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January 25, 2017

DELIVERED ELECTRONICALLY AND BY FIRST CLASS MAIL

Donna Jerry Senior Health Policy Analyst Green Mountain Care Board 89 Main Street, Third Floor City Center Montpelier, Vermont 05620

Re: Docket No. GMCB-010-15con, Proposed Ambulatory Surgery Center Response to Questions 006 posed on 08/25/2016

Dear Donna:

Enclosed please find the following:

- ACTD LLC's responses to Questions 006 posed on 08/25/2016 by the Green Mountain Care Board.
- ACTD LLC's complete and CONFIDENTIAL response to question 16 of Questions 006, submitted separately and in accordance with the Board's letter dated November 17, 2016. This CONFIDENTIAL response to question 16 is exempt from disclosure under 1 V.S.A. §§ 317(c)(7) and 317(c)(9).¹
- 3. ACTD LLC's Proposed Response For Interested Parties to question 16 of Questions 006 in accordance with the Board's letter dated November 17, 2016.²

Please let us know if you have any additional questions or need clarification regarding any of these responses.

Sincerely,

Eileen Elliott, Esq.

Cilan Milliott

Dunkiel Saunders Elliott Raubvogel & Hand, PLLC

cc: Judy Henkin, Esq., General Counsel, Green Mountain Care Board
Lauren Layman, Esq., Vermont Association of Hospitals and Health Systems
Anne Cramer, Esq., Vermont Association of Hospitals and Health Systems
Jill Berry Bowen, CEO, Northwestern Medical Center
Jonathan Billings, V.P. of Planning & Community Relations, Northwestern Medical Center
Lila Richardson, Esq., Office of the Healthcare Advocate
Kaili Kuiper, Esq., Office of the Healthcare Advocate

¹ Item 2 was sent only to the Green Mountain Care Board.

² Item 3 was sent only to the Green Mountain Care Board.



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Re: Docket No. GMCB-010-15con, Proposed Ambulatory Surgery Center Response to Questions 006 posed on 08/25/2016

Dear Donna:

Thank you for the questions in your August 25, 2016 letter. Below are ACTD LLC's responses to these questions. As requested, we have restated the questions in **bold** font and answered the questions in unbolded font.

1. Although your response to our questions indicate there will be no increase in volume (annual utilization) in the low/medium/high scenarios (see Response to Q003, July 15, 2016, at 3-4), and that volumes for physicians A-P indicate level or decreased volumes from 2013 to 2015, (Confidential Filing, Response to Q004, Question 2.), you state there will be a "strong demand" for operating and procedure room time (Application at 20), and a "significant additional demand" for operating and procedure room use. (Responses to Q001, December 23, 2015, at 4). Based on this inconsistency, revise the tables to accurately reflect expected volume increases in ASC approved procedure list established by CMS in the three four-year scenarios and resubmit, or in the alternative, confirm that the tables are accurate and explain why there will not be any increased volumes.

We confirm the accuracy of the projected tables we created in response to the GMCB's question 1, Q003, filed on July 15, 2016, and reiterate that we do not expect any material increases in volumes during this period. As we have noted elsewhere, the projections reflected in the tables were based upon interested physicians' historical volumes and expectations about their use of the ASC, and adjusted to reflect an annual growth rate of approximately 1.0% once the ASC is fully operational. The growth rate was recommended by our consultant, Avanza, based on its research and experience with other ASCs nationwide, as being typical for an ASC of the size and scope of the Green Mountain Surgery Center (GMSC). Aside from this modest growth, we do not expect that shifting the site of care from hospitals to the ASC will have a material impact on the surgical volumes for these physicians. Of course, because the high/medium/low scenarios are four-year future projections based on interested physicians' historical volume, we cannot predict with 100% certainty that these numbers will be precisely the final numbers of procedures performed. Some degree of uncertainty is inherent in all projections by all sources. Patients and their physicians will decide whether a patient's surgical procedures take place in a hospital outpatient facility, currently the only "choice," or the GMSC.

Reasons that patients might utilize the ASC more than we project include faster scheduling and shorter wait times, lower cost, lower or comparable infection rates, good quality and the same specialist performing the same surgical procedure but at a different and generally more convenient facility with better parking. In addition, as our application has been pending, it has become increasingly clear that Vermont employers are enthusiastic about the promise of an alternate, more convenient, and lower cost alternative venue for their employees. See the six (6) letters of support attached to the Application (AARP Vermont, Burton, Vermont Campaign for Health Care Security Education Fund, Vermont State Employees' Association, Vermont Education Health Initiative, Vermont State Troopers' Association, Inc.), as well as the support letters filed by local businesses with the GMCB as part of the record (the Boys and Girls Club, Rhino Foods, Lake Champlain Chocolates, Main Street Landing, Flex-a-Seal, Burlington Housing Authority, the Town of Colchester, Champlain Cable and Seventh Generation). Most recently, MVP Health Care submitted a letter in support of our application indicating the benefits that the GMSC would offer from the perspective of a payor. Given the widespread support that our application has received from local businesses, it may be that demand for the ASC exceeds our projections, but we do not have an empirical basis for such a conclusion at this time.

2. Consistent with your revision or confirmation per Question 1, above, revise and resubmit Tables 3 and 4 (Responses to Q001, December 23, 2015 at 3) to reflect low/medium/high.

N/A – See the response to Question 1. The tables we submitted on December 23, 2015 are correct.

3. Consistent with Questions 1 and 2, above, revise and resubmit the response to Question 6 (Responses to Q003, July 15, 2016, at 6-8).

N/A – See the response to Question 1. The response we submitted on July 15, 2016 to Question 6, 003, is correct.

4. In your July 15, 2016 responses (page 2), you stated that GMSC expects to perform cases at the ASC beyond what was included in the projections. In your December 23, 2015 responses (page 4), you represented that because utilization and financial projections are conservative, a strategic decision was made to size the facility to accommodate growth beyond four years. Please provide a detailed explanation for these statements and assumptions, and any available supporting data.

In our December 23, 2015 responses (page 4), we stated: "The projections are based on actual historical outpatient cases (based on average 2014 monthly volumes) performed by the physicians who have expressed interest in the project, as reported by those physicians. Based on physician input, we determined a separate capture rate based on the percentage of surgical cases that each physician expects to perform at the proposed ASC.... Our projections show a very conservative annual rate of case growth at 1%, an estimate typically used for ASC financial modeling."

In our planning, we have recognized the likelihood that once the GMSC has been constructed and commenced operations, other doctors or providers such as dentists, oral surgeons, or podiatrists who have not yet expressed interest in utilizing the GMSC may do so. To limit the design of the facility solely to the historical volumes of the interested physicians would, in our view, be shortsighted, and we believe could lead to a shortage of capacity. We have accordingly, in close consultation with our ASC consultant and architect, designed the GMSC to have sufficient capacity for modest future growth. Our consultants have advised us that the size and scope of the proposed ASC is consistent with industry

standards. As Vermont has no other freestanding multi-specialty surgery centers, we cannot predict with certainty the extent to which additional providers will want to utilize the GMSC.

We have also explained our decision to allow room for modest growth to accommodate other interested providers elsewhere as follows:

In the Application, page 12, ¶2, we stated: "Its medical staff will be open to any Board certified or Board-eligible specialty physicians practicing in the service area and able to accept responsibility for patient post-operative care and follow-up, and who satisfy other customary criteria set forth in the ASC's medical staff bylaws."

In the Application, page 14, ¶ 3, we stated, "The company expects to add additional minority owners, anticipated to consist of local physicians, upon approval of this Application."

In the Application, page 20, ¶ 1, we stated, "Due to interest from surgeons and patients in an ASC that offers lower costs, easier scheduling and greater efficiency for non-emergent surgeries and procedures than alternative sites of care, we anticipate that once the Green Mountain Surgery Center is up and running, there will be strong demand to provide operating and procedure room time for physicians working in other specialties, including orthopedics, gynecology and plastic surgery."

In the Application, page 26, ¶ 1, we stated, "At the time of this application, ACTD has identified a minimum of 16 physicians who are extremely interested in performing cases at the proposed ambulatory surgery center. The most prevalent reason given was to give their patients an option of a lower cost location for their routine, elective procedures. This reason was closely followed by the physicians' desire for their patients and their families to have the option of a more efficient and friendly environment for their ambulatory procedures. The physicians also anticipate that scheduling procedures at the ASC will be easier and that their patients will be able to receive outpatient surgical services in a more timely manner than is presently possible."

5. Explain in detail the assumptions and data used to determine unmet need relative to surgeries and procedures. Include in the explanation why there is a need for additional procedure rooms (PR) and operating rooms (OR), in light of data submitted by the Vermont Association of Hospitals and Health Systems indicating excess capacity.

The unmet need is in affordable, convenient locations for timely non-emergent surgical procedures, not the "capacity" extolled but controlled and meted out by hospitals. As we have said repeatedly, the need for hospital ORs and PRs is not the same as the need for less costly, more accessible care.

In the Application, pages 64 to 68, the third of eight statutory criteria required to be satisfied for the granting of a CON compelled a showing that "there is an identifiable, existing, or reasonably anticipated need for the proposed project which is appropriate for the applicant to provide." We provided a four page rationale for why ASCs are needed in Vermont, complete with footnotes and a table. The response articulates in detail both our assumptions and the underlying data used to determine why the GMSC is needed. Please see pages 64 to 68.

In Q001, you asked in question 6: "Page 11 of the application states that there is "an identifiable need for expanded outpatient surgery capacity in Chittenden County." Please provide: 1) a more detailed

explanation of the unmet need for the surgeries and procedures that GMSC will offer; 2) specific data to support the need in the primary and secondary services areas; and 3) the need for additional operating and procedure rooms." And, in question 7 you asked: "Page 12 states: "There is a particular need to add operating capacity for affordable GI procedures (e.g., diagnostic, preventive and screening colonoscopies..."). Please provide the data to support this statement."

We filed a response on December 23, 2015. These two questions seem to call for the same information as is being requested in this question. To avoid duplication, please refer to pages 6-12 of our response. Although we did not have the hospital capacity data when we responded, our answer starting at page 7 indicates that the need for the GMSC is not for expanded hospital outpatient capacity but for the lower cost, greater efficiency, enhanced patient experience, increased price transparency, and physician demand associated with an ASC.

In Q003 dated February 10, 2016, you asked in question 6, "Provide a cost benefit analysis through 2020 that supports the need for the project which includes an analysis of the impact on Vermont hospitals offering the same services. Please see the response we filed on July 15, 2016, pages 6-8.

Similarly, you asked in question 7 of 003, "Explain how the GMSC will provide health care services that are distinct from services currently provided at NMC and UVMMC. If there is little or no distinction, provide data demonstrating the need for duplication of existing services in Chittenden and Franklin counties." Although these two latter questions are phrased differently, each requests a need justification, and the data supporting it, in light of VAHHS's existing OR and PR capacity. To avoid duplication and reiteration, please see our response, dated July 15, 2016, pages 8-10.

Even if "unmet need" could be equated to existing OR and PR capacity, there is no data showing the hospitals are (or are not) operating at capacity. The data submitted by VAAHS on May 6, 2016 does not attempt to quantify patient wait times for surgeries and procedures. The GMCB cannot know if there is an access problem, or unused capacity, without some data related to wait time. VAAHS's inability to provide such data suggests a deafness to patient and physician complaints of excessive wait times at the member hospitals. A recent article by Dan D'Ambrosio on hospital wait times that appeared in the Burlington Free Press, and which is attached as Exhibit 5 to this response, bears this out.

To verify if the capacity that hospitals claim is available is actually available to be used effectively, the GMCB would have to review the intake room to procedure room ratio and the staffing availability to utilize a higher percentage of the current room use, as the ability to use rooms is dependent on having the appropriate numbers of trained staff working in the appropriate shifts. It may be the case that any "available capacity" identified by the hospitals in their May 6, 2016 response is permanently unusable capacity due to OR/PR intake room ratios and staffing constraints. Therefore, the current utilization of actually available capacity may be 100% and the GMCB has no way of verifying if this is the case without reviewing the room layout and current staffing protocols of each of the five hospitals that submitted data.

6. If a decision about which procedures and surgeries will be offered at GMSC will not be made until after the Board issues a CON, (Response to Q004, at 1-2, explain the rationale for the number of PRs, ORs and pre- and post-op beds requested in this application.

The rationale for the number of ORs and PRs was requested on August 28, 2015, in Q001, question 3: "Provide a detailed explanation and full set of assumptions supporting the need for two ORs, 4

procedure rooms and 14 pre- and post-op beds. Also provide the full set of utilization assumptions for each year 1-4."

We responded on December 23, 2015, on pages 3-5, and direct you to this answer for our rationale for the number of PRs, ORs and pre- and post-op beds.

Also in Q003, question 5, the GMCB asked "Provide full copies of all studies, reports and/or analyses and assumptions for each scenario analyzed relative to the number of operating rooms, procedure rooms, and pre-and post-op beds."

We responded on July 15, 2016, at pages 5-6, and direct you to this answer for further explanation on the number of PRs, ORs and pre- and post-op beds.

Finally, while we cannot predict with certainty the entire universe of procedures that will be performed at the GMSC, we do have an expectation of what the initial procedures performed at the ASC will likely be (see response to CON standard 3.13, on page 51 of our Application and Exhibit 3 to our Application), as well as what the highest volume procedures are likely to be (see our response to Question 7 below). Thus, our projections are not untethered from expectations relating to procedures to be performed at the surgery center; it is just that we cannot state with absolute certainty every type of procedure that will be performed at the center, as this can change with physician interest and availability as well as changing lists of approved procedures to be done in ASCs by governing bodies such as The Centers for Medicare & Medicaid Services(CMS).

7. To assist the Board with its evaluation of the impact on existing facilities, specifically identify CPT codes for procedures and surgeries by specialties to be offered at GMSC in Years 1, 2, 3 and 4. Use the CPT for the most recent period available (specify date), with the understanding that the approved CPT codes for ASCs are constantly changing.

The following is a chart of the highest volume procedures and surgeries expected to be performed at the Green Mountain Surgery Center by specialty. This list was compiled based on feedback from the interested physicians and their indication of which procedures and surgeries would be most appropriate to perform in the ASC setting.

CPT Code	Specialty
45380	GI
45385	GI
45378	GI
43239	GI
G0121	GI
49585	GENERAL SURGERY
19120	GENERAL SURGERY
38525	GENERAL SURGERY
49587	GENERAL SURGERY
68720	GENERAL SURGERY
68815	GENERAL SURGERY
45378	GENERAL SURGERY

55250	GENERAL SURGERY
49505	GENERAL SURGERY
47562	GENERAL SURGERY
58660	OB/GYN
58672	OB/GYN
58563	OB/GYN
58120	OB/GYN
58661	OB/GYN
58558	OB/GYN
58662	OB/GYN
58522	OB/GYN
58571	OB/GYN
29848	ORTHO
25447	ORTHO
64718	ORTHO
26005	ORTHO
25111	ORTHO
63650	PAIN MANAGEMENT
64633	PAIN MANAGEMENT
64634	PAIN MANAGEMENT
64493	PAIN MANAGEMENT
64490	PAIN MANAGEMENT

CPT codes as identified in the CMS 2017 proposed payment rule for ASCs and hospital outpatient departments (HOPDs). The link to the rule is:

 $\frac{https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASC-Regulations-and-Notices-Items/CMS-1656-P.html?DLPage=1\&DLEntries=10\&DLSort=2\&DLSortDir=descending.$

Also, please see our response filed on July 15, 2016, pages 1-3, in response to Q 004, question 1, posed on April 5, 2016.

We also provided a list of the procedures to be initially performed at the GMSC as Exhibit 3 to our July 3, 2015 Application. The text explaining the Exhibit is our response to CON standard 3.13, on page 51.

8. Identify and explain in detail each of the alternative room complements explored and why the proposed room complement (two ORs, four PRs and 14 pre- and post-op beds) was selected over any of the alternatives considered. Provide full copies of all documents including analysis, studies, summaries and recommendations completed by Avanza and other consultants for each alternative.

We did not explore alternative room complements in depth, but rather relied on the recommendations of our consultant, Avanza, based on their experience with ASCs of similar size and scope. In addition, as we answered in our response to question 5 of Q003 submitted on July 15, 2016 (referenced below), we

did explore one alternative location for the surgery center on the first floor of the building at 40 Idx Drive in South Burlington. This location would have suited only a slightly different room complement of two ORs, four PRs, and 16 pre-and post op beds. We have included the lease profile and site plan for this alternative, as well as the proposed floor plan and the functional space program that was developed by our architectural advisors, AMB Development Group, as Exhibits 8.a, 8.b and 8.c to this response. For a summary of the rationale and recommendations from our advisors for choosing the current proposed site and configuration at 535 Hercules Drive over the alternative option at 40 IDX drive, please see our answer to CON Standard 1.11 on page 47 of our initial application submitted on July 2, 2015. Our response to 18 VSA 9437(2)(c) in the original application on page 63 further summarizes the recommendations of our advisors on this issue.

In addition, you asked in question 5, Q003: "Provide full copies of all studies, reports and/or analyses and assumptions for each scenario analyzed relative to the number of operating rooms, procedure rooms, and pre-and post-op beds."

We responded on July 15, 2016, pps. 5-6, as follows:

We relied on our consultant Avanza to assist us in planning the size and capacity of the GMSC facility, and did not separately rely on any studies, reports, or analyses related to calculating the number of operating rooms and procedure rooms. According to Avanza's research and experience, between 1,000 and 1,200 cases per year can be performed in each operating and procedure room. Obviously this number can vary based on factors such as the mix of cases performed at the ASC and the acuity of the patients, but we understand that 1,000-1,200 cases is a good benchmark which is supported by Avanza's research and experience with ASCs nationwide.

The minimum number of pre and postoperative beds is dictated by the regulatory entities, which for the proposed GMSC are CMS and the Accreditation Association for Ambulatory Health Centers, Inc. The determination for the GMSC follows the latest recommendation by the Facility Guidelines Institute (FGI).

The following is a quote related to post-op space requirements from the FGI's most current *Guidelines for Design and Construction for Hospitals and Outpatient Facilities* (2014).

3.7-3.4.3.1 (1)(b) size of phase I recovery area. A minimum of 1.5 recovery patient care stations per operating room shall be provided.

Appendix A3.7-3.4.3.1 (1)(b) determining the number of Phase I patient care stations. When use of the formula results in a fraction for the number of patient care stations to be provided the fraction should be rounded up to the next whole number. When designing the recovery area and determining the number of recovery positions required, at minimum, consideration should be given to the types of surgery and procedures performed, types of anesthesia used, average recovery periods for patients, and anticipated staffing levels.

9. Provide the applicant's policy to ensure that procedures/surgeries will be performed on ASA PS Level III patients in a safe manner, and the implementation plans for that policy.

The draft anesthesia classification policy is attached as Exhibit 9.a. Also attached is the GMSC's draft anesthesia care protocol that details how anesthesia will be provided. Exhibit 9.b.

The draft policy and protocol are consistent with our Application, where we stated on page 20, ¶ 4:

Many CMS-approved procedures that will be performed at the Green Mountain Surgery Center first require the authorization of a patient's primary care provider, plus the surgeon and, where general, regional or local anesthesia is indicated, the approval of the Center's anesthesia provider. Patients with an American Society of Anesthesiologists (ASA) classification of I ("A normal healthy patient") and II ("A patient with mild systemic disease") will be seen at the Center, after being cleared for surgery by the requisite provider(s). The Center may also accept certain patients with an ASA classification of III ("A patient with severe systemic disease") on a case-by-case basis, only after having been cleared for surgery by their primary care provider, the surgeon, and the Green Mountain Surgery Center's anesthesia provider. Patients who are clinically high-risk as assessed by their primary care and specialty care providers due to the presence of co-morbidities, very advanced age, or other factors will have their procedures scheduled at a local hospital that is equipped to deal with complex cases.

As stated in the draft policy, the GMSC will focus its services on healthy patients, primarily those classified as ASA I and II. The Center's final policies and procedures will be developed by the Medical Director and reviewed and approved by the Center's Governing Board. The attached policies address specifically how the patients will be approved for surgery at GMSC.

The Medical Director will have the responsibility to ensure that all Center staff follows the policies. In addition to on-site oversight, the Medical Director will oversee regular quality of care audits and peer review activities to ensure the policies are being adhered to diligently.

10. For each of the five highest volume procedures or surgeries in each of the specialty areas in which you anticipate offering services, provide in a table format the average facility charge for room time, medications, and recovery, and the average professional charge for Years 1, 2, 3, and 4. Provide the assumptions used to determine the average charges reflected in the table.

With regards to facility charges, we have not developed projected per-procedure facility charges for the surgery center's cases. Instead, our revenue projections are based on estimates of the "allowed amount" that insurers will pay the GMSC for room time, medications, and recovery. Avanza has developed a proprietary database, which has been augmented over the years, which provides an average reimbursement rate by payer (Medicare, Medicaid, Commercial and Self-Pay) for a typical sampling of procedures performed in ASCs from each of the different specialty areas (GI, Pain Management, OB/GYN, etc.). These average per case reimbursement rates by specialty area were used in conjunction with the GMSC's Projected Cases by Specialty (Table 6 on page 28 of the original application submitted July 2, 2015) to develop the revenue projections shown in Table 7 Revenue (Before Deductions) By Payor Category also on page 28 of the original application.

With regards to professional charges, we also have not developed per-procedure professional charge estimates, as we stated on page 23 of the initial application under Section 1 G. Charge Structures and Patients Savings:

The Center will not employ physician staff. It will not lease its operating rooms to physicians. Its billings, income, and expenses will be totally separate from those of the surgeons who will perform surgical cases there. The ASC's charges for surgery, which

include room time, medications, and recovery, will be separate and independent of the surgeons' and/or anesthesiology providers' professional charges for performing the surgeries. Therefore, unless otherwise stated, any financial comparisons to hospitals provided in this application are facility-to-facility cost comparisons. They do not include physician charges. Surgeons' fees are not relevant, being identical in both settings.

We hope to avoid ever developing a conventional "charge master" at the GMSC with a list of charges that are not connected with what any payor or patient actually pays for procedures. The payment rates set by Medicare and Medicaid for procedures are already set independently of any provider's "charge master" and are transparent to the public. In like fashion, we hope to make our negotiated payment rates with private insurers identical for each insurer and transparent to commercial policyholders, obviating a need for a separate list of conventional "charges." For self-pay procedures that are not covered by public or private insurance plans, and are paid for directly by the patients, a schedule of prices will have to be established. However, as noted above, we have not yet developed a schedule of per-procedure prices.

11. Explain how the OR floor plans will be adjusted to meet requirements of the updated 2014 FGI Guidelines (attached). Provide a breakdown of the additional costs that will be incurred to comply with the FGI Guidelines updates.

The GMSC has been designed to meet the FGI 2014 guidelines. See the Application, page 49 for the following response:

CON STANDARD 1.12: New construction health care projects shall comply with the Guidelines for Design and Construction of Health Care Facilities as issued by the Facility Guidelines Institute (FGI), 2014 edition.

The proposed Green Mountain Surgery Center has been designed to comply with the Guidelines for Design and Construction of Health Care Facilities as issued by the Facility Guidelines Institute (FGI), 2014 edition. ACTD has engaged the firm of AMB Development Group, LLC to assist in the programming, design and specification of the surgery center. AMB has significant experience nationally with the FGI standards and has never failed to obtain licensure, certification and accreditation on any surgical center which it has developed. A table setting forth the applicable FGI Guidelines and a statement as to how the project will comply with each such Guideline is included as **Exhibit 4**.

We confirmed our compliance with the FGI 2014 Standards in response to Q003, question 22, in which the GMCB asked: "The plans submitted for the surgical center suite do not meet FGI 2014 guidelines, including the layout for sterile processing. Explain how GMSC will revise the plans to address deficiencies, and whether GMSC will incur additional costs, directly or indirectly, in order to comply with FGI guidelines."

Our response, which was filed on July 15, 2016, was as follows:

The GMSC has been designed to meet the 2014 Edition of the FGI Guidelines for Design and Construction of Hospitals and Outpatient Facilities. In our Application, Exhibit 4, we included a 19 page summary of the applicable 2014 FGI requirements and how the surgical center plans meet them. Our architect, who has developed hundreds of outpatient facilities nationwide, is perplexed

that the Board has concluded the plans for the GMSC, specifically the layout for sterile processing, fail to meet the 2014 FGI guidelines.

The sterile processing area consists of two rooms. The first room is the soiled work room or decontamination room. This room is accessible from the semi-restricted corridor. The room has a washer sanitizer, clinical sink, instrument washing sink, and hand washing sink with countertop. The washer sanitizer feeds the instruments into the sterile processing room. The room also has a pass through window. The second room is the sterile processing room, which includes a countertop with hand washing sink, and base and upper storage cabinets. The room also includes a cabinet sterilizer, wrapping table and rack storage system. This room is also accessible from the semi-restricted corridor.

The Application includes the following analysis regarding the FGI Guidelines relative to the sterile processing area:

3.7-5	GENERAL SUPPORT FACILITIES	
3.7-5.1	Y Sterilization facilities - on-site sterile	
	processing room	
3.7-3.6.13	On-Site Sterile Processing Room:	
3.7-3.6.13.1		
(1)	Y consists of decontamination area &	
	clean work area	
(2)	Location:	
	Y designed to provide one-way	
	traffic pattern of contaminated	
	materials/instruments to clean	
	materials/instruments to sterilizer	
	equipment	
(a)	Y entrance to contaminated side of	
	sterile processing room from	
	semi-restricted area	
(b)	Y exit from clean side of sterile	
	processing room to semi-restricted	
	area or to operating room (may be	
(3)	shared between two or more OR's)	
3.7-3.6.13.2	Y decontamination area	Ventilation:
(1)		Y Min. 6 air changes per hour Table 7.1
(a)	<u>Y</u> countertop	Y Negative pressure
(b)	<u>Y</u> handwashing station	Y Exhaust
	Y separate from instrument-	Y No room recirculating units
	washing sink	
(c)	Y sink for washing instruments	
(d)	Y storage for supplies	
(2)	Y min. 4'-0" distance from edge of	
	decontamination sink to clean	
	work area	

3.7-3.6.13.3	Y clean work area	Ventilation:	
(1)	<u>Y</u> countertop	Y Min. 4 air changes per hour T	Table 7.1
(2)	<u>Y</u> sterilizer	Y Positive pressure	
(3)	Y handwashing station	Y No room recirculating units	
(4)	Y built-in storage for supplies		
3.7-5.2	Y Linen services		
3.7-5.2.1	Y clean linen storage		
3.7-5.2.2	Y soiled linen holding		
3.7-5.5	<u>Y</u> Environmental services room		
3.1-5.5.1.1	Y min. one ES room per floor		
3.1-5.5.1.2		Ventilation:	
(1)	Y service sink or floor-mounted mop sink	Y Min. 10 air changes per hour T	Table 7.1
(2)	Y provisions for storage of supplies &	<u>Y</u> Exhaust	
	housekeeping equipment	Y Negative pressure	
(3)	Y handwashing station or hand		
	sanitation dispenser		

It is our opinion that GMSC's design will <u>not</u> need to be adjusted to meet the September 2015 FGI Bulletins entitled *Operating Room Requirements for 2014 and Beyond* and *Sterile Processing in the Surgical Suite* because each of those bulletins provide an explanation of how the 2014 standards for operating rooms and sterile processing changed from the 2010 standards. By designing the GMSC to comply with the 2014 FGI standards, our architect AMB has already included the updates. For further clarity, we offer the following information:

Operating Room Requirements

The Operating Rooms (ORs) are 427 square feet which are in excess of the minimum 250 square foot size stipulated in the Guidelines. A minimum 4 feet clearance on all four sides of the sterile field has been provided. A 9 square foot rectangle has been provided to allow for clear door swing when a stretcher is in the room. The OR sizes provided in the facility are adequate to accommodate all equipment and staff necessary for the outpatient procedures to be performed at the facility.

A minimum of 1.5 Phase I patient care stations per OR have been provided. One hand washing station has been provided for every patient care station at the appropriate locations. One scrub sink has been provided for each OR next to the entrance of each operating room. The scrub stations do not impede on the width of the corridor. 'Sub-Sterile Rooms' between the ORs have not been provided as they are not required by the updated Guidelines.

Hybrid Operating Rooms and Inpatient Operating Rooms have not been provided in the facility since they are not required under the Guidelines.

The Procedure Rooms are 200 square feet which are in excess of the 150 square foot minimum size stipulated in the Guidelines.

Sterile Processing Requirements

A sterile processing room has been provided in accordance with 2.2-3.6.13. The sterile processing layout includes a decontamination area (Soiled Work Room) and clean work area (Sterile Processing Room), separated by a wall with a pass through and a washer sanitizer pass through at the wall. This provides for a separation between clean and dirty and a one-way traffic flow. This layout meets the requirements of the Guidelines and is superior to a single room dirty/clean layout. If a single room is required by the GMCB, then the wall separating the two rooms can be removed which will result in a reduction in construction cost.

Entrance to the Soiled Work Room is from the semi-restricted corridor. Exit from the Sterile Processing Room is from the semi-restricted corridor.

In our opinion, the schematic plan submitted to the GMCB meets the requirements of the 2014 FGI Guidelines.

12. Relative to Statutory Criterion 7, explain whether you anticipate and will request that a bus stop will be available at the facility's 535 Hercules Drive address, or if the closest stop will be the existing stop a half mile from the facility.

If we are awarded a CON, we will inquire with the Colchester and CCTA authorities as to whether the existing bus route can be modified. However, we believe that it is premature for us to inquire about this matter before a CON has been issued.

13. Explain in detail the process, policy or guidelines that will be in place to ensure that physicianinduced demand or supply-induced demand does not occur.

This question seems to ask for the same information as Q001, question 10: "Provide a detailed explanation of protocols that will be in place to ensure that over-utilization, unnecessary or inappropriate surgeries and procedures are not encouraged or performed."

We responded on December 23, 2015, pages 14-15:

Over-utilization is one of the unfortunate side-effects of the fee-for-service payment model, which encourages more care. Many of the Green Mountain Surgery Center's investors are involved with Vermont's health reform initiatives, including the Green Mountain Care Board's efforts to rein in health care spending by testing new ways to pay for health care. The Green Mountain Surgery Center will adopt the statewide payment reform initiatives developed by the GMCB, which will address paying for the quality, not just the quantity, of care provided. Regardless of whether new OR capacity is added to our community in a freestanding low-cost ASC, or whether more OR capacity is added by the local hospital, the concern about unnecessary care and over-utilization will exist until the fee-for-service payment model is replaced with payments aimed at keeping patients well.

The Green Mountain Surgery Center will also have a peer review policy as part of its quality monitoring and reporting program that will specifically target incidences or patterns of overutilization and unnecessary or inappropriate surgeries for review. A copy of the draft peer review policy is attached as Exhibit 4. As stated in our response to CON Standard 1.6, GMSC will have an overarching quality improvement strategy that continuously monitors surgeries and

procedures performed on site to ensure delivery of the right amounts of high quality care as well as compliance with legal requirements regarding referrals.

Finally, it is also important to understand the role of the accountable care organization ("ACO") network in curbing unnecessary surgeries. These networks have strong financial incentives to ensure that additional surgeries of questionable necessity do not take place. All of the surgeons who plan to operate at the Green Mountain Surgery Center are participating in HealthFirst ACOs through signing the Collaborative Care Agreement that commits them to supporting the goals of the ACO and reducing unnecessary care. ACO networks also have data to compare the utilization and value of specialists whom primary care physicians within the network refer to. Green Mountain Surgery Center will use the data to inform its peer review and other quality policies to make sure the Green Mountain Surgery Center's surgeries are well within the community norm.

The positioning of primary care doctors at the center of a re-envisioned health care system is also well aligned with how the Green Mountain Surgery Center will operate because the vast majority of GI procedures, which will account for the bulk of procedures performed at the center, are already "open access" meaning that they are ordered by primary care physicians and not by the GI physician who performs the procedure. This is in contrast to orthopedic or ophthalmology procedures, which are typically ordered by the specialist after a consult.

The Draft Peer Review Policy, referred to in the quote above and attached as Exhibit 4 to our December 23, 2015 filing, has the following provision in Section II (f): "Quarterly, a random number of patient medical charts ... up to 5% or 20, whichever is less, will be subject to a peer review to ensure that the GMSC's procedures are medically necessary and appropriate for the patient's diagnosis."

14. Explain in detail the process, policy or guidelines to ensure that patient payer mix (Medicare, Medicaid, commercial payer, self-pay, and charity care) will remain in similar proportion to hospital referred patients. Explain how ACTD will ensure that GMSC physicians do not disproportionally refer Medicaid or patients unable to pay for services to hospitals for their treatment (Application at 73).

On January 20, 2016, the GMCB's Q002 question 8 sought similar information to the above:

"Explain if there will be measures in place to avoid selective referral of the most profitable patients (commercially insured and private pay) to the ASC. Specifically, explain whether the entity will institute any policies to avoid and monitor this issue as it relates to physicians with a financial interest in the ASC."

The Applicant responded on March 31, 2016 as follows:

Yes. The policy of the GMSC is not to make determinations of whether to accept or not to accept a patient based on the patient's insurance status, as stated in our Application at page 21. The following language will be included in our Medical Staff Bylaws: "Non-Discrimination. The Company and all Members utilizing the ASC shall treat patients receiving medical benefits or

¹ Since submitting this answer, the Collaborative Care Agreement has been broadened to provide that participants will support the ACO programs that Health *first* operates, as well as the activities of any group contract that involves quality and performance targets.

assistance under any Federal health care program in a non-discriminatory manner." The Medical Staff Bylaws will apply to and govern all physicians who become credentialed at and use the GMSC to perform surgeries.

Also, to ensure the GMSC is providing sufficient access to the least profitable patients the GMSC will provide quarterly reports to Vermont's Department for Disabilities, Aging and Independent Living (DAIL) documenting the amount of free care and charity care provided at the center and the total amount of patient revenues generated so the agency can ensure the charity care provided is a stable portion of the revenue generated. DAIL has regulated the Eye Surgery Center in this manner for the past seven years since the center opened. As part of this reporting process, the amount and value of services provided to patients on Medicaid can also be provided. Other states have implemented reporting requirements for ASCs that include documenting the amount of Medicaid services provided, in addition to free care and total patient revenue, to help ensure that ASCs are not selectively providing access to services to only the most profitable patients.

It is important to note that an ASC's value in the health care system is to "right size" health care by providing an alternative, lower-cost setting for routine, low-risk surgeries. Only certain surgeries in specific specialties are performed at ASCs, leading to greater efficiency and predictability around supply, personnel and equipment costs. Additionally, only patients who are determined to be no risk or low-risk by their physician are eligible to have their surgeries performed at an ASC.² ASCs also have lower overhead costs as they have no emergency rooms nor are they equipped to provide overnight care. Yet, these same factors that reduce health care costs (and lead to reduced reimbursement by Medicare) may have unpredictable consequences on payer mix. While we can guard against our owners and members intentionally referring only privately insured patients to the ASC, we cannot forgo the cost efficiencies that define an ASC and may unintentionally drive whether a patient is considered "profitable" or not.

The Medical Staff Bylaws, plus the aforementioned peer review policy, the investor language in the Operating Agreement referred to in question 17, below, and the monitoring reports submitted to regulators indicate the Applicant's commitment to ensuring that its facility and the doctors who use it will not discriminate based on a patient's insurance status or ability to pay.

15. Explain in detail the process, policy or guidelines for shared decision making regarding procedures and surgeries performed at GMSC.

Shared decision making is a collaborative process that allows patients and their providers to make health care decisions together. It takes into account the best clinical evidence available, as well as the patient's values and preferences. The practice is aimed at achieving the goal of better decision making to help achieve health outcomes that matter most to the patient. In order to lay the foundation for development and implementation of a sound shared decision making practice, the Green Mountain Surgery Center intends to:

² 42 C.F.R. § 416.166 establishes that covered surgical procedures are those that are not expected to pose a significant safety risk to a patient when performed in an ASC and for which standard medical practice dictates that the patient would not typically be expected to require active medical monitoring and care at midnight following the procedure.

- 1) Adopt a Policy of Evidence-Based Medicine Promotion. (See Draft Policy attached as Exhibit 15). This will help to ensure that practitioners are making use of the best and latest clinical evidence available at all times.
- 2) Develop a 'Patient Bill of Rights' to be displayed at the surgery center and on the website. The Patient Bill of Rights will include the right to be informed about health status and care options, and the right to engage a cooperative process of decision-making and notification.
- As part of the GMSC's Quality Improvement Plan, identify relevant "Patient Decision Aids" developed by organizations such as the Agency for Healthcare Research and Quality (an agency of the U.S. Department of Health & Human Services) and the Mayo Clinic, among others, and make these decision aids available to providers and patients who will utilize the GMSC.

Furthermore, in our Application at page 40, in our discussion of CON standard 1.6, which relates to the Applicant's plans for collecting and monitoring data relevant to health care outcomes and quality, we explained in ¶ 2:

...the proposed Center will comply with the Medicare conditions of participation. In accordance with 42 C.F.R. § 416.41, the Green Mountain Surgery Center will have a governing body that assumes full legal responsibility for determining, implementing, and monitoring all policies governing the Center's operation, and its governing body will have oversight and accountability for the quality assessment and performance improvement program and ensure that the Center's policies and programs are administered so as to provide quality health care in a safe environment. The governing body will, among other things, oversee the Green Mountain Surgery Center's Medical Executive Committee, who shall in turn oversee the Quality Improvement Committee. The Quality Improvement Committee will implement and directly oversee the Quality Improvement Plan. The proposed Center's complete Continuous Quality Improvement Flowchart organizational flowchart is included in **Exhibit 2**.

Exhibit 2 includes the Quality Improvement Plan, the Continuous Quality Improvement Flowchart, and the Facility Plan for Patient Care. The policies explain the roles and composition of the Governing Board of Directors, the Medical Executive Committee, and the Quality Improvement Committee who together are responsible for the procedures performed and the patient care given at the GMSC.

16. Provide the name, percentage of ownership interest, and amount of initial capital investment in the ASC for each member of ACTD, LLC. In addition, for each member provide a description of all relevant experience in owning, operating, or being employed by ASC(s) or other health care facility(s). Include the names(s) and location(s) of the ASC(s) or health care facility(s).

The full response to Question 16 has been submitted by the Applicant to the Green Mountain Care Board separately under confidential cover in accordance with the Board's letter dated November 17, 2016. The Applicant has also submitted separately to the Green Mountain Care Board a proposed redacted and generalized version of the response to Question 16 which, upon approval by the Board, may be provided to the interested parties in accordance with the Board's letter.

17. Provide a list of owners in the ASC who are physician investors or investors in a position to make referrals to the ASC. For each:

(a) Provide the terms of investment to verify that it is not based on referrals and that there are no loans by such investors;

The list of investors provided in response to Question 16 identifies the physician owners of the ASC. Each investor signed ACTD LLC's 'Subscription Agreement' outlining the terms of their investment when their shares were purchased. Each owner attested to the following provisions in the ACTD LLC 'Subscription Agreement':

Section 5. Subscriber Representations and Warranties: ...

- o. No aspect of this Subscription Agreement, nor any remuneration paid or consideration given in connection with this Subscription Agreement, contemplates, intends or requires the referral of any patient by Subscriber to the Company or any of the Company's investors, managers, members or officers, or by the Company or any of the Company's investors, managers, members or officers to the Subscriber.
- p. The Units are being purchased by Subscriber for fair market value, as a result of an arm's length transaction between the Subscriber and the Company.
- q. If Subscriber is a physician, Subscriber reasonably anticipates that, if the Company's Certificate of Need application for the development and operation of an ambulatory surgery center ("ASC") is approved by the Vermont Green Mountain Care Board, that the Subscriber will perform procedures at the ASC and intends to use the ASC as an extension of his or her medical practice. Subscriber has not received any loan or any loan guaranty from the Company or from any other investor of the Company for purposes of financing in part or in whole Subscriber's purchase of the Units.
- (b) Demonstrate that each owner qualifies for and will remain in the anti-kickback safe harbor by
 - (i) confirming that at least 1/3 of the owner's medical practice income, from all sources, for the previous fiscal year or previous 12-month period was derived from his/her performance of procedures set forth on the ASC approved procedure list established by CMS, and
 - (ii) at least 1/3 of the ASC procedures performed by the owner will be performed at the ASC.

The anti-kickback statute prohibits the exchange, or offer to exchange, of anything of value, in an effort to induce or reward the referral of federal health care business. 42 U.S.C. § 1320a-7b. To violate the law, a party must "knowingly and willfully" engage in the prohibited conduct, with the intention of engaging in unlawful conduct. Id. §§ 1320a-7b (b), (h). One can comply with a safe harbor under the anti-kickback law to receive assurance that the conduct does not violate the law. See 42 C.F.R. § 1001.952. However, compliance with a safe harbor is not mandatory under the law and transactions that do not fall within a safe harbor are not per se violations of the law. See Office of Public Affairs, Office of Inspector General, Department of Health & Human Services, Fact Sheet, November 1999, Federal Anti-Kickback Law and Regulatory Safe Harbor. Rather, transactions are evaluated by the Office of the Inspector General on a case-by-case basis. ACTD LLC will require its investors to comply with the requirements of the safe harbor as fully as practicable, but ACTD LLC recognizes that strict compliance with all requirements may not be possible for all investors. All investors who subscribe to ACTD LLC will expressly covenant that they will not engage in any conduct prohibited under the anti-kickback law.

18. Provide the expected timeline for completion of the following preliminary steps for an accreditation survey: a) submission and approval of CMS-855B Medicare Provider Enrollment Application; b) commencement of operations at the ASC (i.e. date of issuance of Certificate of Occupancy; c) completion of a sufficient number of procedures at the ASC to allow the private accrediting body to review a minimum of 10 medical records; and d) submission of Joint Commission or AAAHC application for deemed status.

Months	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Tasks														
Approval of the CON														
Facility Development (Estimated Construction Timeline)														
Appoint Governing Board														
Appoint Medical Executive Committee (MEC)														
a) Submit CMS 855B Medicare Provider Enrollment Application														
Submit CMS 588														
Submit CMS 1561														
Submit CMS 377														
Submit CMS 370														1
Submit NPI Application														
Submit CLIA Waiver Application														
Submit DEA Application														1
Hire Administrator														i
Approve Procedure List														
Credential Medical Staff														
Review and Approve Policies and Procedures														
Review and Approve QAPI, Infection Control, Safety, HIPPA Plans														
Review and Approve Agreements for Outside Services														
Review and Approve Formulary														
Review and Approve Fee Schedule														
Review and Approve Clinical Forms														
Post/Advertise Staff Positions														
Interview and Hire Clinical and Admin Staff														
Train and In-service Staff														
Supply Selection and Ordering														
b) Commencement of Ops - Schedule and Perform Initial Procedures														
c) Submit AAAHC/Joint Commission Deemed Application														
d) AAAHC/Joint Commission Survey														

19. Provide an organizational chart for ACTD, LLC.

Attached as Exhibit 19.

This plan is consistent with the staffing description provided in the Application, page 19:

The Green Mountain Surgery Center plans to open with a staff of 22 FTEs. The staff is anticipated to include 15 registered nurses, 4 surgical technologists, and 3 administrative and clerical staff. A fulltime Administrator, who will be under the direct supervision of the Board of Managers, will have day-to-day management responsibilities for the ASC. The Administrator will collaborate with a physician Medical Director, appointed by the Green Mountain Surgery Center's Board of Managers, who will be responsible for clinical operations.

Please let us know if you have any additional questions or need clarification regarding any of these responses.

Sincerely,

Eileen Elliott, Esq.

Dunkiel Saunders Elliott Raubvogel & Hand, PLLC

ilun Jelliott

cc: Judy Henkin, Esq., General Counsel, Green Mountain Care Board
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Patients struggle with long waits at UVM Medical Center

Dan D'Ambrosio, Free Press Staff Writer

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(Photo: GLENN RUSSELL/FREE PRESS)

Last August, Sue Schermerhorn's active lifestyle ended when she developed a pain in her neck that didn't go away. The 72-year-old retiree lives with her husband on a small farm in Charlotte where she rode horses, walked three miles daily and gardened.

"(The pain) is pretty constant." Schermerhorn said. "It's like a muscle spasm. It hurts. I can't shop very long. I'm sure I'm not the nicest person to live with, with constant pain for so long. It impacts what I can do and where I can go."

Schermerhorn's doctor, Andrea Regan, started her on massage, stretching and physical therapy.

After two months, Schermerhorn was still suffering, so Regan referred her to the University of Vermont Medical Center's Spine Program. Schermerhorn called for an appointment and was told the first available slot was on Feb. 17, three months out.

"My first response ... was I could be dead by then," Schermerhorn remembered.

Linda Borman, 67, began having recurrent ear infection about two years ago. She was prescribed antibiotics by her primary care doctor, Marie Sandoval, and the infection went away, but it kept coming back.

"I never had ear infections my whole life until now," Borman said. "I wanted to know why I was getting these ear infections, so I wanted to see a specialist."

Borman, with the approval of Sandoval's office, called for an appointment with UVM Medical Center's ear, nose and throat practice in July and was told the first available appointment was in December.

"I was so shocked it was going to take so long to deal with something that had to be attended to," Borman said.

The experiences of Schermerhorn and Borman are not unusual, according to independent physicians interviewed by the Burlington Free Press, and the Green Mountain Care Board, which oversees health care in Vermont. Both physicians and the Care Board are concerned about long wait times to see specialists, and the effect that has on the health care of Vermonters. The Care Board has asked UVM Medical Center, Dartmouth-Hitchcock Medical Center in New Hampshire and other hospitals to provide data on wait times for access to medical specialties.

Buv Photo



"Sometimes it isn't the length of the wait, it's the acuity of the situation that's the scary part," Dr. Andrea Regan of Charlotte Family Health Center said. "I'm getting used to handling more and more outside my comfort zone, but there are people who needed to be seen yesterday." (Photo: RYAN MERCER/FREE PRESS)

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Susan Barrett, executive director of the Care Board, said Board Member Jessica Holmes, a professor of economics at Middlebury College, raised the wait time issue at the board's Dec. 1 meeting. Holmes said she was hearing anecdotally that there are long waits to see specialists and even primary care doctors.

"One of our goals is to help ensure that Vermonters have access to the care they need so we have requested more information from the provider community," Holmes said in an email to the Burlington Free Press.

Officials at the UVM Medical Center acknowledge there are long wait times to see their doctors in some specialties, and point to high demand and a shortage of doctors as the reasons.

"The physician workforce in this country is aging," said Lisa Goodrich, vice president of operations for the UVM Medical Group. "We will at some point hit a crisis of physicians aging out of the workforce without bringing in as many new people. Medicine is not the only place for bright young people to go any more."

Responding specifically to the three-month wait Schermerhorn faced to get into the spine clinic, Goodrich said her records show the wait for an appointment in the clinic in November was 27 days, or less than a month. For the ear, nose and throat practice, where Borman experienced a five-month wait, Goodrich said her records show a 56-day wait when Borman called for an appointment in July, or about two months.

Doctors wanted

Goodrich works with access numbers, "day in and day out," she said. Chris Oliver, vice president of clinical services for UVM Medical Center, said the hospital tracks wait times for imaging — MRIs, mammograms and the like — and for access to physicians.

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University of Vermont Medical Center in Burlington. (Photo: GLENN RUSSELL/FREE PRESS FILE)

"Is it easy for everyone to get in when a person wants? No," Goodrich said.

Goodrich points to dermatology as a specialty with a wait time for a routine appointment of close to 100 days, or 14 weeks.

"It's a capacity and demand issue, pure and simple," she said.

Patients with something that looks like skin cancer will get in the next day, Goodrich said, but for patients with rashes, for example, there will be a conversation between a UVM dermatologist and the primary care doctor.

"Primary care doctors can manage a lot of skin conditions," she said.

There are long waits for appointments in both rheumatology and endocrinology, Goodrich said, similar to dermatology.

"In those two areas we have lost physicians in the last several months and we have been actively recruiting for two more physicians in each practice," she said.

Goodrich said in the specialty areas of endocrinology, rheumatology and neurology, the nation is not graduating enough doctors to fill all of the open positions.

It's the monopoly

Dr. Paul Reiss of Evergreen Family Health, an independent practice in Williston, blames Vermont's long wait times for specialized care on UVM Medical Center's monopolistic position in the health care marketplace.

Related:

Independent doctors say hospital thwarts competition

(http://www.burlingtonfreepress.com/story/news/2016/11/27/independent-doctors-say-university-of-vermont-medical-center-thwarts-competition/91553424/)

"The longest wait times in general are the specialties with no options to the UVM Medical Center," Reiss said.

As an example, Reiss points to Associates in Orthopaedic Surgery on San Remo Drive in South Burlington. UVM Medical Center bought the practice — the last remaining independent orthopedic practice in Chittenden County — in April. Reiss said before Associates in Orthopaedic Surgery joined UVM Medical Center, he could get appointments for his patients with a doctor in less than a month. Since joining the Medical Center, he says, access to the practice has "plummeted."

"Now it takes two or three months and you're going to see a nurse practitioner," Reiss said.

Lisa Goodrich said it was always Associates in Orthopaedic Surgery's practice to have patients initially be seen by a nurse practitioner or the equivalent. She said she has been tracking access to the clinic since it joined UVM Medical Center on April 1, and that wait times have ranged from two to 21 days between April and December.

"It doesn't sound consistent with what Dr. Reiss is communicating," Goodrich said. "We have not had wait times longer than three weeks."

Reiss cited wait times to see specialists at UVM Medical Center of one to seven months for neurology; four to six months for endocrinology; two to four months for rheumatology; two to four months for ear, nose and throat; and up to nine months for dermatology.

"That's a long time to wait for even routine appointments," Reiss said. "It's a lot of worry. Patients are seeing specialists because they have problems that need to be managed."

Long wait times also force primary care doctors to manage problems they're not comfortable managing, Reiss said.

"If a referral is made it means the primary care physician is now beyond their comfort level," he said. "That wait time is filled with both the patient and physician being somewhat uneasy with that patient's medical care."

Question of competition

UVM Medical Center maintains Vermont has about the right capacity for health care, and argues more access to care would drive up costs through increased utilization by patients.

Independent doctors disagree, saying the Medical Center's monopoly needs to be broken, allowing competition into the marketplace.

The issue is coming to a head in the certificate of need application for Green Mountain Surgery Center, an independent facility that would focus on providing colonoscopies and endoscopies, but will also do pain management procedures and general surgeries. The Surgery Center submitted its application to the Green Mountain Care Board in July 2015, citing shorter waiting times as one of the benefits the facility would bring to Vermonters.



In April, the Care Board asked UVM Medical Center, and all of the state's hospitals, to provide data on the 10 surgeries and/or procedures with the longest wait times for the services the Green Mountain Surgery Center plans to provide.

The Care Board also asked the hospitals for the factors that have the greatest impact on wait times and the steps that have been taken or planned to reduce wait times.

UVM Medical Center responded it does not track wait times for any surgeries or procedures. It only tracks wait times for imaging and access to physicians. Chris Oliver, vice president of clinical services, explained there are many variables that affect wait times for surgeries and procedures, including some that are out of the hospital's

Director of Health Care Reform Robin Lunge, seen in Montpelier on Wednesday, November 16, 2016, has been named to the Green Mountain Care Board. (Photo: GLENN RUSSELL/FREE PRESS) control. Patients sometimes want to postpone surgeries. There can be insurance issues, or pre-op testing that needs to be done.

"Wait times is not an accurate measure," Oliver said. "What we track is capacity of operating rooms for the hours you staff them. I do want to point out if a patient presents with an urgent condition they are done the same day."

Oliver said the operating rooms at the Medical Center are utilized at about 76 percent of capacity, while the operating rooms at the Fanny Allen campus are utilized at about 70 percent of capacity. UVM Medical Center also told the Care Board that in the past three fiscal years, there have been no complaints from independent surgeons about access to operating rooms.

For all those reasons, the Vermont Association of Hospitals and Health Systems opposes granting a certificate of need to Green Mountain Surgery Center. UVM Medical Center is a member of the association.

Confusion reigns

Sen. Tim Ashe, D/P- Chittenden, the new president pro tempore of the Vermont Senate, believes Vermont's certificate of need process "comes across as a little ad hoc when it comes to the potential creation of new facilities or expansion of existing ones."

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Sen. Tim Ashe, P/D-Chittenden, says it may be time to look at the certificate of need process that considers new health care facilities in Vermont. (Photo: Free Press File)

"The fact that there's so much debate or confusion about how long someone must wait for a procedure ... means the certificate of need process probably needs a fresh look," Ashe said.

Ashe said UVM Medical Center's contention that Vermont has about the right capacity to provide health care and therefore doesn't need competing health care facilities raises a philosophical question.

"OK, maybe one entity should do it, but why should it be you?" Ashe asked. "They are essentially a guaranteed monopoly. All the hospitals are. We don't have competition like they do in Boston."

Amy Cooper, executive director of HealthFirst, the association of independent doctors in Vermont, is leading the effort to establish the Green Mountain Surgery Center. Cooper said wait times for operating rooms and procedures matter too, despite what Oliver says.



Amy Cooper, executive director of HealthFirst, in Burlington on Thursday, October 6, 2016. (Photo: GLENN RUSSELL/FREE PRESS)

"You can't improve anything you don't measure," Cooper said. "There's no accountability for wait times. If the hospital isn't monitoring itself and the (Green Mountain Care Board) isn't doing it, there's no accountability and patients are the ones getting impacted negatively."

'We want to know what's happening out there'

Sue Schermerhorn made an appointment at Vermont Interventional Spine Center — an independent practice — for Jan. 3, six weeks earlier than the UVM Medical Center Spine Program could see her. She learned she is suffering from arthritis in her neck, and a few other issues.

"Old age generally," Schermerhorn summarizes.

The Spine Center can alleviate her pain, Schermerhorn said, but can't make it go away. Her first treatment is scheduled for Jan. 24.

Linda Borman said she got two more ear infections while she was waiting for her appointment in December. She said she called to try to get in earlier and was told nothing was available.

When Borman asked if there was someplace else to go, she was told she could try Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire.



Dartmouth-Hitchcock Medical Center in Lebanon, N.H. (Photo: AP FILE)

"I didn't even bother calling them," Borman said of Dartmouth-Hitchcock. "It's another huge institution."

Borman had her appointment at UVM Medical Center's practice in December, which she said lasted 15 minutes.

"You're in and you're out," Borman said. "It feels like an assembly line."

Lisa Goodrich said appointments at UVM Medical Center are scheduled based on the patient's presenting complaint, and that in the case of Borman, 15 minutes was appropriate.

"Not every appointment is scheduled for 15 minutes," Goodrich said. "If a patient has complex needs she is scheduled for a longer period of time. Also a physician doesn't walk out of the room after 15 minutes. If they're not done, they don't finish the appointment until they make sure they've addressed the patient's concern."

Goodrich said UVM Medical Center monitors patient satisfaction with surveys, and that on average, 92 percent of patients rate their experiences with providers as "very good," or "excellent."

Susan Barrett of the Green Mountain Care Board is uncertain when the board will receive wait time data from UVM Medical Center, Dartmouth-Hitchcock and other providers. Barrett hopes, however, to schedule a board meeting in late February or early March to discuss the issue. The meeting will be open to the public.

"We really want to know what is happening out there," Barrett said.

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(http://www.burlingtonfreepress.com/story/news/2016/11/27/independent-doctors-say-university-of-vermont-medical-center-thwarts-competition/91553424/)

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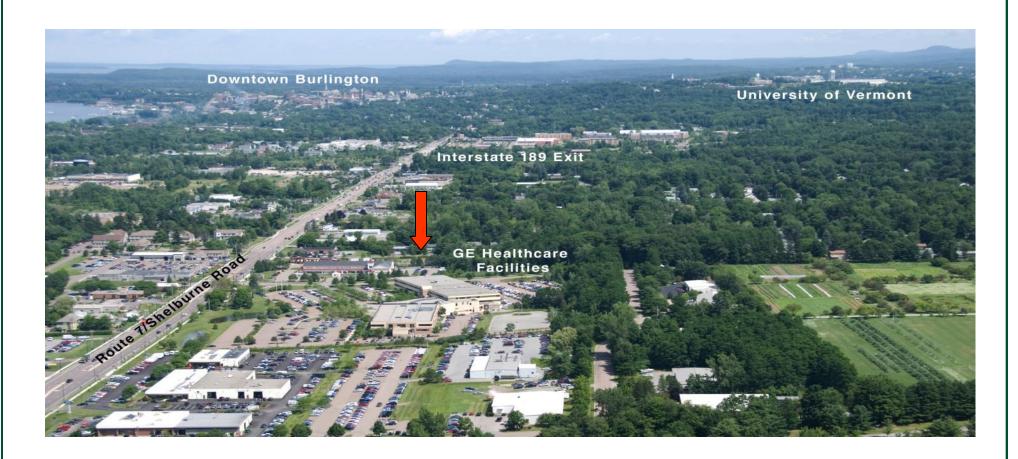
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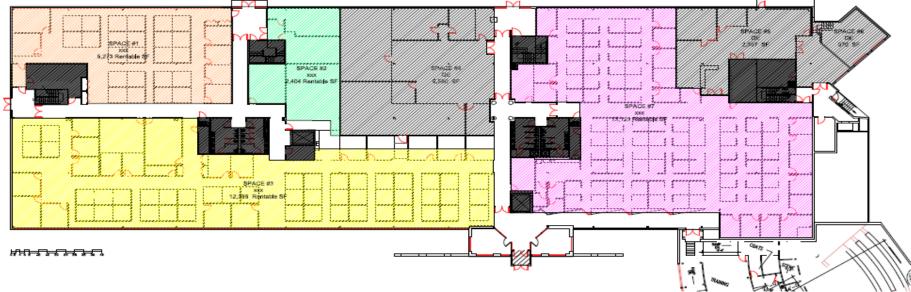
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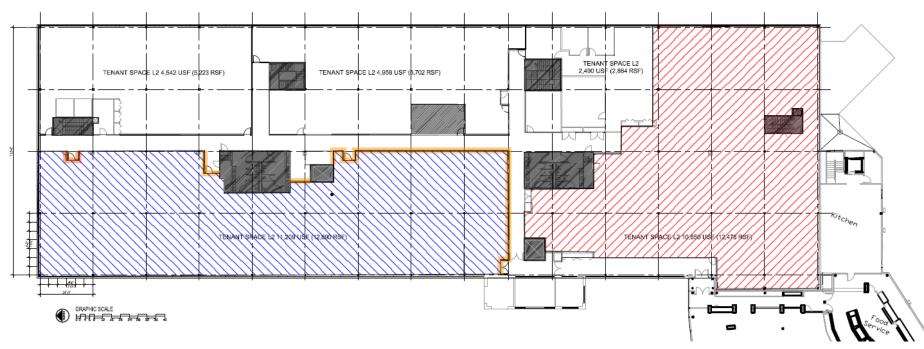


SITE KEY

BUILDING 100 40 IDX DRIVE. 1st FLOOR

1st Floor Multi-Tenant Concept Rendering

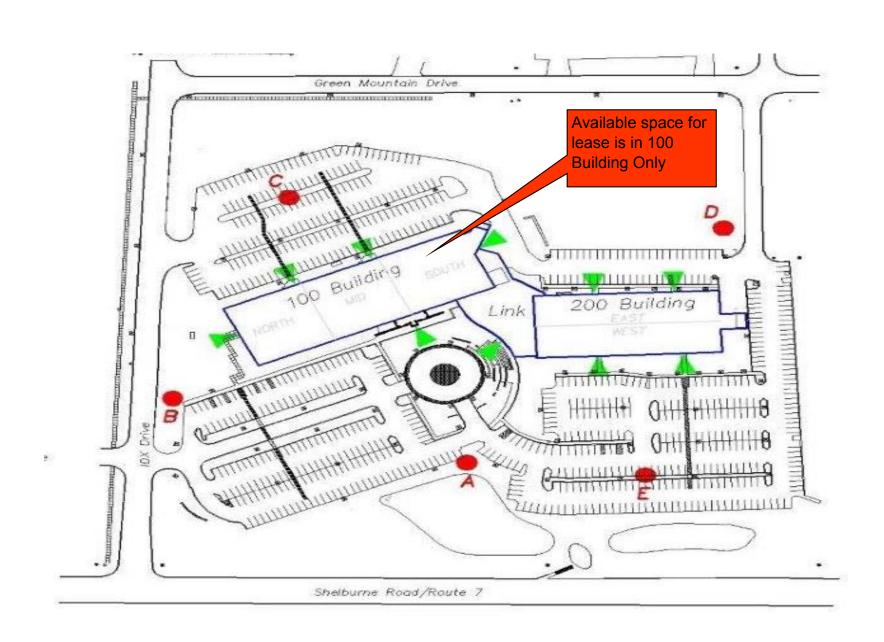




2nd Floor Multi-Tenant Concept Rendering



3rd Floor Multi-Tenant Concept Rendering



Site Plan



ACTD Ambulatory Surgery Center Functional Space Program

Public Spaces		630
Administration/Business		540
Pre/Post Operative	16 Bays	2,610
Surgical Suite	2 Class C Rooms	2,130
Special Procedure Suite	4 Procedure Room	1,280
Staff Facilities		785
Service Areas	<u> </u>	910
	NET AREA	8,885
Corridors, Interior Wall Massing, Columns, Chases	35%_	3,110
	TOTAL GROSS AREA	11,995
	SAY	11,990

	Net Useable	Number of	Total Net
Functional Area	Space	Spaces	Area
Public Spaces			
101 Vestibule	-	-	_
102 Reception - Private Interview Area	180	1	180
103 Family Waiting	400	1	400
104 Refreshments-Vending	50	1	50
105 Public Toilets	-	-	-
Net Area			630
Administration/Business			
201 Business Office (open plan - 4 workstations)	200	1	200
202 Multi-purpose Conference Room	100	1	100
203 Administrator Private Office	110	1	110
204 Mailroom - Supplies Storage	30	1	30
205 Computer Room - Records Storage	100	1 _	100
Net Area			540
Pre/Post Operative			
301 Pre/Post Operative Bays (3 hard walls, curtain wall front)	110	16	1,760
302 Nurse Station	225	1	225
303 Patient Toilet/Changing Room	100	3	300
304 Clean Utility	120	1	120
305 Dirty Utility	120	1	120
306 Staff Toilet	60	1	60
307 Patient Lockers	25	1	25
Net Area			2,610

AMB Development Group 2/27/2015

ACTD Ambulatory Surgery Center Functional Space Program

Surgical Suite 401 'Class C' Operating Room 420 2 402 Scrub Station/Sub-Sterile 200 1 403 Equipment Holding 200 1 404 OR Nurse Control Station/Anesthesia Work Room 150 1 405 Janitor Closet 60 1	840 200 200 150 60
402Scrub Station/Sub-Sterile2001403Equipment Holding2001404OR Nurse Control Station/Anesthesia Work Room1501	200 200 150 60
403 Equipment Holding2001404 OR Nurse Control Station/Anesthesia Work Room1501	200 150 60
404 OR Nurse Control Station/Anesthesia Work Room 150 1	150 60
	60
405 Janitor Closet 60 1	
406 Soiled Processing/Decontamination 200 1	200
407 Sterile Processing - Prep/Pack 200 1	200
408 Clean/Sterile Supplies 200 1	200
409 Waste/Refuge Holding 80 1	80
Net Area	2,130
Special Procedure Suite	
501 Endoscopy/GI Procedure Room 200 4	800
502 Decontam/Soiled Room 120 2	240
503 Clean Room/Scope 120 2	240
Net Area	1,280
Staff Facilities	
601 Staff Lounge 225 1	225
602 Locker Room - Female 240 1	240
603 Locker Room - Male 240 1	240
604 Shower 80 1	80
Net Area	785
Service Areas	
701 General Storage 300 1	300
702 Electrical Rooms 200 1	200
703 Water Room 200 1	200
704 Vacuum Room 100 1	100
705 Medical Gas Room 110 1	110
Net Area	910

AMB Development Group 2/27/2015

Chapter Name: Anesthesia Services	Policy #: 9.25	AAAHC Standards:
Title: ASA Classifications	Date: 6/6/2016	Medicare CfC:

Policy Statement

The anesthesiologist provider assigns patients ASA classifications.

Green Mountain Surgery Center will routinely treat patients classified as ASA I and II. Patents with other classifications will only be treated at this Center upon medical clearance by the Medical Director (or his/her designee).

Procedures

I. Patients admitted to Pre-Op will be assigned an ASA rating by the anesthesiologist. This grading system is based on the presence of disease determined pre-operatively. The following criteria has been listed by the American Society of Anesthesiologists for grading purposes:

A. ASA I:

1. No organic pathology or patients in whom the pathological process is localized and does not cause any systemic disturbances or abnormalities. No moderations or changes in lifestyle. Example: a fibroid uterus in an otherwise healthy woman.

B. **ASA II:**

1. A mild but definite systemic disturbance caused by either the condition that is to be treated by surgical intervention or which is caused by other existing pathological process. Examples: smokers, obesity, old age, infants, mild diabetes, malignant disease without metastasis.

C. ASA III:

 Severe systemic disturbance from any cause or causes that limits activity but is not incapacitating. It is not possible to state an absolute measure of severity since this is a matter of clinical judgement. Examples: Heavy smokers with COPD, extreme obesity/age, poorly regulated diabetes, combination of multiple ASA 11 criteria, cancer with metastasis, recent CABG.

D. **ASA IV**:

1. Extreme systemic disorder which is incapacitating and is a constant threat to life regardless of the type of treatment. This class is intended to include only patients that are in extremely poor physical state. Examples: Cardiovascular-renal disease with marked impairment, patients who require surgery in the presence of marked blood loss, malignant disease with brain metastasis or metastasis to other organs.

E. ASA V:

1. The patient is not expected to survive without delay.

Who Should Know this Policy:						
✓ All Employees✓ OR Staff✓ Administrator✓ All Business Office Staff	 ☐ All Clinical Staff ☐ Pre-Op Staff ☐ Medical Director ☐ Business Office Manager 	☐ All Medical Staff ☐ Post-Op Staff ☐ Nurse Manager				

Chapter Name: 9 - Anesthesia Services	Policy #: 9.00	AAAHC Standards: 9-A,B,C and D
Title: Anesthesia Care Protocol	Date: 6/6/2016	Medicare CfC: 416.42(b)(1), 416.42(b)(2)

Policy Statement

The medical management and conduct of anesthesia will be in accordance with current accepted practices and procedures in the field of anesthesiology

Procedures

Anesthesiology is a discipline within the practice of medicine specializing in:

- The medical management of patients who are rendered unconscious and/or insensible to pain and emotional stress during surgical, obstetrical, and certain other medical procedures (involves pre-operative, intra-operative, and post-operative evaluation and treatment of these patients);
- The management of problems in pain relief;
- The management of Cardiopulmonary Resuscitation;
- The management of problems in pulmonary care.

Within the scope of this document, the phrase 'anesthesia person' shall refer to a physician anesthesiologist with credentials to practice anesthesia as outlined in the Medical Staff By-Laws.

"ASA" refers to the American Society of Anesthesiologists.

1. Personnel

- a. There will be a Medical Director/ whose responsibility is to direct the anesthesia services within the framework of the Medical Staff By-laws and Rules and Regulations, the Center's Policies & Procedures, and any applicable regulatory guideline. In addition, the Medical Director/Chief is to provide personnel and equipment adequate to meet the anesthetic requirements of the Center and as outlined in the contractual agreement.
- b. Any appointment of an Anesthesiologist or Certified Nurse Anesthetist shall conform to the procedures outlined in the By-Laws.
- There will be an Anesthesiologist available during operational hours and until all
 patients are discharged home. He/she will be available for emergencies requiring
 specialized skills in resuscitation anywhere in the Center, as well as in the Operating
 Room.
- An Anesthesiologist should supervise all anesthetics conducted with the aid of a CRNA if appropriate. The Anesthesiologist will be present for induction and

- emergence, and immediately available for assistance and consultation as deemed necessary by the particular individuals of each individual case.
- 4. No patient shall receive deep sedation or general anesthesia unless one or more additional physicians, dentists, or physician-supervised qualified individuals, beside the one performing the surgery, are present.
 - a. Available Anesthesia Provider(s) shall respond to the resuscitation signal when and as it happens for the purposes of assisting in the resuscitation of the patient.

5. Anesthesia Care Summary

- a. The medical management and conduct of anesthesia will be in accordance with current accepted practices and procedures in the field of Anesthesiology. Each patient will be evaluated by an Anesthesiologist prior to surgery. This evaluation will include a chart review and patient interview/exam including:
 - 1. Previous anesthetic experiences;
 - 2. Current drug therapy;
 - 3. Drug allergies;
 - 4. Co-morbid conditions
 - 5. Physical evaluation (airway, heart and lungs at a minimum);
 - 6. Admission vital signs;
 - 7. Confirmation of NPO status;
 - 8. Assignment of ASA classification
- 6. Review of options/risks with the patient.
 - a. Prior to elective surgery, the following information should be present in the patient's medical record:
- 7. Anesthesia evaluation (as listed above)
- 8. Completed pre-op nursing record and consent form
- 9. Current history and physical.
 - a. Anesthetic apparatus must be inspected, tested, and made serviceable by the Anesthesia Provider before induction. In particular, the anesthesia machine must be inspected according to the policy regarding anesthesia safety, equipment care, and infection control. Monitoring techniques (invasive and non-invasive) employed during an anesthetic will be selected based on the patient's medical status and the type and magnitude of the surgical procedure. The Department and all of the members shall adhere to the "Standards of Basic Intra-operative Monitoring" endorsed by the American Society of Anesthesiologists. These standards will be followed during all General Anesthetics, Regional Anesthetics, and Monitored Anesthesia Care.
 - b. The time based anesthesia record shall include at a minimum:
 - a. Pre-op evaluation as described above;*
 - b. Dosage of all drugs and agents employed;
 - c. Type and amount of fluids given;
 - d. Evidence of monitoring; (intra-op physiologic monitoring must include continuous use of a pulse oximeter and blood pressure determination at frequent intervals)**

- e. Airway management and ventilation used;
- f. Techniques employed;
- g. Unusual event during the anesthesia period;
- h. Status of the patient at the conclusion of anesthesia;
- Patient status at conclusion of surgery and admission to recovery room;
- j. Evaluation prior to discharge.
- c. The Surgery Center will provide adequate facilities for the storage of anesthetic gases and oxygen to meet requirements of the N.F.P.A. #56 (Series 50). Flammable anesthetic agents will not be used. Equipment and drugs for treatment of "malignant hyperthermia" will be immediately available in the facility at all times.
- d. Continuous EKG monitoring and end-tidal CO₂ determination is required with all general anesthesia; a means of measuring body temperature will be readily available.
- e. At the conclusion of anesthetic, the patient will be evaluated for postanesthesia management. In the case of most local anesthetics, the patient may be discharged directly from the operating room to the secondary recovery room.
- 10. The anesthesia provider shall remain with the patient until the initial set of vital signs has been determined. The recovery room nurse should be informed of any specific problems presented by each patient. The patient shall remain in the recovery room until consciousness has been established (when appropriate) and vital signs are stable.
- 11. A physician or dentist is responsible for the medical discharge of the patient. Medical discharge refers to discharging a patient following clinical recovery from surgery and anesthesia.
- 12. Before medical discharge from the facility, each patient must be evaluated by a physician, dentist, or a delegated, qualified individual supervised by a physician or dentist, approved by the Governing Body, to assess recovery. If medical discharge criteria have previously been set by the treating physician, dentist, and approved by the Governing Body, a delegated qualified individual may determine if the patient meets such discharge criteria, and if so, may discharge when those criteria are met.*
- 13. Personnel qualified to provide anesthesia and personnel qualified in advanced resuscitative techniques (i.e. PALS, ACLS) are present or immediately available until the patient has been medically discharged.
- 14. Patients who have received moderate sedation/analgesia, deep sedation/analgesia, regional anesthesia, or general anesthesia are discharged in the company of a responsible adult.

Who Should Know th	nis Policy:	
 ☑ All Employees ☐ OR Staff ☐ Administrator ☐ All Business Office Staff 	☐ All Clinical Staff ☐ Pre-Op Staff ☐ Medical Director ☐ Business Office Manager	☐ All Medical Staff ☐ Post-Op Staff ☐ Nurse Manager

Promotion of Evidence-Based Medicine

Policy Statement

The Green Mountain Surgery Center (GMSC) is committed to promoting Evidence-Based Medicine (EBM) through a defined process that fosters the development, implementation, review and updating of evidence-based guidelines in the delivery of care to our patients. GMSC will utilize nationally-available resources based on scientific methods and guidelines focused on EBM to identify evidence-based clinical care processes. The Quality Improvement Committee will collaboratively participate in the development, implementation and review of additional guidelines when appropriate.

Definitions

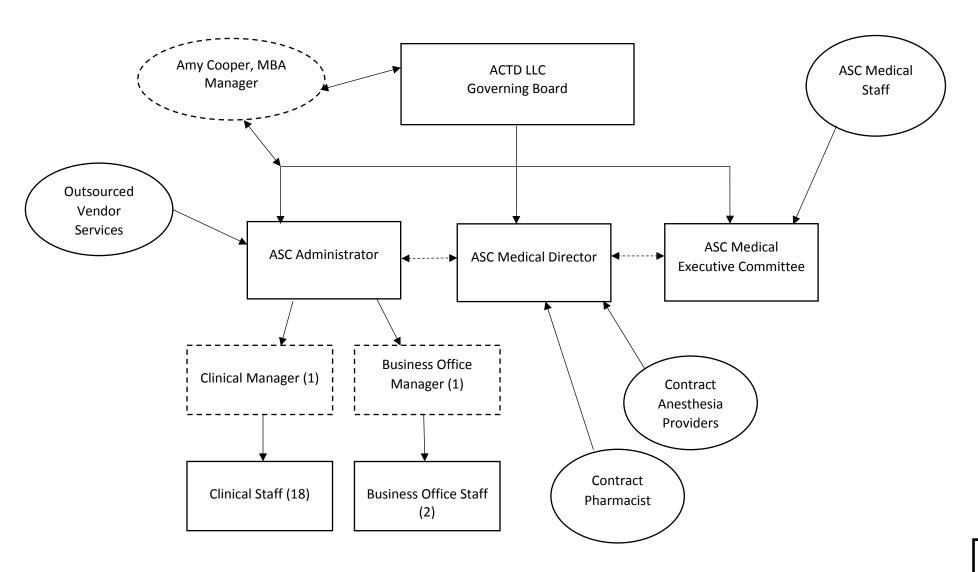
Evidence-Based Medicine (EBM) – the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.

Procedure

- A. Evidence-based guidelines will be utilized where possible to coordinate patient care based on the conditions, diseases or clinical needs identified.
- B. Suggested guidelines for use include: National Quality Forum (NQF), Institute for Clinical Systems Improvement, the Centers for Medicare and Medicaid Services (CMS) Agency for Research and Quality, CMS National Coverage Determination Guidelines, CMS Quality Incentive Program Guidelines and specialty-specific guidelines.
- C. The Quality Improvement (QI) Committee will monitor the use of guidelines protocols will include, when appropriate, the following concepts:
 - 1) Pre-visit planning;
 - 2) Clinical (practitioner-driven) and non-clinical standing orders;
 - 3) Patient education tools;
 - 4) Individual Care Plan development and processes to determine challenges that may be barriers to meet treatment goals;

- 5) Process for monitoring medication reconciliation and compliance;
- Patient-centered tools that develop resources to meet the cultural and linguistic needs of the patients and their families;
- 7) Community resources and referrals, including identifying specialty care related to important conditions;
- 8) Specific plans for preventing emergency room visits and hospitalizations and post-visit follow-up,
- D. Participants and care coordinators will utilize the following tools within the Electronic Medical Records (EMR) or appropriate documentation system that provide support for EBM protocols:
 - 1) Clinical documentation system (EMR; hospital system; care coordination system);
 - 2) Proven knowledgebase and patient education tools (ex: Healthwise);
 - 3) Approved online sites where EBM guidelines are available (defined by practice or specialty); and
 - 4) Community resources with specialty expertise.

ACTD LLC Organizational Chart



Form A – Verification Form

STATE OF VERMONT GREEN MOUNTAIN CARE BOARD

In re: ACTD LLC MULTI-SPECIALTY)	
AMBULATORY SURGERY CENTER)	Docket No. GMCB-010-15com
)	
)	
)	

Verification Under Oath – Responses and Supplemental Exhibits

Amy Cooper, being duly sworn, states on oath as follows:

- 1. My name is Amy Cooper. I am the manager of ACTD LLC. I have reviewed the Responses and Supplemental Exhibits being submitted with this Verification to support the Certificate of Need Application for the Green Mountain Surgery Center ("Responses").
- 2. Based on my personal knowledge, after diligent inquiry, the information contained in the Responses is true, accurate and complete, does not contain any untrue statement of a material fact, and does not omit to state a material fact necessary to make the statement made therein not misleading, except as specifically noted in the Responses.
- 3. My personal knowledge of the truth, accuracy and completeness of the information contained in the Responses is based upon either my actual knowledge of the subject information or, where identified below, upon information reasonably believed by me to be reliable and provided to me by the individuals identified below who have certified that the information they have provided is true, accurate and complete, does not contain any untrue statement of a material fact, and does not omit to state a material fact necessary to make the statement made therein not misleading.
- 4. I have evaluated, within the 12 months preceding the date of this affidavit, the policies and procedures by which information has been provided by the certifying individuals identified below, and I have determined that such policies and procedures are effective in ensuring that all information submitted or used by ACTD LLC in connection with the Certificate of Need program is true, accurate and complete. I have disclosed to ACTD LLC all significant deficiencies, of which I have personal knowledge after diligent inquiry, in such policies and procedures, and I have disclosed to ACTD LLC any misrepresentation of facts, whether or not material, that involves management or any other employee participating in providing information submitted or used by ACTD LLC in connection with the Certificate of Need program.

- 5. The following certifying individuals have provided information or documents to me in connection with the Responses, and each such individual has certified, based on his or her actual knowledge of the subject information or, where specifically identified in such certification, based on information reasonably believed by the certifying individual to be reliable, that the information or documents they have provided are true, accurate and complete, do not contain any untrue statement of a material fact, and do not omit to state a material fact necessary to make the statement made therein not misleading:
 - a. Joan Dentler Avanza Strategies; provided the financial and clinical projections and assumptions underlying the proposed ASC, recommendations regarding size, scope and staffing of the proposed ASC the policies and protocols attached as Exhibits 9.a and 9.b and information relating to CPT codes.
 - b. Jack Amormino AMB Development Group; provided information relied upon in our response to Question 8, Exhibits 8.a, 8.b and 8.c, and information relating to compliance with FGI Guidelines.
 - c. Physicians practicing in the area who wish to remain anonymous; provided biographical information and information relating to CPT codes and historical data underlying projections.
- 6. In the event that the information contained in the Responses becomes untrue, inaccurate or incomplete in any material respect, I acknowledge my obligation to notify the Green Mountain Care Board and to supplement the Responses, as soon as I know, or reasonably should know, that the information or document has become untrue, inaccurate or incomplete in any material respect.

On January 24, 2017, Amy Cooper appeared before me and swore to the truth, accuracy and completeness of the foregoing.

Notary public 1 mm 4

My commission expires February 10, 2019