Report to
The Vermont Legislature

Report Evaluating the Statewide Opioid Antagonist Pilot Program (From Inception to November 2015)

In Accordance with Act 75, Section 18 (d),
An Act Relating to Strengthening Vermont's Response to Opioid Addiction and Methamphetamine Abuse

Submitted to: **House Committees on Human Services and on Health Care; Senate Committee on Health and Welfare; and House and Senate Committees on Judiciary**

Submitted by: **Harry Chen, MD Commissioner of Health**

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Report date: **January 7, 2016**

VERMONT
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Department of Health

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Executive Summary

In accordance with Act 75 of 2013, Section 18 (d), (Appendix A), the Vermont Department of Health (VDH) evaluated the statewide opioid antagonist pilot program by reporting on findings that pertain to the cost and effectiveness of naloxone, and by making recommendations as to whether the program should be continued after June 30, 2016.

During the pilot project, overdose rescue kits containing naloxone have been distributed to participating sites around Vermont. The types of sites currently involved include: regional medication-assisted treatment hubs, syringe exchange programs, and select recovery centers. Individuals receive overdose prevention and overdose response training designed and approved by VDH at the time of kit distribution. Beginning with two sites in December of 2013, the pilot had expanded to ten sites by July of 2015 9 (Appendix B).

The items required for operation of the pilot include individual doses of naloxone, each paired with a separately-packaged nasal atomizer device, and the instructional brochure that accompanies each kit. The cost per dose at the outset of the pilot was approximately $15.00. This cost had risen to $30.00 per dose by November of 2015 due primarily to price increases for the naloxone syringe. Vermont has entered into a price stabilization agreement with the naloxone manufacturer, an agreement that is expected to provide stable pricing for at least the next year.

The Health Department has provided almost 7,000 doses of naloxone to partner organizations through September 30, 2015. Pilot Sites have dispensed over 4,182 doses to new first-time clients and 2,807 doses of naloxone in the form of a refill to returning clients. The majority of the clients requested refills because they reported having used some/all of their kit doses in response to a perceived overdose on 401 occasions as of Oct. 2015.

The Department recommends continuation of the program utilizing the existing model of dispensing via the ten sites at community-based substance abuse organizations. Perpetuating the distribution of naloxone should be considered an essential harm reduction strategy in alignment with other efforts that aim to alleviate the burden of secondary disease and consequence associated with the misuse of opiates/opioids. As a harm reduction strategy, the use of overdose rescue kits containing naloxone by trained "responders" aims to have an impact on the accidental death rates associated with overdoses. The use of naloxone, like only a few other emergency interventions, hinges on it being available in the right place at the right time to reverse an overdose. Based on the over 400 known incidents of naloxone use during the pilot, the data suggest that the pilot succeeded in matching the need with the resource in the right place at the right time.

Report Evaluating the Statewide Opioid Antagonist Pilot Program (From Inception to November 2015)

January 7, 2016

Introduction

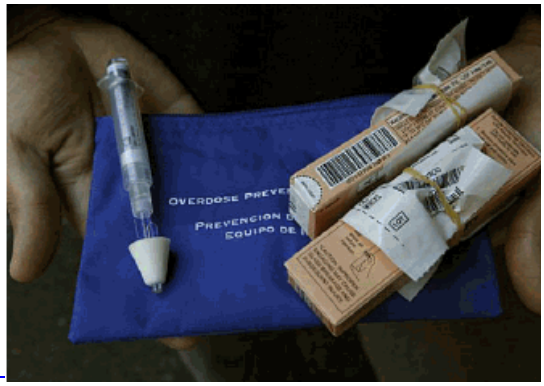
In accordance with Act 75 of 2013, Section 18 (d), (Appendix A), *An Act Relating to Strengthening Vermont's Response to Opioid Addiction and Methamphetamine Abuse,* the Vermont Department of Health (VDH) submits the following report which evaluates the statewide opioid antagonist pilot program by:

- reporting findings that pertain to the cost;
- reporting findings that pertain to the effectiveness; and
- making recommendations as to whether the program should be continued after June 30, 2016.

This report utilizes information and data gathered by the Vermont Department of Health to address this legislative request. The time period covered by this report is December 1, 2013 through October 31, 2015. Limitations associated with the data used include the voluntary self-reporting and accuracy considerations of participating citizens and the diligence of partner community-based organization in collecting/reporting data.

Background

Opioids and opiates are a highly addictive class of drugs that include pain relievers such as oxycodone, codeine, fentanyl and morphine, and street drugs such as heroin, as well as methadone used to treat opioid addiction. Deadly heroin overdoses have been increasing in Vermont.[1]



[1] http://healthvermont.gov/research/documents/databrief_drug_

To potentially save lives, VDH, through community-based partners, has been distributing overdose rescue kits with intranasal naloxone (sometimes referred to by its trade name of Narcan®), an opioid antagonist medication that can reverse an opioid overdose. Each overdose rescue kit contains two doses of naloxone with two atomizer devices and an instructional brochure.

Intranasal Naloxone (Narcan®)

In an overdose, opioids can slow breathing to the point of death. Naloxone, which can be administered in several ways, is safe and effective when sprayed into the nose of someone who has overdosed by blocking the effects of opioids and restoring normal breathing. VDH elected to use the intranasal method of administration based on considerations of rescuer safety and the need to minimize risk of exposure to potentially infectious needles. Naloxone should be administered as quickly as possible after an overdose, which necessitates that the naloxone be available in the right time, at the right place, and in the hands of someone trained to intervene. Naloxone is safe, easy to administer, and has no potential for abuse.

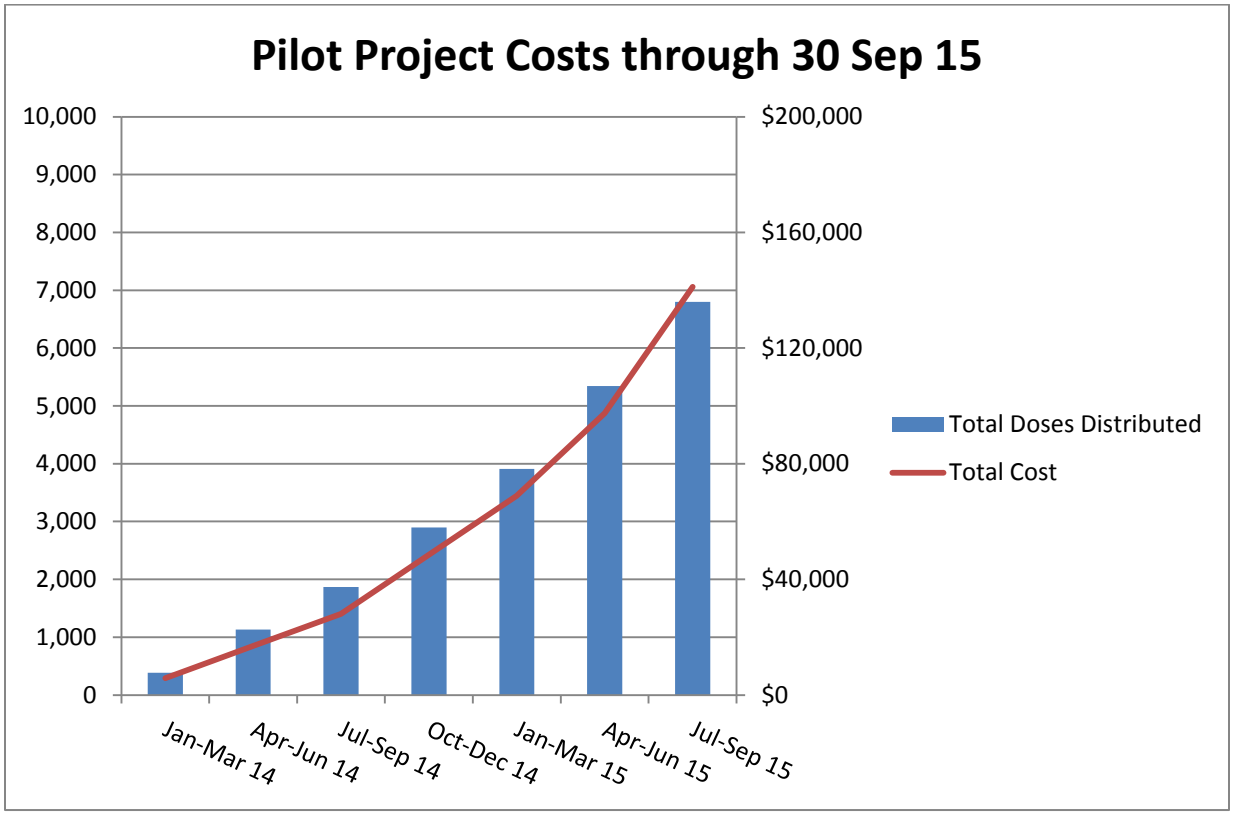
Through the pilot project, overdose rescue kits containing naloxone are distributed at participating sites around Vermont. The types of sites currently involved include: regional medication-assisted treatment hubs, syringe exchange programs, and select recovery centers. Individuals receive overdose prevention and overdose response training designed and approved by VDH at the time of kit distribution. Beginning with two sites in December of 2013, the pilot had expanded to ten sites by July of 2015. (Appendix B).

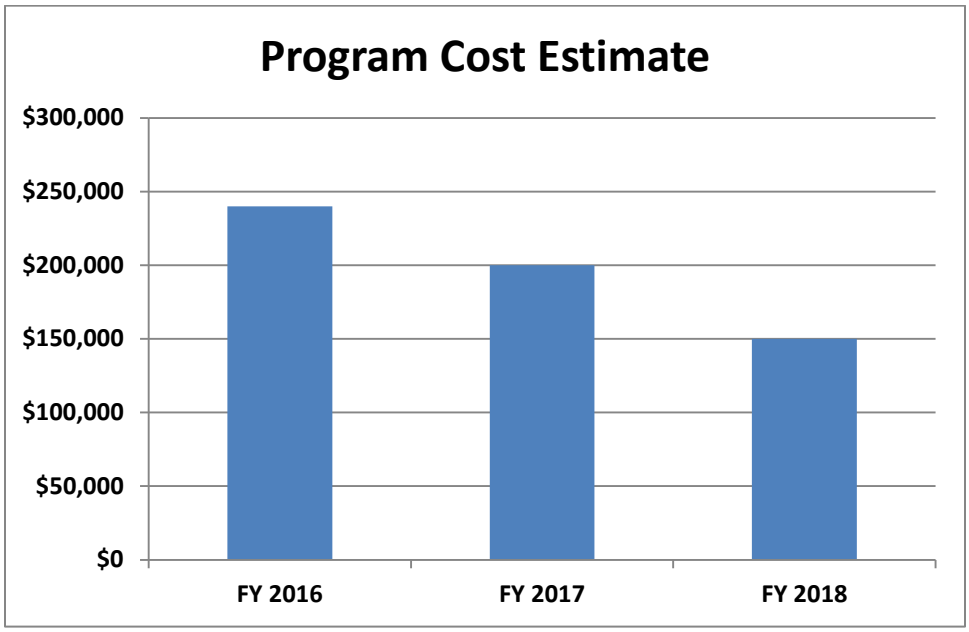
Findings Pertaining to Cost

The items required for operation of the pilot include an individual doses of naloxone, paired with a separately-packaged nasal atomizer device, and the instructional brochure that accompanies each kit.

The cost per dose at the outset of the pilot was approximately $15.00. This cost had risen to $30.00 per dose by November of 2015, due primarily to price increases for the naloxone syringe. The state has entered into a price stabilization agreement with the naloxone manufacturer to provide stable pricing for at least the next year.

The Health Department has provided almost 7,000 Naloxone doses to partner organizations through September 30, 2015. The graph below illustrates the rate of growth in program activity and cost.





The primary cost variable for program continuation is the number of doses to be distributed annually. The Department's cost estimate is based on these assumptions:

1. The program's ten sites effectively provide statewide coverage and additional sites will not contribute significantly to total demand;
2. The program will stabilize at about 6,000 doses in circulation and a 50% annual replacement rate;
3. Cost per dose is estimated to increase at a rate of 10% per fiscal year; and
4. The Department's staffing costs for program administration are estimated at 15% of total operating expense.

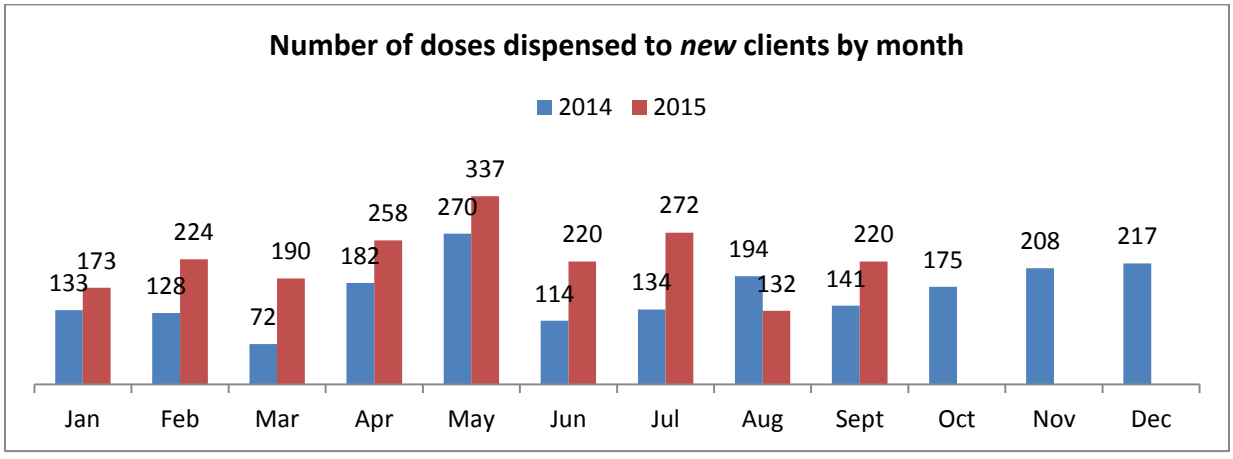
Findings Pertaining to Effectiveness

Effectiveness of the pilot was evaluated in part by examining the distribution of overdose rescue kits by partner community-based organizations. Data are gathered at the time of initial kit distribution and whenever an existing client seeks a refill of a kit. While a unique identifier is used to associate initial and refill visits, clients remain anonymous.

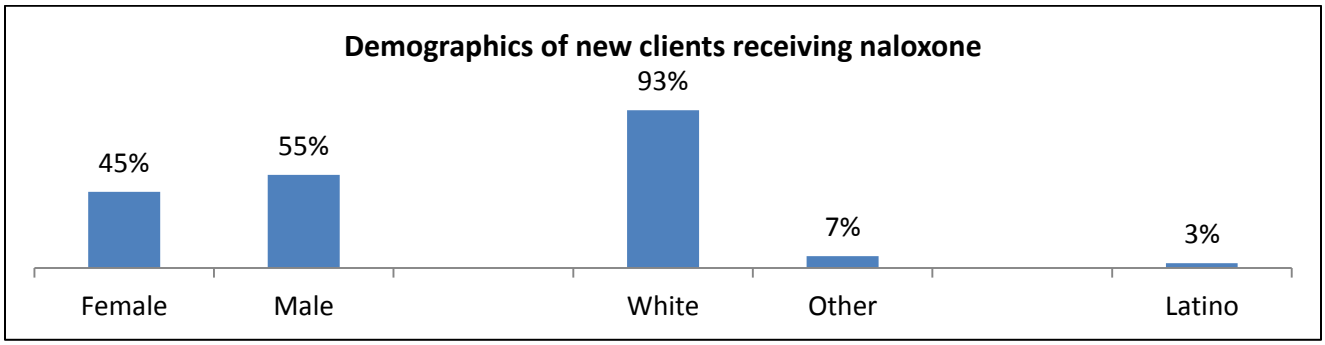
Naloxone was first dispensed by pilot sites in December of 2013. From December 2013 through September 2015 the following have been dispensed by pilot sites:

	Doses of naloxone	**Clients**
New Clients	**4,182**	**1674**
Returning Clients	**2,807**	**629**

A breakdown of doses dispensed to new clients by month (excluding December 2013) is included below. During the course of the pilot, additional sites were being gradually brought online to reach the current total of ten sites.



Client demographics for new clients, December 2013 through September 2015:

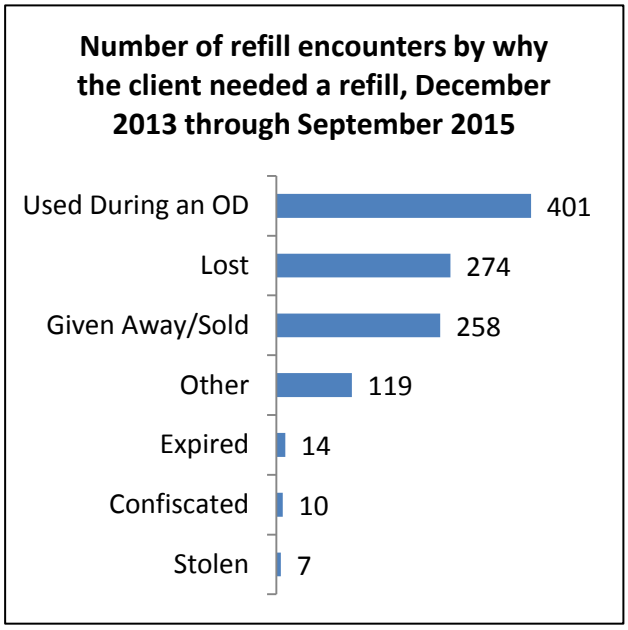


Health and social Indicators for new clients, December 2013 through September 2015

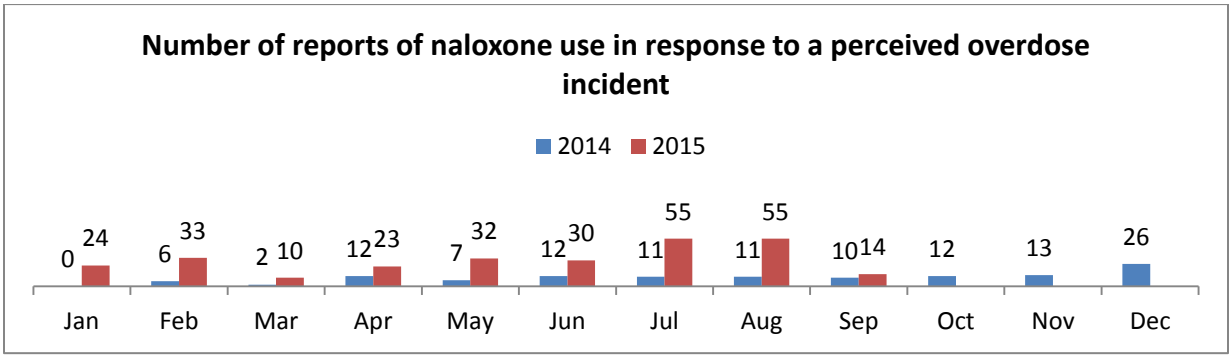
Of the new clients who received Naloxone, 13% were non-drug-users, 43% were active users, 44% were users in treatment or recovery. Overall, 36% of these individuals had personally experienced an overdose and 63% had witnessed an overdose. Seventeen percent reported having been given Naloxone previously by medical personnel, and 3% reported being given Naloxone by a non-medical person (bystander). When asked if they would like to be referred to treatment, 29% wanted a referral, 8% were on a waiting list for treatment, and 37% were currently in treatment.

Information on naloxone dispensed to returning clients

Pilot Sites have dispensed over 2,807 doses of naloxone in the form of a refill to returning clients. The majority of the clients requested refills because they reported having used some/all of their kit doses in response to a perceived overdose. Data are based on information reported by the individual seeking a refill, not by medical personnel, and are not a census of naloxone used in the field. Use of naloxone by clients is likely to be under-reported based on the mechanism used to gather data from only those actively seeking a refill from a pilot site.



The circumstances surrounding the use of a kit/dose of naloxone are ultimately unknowable, and the self-reported data collected at the pilot sites therefore has limitations. The following figure presents data on reports of use of kits in response to perceived overdose incidents by month/year and associated characteristics of these reported incidents:



Characteristics reported by clients reporting using naloxone in an overdose incident, December 2013 through September 2015	
Measure	**% of incidents**
Drugs involved	
Heroin	**94%**
Benzodiazepines	3%
Alcohol	3%
Cocaine	2%
Other	2%
Gender	
Female	35%
Male	61%
Who naloxone was used for	
Friend	64%
Client (person requesting refill)	13%
Stranger	11%
Partner	6%
Family	5%
How many doses of naloxone used	
One	45%
Two	31%
Three+	8%
Woke up in less than five minutes	68%
EMS	
Called 911	28%

Feedback on Pilot Program from Participating Sites

(gathered via anonymous survey of site leadership, November 2015):

"I think the most valuable part of the education is the message that they matter. Clients know we care about their lives and their safety and let us know they recognize it."

"We have reports that people have successfully reversed overdoses without training. For this reason, I think the primary focus should be on getting kits with the instructional brochure in the hands of those who need them with or without one on one client education. Where possible, client education is very valuable because it helps people gain information, get questions and concerns answered, and start conversations that permit us to also offer referrals to drug treatment and other services they need. It also gives us a chance to talk about the Good Samaritan law, and other important information not included in the brochure included in the kit. Many people have accessed drug treatment and other services because the conversation about overdose created an opportunity to assess needs and offer other services"

"We have limited staff, stretched too thin. While being a Pilot Site is a privilege, high priority and great responsibility (in my opinion), we are stretched thin in just maintaining daily duties, that there's no free to time to get creative and raise more awareness about the Pilot Program."

In response to "***What client feedback about the Naloxone Pilot have you received***?"

Responses	
They felt the educational piece was very informative and easy to understand. They leave feeling confident that they could save a life if needed.	They are very appreciative that we care about them and that it is free and easy to obtain.
Clients have stated that they feel safer knowing how to user naloxone.	Clients are extremely grateful.
People often say that they are very grateful to have access to naloxone, that they find it empowering, and that it makes them feel like the community cares about them and the struggles they face.	Clients were relieved when they found out that they had access to naloxone anonymously.
The ease of training and administering it.	Very good reviews, thankful for the program.

Recommendations on Continuation

Recommendation 1. Continue the program utilizing existing model of dispensing via the ten sites at community-based substance abuse organizations:

1. Statewide, opioid addiction and misuse continues to be a significant issue. As of late October 2015, waitlists from across the state for medication-assistant therapy totaled 462 citizens. Those represent the willing portion of users that sought help; presumably many others remain in the shadows and are at real risk of dying from a fatal overdose.
2. Continuing the distribution of naloxone is considered an essential harm reduction strategy in alignment with other efforts that aim to alleviate the burden of secondary disease and consequences associated with the misuse of opiates/opioids. As a harm reduction strategy, the use of overdose rescue kits containing naloxone by trained "responders" aims to have an impact on the accidental death rates associated with overdoses.
3. The program should examine innovative strategies to increase calls to E911 and use those opportunities to connect people who overdose to treatment.

Recommendation 2. Expand related program enhancements:

1. Pursue innovative opportunities for medical community engagement, including more widespread sharing of information about the overdose prevention program in Vermont and safe/co-prescribing of naloxone. [2] Continue to assist Emergency Departments (ED) with refining standardized guidance/protocols to ensure "near-miss" overdose survivors are provided referrals to treatment and also explore options for incorporating mental health and/or volunteer recovery coaches in the ED-based process after a near-fatal event.
2. Reinforce the collaboration and readiness enhancements in place among law enforcement and emergency services agencies that carry and use naloxone to ensure the greatest chances of a citizen surviving an overdose and then hopefully entering treatment/recovery.
3. To address funding sustainability challenges for the long term, leverage reimbursement mechanisms/other payers for the distribution of naloxone via pharmacies and other

[2] Risk assessments of patients using certain opioids may indicate benefit to providing overdose prevention education and co-prescription of naloxone.

pathways that incorporate prescribers, including possible use of standing orders or collaborative practice agreements as necessary.

Appendix A: Statutory Reference for Pilot

No. 75. An act relating to strengthening Vermont's response to opioid addiction and methamphetamine abuse.

Sec. 18. STATEWIDE OPIOID ANTAGONIST PILOT PROGRAM

(a) The Department of Health shall develop and administer a statewide pilot program for the purpose of distributing opioid antagonists to:

1) individuals at risk of an opioid overdose;

2) the family and friends of an individual at risk of experiencing an opioid overdose; and

(3) others who may be in a position to assist individuals experiencing an opioid overdose

(b) In developing and implementing the pilot program, the Department shall collaborate with community-based substance abuse organizations that have experience delivering opioid-related prevention and treatment services as determined by the Commissioner.

(c) The pilot program shall be in effect from July 1, 2013 through June 30, 2016. During the term of the pilot program, the Department shall purchase, provide for the distribution of, and monitor the use of opioid antagonists distributed in accordance with this section.

(d) On or before January 15, 2016, the Department of Health shall submit a report to the House Committees on Human Services, on Health Care, and on Judiciary and to the Senate Committees on Health and Welfare and on Judiciary evaluating the statewide opioid antagonist pilot program. The report shall include findings that pertain to the cost and effectiveness of the program and recommendations as to whether the program should be continued after June 30, 2016.

Appendix B: Sites Participating in Kit Distribution

BAART Behavioral Health Services 475 Union St. Newport, VT 05855 802-334-0110	**Central Vermont Addiction Medicine** 300 Granger Rd. Berlin, VT 05602 802-223-2003
Habit Opco - Brattleboro 16 Town Crier Dr. Brattleboro, VT 05301 802-258-4623	**Howard Center Safe Recovery Program** 45 Clark St. Burlington, VT 05401 802-488-6067
HIV/HCV Resource Center- Syringe Exchange Program 70 North Main St. White River Junction, VT 05001 802-295-1868 (M & Th 2:30–4:30)	**Turning Point of Addison County** 228 Maple Street (in the Marbleworks) Middlebury, VT 05753 802-388-4249
Turning Point of Bennington County 465 Main Street, P.O. Box 454 Bennington, VT 05201 802-442-9700	**Turning Point of Franklin County** 182 Lake Street St. Albans, VT 05478 802-782-8454
Vermont CARES 1091 Hospital Dr. St. Johnsbury, VT 05819 802-748-9061	**West Ridge Center for Addiction Recovery** 1 Scale Ave., Building 10 Rutland, VT 05701 802-776-5800