

VERMONT2007

Mobile Screening Clinics

Report to the Legislature on **Act 27 §10**
November 30, 2007



DEPARTMENT OF HEALTH
Agency of Human Services

108 Cherry Street, PO Box 70
Burlington, VT 05402
1.802.863.7341
healthvermont.gov

Table of Contents

Executive Summary	4
Introduction	5
Mobile Health Facilities	5
Mobile Screening Services	7
Screening Recommendations	8
Risks, benefits and concerns	9
Applicable Vermont Laws	11
Conclusion	13
Recommendation	14
Appendix A: U.S. Clinical Preventive Services Task Force Ratings	15

Executive Summary

In accordance with **Act 27§10**:

Mobile health facilities can be an important adjunct to health services if they are carefully planned to address problems of access to a specific service or for a defined population group, and when the mobile service is closely aligned with other fixed services in the community. The mobile screening services that are the subject of this report do not meet those criteria. They are offered to all without regard to need, are not linked to Vermont based services, and do not support the systems approach represented by the programs of Green Mountain Care and the Blueprint for health.

The specific screening services that are provided are generally not recommended by the US Preventive Services Task Force for the general population; rather, they are recommended only for those in specific age or gender categories or risk groups. The biggest risk to consumers in using these services is the potential for a report of a health problem that requires extensive follow-up leading to increased cost and anxiety and, in the end, does not exist (false positive).

The one company that is known to operate in Vermont appears to be in compliance with relevant Vermont laws.

Despite the many concerns regarding mobile screening services, we have been unable to identify specific instances of harm to the public. We have therefore concluded that additional regulatory action is not warranted at this time.

Introduction

This report has been prepared in response to Act 27§10.

The general assembly finds that there have been concerns raised about the practices of private mobile health facilities that enter the state of Vermont for the purpose of providing one-day diagnostic screenings to Vermont residents for a specified fee. The general assembly requests that the commissioner of health, in consultation with the office of the attorney general, review whether the practices of such mobile health facilities serve the best interests of Vermonters and report his or her findings to the general assembly not later than November 30, 2007.

Preparation of this report involved review of the literature and consultation with colleagues. The draft was reviewed by staff of the Department of Health, the Department of Banking, Insurance, Securities and Health Care Administration, and the Office of the Attorney General. Their comments and suggestions have been included in this final report.

The report documents a basis for appropriate use of mobile medical facilities and the operation of mobile screening services and reviews the screening recommendations of the U.S. Preventive Services Task Force and Vermont laws. Benefits, risks and concerns are identified. Despite a high level of concern about these services, the inability to document real harm to the public leads to a recommendation that additional regulatory action is not warranted at this time.

Mobile Health Facilities

The International Committee for the Red Cross (ICRC) has set guidelines for deploying mobile health units to meet health care needs.¹ They recommend MHUs only as an exceptional strategy, to be used when access to services is otherwise unavailable. They note that MHUs, because they are present in the field only intermittently have intrinsic

¹ Mobile health Units: Methodological Approach. ICRC, Geneva, Switzerland. May 2006

constraints than necessitate careful planning, must respond to the specified priority concerns; and, should “always be linked to a fixed health facility to which patients can be referred if necessary”. While the ICRC’s focus is clearly on use of MHUs in disasters, their guidance has broader applicability to use of MHUs in other settings as well.

The concept of taking care to people via MHUs rather than expecting people to come to a central facility has been used in multiple situations. They have been successfully used to bring methadone treatment to rural areas (in Vermont), nursing services to the elderly², healthcare to the homeless³ and to displaced populations⁴, mental health care services to non-traditional settings⁵ and in other situations where need is high and services are poorly accessible.

Mobile services may also be used in the context of an existing health care facility to bring services that have relatively high cost equipment cost and low utilization to ensure accessibility within the community. In Vermont, the Department of Banking, Insurance, Securities and Health Care Administration (BISHCA) has granted Certificates of Need (CON) for CT, MRI and PET/CT fixed and mobile equipment. Currently, all CT, MRI and PET/CT CONs have been granted to Vermont hospitals.

In virtually all of these circumstances in which mobile clinics operate the three core components of the ICRC guidelines are evident:

- There has been significant planning on the part of the agencies providing the services
- They target a specific population and/or a particular health service of concern
- All are linked to another larger health system

² Alexy BB, Elnitsky C. Rural Mobile Health Unit: Outcomes. *Public Health Nursing* 1:3; 1998.

³ Post, P. Mobile Health Care for Homeless People: Using Vehicles to Extend Care. *National Health Care for the Homeless Council*. May 2007

⁴ Krol DM, Redlener M, Shapiro A, Wajnberg A. *A Mobile Medical Care Approach Targeting Underserved Populations in post-Hurricane Katrina Mississippi*. *Journal of Health Care for the Poor and Underserved* . 18: 331-340. May 2007.

⁵ Guo S, Biegel DE, Johnson JA, Dyches H. Assessing the Impact of Community Based Mobile Crisis Services on Hospitalization. *Psychiatric services* 52: 223-228; 2001.

Mobile Screening Services

The “*private mobile health facilities that enter the state of Vermont for the purpose of providing one-day diagnostic screenings*” referred to in the legislation follow a very different business model. There is no indication that the planning that went into determining the services available is related to health need, access, cost or other factors that are considered by most health care providers. They are “direct to consumer” retail establishments that offer screening services to all who want them, presumably at a profit to the owners, and are not linked to the existing health care system in any way.

A search indicates only one company Life Line Screening of America, Cleveland, Ohio⁶ is active in Vermont at this time. In the month beginning October 15, 2007, their mobile screening van was scheduled to visit six towns in Vermont and three just across the river in New Hampshire. In the past, a second company, Ultra Life, Inc., Huntington Beach, California⁷ considered entering the Vermont market, but did not have a Vermont provider to oversee the diagnostic component. It is possible that others operate here.

Life Line offers ultrasound screening for four conditions: Stroke (carotid artery occlusion), peripheral arterial disease, abdominal aortic aneurysm, and osteoporosis. Tests are conducted on site by technicians and sent to Vermont licensed physicians (located out-of-state) to review the results. A report is mailed to the customer within 21 days.

Charges for these tests vary by test; according to the website the four ultrasound tests are available for \$139. Medicare, Medicaid and private health insurance do not reimburse the individual for the cost of testing.

⁶ <http://www.lifelinescreening.com/Pages/index.aspx>

⁷ <http://www.ultralifebodyscan.com/idl.html>

Screening Recommendations

The U.S. Clinical Preventive Services Task Force publishes screening recommendations for a variety of health conditions. Based on a review of the literature, recommendations are in one of five classifications reflecting the strength of evidence and magnitude of net benefit (benefits minus harms of screening). Recommendations are specific to eligible populations. The classification system is summarized in the box on this page and included in Appendix A.

U.S. Clinical Preventive Services Task Force Ratings

A—Strong recommendation
 B—Recommendation
 C—No recommendation
 D—Recommend against screening
 I—Insufficient evidence to make a recommendation

Current recommendations for the four ultrasound screenings provided by Life Line.

Peripheral arterial disease⁸

- The USPSTF recommends against routine screening for peripheral arterial disease (PAD). Rating: **D**

Abdominal aortic aneurysm⁹

- The USPSTF recommends one-time screening for abdominal aortic aneurysm (AAA) by ultrasonography in men aged 65 to 75 who have ever smoked. Rating: **B**
- The USPSTF makes no recommendation for or against screening for AAA in men aged 65 to 75 who have never smoked. Rating: **C**
- The USPSTF recommends against routine screening for AAA in women. Rating: **D**

Osteoporosis¹⁰

- The U.S. Preventive Services Task Force (USPSTF) recommends that women aged 65 and older be screened routinely for osteoporosis. The USPSTF recommends that

⁸ <http://www.ahrq.gov/clinic/uspstf/uspspard.htm>

⁹ <http://www.ahrq.gov/clinic/uspstf/uspsaneu.htm>

¹⁰ <http://www.ahrq.gov/clinic/uspstf/uspsoste.htm>

routine screening begin at age 60 for women at increased risk for osteoporotic fractures. Rating: **B**

- The USPSTF makes no recommendation for or against routine osteoporosis screening in postmenopausal women who are younger than 60 or in women aged 60-64 who are not at increased risk for osteoporotic fractures. Rating: **C**

Stroke (carotid artery occlusion): ¹¹

The USPSTF recommendation for screening for stroke has been removed from their website and is being updated. This now outdated recommendation is as follows:

- There is insufficient evidence to recommend for or against screening asymptomatic persons for carotid artery stenosis, using physical examination or carotid ultrasound ("C" recommendation). A recommendation may be made on other grounds to discuss the potential benefits of screening with high-risk patients (e.g., persons over age 60 at high risk for vascular disease), provided that high-quality vascular surgical care is available (surgical morbidity and mortality less than 3%).

Risks, benefits and concerns

There are no studies of who uses mobile screening or why. It is likely that the population using such screening is highly health conscious, has at least a modest income, and is older than the population at large. The most likely reasons for using such services would seem to be reassurance about one's health, to obtain a relatively low-cost second opinion, or to self-monitor an existing condition.

None of the screenings offered are recommended by the USPSTF for routine identification of health problems in the general population; rather, these tests are recommended only for certain risk groups or when symptoms are evident. In the absence of symptoms or risk factors, there is no need for these tests. Screening for osteoporosis is

¹¹ Guide to Clinical Preventive Services, 2nd Edition, 1996

recommended using a bone mineral density test of the spine and femur, not ultrasound of the heel as is done in these clinics.

Safety, effectiveness, appropriateness and accuracy cannot be assured for mobile screeners. The only assurances are those that are made by the company. As described on the Life Line web-site, the equipment is routinely maintained and frequently monitored; the technicians have been trained to use the equipment properly; and supervision is provided. The website also provides the results of a study which found that results of mobile screening were comparable in quality to those done at a hospital site^{12, 13}

Potential negative consequences from the screening results come primarily from the potential for the screening to identify a possible condition, which on follow-up does not exist. Such a “false positive” result, could lead to unnecessary and costly repeat and/or follow-up tests and possibly significant emotional and financial stress on the individual. There have been no reports from insurance companies or physicians that this has occurred in Vermont.

Cardiovascular disease, diabetes and osteoporosis are all relatively common conditions where progression can be slowed by appropriate, early intervention. They are not however, all of the health problems that a primary care provider will screen for in a routine preventive services visit. To the extent that people may use these screening in lieu of visiting their health care provider, the risk of late diagnosis of other health condition may be increased.

Mobile screening is inconsistent with the comprehensive system of care that Vermont has been pursuing with the various benefit programs of Green Mountain Care and the Blueprint. They do not follow the evidence based screening protocols and practice

¹² <http://www.lifelinescreening.com/QUALITY/Pages/HealthScreeningQualityAssurance.aspx>

¹³ <http://www.lifelinescreening.com/QUALITY/Pages/qualityexplain.aspx>

guidelines we are working to implement here. There is no connection between this activity and a patient's medical home or other care providers.

Rarely, the mobile screening can be expected to identify disease in the absence of risk factors or symptoms. Clearly for the individuals involved, this is a benefit to the mobile clinic, and helps drive on-going support for and interest in having this option available to consumers.

The company does not publish results, even in aggregate form and results are sent only to the individual. This means there are no data available to understand the characteristics of participants, the number of positive findings, the false positive rates for these services, or the number of lives potentially saved.

Applicable Vermont Laws

Licensing and scope of practice of mobile clinic staff

The Vermont Board of Medical Practice requires a Vermont licensed physician to supervise the test technicians and review and report results (26 VSA Sections 1311 and 1314). The technicians themselves do not have to be licensed. Life Line has secured the services of a Vermont licensed physician to review all screenings done and determine the content of the recommendations sent to the consumer.

With few exceptions, the staff in the mobile clinic do not report results or indicate a possible "positive" diagnosis to the consumer; rather the customer receives a report in the mail later, after the results have been interpreted by the physician. The exception is when the screening identifies a problem that is considered, by protocol, to require immediate action. In that case, the data is given to the patient and they are advised to see a physician within 24 hours.

Certificate of Need for Health Services

Vermont's Certificate of Need program has been in place since the 1970's. All "health care facilities," as defined by 18 V.S.A. § 9432, are subject to CON review if offering a "new health care project" as defined by statute. The definition of "health care facility" is broad and includes hospitals and "all persons or institutions, including mobile facilities * * * which offer diagnosis, treatment, inpatient, or ambulatory care to two or more unrelated persons * * *."

For non-hospital health care facilities, pursuant to 18 V.S.A. § 9434(a), the following "new health care projects" must have a Certificate of Need before development:

- Construction, development, purchase, renovation or other establishment of a health care facility, or any capital expenditure by or on behalf of a health care facility, for which the capital cost exceeds \$1,500,000.
- A change from one licensing period to the next in the number of licensed beds of a health care facility through addition or conversion, or through relocation from one physical facility or site to another.
- Offering any home health service.
- The purchase, lease, or other comparable arrangement of a single piece of diagnostic or therapeutic equipment for which the cost, or in the case of donation, the value is in excess of \$1,000,000.
- Offering a health care service or technology having annual operating expense that exceeds \$500,000 for either of the next two budgeted years, if the service or technology was not offered or employed by the health care facility within the previous three fiscal years.

BISHCA reviewed materials from Life Line in 2004 and did not identify any Certificate of Need concerns.

Consumer protection

The Vermont Consumer Fraud Act, 9 V.S.A. sec. 2453(a), prohibits unfair and deceptive trade practices. The three-part test for deception was set out by the Vermont Supreme Court in *Carter v. Gugliuzzi*, 168 Vt. 48, 56 (1998): "To establish a 'deceptive act or practice' under the Act requires three elements: (1) there must be a representation, omission, or practice likely to mislead consumers; (2) the consumer must be interpreting the message reasonably under the circumstances; and (3) the misleading effects must be material, that is, likely to affect the consumer's conduct or decision regarding the product.

Likewise, the sale of unnecessary screening services to consumers could be considered unfair under this analysis, if the price of the services were high enough and there were no offsetting benefit to consumers, though analysis of the second of these factors is difficult to undertake in the absence of more information on the number, makeup and experience of the population of consumers of screening services.

The Office of the Attorney General is not aware of any consumer complaints to date against a mobile screening service.

Conclusions

- Mobile clinics are most supportive of the health care system when there has been significant planning, they target a specific population and/or a particular health service of concern, and when they are linked to another larger health system. The mobile screening services that are the subject of this report do not appear to meet any of these three criteria.
- The only known mobile screening clinic doing business in Vermont appears to be in compliance with state laws regarding regulation of health services and medical practice.

- Mobile screening as done in these clinics is inconsistent with the comprehensive system of care that Vermont has been pursuing; evidence based screening protocols and practice guidelines are not used; and, there is no connection between this activity and a patient's medical home.
- The screening tests offered are not recommended by the U.S. Preventive Services Task Force for the general population, they are recommended only for people with demonstrated risk factors.
- Mobile screening clinics offer a service that people appear to want, and at a cost they feel they can afford.
- The greatest risk of using these services would be from inaccurate findings (false positives) that lead to anxiety and follow-up costs, and there is no evidence that this has occurred.
- There is little information to understand why people use these services or what might be done to help them make another decision. Increased education about screening might be helpful to some.

Recommendation

Despite the many concerns relative to these services, increased regulatory authority over mobile screening clinics does not seem warranted at this time. There is only one provider, no data or physician reports to indicate possible harm to consumers from false positive results, and no complaints by consumers.

Appendix A: U.S. Clinical Preventive Services Task Force Ratings

Strength of Recommendations¹⁴

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations according to one of five classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms).

A.— The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. *The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.*

B.— The USPSTF recommends that clinicians provide [this service] to eligible patients. *The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.*

C.— The USPSTF makes no recommendation for or against routine provision of [the service]. *The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.*

D.— The USPSTF recommends against routinely providing [the service] to asymptomatic patients. *The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.*

I.— The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. *Evidence that the [service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.*

Quality of Evidence

The USPSTF grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor):

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor: Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

¹⁴ U.S. Preventive Services Task Force Ratings: Strength of Recommendations and Quality of Evidence. *Guide to Clinical Preventive Services, Third Edition: Periodic Updates, 2000-2003.* Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/clinic/3rduspstf/ratings.htm>