emergency, trains individuals to be operators of automated external defibrillators, or orders automated external defibrillators, shall be

immune from civil liability for any personal injury that results from any act or omission in the use of an automated external defibrillator in an emergency where the person performing the defibrillation acts as an ordinary, reasonably prudent person would have acted under the same or similar circumstances, unless such personal injury results from gross negligence or willful or wanton misconduct of the person rendering such emergency care.

8. Is a volunteer in good standing and certified to render emergency care by the National Ski Patrol System, Inc., who, in good faith and without compensation, renders emergency care or assistance to any injured or ill person, whether at the scene of a ski resort rescue, outdoor emergency rescue or any other place or while transporting such injured or ill person to a place accessible for transfer to any available emergency medical system unit, or any resort owner voluntarily providing a ski patroller employed by him to engage in rescue or recovery work at a resort not owned or operated by him, shall not be liable for any civil damages for acts or omissions resulting from the rendering of such emergency care, treatment or assistance, including but not limited to acts or omissions which involve violations of any state regulation or any standard of the National Ski Patrol System, Inc., in the rendering of such emergency care or assistance, unless such act or omission was the result of gross negligence or willful misconduct.

9. Is an employee of a school board, authorized by a prescriber and trained in the administration of insulin and glucagon, who, upon the written request of the parents as defined in § 22.1-1, assists with the administration of insulin or administers glucagon to a student diagnosed as having diabetes who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment if the insulin is administered according to the child's medication schedule or such employee has reason to believe that the individual receiving the glucagon is suffering or is about to suffer life-threatening hypoglycemia. Whenever any employee of a school board is covered by the immunity granted herein, the school board employing him shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such insulin or glucagon treatment.

10. Is a school nurse or an employee of a school board, authorized by a prescriber and trained in the administration of epinephrine, who provides, administers, or assists in the administration of epinephrine to a student believed in good faith to be having an anaphylactic reaction, or is the prescriber of the epinephrine, shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment.

11. In good faith and without compensation, administers naloxone in an emergency to an individual who is experiencing or is about to experience a life-threatening opiate overdose shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment if such administering person is a participant in a pilot program conducted by the Department of Behavioral Health and Developmental Services on the administration of naloxone for the purpose of counteracting the effects of opiate overdose.

B. Any licensed physician serving without compensation as the operational medical director for a licensed emergency medical services agency in this Commonwealth shall not be liable for any civil damages for any act or omission resulting from the rendering of emergency medical services in good faith by the personnel of such licensed agency unless such act or omission was the result of such physician's gross negligence or willful misconduct.

Any person serving without compensation as a dispatcher for any licensed public or nonprofit emergency services agency in this Commonwealth shall not be liable for any civil damages for any act or omission resulting from the rendering of emergency services in good faith by the personnel of such licensed agency unless such act or omission was the result of such dispatcher's gross negligence or willful misconduct.

Any individual, certified by the State Office of Emergency Medical Services as an emergency medical services instructor and pursuant to a written agreement with such office, who, in good faith and in the performance of his duties, provides instruction to persons for certification or recertification as a certified basic life support or advanced life support emergency medical services technician shall not be liable for any civil damages for acts or omissions on his part directly relating to his activities on behalf of such office unless such act or omission was the result of such emergency medical services instructor's gross negligence or willful misconduct.

Any licensed physician serving without compensation as a medical advisor to an E-911 system in this Commonwealth shall not be liable for any civil damages for any act or omission resulting from rendering medical advice in good faith to establish protocols to be used by the personnel of the E-911 service, as defined in § 58.1-1730, when answering emergency calls unless such act or omission was the result of such physician's gross negligence or willful misconduct.

Any licensed physician who directs the provision of emergency medical services, as authorized by the State Board of Health, through a communications device shall not be liable for any civil damages for any act or omission resulting from the rendering of such emergency medical services unless such act or omission was the result of such physician's gross negligence or willful misconduct.

Any licensed physician serving without compensation as a supervisor of an automated external defibrillator in this Commonwealth shall not be liable for any civil damages for any act or omission resulting from rendering medical advice in good faith to the owner of the automated external defibrillator relating to personnel training, local emergency medical services coordination, protocol approval, automated external defibrillator deployment strategies, and equipment maintenance plans and records unless such act or omission was the result of such physician's gross negligence or willful misconduct.

C. Any communications services provider, as defined in § 58.1-647, including mobile service, and any provider of Voice-over-Internet Protocol service, in this Commonwealth shall not be liable for any civil damages for any act or omission resulting from rendering such service with or without charge related to emergency calls unless such act or omission was the result of such service provider's gross negligence or willful misconduct.

Any volunteer engaging in rescue or recovery work at a mine or any mine operator voluntarily providing personnel to engage in rescue or recovery work at a mine not owned or operated by such operator, shall not be liable for civil damages for acts or omissions resulting from the rendering of such rescue or recovery work in good faith unless such act or omission was the result of gross negligence or willful misconduct. For purposes of this subsection, the term "Voice-over-Internet Protocol service" or "VoIP service" means any Internet protocol-enabled services utilizing a broadband connection, actually originating or terminating in Internet Protocol from either or both ends of a channel of communication offering real time, multidirectional voice functionality, including, but not limited to, services similar to traditional telephone service.

D. Nothing contained in this section shall be construed to provide immunity from liability arising out of the operation of a motor vehicle.

E. [Expired.]

F. For the purposes of this section, the term "compensation" shall not be construed to include (i) the salaries of police, fire or other public officials or personnel who render such emergency assistance, (ii) the salaries or wages of employees of a coal producer engaging in emergency medical technician service or first aid service pursuant to the provisions of § 45.1-161.38, 45.1-161.101, 45.1-161.199*,* or 45.1-161.263, (iii) complimentary lift tickets, food, lodging or other gifts provided as a gratuity to volunteer members of the National Ski Patrol System, Inc., by any resort, group or agency, (iv) the salary of any person who (a) owns an automated external defibrillator for the use at the scene of an emergency, (b) trains individuals, in courses approved by the Board of Health, to operate automated external defibrillators at the scene of emergencies, (c) orders automated external defibrillators for use at the scene of emergencies, or (d) operates an automated external defibrillator at the scene of an emergency, or (v) expenses reimbursed to any person providing care or assistance pursuant to this section.

For the purposes of this section, an emergency medical care attendant or technician shall be deemed to include a person licensed or certified as such or its equivalent by any other state when he is performing services which he is licensed or certified to perform by such other state in caring for a patient in transit in this Commonwealth, which care originated in such other state.

Further, the public shall be urged to receive training on how to use cardiopulmonary resuscitation (CPR) and an automated external defibrillator (AED) in order to acquire the skills and confidence to respond to emergencies using both CPR and an AED.

§ 54.1-3408. Professional use by practitioners.

A. A practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine or a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 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 them to be administered by a nurse, physician assistant or intern under his direction and supervision, or he may prescribe and cause drugs and devices to be administered 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 by other persons who have been trained properly to administer drugs and who administer drugs only under

the control and supervision of the prescriber or a pharmacist or a prescriber may cause drugs and devices to be administered to patients by emergency medical services personnel who have been certified and authorized to administer such drugs and devices pursuant to Board of Health regulations governing emergency medical services and who are acting within the scope of such certification. A prescriber may authorize a licensed respiratory care practitioner as defined in § 54.1-2954 to administer 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 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, a school nurse, or any school board employee who is authorized and trained in the administration of epinephrine, may possess and administer epinephrine.

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, or to possess and administer epinephrine for use in emergency cases of anaphylactic shock.

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 immediate and direct 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 a school board 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.

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 immediate and direct 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, certified emergency medical technician-intermediate, or emergency medical technician-paramedic under the direction of an operational medical director when the prescriber is not physically present. Emergency medical services personnel 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, to possess and administer topical oral fluorides, topical oral anesthetics, topical and directly applied antimicrobial agents for treatment of periodontal pocket lesions, as well as 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.

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 a child in a child day program as defined in § 63.2-100 and regulated by the State Board of Social Services or a local government pursuant to § 15.2-914, provided such person (i) has satisfactorily completed a training program for this purpose approved by the Board of Nursing and taught by a registered nurse, licensed practical nurse, doctor of medicine or osteopathic medicine, or pharmacist; (ii) has obtained written authorization from a parent or guardian; (iii) 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 (iv) administers only those drugs that were dispensed from a pharmacy and maintained in the original, labeled container that would normally be administered by a parent or guardian to the child.

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 or 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; (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 (§ 54.1-2729.1 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 § 32.1-126.4.

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 nurse or a dental hygienist may possess and administer topical fluoride varnish to the teeth of children aged six months to three years pursuant to an oral or written order or a standing protocol issued by a doctor of medicine, osteopathic medicine, or dentistry that conforms to standards adopted by the Virginia Department of Health.

W. A prescriber, acting in accordance with guidelines developed pursuant to § 32.1-46.02, 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, certified emergency medical technician-intermediate, or emergency medical technician-paramedic when the prescriber is not physically present.

X. Notwithstanding the provisions of § 54.1-3303 and only for the purpose of participation in pilot programs conducted by the Department of Behavioral Health and Developmental Services, a person may obtain a prescription for a family member or a friend and may possess and administer naloxone for the purpose of counteracting the effects of opiate overdose.

2. That the Department of Behavioral Health and Developmental Services, in cooperation with the Department of Health, the Department of Health Professions, law-enforcement agencies, substance abuse recovery support organizations, and other stakeholders, shall conduct pilot programs on the administration of naloxone to counteract the effects of opiate overdose. The Department of Behavioral Health and Developmental Services shall evaluate, implement, and report results of such pilot programs to the General Assembly by December 1, 2014.