
**Report to
The Vermont Legislature**

Increasing Access to Opioid Addiction Treatment

**In Accordance with Act 75, 2013, Section 14b
*An Act Relating to Strengthening Vermont's Response to
Opioid Addiction and Methamphetamine Abuse***

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

Submitted by: **Harry Chen, M.D.
Commissioner of Health**

Prepared by: **Barbara Cimaglio
Deputy Commissioner**

Report Date: **April 10, 2014***

*This report, originally submitted to the Legislature on January 15, 2014, had an inaccurate statement on page 4 referring to the increased incidence of heroin use in Vermont. The report should have stated that the number of people receiving treatment in the ADAP system of care for heroin addiction increased by 35% from 2011 to 2012. This report was corrected and resubmitted April 10, 2014. The Vermont Department of Health regrets any confusion this may have created.



108 Cherry Street
PO Box 70
Burlington, VT 05402
healthvermont.gov

Index

Introduction.....	3
Vermont’s Challenge.....	3
Vermont’s System of Opioid Addiction Services.....	4
Options for Expanding Access to Treatment	6
Recommendations and Conclusions.....	10
Appendix 1 - Physician Office as “Medication Unit”.....	11
Appendix II - Pharmacy as “Medication Unit”.....	12
Endnotes.....	13

Executive Summary

Increasing Access to Opioid Addiction Treatment Act 75, Sec. 14b April 10, 2014

Section 14b of Act 75, *an act relating to strengthening Vermont's response to opioid addiction and methamphetamine abuse*, calls for the Vermont Department of Health (VDH) to study how Vermont can increase access to opioid treatment. Specifically, the Act directs an exploration of how to increase access by establishing a program whereby state-licensed physicians who are affiliated with a licensed opioid maintenance treatment program may provide methadone or Suboxone (buprenorphine) to opioid-addicted people.

The report describes Vermont's newly implemented Care Alliance for Opioid Addiction, sometimes referred to as the Hub and Spoke system, a unique partnership between VDH's Division of Alcohol and Drug Abuse Programs (ADAP) and the Department of Vermont Health Access's Blueprint for Health. It explains the structure and function of the system, the clinical support services that are an inherent component of treatment and the different federal laws and regulations that apply to the administration of methadone and Suboxone.

The intent of the report is to improve access to opioid addiction treatment for people who are geographically distanced from methadone treatment hubs. The options for increasing methadone dosing sites in local physicians' offices or pharmacies are discussed as are the federal regulatory requirements associated with each. In spite of the advantages of increasing access to addiction treatment, the regulatory hurdles would most likely make pursuit of these options impractical at this time.

The report concludes that because the Alliance system is new, it is not possible to quantify any regional unmet need. Until the system has some operational history, it will not be possible to determine if the system's capacity is adequate to meet the needs of Vermonters. The report recommends that no efforts to pursue service expansion should be pursued at this time.

No new legislation is recommended

Increasing Access to Opioid Addiction Treatment

Act 75, Sec. 14b

April 10, 2014

Introduction

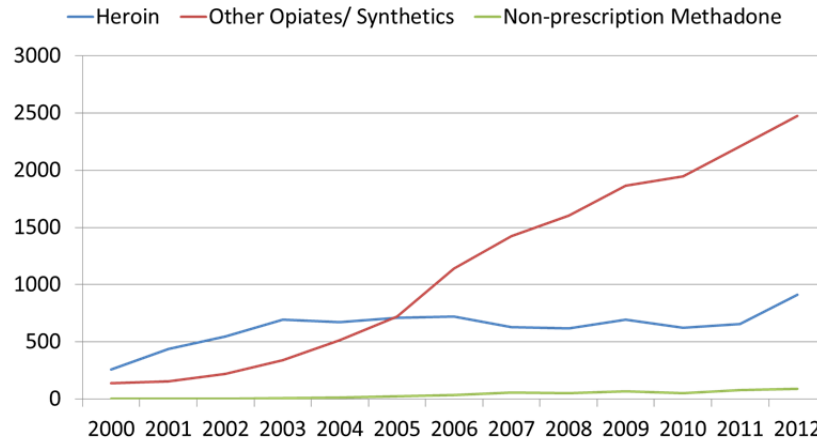
In 2013, the Vermont General Assembly passed Act 75, *an act relating to strengthening Vermont's response to opioid addiction and methamphetamine abuse*. The intent of the Act is to provide a comprehensive approach to combatting opioid addiction and methamphetamine abuse in Vermont through strategies that address prevention, treatment, and recovery. Section 14b of the Act addresses access to treatment and requires the Vermont Department of Health (VDH) to study how Vermont can increase access to opioid treatment by establishing a program whereby state-licensed physicians who are affiliated with a licensed opioid maintenance treatment program may provide methadone or Suboxone to opioid-addicted people. In Vermont's current treatment system, methadone cannot be dispensed by community physicians; methadone can only be dispensed at Hubs, discussed below, formerly known as methadone clinics. The issue to be studied would enable licensed physicians to prescribe methadone outside of a Hub under strict federal regulations. This report summarizes the Department's research on this issue and presents recommendations for future actions. As discussed in the report, VDH does not recommend any legislative or rulemaking at this time.

Vermont's Challenge

Prescription and illegal opioid drug abuse is a major public health problem in Vermont. In 2011, Vermont had the second highest per capita rate of all states for admissions to treatment for prescription opiates, with only Maine being higherⁱ. The majority (57%) of these admissions were young people 20 to 29 years old.ⁱⁱ In 2006, other opiates, including oxycontin and other prescription opioids, surpassed heroin as the primary source of opioid addiction for people receiving treatment at programs funded by the Division of Alcohol and Drug Abuse Programs (ADAP) at VDH. Furthermore, the number of people seeking and in treatment for addiction to other opiates has continued to increase each year (Figure I.). Between 2011 and 2012, the

number of people receiving treatment in the ADAP system of care for heroin addiction increased by 35%. The challenge for Vermont is to develop a service system that has the capacity to respond to opioid dependence and addiction.

Figure 1: Treatment for Opioid Use by State Fiscal Year (Vermont)



Vermont’s System of Opioid Addiction Services

A December 15, 2013 legislative report jointly written and submitted by VDH and the Department of Vermont Health Access (DVHA) reviews the history of opioid treatment in Vermont and discusses evolution of the current system of treatment including outpatient and residential services, and a new initiative known as the Care Alliance for Opioid Addiction (sometimes referred to as the Hub and Spoke system). That report, titled *Opioid Addiction Treatment Programs*, discusses the evolution of the newly implemented system of opioid dependence treatment and remaining policy and operational issues that need to be resolved in order for the system to respond to the demand for treatment.¹ The focus of this report is to study the feasibility and merits of expanding the system to improve statewide access to methadone treatment.

¹ Available at Vermont Legislative Council’s website. at <http://www.leg.state.vt.us/reports/2013ExternalReports/295237.pdf>

Implementation of the Care Alliance

The implementation of the Care Alliance initiative began in 2013 as a unique partnership between ADAP and the DVHA/Blueprint for Health. It is designed to expand the capacity of both the methadone treatment programs and office-based treatment services for buprenorphine by creating a coordinated, systemic response to the complex issues of opiate and other addictions in Vermont. Integral to this system is the delivery of Medication Assisted Therapy (MAT). The definitions of MAT and other key components of the system follow:

Medication Assisted Therapy (MAT) is the use of the addiction treatment medications methadone and buprenorphine in combination with counseling and behavioral therapies, to provide a whole patient approach to the treatment of opioid addiction. MAT in Vermont is delivered through an integrated treatment model, known as the Hub and Spoke. It relies on the strengths of the specialty methadone addiction treatment clinics (Hubs), the physicians who prescribe buprenorphine in office-based settings (Spokes), and the local Blueprint Community Health Teams and medical home infrastructure.

A HUB is a regional Opioid Treatment Program (OTP) responsible for coordinating care and support services for patients who have complex addictions and co-occurring substance abuse and mental health conditions. Vermont now has five regional Hubs and seven Hub dispensing sites. Patients who need methadone must be treated in a Hub due to federal regulations. Hubs dispense methadone under carefully controlled, observed and regulated conditions. Patients who need buprenorphine, on the other hand, may be treated at a Hub or may be treated in an office based practice, depending on their clinical profile and addiction history. Their buprenorphine can either be dispensed or prescribed.

Vermont's five regional Hubs replace the state's former methadone clinics. Hubs serve as the regional consultants and subject matter experts on opioid dependence and treatment, and provide consultation and support to the office-based physicians (Spokes), essentially linking the two previously separate systems of care.

A Spoke is a team of health care professionals providing ongoing care for patients receiving buprenorphine in in Office Based Opioid Treatment Programs (OBOT). Spokes

do not dispense methadone. The Spoke system provides buprenorphine MAT to patients who are less clinically complex than the patients who must receive buprenorphine in the Hubs. A team of collaborating health and addictions professionals monitor adherence to treatment, coordinate access to recovery supports, and provide counseling, contingency management, and case management services to individuals receiving treatment.

Options for Expanding Access to Treatment

Because of the health, safety, economic and social costs of opioid addiction, it is essential that people with opioid dependence have access to appropriate treatment. In spite of the implementation of the Hub and Spoke system, there are areas of the state where access to Hubs is difficult. For example, even with the opening of the West Ridge Addiction Treatment Center in Rutland, Bennington will continue to be one hour away from its closest Hub. This creates access challenges for people who live in the Bennington area and for whom methadone is the preferred MAT. Act 75 Section 14b requires an evaluation of the feasibility of having some licensed physicians dispense methadone through a mechanism the federal government calls *Medication Units*. Throughout this report, the term *Hublet* will be used to refer to what the federal government calls Medication Units.

Hubs, known by the federal government as Opioid Treatment Programs (OTP's), are highly regulated by the federal Drug Enforcement Agency (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA). They must also be approved by the State Opioid Treatment Authority (SOTA), or ADAP in Vermont, and be accredited by a national accreditation body such as The Joint Commission, or Commission on Accreditation of Rehabilitation Facilities (CARF) or the Council on Accreditation. Treatment requirements are prescribed by federal regulations, 42 CFR part 8ⁱⁱⁱ, and state rules^{iv}. Medications must be dispensed in a highly controlled manner with any decrease in treatment structure determined by factors including behavioral stability, treatment engagement/compliance and response, and required time in treatment. The storage, security, safe handling and record keeping requirements are highly regulated and reviewed by the DEA to ensure compliance with their requirements. Opioid Treatment Programs (OTP's) require verification of a valid DEA number prior to

ordering stock medications, as well as approval by the SOTA and SAMHSA prior to dispensing any opioid medications.

MAT medications through OTP's are not provided by written prescriptions. Rather, the medications are dispensed under physician orders within a clinic setting, similar to a day hospital type setting. Because the medication is dispensed rather than prescribed, OTP's are not subject to the same patient limits that office-based physicians who prescribe buprenorphine are subject to under the federal law, DATA 2000.

One option for Vermont to increase access to methadone treatment for people who don't live near Hubs would be to create satellite dosing sites called Hublets. Federal law provides two options for establishing Hublets, but there are many federal requirements for each option. The options are as follows:

Option 1 - Physician Office as Hublet

One option would be for the medication to be a state-licensed physician's office. There are two models for implementing the physician office option:

1. The physician office receives the medication daily but does not store any medications on site. The medications are delivered daily to the medication unit and are dispensed at the medication unit the same day. Any unused medications are returned to the Hub and accounted for on the same day.
2. The physician office receives the medication from the Hub and stores it on site for daily dispensing. The medications are accounted for at the physician office and stored according to DEA regulations.

Option 2 – Pharmacy as Hublet

Another option would be the use of a state-licensed pharmacy as the medication unit. The same models discussed above could be used with either daily transport of the medication from the Hub to the pharmacy, or storage of the medication at the pharmacy.

In either of the above two options, a Hublet can only provide two services, dosing and toxicology testing (urine screens). All other psychosocial support services ancillary to the provision of MAT must be provided by the Hub. Appendices I and II provide graphic presentations of the operations of these two dispensing options.

Regulatory Challenges for the Development of Hublets

In spite of the potential for improving access to methadone treatment by creating Hublets, there are federal regulatory and operational challenges that may make pursuit of this strategy impractical. They are as follows:

1. **Limits on Hub Services** Federal rules regulating medication units limit the services they can provide to dispensing medication and conducting urine screening. Other ancillary and clinically essential support and counseling services must be provided by a Hub. Since these ancillary services are a requirement for a Hub, the individual receiving medication from a Hublet would need to travel to a Hub for ancillary services. As a result, the convenience of a local Hublet for dispensing medication is offset by the required travel to a Hub for ancillary services. This fact renders the Hublet option an imperfect strategy for improving access to addiction treatment services.
2. **Transport and Storage of Medication** Federal regulations require that all medications must be purchased by and initially delivered to an OTP (Hub). The federal requirement for daily transport of medication to a Hublet and back to a Hub creates costly operational and logistical disincentives to implement this treatment model. Transport security arrangements in the form of a Chain of Custody agreement would need to be formalized to implement this model. Physicians who would choose the option of storing the medication on site would need to comply with federal DEA requirements for safety, storage and dispensing of Schedule II and III narcotics. And, unlike pharmacies, physician offices would need to make environmental modifications to meet federal storage and safety specifications. The costs associated with this would most likely be prohibitive.

3. **Provider liability and costs** Perhaps the most significant barrier to the development of Hublets would be the hesitancy of physicians and pharmacies to assume the responsibilities, costs and risks of doing so. Unlike in the Office Based Opioid Treatment (OBOT) model for prescribing buprenorphine where a physician conducts an office visit and writes a prescription, a Hublet would require the physician office to dispense medications and witness dosing. Other burdensome requirements Hublets would face include:
- a. As a dispensing site, the need to dispense during 7 days a week;
 - b. The need to coordinate dispensing and assume liability for actions on their premises without authority and responsibility for the individual's care;
 - c. The need to perform toxicology screening (urine screening) in compliance with all applicable DEA laws and regulations.
 - d. The costs of additional personnel, insurance and environmental modifications to ensure safe and secure storage of medications.

Potential Benefits to the Development of “Medication Units” or “Hublets”

In spite of the regulatory and logistical challenges, there would be some benefits to implementing Hublets as a means of expanding access to MAT treatment. For individuals with co-occurring medical or psychiatric conditions, the ability to receive medication and health care from a local physician would likely yield improved management of health problems and compliance with treatment recommendations. In addition to decreasing barriers to care, local dosing would allow for improved engagement in other aspects of the individuals' lives previously lost to transportation time. Although the individual would be required to travel to a Hub for ancillary services, local dosing would decrease the travel. The stability of the patient, time in treatment and a variety of other clinical factors will have an impact on the frequency with which individuals need to return to Hubs. The key system development and policy issues are whether or not the potential benefits are worth the onerous regulatory and operational requirements inherent in a Hublet model.

Recommendations and Conclusions

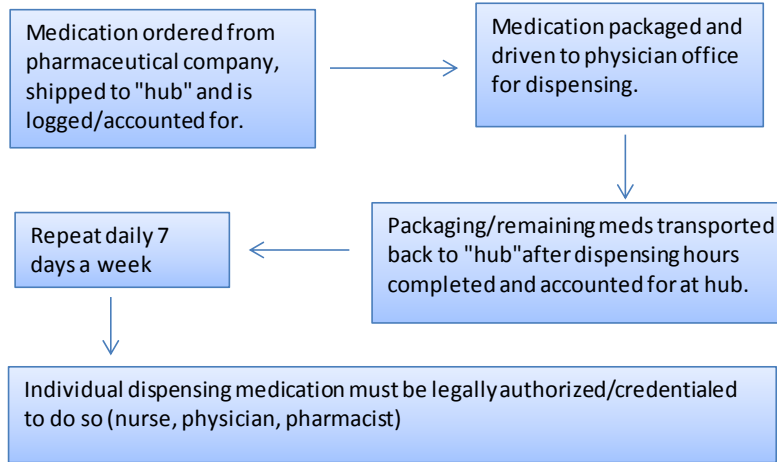
The concern about ensuring that Vermonters with opioid dependence have access to MAT statewide is valid. In spite of the newly implemented Hub and Spoke system, there continue to be some areas that are geographically isolated from Hubs. This is particularly challenging for individuals who need methadone treatment, because, unlike buprenorphine, methadone can currently only be dispensed at Hubs in Vermont. State and federal regulations would make feasible the creation of medication units, or Hublets, in Vermont, and would move methadone dispensing closer to individuals for whom methadone is the clinically preferred MAT. The state and federal regulations for creating and operating such sites, however, are onerous.

Because the Hub and Spoke system is new to Vermont, it is difficult to project how adequately this system will meet the needs of individuals needing MAT. Over time, the monitoring of access and waitlists will show any geographic patterns of unmet need. The significant investments in Hublet medication units would be premature prior to a reasonable assessment of the effectiveness of the newly implemented Hub and Spoke System in meeting treatment needs. It is therefore recommended that Vermont not pursue the creation of Hublets until any significant unmet need can be documented. This conclusion implies that no Vermont legislative or regulatory action be pursued at this time.

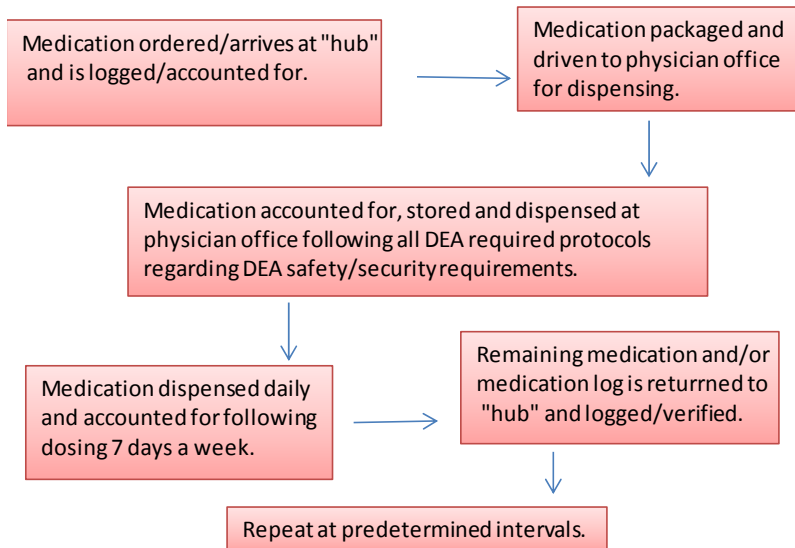
Appendix 1

Physician Office as “Medication Unit”

Model 1A Daily medication transport to physician office



Model 1B Medication stored at physician office

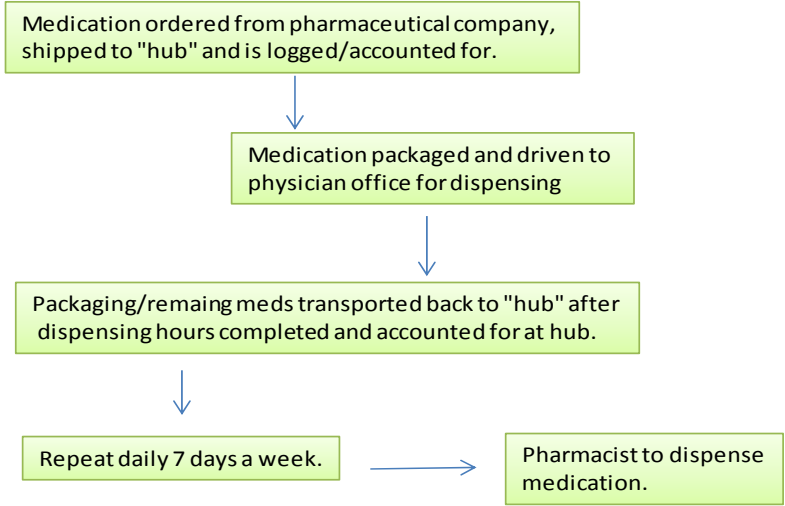


Appendix II

Pharmacy as "Medication Unit"

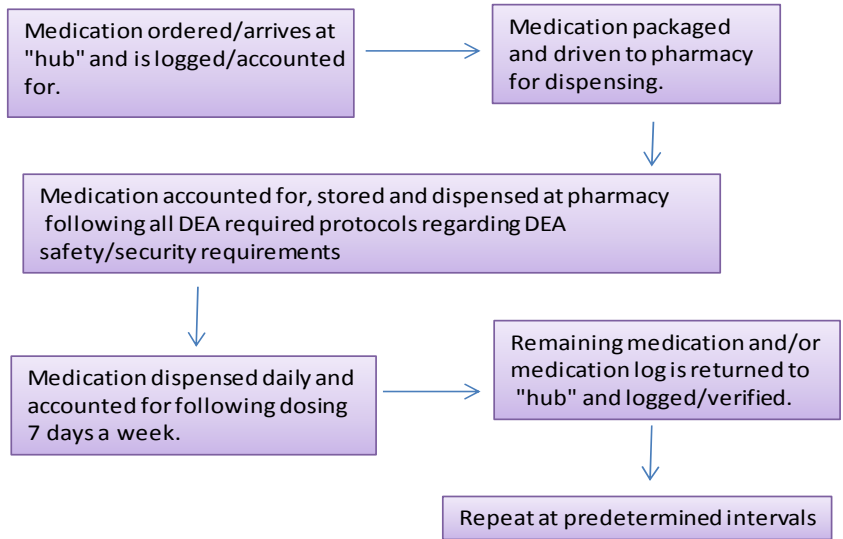
Model 2A

Daily Medication transported to pharmacy



Model 2B

Medication stored at pharmacy



Endnotes

ⁱ Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 10.10.11.

ⁱⁱ Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 10.10.11.

ⁱⁱⁱ 42 CFR, Part 8, Federal Opioid Treatment Standards. Federal Register, Volume 66, No. 11, January 17, 2001, Rules and Regulations.

^{iv} http://healthvermont.gov/regs/documents/opioid_dependence_rule.pdf