CERTIFICATE OF NEED - RESPONSES TO GMCB QUESTIONS

SILVER PINES

DEVELOPMENT OF A MEDICALLY SUPERVISED WITHDRAWAL TREATMENT CENTER FOR INDIVIDUALS WITH SUBSTANCE USE DISORDER IN STOWE, VT

Docket No: GMCB-016-19con

January 21, 2019

1. Provide a full copy of any market study or feasibility analysis that has been performed for this project.

A formal market study or feasibility analysis was not conducted for this project. A comprehensive literature review was done to gain understanding of the epidemiology of substance use disorders (SUDs) and treatment efficacy. This literature review plus in-depth conversations with several national experts identified areas of the unmet need for high-quality treatment of SUDs. Additionally, Professor Cats-Baril visited several treatment facilities across the country to gain a better understanding of the practical elements associated with treatment delivery.

As mentioned in the Certificate of Need (CON) application on pp. 9-11, approximately 21.2 million people age 12 and older needed substance use treatment in the United States in 2018. Of those, only 17.4% (3.7 million people) received it and an even smaller percentage (11.3% or 2.4 million) received it in a specialized treatment setting.[1]

The treatment data for Vermont are similar. Among individuals in Vermont aged 12 and older, during 2015-2017, 10% (or 54,000 people) had a SUD in the past year, which is comparable to the regional average (9.6%). Of these 54,000 Vermonters, in a single-day count on March 31, 2017, only 7,015 people or 12.9% were enrolled in treatment.[2]

Currently in Vermont, there is only one ASAM 3.7-level facility located in the southern part of the state, and individuals in need of such services outside of that area are using Emergency Departments (EDs) and inpatient hospitalizations at a significant cost.[3] While specific quantitative information on the number of Vermonters in this category is not publicly available, this assertion is based on a combination of publicly accessible local and national data. According to the 2017 Vermont Hospitals Report, the yearly totals for inpatient hospital admissions in Vermont where the primary diagnosis was alcohol- and substance-related were 751 in 2014, 837 in 2015, 818 in 2016, and 867 in 2017.[4]

---

[1] Substance Abuse and Mental Health Services Administration. (2019). Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health (HHS Publication No. PEP19-5068, NSDUH Series H-54). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

[2] Substance Abuse and Mental Health Services Administration. Behavioral Health Barometer: Vermont, Volume 5: Indicators as measured through the 2017 National Survey on Drug Use and Health and the National Survey of Substance Abuse Treatment Services. HHS Publication No. SMA-19-Baro-17-VT. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2019. Retrieved from https://www.samhsa.gov/data/sites/default/files/Vermont_BHBarometer_Volume_4.pdf.

[3] According to the Health Care Cost Institute and Kaiser State Health Facts, the typical costs of an ED visit and inpatient hospitalization per day are $1,917 and $2,244, respectively.
Health Care Cost Institute. (2018, January). 2016 Health Care Cost and Utilization Report. Retrieved from https://www.healthcostinstitute.org/research/annual-reports/entry/2016-health-care-cost-and-utilization-report/.
Ellison, A. (2019, January 4). Average hospital expenses per inpatient day across 50 states: Below are the adjusted expenses per inpatient day in 2016, organized by hospital ownership type, in all 50 states and the District of Columbia, according to the latest statistics from Kaiser State Health Facts. Retrieved from https://www.beckershospitalreview.com/finance/average-hospital-expenses-per-inpatient-day-across-50-states.html.

[4] Vermont Green Mountain Care Board. (2019). *2017 Vermont Hospitals Report*. Burlington, VT: Vermont Department of Health, Division of Health Surveillance.

The unmet need for treatment of SUDs has been shown to be associated with higher rates of repeat ED utilization and hospital admission after presenting to the ED.[5] Similarly, a 2018 study showed that the number of accessible addiction treatment programs in a person's local area predicted a lower likelihood of repeat emergency department presentations.[6]

According to the Substance Abuse and Mental Health Services Administration (SAMHSA), each year at least 300,000 patients with SUDs or acute intoxication undergo medically supervised withdrawal (MSW) in general hospitals, while additional numbers obtain MSW in other settings. Only 20 percent of people discharged from acute care hospitals receive substance use treatment during that hospitalization. Only 15 percent of individuals who are admitted to a MSW program through the emergency department and then discharged go on to receive treatment.[7]

The conclusion—based on the epidemiological data, the opinion of SUD experts, and the visits to several clinics providing residential care—is that the need for timely, individualized, and evidence-based substance use treatment in United States and Vermont is clear.

2. Provide any articles from peer reviewed journals that support the efficacy of seven- to ten-day supervised substance use withdrawal programs, with or without remote follow-up after discharge.

Findings from peer-reviewed research literature that support the efficacy of brief residential treatment include:

(a) Inpatient treatment episodes longer than 7-10 days incur higher costs without clearly improving outcomes;[8,9]
(b) Decreases in substance use after inpatient treatment persist at 6 months;[10]
(c) Inpatient treatment is associated with higher rates of treatment completion[11] and 3-month abstinence[12] compared to outpatient;

[5] Rockett IR, Putnam SL, Jia H, Chang CF, Smith GS. Unmet substance abuse treatment need, health services utilization, and cost: a population-based emergency department study. Ann Emerg Med. 2005; 45(2):118–127. [PubMed: 15671966].
[6] Andrews CM et al. 2018. Availability of outpatient addiction treatment and use of emergency department services among Medicaid enrollees. Psychiatric Services 69:729-732.
[7] Center for Substance Abuse Treatment. Detoxification and Substance Abuse Treatment. Treatment Improvement Protocol (TIP) Series No. 45. HHS Publication No. (SMA) 15-413. (2006). Rockville, MD.
[8] Foster JH et al. 2000. Outcome after in-patient detoxification for alcohol dependence: a naturalistic comparison of 7 versus 28 day stay. *Alcohol & Alcoholism* 35:580-586.
[9] Eastwood B et al. 2018. Effectiveness of inpatient withdrawal and residential rehabilitation interventions for alcohol use disorder: a national observational, cohort study in England. *Journal of Substance Abuse* 88:1-8.
[10] Chutuape MA et al. 2001. One-, three-, and six-month outcomes after brief inpatient opioid detoxification. *Am J Drug Alcohol Abuse* 27:19-44.
[11] Myers B et al. 2018. Substance abuse treatment engagement, completion and short-term outcomes in the Western Cape province, South Africa: findings from the Service Quality Measure Initiative. *Drug and Alcohol Dependence* 185:278-284.
[12] Hser Y-I et al. 2007. Predictors of short-term treatment outcomes among California's Proposition 36 participants. *Evaluation and Program Planning* 30:187-196.

(d) The benefits of brief inpatient treatment can be increased further by combining with community-based treatment after discharge.[9,13]

The individual studies referenced are summarized below:

1. Chutupe et al (2001): This observational study showed decreases in alcohol, heroin, and cocaine use sustained at 6 months after a 3-day inpatient program; at 6-month follow-up of 116 patients, opiate-positive urine drug tests (UDTs) were decreased from 100 to 69% and cocaine from 90 to 69%, while employment over the same time period rose from 8.8% to 21%.
2. Eastwood et al (2018): In a cohort of 3,812 adults seeking treatment for alcohol use, those treated in medically staffed intensive withdrawal programs lasting 5-7 days compared to those who attended residential programs lasting 6-12 weeks had similar rates of successful treatment completion without repeat treatment in the following 6 months.
3. Hser et al (2007): Among 1,104 individuals entering treatment via the legal system, drug abstinence at 3-month follow up was higher among those who attended inpatient rather than outpatient treatment (OR 1.86, 95% CI 1.28-2.70) in an analysis that took into account factors including demographics, baseline employment, substance use and treatment history, and days in treatment.
4. Hser et al (2000): Comparing inpatient treatment episodes of 7 days or less with those lasting 8 to 21 days, researchers found no significant difference in relapse rates between the 32 patients in each group after 3 months (66% vs 56%, p = 0.301).
5. Myers et al (2018): In a sample of 933 people entering SUD treatment, the odds ratio for completing treatment was 2.28 (higher) in residential compared to outpatient treatment.
6. Stein et al (2019): In a 6-month randomized trial including 115 patients who received brief inpatient treatment for opioid withdrawal, initiation of buprenorphine and linkage to ongoing office-based treatment was associated with lower rates of illicit opioid use at all follow-up points.

3. Provide additional information on the neural network treatment planning model and algorithm:

a) On page 15 of the Responses to Questions (Dec. 17, 2019), question 12, you state that "machine learning and neural network models have been used with success in many areas of medicine" and specifically note that have been used "to successfully develop a model to stratify patients by risk of imminent suicide." Have the algorithms you have developed been tested for use in the patient population you will be serving? Is there any literature or evidence regarding the effectiveness of using machine learning and neural networks in the treatment of individuals with substance use disorders? If so, please provide.

[13] Stein M et al. 2019. Initiating buprenorphine treatment for opioid use disorder during short-term inpatient 'detoxification': a randomized clinical trial. *Addiction* 115:82-94.

Applications of machine learning techniques in the treatment of substance use disorders have appeared recently in the medical literature.[14] For example, machine learning techniques have been used to predict risk of relapse in alcohol use disorder,[15,16] development and course of substance use disorders,[17,18] and successful completion of treatment[19] using baseline patient characteristics. Work is also ongoing using these techniques to identify biomarkers for use of substances including alcohol,[20] cocaine,[21] and heroin,[22] and to predict risk of overdose amongst patients prescribed opioid analgesics.[23]

The number and type of applications of machine learning methods are growing and recent published research suggests that machine learning methods are increasingly being used in addiction psychiatry for informing medical decisions.[24]

b) What types of data inputs are needed for this algorithm (e.g., past treatment history for substance use disorder, social determinants of health, and income and demographic information)? Provide more detail regarding how you plan to obtain this information for patients receiving treatment at Silver Pines.

The types of data inputs utilized in the algorithm include: demographic information; age of first substance use; substance(s) used; route(s) of administration; frequency of use; prior treatment outcomes; presence of co-occurring medical and/or psychiatric conditions; family history; social determinants of health; strength of recovery supports; and, insight and level of motivation for sobriety.

This information will be obtained during the intake and admission process via phone and in person. Silver Pines staff will gather the information from patient interviews as well as from

[14] Ferreri F et al. 2018. E-addictology: an overview of new technologies for assessing and intervening in addictive behaviors. *Front Psychiatry* 9:51.
[15] Connor JP et al. 2007. The application of machine learning techniques as an adjunct to clinical decision making in alcohol dependence treatment. *Subst Use Misuse* 42:2193–2206.
[16] Acion L et al 2017. Use of a machine learning framework to predict substance use disorder treatment success. *PLoS One* 12:e0175383.
[17] Jing Y et al. 2019. Analysis of substance use and its outcomes by machine learning I. Childhood evaluation of liability to substance use disorder. Drug Alcohol Depend [ePub in press] https://doi.org/10.1016/j.drugalcdep.2019.107605.
[18] Ziheng H et al. 2019. Analysis of substance use and its outcomes by machine learning: II. Derivation and prediction of the trajectory of substance use severity. Drug Alcohol Depend 206 [ePub in press]. https://doi.org/10.1016/j.drugalcdep.2019.107605.
[19] Chih MY et al. 2014. Predictive modeling of addiction lapses in a mobile health application. J *Subst Abuse Treat* 46:29–35.
[20] Mumtaz W et al. 2017. An EEG-based machine learning method to screen alcohol use disorder. *Cogn Neurodyn* 11:161–171.
[21] Ahn WY et al. 2016. Utility of machine-learning approaches to identify behavioral markers for substance use disorders: impulsivity dimensions as predictors of current cocaine dependence. *Front Psychiatry* 7:34.
[22] Ahn WY, Vassileva J. 2016. Machine-learning identifies substance-specific behavioral markers for opiate and stimulant dependence. *Drug Alcohol Depend* 161:247–57.
[23] Lo-Ciganic W-H et al. 2019. Evaluation of machine-learning algorithms for predicting opioid overdose risk among Medicare beneficiaries with opioid prescriptions. *JAMA Network Open* 2:e190968.
[24] Mak KK, Lee K and Park Cl. 2019. Applications of machine learning in addiction studies: A systematic review. Psychiatry Res 275:53–60.

evidence-based assessment tools, including the Patient Health Questionnaire (PHQ)-9, Generalized Anxiety Disorder (GAD)-7, Diagnostic and Statistical Manual (DSM)-5 Cross-Cutting Symptom Measure, and the Systematic Expert Risk Assessment of Suicide (SERAS).

c) On page 15 of the Responses to Questions (Dec. 17, 2019), question 12, you state that the proprietary algorithm will be used to guide and augment clinical decisions at Silver Pines and, as individuals complete the program, you will track outcomes and add patients' experience to the algorithm to enhance the consistency of decision-making and care across all health care professionals and staff at Silver Pines. Will the algorithms be used only to guide clinical decisions at Silver Pines, or will they also be used to develop a treatment plan for patients after discharge from Silver Pines? Please explain in more detail.

The algorithms will be used to both (i) guide clinical decisions; and, (ii) develop treatment plans for patients after discharge.

The treatment algorithm will classify patients during the admission process using diagnostic evaluation, disease severity, and prior treatment responses. Patients will then be assigned to different treatments based on this classification.

We will use the aftercare algorithm to create customized aftercare programming and outreach. This algorithm will utilize both the epidemiological variables listed above and include real-time treatment and response information associated with each individual, augmented over time by the results of follow-up assessments of patients who have completed the program. As we accumulate data on patients' longer-term experiences and outcomes in outpatient follow-up, these will be combined with data collected during acute treatment at Silver Pines to help predict the most effective forms of ongoing care for each patient based on characteristics such as demographics, presenting problems, individual preferences, and responses to inpatient treatment modalities. This data-driven algorithmic approach will help to distinguish, for example, patients most likely to benefit from psychosocial treatment using an Acceptance and Commitment Therapy-based approach from those for whom Family Behavior Therapy is more likely to be helpful.[25]

4. The application states on page 15 that the Medical Director will have expertise in treating addiction. Please explain in more detail what addiction treatment expertise the Medical Director will have. Please also specify whether the Medical Director and the MDs on staff will be psychiatrists and whether they will be ABAM certified.

The Medical Director of Silver Pines will have one of the following qualifications, which are clinically- and academically-accepted standards:

a. Board eligible or board certified in Addiction Psychiatry, or
b. Board eligible or board certified in Addiction Medicine. Please note that this designation is replacing the American Board of Addiction Medicine (ABAM) certification because

[25] Donohue, B.; et al. Family Behavior Therapy for substance abuse: A review of its intervention components and applicability. Behavior Modification 33:495–519, 2009.

> Addiction Medicine is now recognized as a subspecialty under the American Board of Preventive Medicine.[26]

The physicians on staff will at least have primary board certification in Internal Medicine, Family Medicine, or Psychiatry. Additional board certification in Addiction Medicine or Addiction Psychiatry will be desirable.

In addition, the Medical Director will have at least three years of post-training clinical experience in working with individuals with substance use disorders and mental health conditions.

5. The application states on page 38 that Silver Pines will also provide access to qualified mental health professionals. Explain in detail where such professionals will be located and identify licensure that will be required, such as LCMHC, LICSW, PhD etc.

The mental health professionals referenced on page 38 of the CON applications refer to Licensed Clinical Mental Health Clinicians (LCMHCs) and Licensed Independent Clinical Social Workers (LICSWs), who are dually licensed drug and alcohol counselors (LADCs). They will be salaried employees of Silver Pines, provide individual, family and group therapy, and be located onsite.

The following are licensure requirements for each:

a. LCMHC – Master's or doctoral degree, 60 credits of graduate level course work in mental health counseling, 3,000 hours of post-degree supervised clinical experience (a minimum of 2 years), which includes at least 2,000 hours of direct service work, 100 hours of supervision from someone licensed at least 3 years, 700 hours of practicum/internship experience, and passing scores on both the National Counselors Exam and the National Mental Health Examination.[27]
b. LICSW – Master's or doctoral degree accredited by the Council on Social Worker Education, 3,000 hours of post-degree supervised clinical experience (a minimum of 2 years), which includes at least 2,000 hours of direct service work, one hour of clinical supervision for every thirty hours of supervised practice, and passing score on both the Vermont Jurisprudence Examination and the Association of Social Work Boards master's level examination.[28]

[26] Addiction Medicine. (2020). Retrieved from https://www.theabpm.org/become-certified/subspecialties/addiction-medicine/.
[27] Vermont Secretary of State. (2020). Forms & Instructions: Mental Health Counselors. Retrieved from https://www.sec.state.vt.us/professional-regulation/list-of-professions/allied-mental-health/forms-instructions.aspx.
[28] Vermont Secretary of State. (2020). Forms & Instructions: Licensed Independent Clinical Social Worker. Retrieved from https://www.sec.state.vt.us/professional-regulation/list-of-professions/social-workers/forms-instructions.aspx.

c. LADC – Master's or doctoral degree, 270 hours of substance use disorder education, 2,000 hours of post-degree supervised work experience, 50 hours supervision, and passing score on pass the IC&RC Advanced Alcohol and Drug Counselor exam.[29]

6. Page 2 of the lease states: "In the event that either of the federal H2B Program or J-1 Visa Program are terminated and not replaced with programs providing Tenant with similar opportunities to employ non-resident workers, then Tenant may terminate this lease by providing the Landlord with no less than six (6) months prior written notice." In a table format, specify the title and projected number of staff (FTE) to be hired through each of these two Visa programs in year 1, year 2, and year 3 of the project.

The paragraph on Page 2 of the lease referenced above was erroneously put in the lease. The owners of the property and facility in which Silver Pines will operate own and operate short-term rentals for the Stowe Mountain Resort. The Stowe Mountain Resort hires many temporary employees through the federal H2B Program and J-1 Visa Program. The Silver Pine lease was written using a lease for the Stowe Mountain Resort as a template. The reference to the federal H2B Program or J-1 Visa Program programs should have been deleted from the Silver Pines lease but was left in by error. Silver Pines will not be hiring any employees using the federal H2B Program or J-1 Visa Program, and therefore this reference is not applicable.

7. On page 15 of the Responses to Questions (Dec. 17, 2019), question 12, you cite the SERAS model. Please clarify whether this model will be utilized at Silver Pines, or whether this was provided as an example of the power of machine learning and neural-network models generally.

Concordant with the Joint Commission recommendations,[30] Silver Pines clinical staff will screen every patient for risk of suicide using various evidence-based screening tools, including the SERAS model. SERAS—which is a good example of the application of machine learning and neural-network models in clinical decision making—will be utilized at Silver Pines to stratify patients by risk of suicide and provide an extra layer of patient safety.

By way of background, SERAS was developed in response to a national unmet need for an efficient tool to assess near-term suicide risk. Professor Cats-Baril worked with a group of University of Vermont Medical Center (UVMMC) colleagues to develop this neural-network-based decision support tool that replicates the critical thinking of expert clinicians in weighing risk factors to assess an individual's near-term risk of suicide—defined as suicide within the next 72 hours. SERAS is a patient self-administered assessment delivered on a tablet or mobile device

[29] Vermont Secretary of State. (2020). Forms & Instructions: Licensed Alcohol & Drug Abuse Counselor. Retrieved from https://www.sec.state.vt.us/professional-regulation/list-of-professions/alcohol-drug-abuse-counselors/forms-instructions.aspx.

[30] The Joint Commission. (2018). *R3 Report: Requirement, Rationale, Reference*. Retrieved at https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/suicide-prevention/r3_18_suicide_prevention_hap_bhc_5_6_19_rev5.pdf?db=web&hash=887186D9530F7BB8E30C28FE352B5B8C.

and triages patients by level of near-term risk. It takes on average less than 1 minute to self-administer and, despite the sensitive nature of the question items, 91% of patients rate the interaction favorably. Professor Cats-Baril and his team validated SERAS in 550 patients drawn from the UVMMC medical-surgical units and Emergency Department (ED). He and his group found that SERAS replicates the assessment of near-term risk of suicide made by Board-certified psychiatrists with an accuracy greater than 90%. The few disagreements encountered were all in the direction of SERAS overestimating risk and therefore minimizing the likelihood of a false negative assessment.[31] The questions are listed in the table below.

Question	Choices
1. How much pain are you in?	Likert scale rating scale of 1-10
2. How are you coping?	Not well / So-So / Well
3. How upset are you?	A lot / A little/ Not at all
4. How would you rate your wish to live?	None / weak / moderate to strong
5. How would you rate your wish to die?	None / weak / moderate to strong
6. Have you been considering suicide in the last month?	Yes / No
7. Have you had a recent loss? (e.g.: job loss/change; relationship change; divorce; change of custody of children; death of a loved one; death of a pet; loss of home; forced to move; bankruptcy; dismissal from school; legal troubles, etc.)	Yes / No
8. Have you recently abused substances? (e.g.: Alcohol; Sedatives or Tranquilizers; Stimulants; Pain Killers; Marijuana or Hashish; Cocaine; Club Drugs; Hallucinogens; Opioids; Inhalants or Solvents; Other Drugs etc.)	Yes / No
9. Have you ever attempted to commit suicide?	Yes / No
10. Have you ever been diagnosed with Depression, Panic, Anxiety, or Bipolar Disorder?	Yes / No
11. Have you ever had a previous inpatient psychiatric hospitalization?	Yes / No

SERAS has received a number of competitive research awards including the UVMMC, SPARK-VT innovation awards and a NIH SBIR Phase I grant. In 2016, SERAS was awarded third place (out of over 100 applicants) at the national Patient Safety Movement best innovation competition. The use of SERAS as an integral part of Silver Pines' clinical process provides one more dimension of innovation and constitutes another factor differentiating Silver Pines from other clinics.

8. Provide an update on where Silver Pines is in any Town of Stowe and/or state review process.

In conjunction with the owners of the property (3430 Mountain Road, Stowe, VT), Silver Pines submitted an application for change of use from the former North American Hockey Academy to a medically supervised withdrawal treatment clinic. On November 5, 2019 the Stowe Development Review Board unanimously authorized the zoning administrator, Sarah McShane, to issue a change-of-use permit for Silver Pines of Stowe to operate as a MSW treatment center at that location.

[31] Desjardins I, Cats-Baril W, Maruti S et al. Suicide Risk Assessment in Hospitals: An Expert System-Based Triage Tool. *J Clin Psychiatry. 2016 Jul;77(7):e874-82.*

In the last two months, the owners of the property have received all permits (including Act 250, VTrans and water usage permits) to start the modification of the building. We understand that the final permit from the Town of Stowe will be issued once the final landscaping plan is reviewed and accepted. The landscaping is being changed to add increased privacy.

9. Submit full resumes for all staff known at this time.

At this time, no staff have been hired. Once Silver Pines obtains GMCB approval, Professor Cats-Baril will diligently begin the process of recruiting team members and will share their full resumes once they are hired.

10. The application states that Silver Pines will provide data to the Department of Mental Health. Please clarify whether you meant Vermont Division of Alcohol and Drug Abuse Programs (ADAP).

Yes, we meant ADAP. Silver Pines will provide collected data to Vermont ADAP and any other state agencies that request it.

11. Provide a balance sheet with proposed year 1, 2 and 3 projections in a standard spreadsheet format. Projections for years 1, 2 and 3 are required.

The balance sheet is too large to embed within this document. Please see attached Excel file, *Silver Pines 3 year Balance Sheet_1.21.20*.

12. Gross revenue is included in the financial tables, but deductions from revenue and net revenue are not. It is typically expected that some level of bad debt will occur. Please explain in more detail why you are certain there will be no bad debt and, if necessary, revise the revenue projections to reflect a reasonable level of bad debt.

Full payment will be due at the time of treatment acceptance. We will accept cash, credit card, PayPal, money orders, or cashier's checks. The business model assumes that only when payment has been received in full will individuals be accepted into the facility and, therefore, assumes no bad debt.

13. Clarify whether the financial tables reflect negotiated reimbursements from commercial payers or reflect Silver Pine's full charge and the expectation that commercial payers will pay that amount.

The financial tables reflect Silver Pines' full charge. Full payment will be due at the time of treatment acceptance. We will provide all necessary documentation to individual patients to support insurance reimbursement. We expect that some commercial payers will pay the full

amount and others not; reimbursement from commercial payers is highly variable and depends on the specifics of the plan of the individual patient.