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

> Re: Docket No. GMCB-010-15con, Proposed Ambulatory Surgery Center **Post-Hearing Brief**

Dear Donna:

Enclosed please find ACTD LLC's Post-Hearing Brief.

Sincerely,

Eileen Elliott, Esq.

Dunkiel Saunders Elliott Raubvogel & Hand, PLLC

Vilan Jellutt

Judy Henkin, Esq., General Counsel, Green Mountain Care Board cc: Marisa Melamed, Health Policy Analyst, Green Mountain Care Board Noel Hudson, Esq., Health Policy Director, 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

STATE OF VERMONT GREEN MOUNTAIN CARE BOARD

IN RE: APPLICATION OF ACTD LLC)	
FOR GREEN MOUNTAIN SURGERY)	GMCB-010-15CON
CENTER)	

ACTD LLC'S POST-HEARING BRIEF

The Green Mountain Care Board ("the Board") is charged by statute with the responsibility of "promoting the rational allocation of health care resources in the state." Given the tremendous benefits the Applicant has shown that ambulatory surgery centers ("ASCs") offer, the demonstrated contributions of multispecialty ASCs to the health care systems in every other state in the country, and the widespread public support that this certificate of need application ("the Application") has received from patients, employers, physicians, and payers, the Board cannot reasonably conclude that the appropriate number of freestanding multispecialty ambulatory surgery centers in the State of Vermont is zero. The Green Mountain Surgery Center ("GMSC" or "Center") is the right project at the right time to lower health care costs, improve patient experience and expand access to health care, while maintaining or even improving the quality of health care in the State.

As briefly summarized below, the proposed GMSC satisfies each of the certificate of need ("CON") criteria, and the Board must therefore approve the Application.

18 V.S.A. § 9437. Criteria. A certificate of need shall be granted if the applicant demonstrates and the board finds that:

(1) the application is consistent with the health resource allocation plan;

See the below discussion of the health resource allocation plan standards.

(2) the cost of the project is reasonable, because:

(A) the applicant's financial condition will sustain any financial burden likely to result from completion of the project;

Applicant has demonstrated that the proposed project is financially viable by detailing project costs, projected revenues, and sources of financing.²

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¹ 18 V.S.A. § 9431(a).

See, Certificate of Need Application, *Development of Ambulatory Surgery Center*, Docket Number GMCB-010-15con (July 2, 2105) ("the Application") at 58-59; Applicant's Response to Board Q001 Question 19 (December 23, 2015); Applicant's Response to Board Q002 Question 1-7 (March 31, 2016); Applicant's Response to Board Q005 Question 3 (August 24, 2016); April 13, 2017 Hearing Presentation, Amy Cooper, Manager ACTD LLC, Green Mountain Surgery Center, Routine Outpatient Surgical Care *in the right setting, at the right time, for the right price*.

(B) the project will not result in an undue increase in the costs of medical care. In making a finding under this subdivision, the board shall consider and weigh relevant factors, including: (i) the financial implications of the project on hospitals and other clinical settings, including the impact on their services, expenditures, and charges; (ii) whether the impact on services, expenditures, and charges is outweighed by the benefit of the project to the public;

The GMSC will reduce the cost of medical care for its patients. The GMSC will have a small impact on the two hospitals from which it will draw cases relative to their overall size, and likewise a small impact on their services, expenditures, and charges. The small impact GMSC may have on hospitals is far outweighed by the GMSC's very substantial benefit to the public.

It is undisputed in this proceeding that the proposed GMSC will significantly reduce the cost of health care for the patients it serves, and the government programs and private payers that insure them. Based on recent analysis of this issue by MedPac (2013, 2014), Rand (2011), the Ambulatory Surgery Center Association (2016), and the Office of the Inspector General (2014), ASCs are paid on average between 50-56% of what hospital outpatient surgery departments are paid for the same services.³ Applicant estimates the GMSC will save Medicare \$2 million per year, Medicaid \$500,000 per year, and commercial payers \$3 million per year.⁴

It is also undisputed that the GMSC will draw a relatively small number of cases from the two hospitals it will impact. GMSC will mainly impact the University of Vermont Medical Center ("UVMMC"). Once fully operational, the GMSC expects to draw roughly 4,600 procedures per year from UVMMC, representing roughly 14% of UVMMC's total procedure and surgery volume. ⁵ These routine procedures have low reimbursement profiles compared to all procedures that generate revenue in UVMMC's operating and procedure rooms. The GMSC's impact on Northwestern Medical Center ("NMC") will be even smaller. Once fully operational, the GMSC expects to draw about 200 procedures per year from NMC, representing roughly 3% of NMC's total procedure and surgery volume. ⁶

It follows that any impact on UVMMC's or NMC's services, expenditures, and charges will be small. The revenue impact on UVMMC and NMC will not be directly proportionate to the reduction in procedure and surgery volume, because reimbursement for the low-complexity outpatient procedures that will move to the GMSC is less than for many of the

Applicant's Response to Board Member Lunge's Request for Supplemental Information (April 24, 2017); *See also*, Application at 10, 22-25.

⁴ April 13, 2017 Hearing Presentation, Amy Cooper, Manager ACTD LLC, Green Mountain Surgery Center, Routine Outpatient Surgical Care *in the right setting, at the right time, for the right price.*

⁵ Applicant's Response to Board Q003 Question 6 (July 15, 2016).

⁶ Id.

inpatient procedures the GMSC will not perform. To put the GMSC's impact on UVMMC in perspective, the GMSC projects gross patient revenues in its second year of operation (when it expects to be fully operational) of \$6,854,059, which is 0.67% of UVMMC's projected outpatient gross patient revenues for 2015 at the time the Application was filed, and 0.28% of UVMMC's projected total gross patient revenues for that year. Both UVMMC and NMC have seen budget overages in the tens of millions of dollars over the past two years. Also, notably, neither UVMMC nor NMC suffered financially following the opening of Vermont's only existing ASC, the Eye Surgery Center and Laser Center of Vermont (the "Eye Surgery Center"), in 2008. Rather, UVMMC's total revenues increased at a 5% compound annual growth rate from 2008-2013, and UVMMC grew its operating income at an annualized rate of 32.7% per year. NMC's net patient revenues grew at a compound annual growth rate of 8.4% from 2008 - 2014.

Finally, there is no evidence in the record that either NMC or UVMMC must or will respond to the loss of a small percentage of outpatient surgeries to the GMSC by increasing prices. The hospitals may instead increase efficiencies, reduce overhead, or repurpose space. The Board should not assume that hospitals need to do exactly what they do now into the future, or that the Board's role under the CON law is to maintain the status quo. ¹¹

The bottom line is that the small impact the GMSC may have on UVMMC and NMC is far outweighed by the cost savings and many other benefits the GMSC will offer its patients, as further discussed below with respect to the need for the proposed project.

(C) less expensive alternatives do not exist, would be unsatisfactory, or are not feasible or appropriate;

Hospitals are not a less expensive or satisfactory alternative to the GMSC. The GMSC will offer substantially lower prices, as well as many other unique benefits to patients and providers, as further discussed below with respect to the need for the proposed project. Also, as further discussed below, existing hospital outpatient surgery capacity in Chittenden County is insufficient to meet patient and provider demand.

The Applicant has demonstrated that its plan for construction of the proposed project is appropriate and well considered. The Application details Applicant's work with a real estate consultant, an architect, and an ASC consultant to analyze potential sites for the surgery center in existing buildings, and the process it followed to determine that new

Id.

⁸ Application at 59-61.

⁹ Hearing Transcript (April 19, 2017) at 43 (Cooper).

Applicant's Response to Board Q003 Question 17 (July 15, 2016).

Prefiled Testimony of Andrew Lasser (April 24, 2017); Applicant's Response to Board Q003 Question 17 (July 15, 2016).

construction at the proposed site is the best approach. 12

(3) There is an identifiable, existing, or reasonably anticipated need for the proposed project which is appropriate for the applicant to provide.

The proposed project will meet an identifiable, existing need by establishing the first multispecialty ASC in Vermont. As the Applicant has demonstrated throughout the application process, ambulatory surgery centers are widely used and an integral component of the health care delivery system in every other United States jurisdiction. The interested parties have argued that Vermont is too small to support an alternative to hospital-based outpatient surgery. But this argument is demonstrably false. Other states that have populations under 1,000,000 (like Vermont), have on average 16 ambulatory surgery centers within their borders. Additionally, our neighbors, New Hampshire, Massachusetts and New York, have 29, 59 and 116 ambulatory surgery centers respectively. Prohibiting the development of a multispecialty ambulatory surgery center in Vermont would harm patients who presently have no in-State alternative to hospital-based surgery and continue to face ever-increasing health care costs.

The GMSC Application has received widespread support from patients, employers, payers, and physicians, who recognize the benefits of a high quality, lower-cost option for outpatient surgery.¹⁷ It is uncontested in this proceeding that ASCs offer the following attributes that hospital outpatient surgery departments do not, each of which contribute significantly to the "need" for this project:¹⁸

- ASCs result in lower costs to patients and payers, as they are reimbursed at a lower rate than hospital outpatient surgery departments and charge lower rates than hospital outpatient surgery departments.
- ASCs can offer more convenient locations, shorter wait times, and easier scheduling relative to hospital outpatient departments, and typically offer a smaller, less

¹² Application at 63-64.

See, e.g., Application at 65.

See, e.g., Memorandum in Opposition to the Green Mountain Surgery Center Certificate of Need Application on Behalf of the Vermont Association of Hospitals and Health Systems, March 2, 2017, p. 5.

¹⁵ Application at 63.

¹⁶ Id.

In addition to the numerous public comments that have been submitted in connection with the public hearing, the Application has received letters of support from BlueCross BlueShield of Vermont, Cigna, MVP Healthcare, Vermont Education Health Initiative, AARP Vermont, Vermont State Employees' Association, Vermont State Troopers Association, Vermont Campaign for Healthcare Security Education Fund, Seventh Generation, Inc., Burton Snowboards, Burlington Housing Authority, Flex-A-Seal, Inc., Main Street Landing, Lake Champlain Chocolates, Rhino Foods, Champlain Cable Corporation, ReArch Company, The Boys and Girls Club of Burlington, and the Town of Colchester, among others.

Each of these attributes is described in greater detail in the Applicant's Response to Board Q006 Question 1 (December 23, 2015).

institutional environment than hospitals, and more personalized care, which for many patients may translate to a less intimidating, less stressful experience.

- Freestanding ASCs generally are able to operate more efficiently than hospitals, reducing physician and staff idle time, while improving the use of medical resources.
- ASCs charge a global facility rate for surgery, which means that the facility fee a patient
 is told they will be charged in advance is the only facility charge that will appear on
 their bill, and ASCs typically make pricing information available to their patients in
 advance of surgery.
- ASCs offer services that are appropriately scaled with the health care needs of the patients that they serve.
- ASCs can facilitate the recruitment of physicians to the greater Burlington area.

While the interested parties have argued that the "need" for the project should be narrowly framed in terms of hospital outpatient surgery capacity, ¹⁹ the Department of Banking, Insurance, Securities, and Health Care Administration ("BISHCA") previously determined in its review of the Eye Surgery Center certificate of need application that it is not appropriate to define "need" in such a restrictive manner. ²⁰ In its decision on that application, BISHCA stated that "[w]hether or not a hospital or other health care provider has the capacity to provide eye surgery services in general is . . . not dispositive of the question of whether the Applicant's project is needed," and found the Eye Surgery Center had met the "need" criterion and would not "duplicate" services offered by hospitals on the basis that the services the ASC would provide were in demand by patients and materially different from those available at hospitals due to their lower cost; the different environment and patient experience the ASC would offer; the ASC's convenience for patients and providers; and the ASC's anticipated efficiency and ability to schedule surgeries more quickly. ²¹ These are precisely the attributes, among others, that the proposed multispecialty ASC would offer.

In addition to the foregoing, part of the impetus for this project and another factor that supports (but is not required for) a determination that the proposed project is needed is the current insufficient outpatient surgery capacity in Chittenden County. The Applicant has previously noted that UVMMC recently represented to the Board that "[c]linical capacity in the Ambulatory Care Center [at UVMMC] has been reached (and in many areas exceeded)." The interested parties

Memorandum in Opposition to the Green Mountain Surgery Center Certificate of Need Application on Behalf of the Vermont Association of Hospitals and Health Systems (March 2, 2017) at 10-12.

In re. Application of Eye Surgery Center and Laser Center of Vermont, Docket No. 05-058-H, Statement of Decision (May 10, 2007).

²¹ Id. at 13, ¶¶ 26, 30, 33.

Certificate of Need Application by Fletcher Allen Healthcare, Inc. to Acquire Real Estate in South Burlington, June 2, 2014, p. 17.

now present some internal data purportedly showing that the operating rooms at UVMMC and NMC operate at less than 100% capacity (which the Applicant does not have the ability to test), ²³ but whether these hospitals are operating at 100% capacity is a red herring. Theoretically available hospital capacity does not mean that operating rooms are actually available when patients want or need surgery. For example, physicians who perform endoscopies at UVMMC report that 70-74% utilization is full capacity use of UVMMC procedures rooms where endoscopies are performed, because there are not enough intake rooms to support simultaneous use of all the procedure rooms.²⁴ Similarly, the theoretical ability of hospitals to extend operating room hours or open them on weekends does not translate to meaningful increased access due to the understandable reluctance of physicians to schedule surgeries in the evening or over the weekend. The record is replete with the experiences of patients and physicians who have experienced long wait times due to the unavailability of hospital operating or procedure rooms at the necessary times.²⁵ In short, from the perspective of patients and physicians seeking to utilize operating and procedure room time, the current capacity at UVMMC is not sufficient. And as Vermont's population continues to age, pressure on the medical center's operating and procedures rooms will only increase. In sum, however "need" is defined, there is a need for a multispecialty ambulatory surgery center in Vermont.

Finally, Applicant has shown that the proposed project is the right size to meet anticipated demand. Once the GMSC is fully operational, Applicant projects procedure room utilization of between 61.6% and 91.3%, and operating room utilization of between 52.1% and 71.5%, depending on how efficiently GMSC is able to turn over procedure and operating rooms.²⁶

(4) The project will improve the quality of health care in the state or provide greater access to health care for Vermont's residents, or both.

The GMSC will both improve the quality of health care and provide greater access to outpatient surgical services for Vermonters. Applicant has provided extensive empirical evidence that has not been contested by the interested parties, including 11 peer-reviewed journal articles and the Medicare Payment Advisory Commission's Report to Congress, ²⁷ that ASCs have a strong track record of providing high quality care, have low infection rates, operate more efficiently than hospital outpatient surgery departments, and have very high patient satisfaction rates. Also, in its review of the Eye Surgery Center's certificate of need application, BISHCA found that the Eye Surgery Center would improve quality of care in the sense that it would offer patients lower costs, convenience, better patient experience, and reduced delays. ²⁸ The Applicant has demonstrated

See Memorandum in Opposition to the Green Mountain Surgery Center Certificate of Need Application on Behalf of the Vermont Association of Hospitals and Health Systems (March 2, 2017) at 27-57.

Hearing Transcript (April 19, 2017) at 38-39 (Cooper).

See, e.g., Application at 66-67; Updated Public Comments through 04/25/2017, available at http://gmcboard.vermont.gov/con/pending/Gr-Mt-Surgery Ctr.

Applicant's Response to Board Q003 Question 11 (July 15, 2016)

See Applicant's Response to Board Q001 Question 12 (December 23, 2015).

In re. Application of Eye Surgery Center and Laser Center of Vermont, ¶ 36.

that the GMSC will similarly improve quality of care.

In addition to improving health care quality, the proposed ASC will increase access for patients. First, outpatient surgery offered at the GMSC will be more affordable than hospital-based surgery to low and middle income Vermonters. The Applicant has presented uncontested evidence that on average, procedures at a free-standing ambulatory surgery center cost approximately half of what they do at a hospital.²⁹ But perhaps just as important to patients, the cost of services at the ASC will be predictable and available to patients in advance of the procedure. Price transparency will remove a key barrier that prevents some patients from accessing health care. Second, by adding outpatient capacity to the system, the proposed ASC will alleviate wait times that have been reported by patients and physicians, most recently in several of the public comments that have been submitted to the Board in connection with this application.³⁰ Third, the GMSC is committed to offering a comprehensive charity care policy comparable to hospital policies that will enable low income Vermonters to access ASC services for free or discounted costs.³¹ This will ensure that Vermonters without means can utilize the many benefits that ASCs offer to those in need of outpatient surgical services. Finally, it must be acknowledged that for some patients, the prospect of receiving surgery in a larger, more institutional hospital setting can be overwhelming or frightening. This is not intended to be a criticism of hospitals, but rather an acknowledgement that for some patients a hospital-based environment can add significant stress to an already a stressful experience. The proposed ASC will offer a smaller-scale, patient-friendly environment, which many patients may prefer and find less intimidating. This may in turn result in more patients seeking care who need it.

(5) The project will not have an undue adverse impact on any other existing services provided by the applicant.

The proposed project will not have an undue adverse impact on any other existing services provided by the Applicant, as the Applicant does not provide any other existing health care services.

(6) The project will serve the public good.

(a) Whether the project will help meet the needs of medically underserved groups and the goals of universal access to health services.

As previously discussed, the GMSC will charge substantially less for its services than hospitals must charge for the same services, and will thereby increase access to health care and meet the needs of persons who are medically underserved due to their inability to afford the cost of care.

See, e.g., Application at 69.

Updated Public Comments through 04/25/2017.

See, e.g., Application at 69.

While the interested parties in this matter contend that the GMSC will not serve low income people, there is no support for this allegation in the record. On the contrary, the evidence shows Applicant's strong 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, and to providing free and discounted care at a level on par with Vermont's tax-exempt hospitals. Financial projections for the GMSC assume 12% Medicaid cases and 2% charity care cases. 32 Applicant's operating agreement and subscription documents include strict nondiscrimination language.³³ The Medical Staff Bylaws that will govern all physicians who become credentialed at and use the GMSC to perform surgeries will state the following: "Non-Discrimination. The Company and all Members utilizing the ASC shall treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner."34 Applicant will adopt a charity care policy that follows provisions of the Internal Revenue Code, codified at 26 U.S.C. § 501(r), which require taxexempt hospitals to provide charity care. 35 Finally, Applicant has noted that some other states require ASCs to report the Medicaid services they provide, and indicated its willingness to accept a reasonable CON condition requiring both service to Medicaid beneficiaries and reporting.³⁶

(b) Whether the project will help facilitate the implementation of the Blueprint.

Vermont's Blueprint for Health is intended to lower health care costs by focusing on preventative health. As described in the Application and in the Applicant's responses to questions posed by the Board, the Applicant projects that GI procedures will constitute the highest volume of procedures performed at the ASC – approximately 60% – and the Applicant has documented that the GMSC will enable greater public access to colorectal screenings, by reducing both procedure costs and wait times.³⁷

The GMSC will also help facilitate implementation of the Blueprint through its credentialing process, which will require all specialists operating at the Center to sign a "Collaborative Care Agreement" to function as part of an effective care delivery network. This agreement is based on Blueprint and national Patient Center Medical Home guidelines and outlines the protocols for effective communication among primary care and specialty physicians. These protocols, which include (i) timely access to care, (ii) communication, (iii) adherence to widely-accepted evidence-based principles of care, and (iv) support of the primary care practice ("PCP") as the medical home for most patients, both support the

April 13, 2017 Hearing Presentation, Amy Cooper, Manager ACTD LLC, Green Mountain Surgery Center, Routine Outpatient Surgical Care in the right setting, at the right time, for the right price.

³³ Id.

Applicant's Response to Q006 Questions 13, 17 (January 25, 2017).

Applicant's Response to Board Q001 Question 18 (December 23, 2015).

Transcript of Public Hearing (April 13, 2017) at 41 (Cooper).

See, e.g., Application at 70-71; Applicant's Response to Board Q001 Question 7 (December 23, 2015); Applicant's Response to Board Q003 Question 9 (July 15, 2016).

patient centered medical home model and contribute directly to greater continuity of care for all patients. The Collaborative Care Agreement also requires specialists who have performed a procedure to provide the patient's primary care physician with guidelines and instructions for follow-up care.

(c) Whether the applicant has demonstrated it has analyzed the impact of the project on the Vermont health care system and the project furthers effective integration and coordination of health care services.

As previously discussed, the GMSC will play an important part in an integrated, coordinated health care system by offering a lower cost alternative to hospital-based care for routine cases that do not require extensive resources or justify high expenses. As discussed below, the GMSC is consistent with current health care reform initiatives and, in particular, will be a low-cost, high-value site of care for the state's Accountable Care Organizations ("ACOs"). As discussed below with respect to CON Standard 1.13, Applicant sees the potential for collaboration with area hospitals. The EMR platform Applicant plans to use is consistent with the Vermont Heath Information Technology plan's focus on integration; it was chosen because integration and interoperability are part of the vendor's core philosophy. Finally, please see the above discussion of Applicant's Collaborative Care Agreement with respect to Criterion 6(b).

(d) Whether the project is consistent with current health care reform initiatives, at the state and federal level.

The proposed GMSC is not only consistent with reform initiatives, but would contribute to the success of any such efforts. Title 18, Section 9371 of the Vermont Statutes Annotated sets forth certain principles as a framework for reforming health care in Vermont. The Center would further these principals by (i) reducing health care costs; ³⁹ (ii) facilitating the ability of Vermonters to choose their health care providers; ⁴⁰ (iii) enabling Vermonters to be aware of the cost of health services they will receive; ⁴¹ (iv) improving the efficiency, quality and safety of health care delivery; ⁴² and (v) facilitating a partnership between consumers, employers, and health care professionals in the delivery of health care. ⁴³

Current health care reform efforts such as accountable care organizations, the Blueprint for Health, bundled care pricing, the all-payer model, and population health strategies focus

April 13, 2017 Hearing Presentation, Amy Cooper, Manager ACTD LLC, Green Mountain Surgery Center, Routine Outpatient Surgical Care in the right setting, at the right time, for the right price at 16.

³⁹ 18 V.S.A. §§ 9371(1), (2).

⁴⁰ Id. § 9371(5).

⁴¹ Id. § 9371(6).

⁴² Id. §§ 9371(9), (10).

⁴³ Id. § 9371(13).

on the ability to prevent disease and manage health in a high quality, cost-effective manner. The implementation and effective use of alternative models of care, such as in ASCs, are instrumental to the success of these reform efforts. For instance, the GMSC will participate in ACOs as an affiliated provider and partner. The GMSC will help ACOs meet health spending targets by reducing the cost of outpatient surgery, while maintaining or improving quality, and will facilitate the State's ability to meet expenditure targets in the APM Agreement with CMS. As care under the ACO model moves to either capitated payments or bundled payments, the GMSC will help ACOs manage the total cost of care under a global budget, and help ACOs achieve shared shavings by managing actual fee-for-service spending to beat program targets. In addition, more timely access and shorter waiting times, due to the additional capacity and increased efficiency offered by the GMSC, will improve ACO Quality Performance Scores with respect to MSSP Measure ACO-4 (Access to Specialists) and MSSP Measure ACO-19 (Colorectal Cancer Screening). In sum, the greater efficiency, high quality, and lower cost of the GMSC will contribute significantly to ACOs successes in meeting health care reform goals.

The GMSC will also participate in other health care reform efforts. We have already described above how the GMSC will facilitate the Blueprint for Health program. The Center will also participate in bundled care pricing programs aimed at lowering health care costs. 44 Of course, the Board will recognize better than anyone that the health care sector is in a state of flux and that no one can predict with certainty what future health care reform initiatives will look like. However, the GMSC is committed to being an integral part of any such initiatives aimed at improving quality, lowering cost, and otherwise achieving the state's and the nation's health care goals.

The interested parties' assertions that ASCs are not consistent with health care reform because they are somehow inextricably linked to the fee-for-service models or that the GMSC will be a "silo" in the statewide health care system are simply false. The GMSC will be paid based on the prevailing payment system, just as other participants in the health care system will be. As explained in the Applicant's response to the interested parties' memoranda opposing the Application, the financial projections for the proposed project are based on fee-for-service payment assumptions, because presently other payment models are uncertain and Applicant does not have the information necessary to model how the GMSC's financials would work in an all-payer waiver model or other alternative payment systems. But the fact that Applicant's financial model is based on currently available fee-for-service payment estimates does not mean that Applicant will not participate in alternative payment models in the future.

(e) Except where circumstances support approval of an emergency Certificate of Need, whether the project was identified prospectively as needed at least two years

Applicant's Response to Board Q003 Question 21 (July 15, 2016); Transcript of Public Hearing (April 13, 2017) at 43 (Cooper).

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ACTD's Reply to Northwestern Medical Center Submission of Information in Opposition to Application; and Vermont Association of Hospitals and Health Systems Memorandum in Opposition to the Green Mountain Surgery Center Certificate of Need Application, March 24, 2017.

prior to the time of filing in the hospital's four-year capital plan.

Not applicable

(f) Whether, and if so to what extent, the project will have an adverse impact on the ability of existing facilities to provide medically necessary services to all in need, regardless of ability to pay or location of residence.

As previously discussed with respect to CON Criterion 2(B), the GMSC will have no impact on any existing facility's ability to provide medically necessary services to all in need.

(7) The applicant has adequately considered the availability of affordable, accessible patient transportation services to the facility.

Applicant chose the site for the GMSC based in part on its accessibility. The Applicant concluded that 535 Hercules Drive in Colchester was among the best available sites for the Center in that it is easily accessible off the interstate, is a short drive from the nearby urban centers of Burlington and Winooski, and the property will have plenty of convenient parking spaces. Patients who are eligible for Special Services Transportation Agency (SSTA) may also access the GMSC via SSTA transportation. And the site is half a mile from the Chittenden County Transportation Authority's (CCTA) Milton Commuter bus stop at nearby Mountain View Drive. If the Board grants a certificate of need for the project, the Applicant will inquire with the transit authorities as to whether the existing bus route can be modified to incorporate a bus stop at the GMSC. However, it is important to recognize that for many outpatient procedures, such as colonoscopies and other GI procedures (which the Applicant predicts will be the majority of procedures performed at the GMSC), the best practice to ensure patient safety is to have the patient arrange a ride home post-surgery (e.g., from a family-member, care-giver or friend).

§ 9437: Consistency with Health Resource Allocation Plan

Finally, as described at length in the Application and the Applicant's responses to questions posed by the Board, the proposed GMSC is consistent with the certificate of need standards of Vermont's Health Resource Allocation Plan. To summarize:

CON STANDARD 1.2: Applicants seeking to expand or introduce a specific health care service shall show that such services have been shown to improve health. To the extent such services have been the subject of comparative effectiveness research, an applicant shall show that the results of this research support the proposed project.

As detailed in the Application,⁴⁶ the GMSC will expand access to affordable outpatient surgery, diagnostic procedures, and pain management procedures, thereby improving population health. Also, as previously discussed, the Application cites peer-reviewed research that documents better health outcomes for patients treated in an ASC than for those treated in a hospital outpatient surgery department.

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See Application at 34-35.

CON STANDARD 1.3: To the extent neighboring health care facilities provide the services proposed by a new health care project, an applicant shall demonstrate that a collaborative approach to delivering the service has been taken or is not feasible or appropriate.

As demonstrated throughout this application process, no existing facilities provide the same unique benefits and patient experience that will be provided by the GMSC. However, as stated in the Application and elsewhere, the Applicant is open and willing to collaborate with UVMMC and other area hospitals. Collaboration, of course, requires a willing partner, and at least at present, it is not clear whether UVMMC has interest in collaborating with the GMSC.⁴⁷ The Applicant is hopeful, however, that once the Certificate of Need has been awarded, the GMSC and UVMMC and other area hospitals can and will collaborate to provide high quality care at lower cost and to further health reform efforts (as described above), as is typical in other jurisdictions.⁴⁸ Specific areas of collaboration may include the following, among others:

- Enabling hospitals to book block time at the GMSC for use by hospital-employed physicians;
- Entering into joint purchasing arrangements;
- Pursuing joint venture opportunities;
- Providing education and training opportunities; and
- Integrating the GMSC into the ACO model.

CON STANDARD 1.4: If an application proposes services for which a higher volume of such service is positively correlated to better quality, the applicant shall show that it will be able to maintain appropriate volume for the service and that the addition of the service at the facility will not erode volume at any other Vermont facility in such a way that quality at that facility could be compromised.

As detailed in the Application,⁴⁹ the GMSC will offer routine outpatient procedures for which there is no *unique* positive correlation between volume and quality. As previously discussed, the GMSC will not have a substantial impact on volumes at any other Vermont facility, and certainly no impact that would threaten quality at any other facility. Furthermore, a drop in the volume of procedures performed at a hospital does not mean the *physicians* performing procedures at the hospital are performing fewer procedures. Rather, it means only that some physicians have shifted some procedures to the GMSC.

The GMSC has reasonable grounds to expect that it will be able to maintain its projected volumes. As discussed in Section I.H of the Application, the projected volumes are based on the actual historical volumes of the physicians who have indicated that they intend to perform surgeries at the Center. Applicant is not aware of any circumstances that would cause the projected volumes for these physicians to materially differ from their historic volumes.

See Letter from UVM Medical Center dated July 29, 2016.

See Application at 36-37.

⁴⁹ See Application at 38-39.

CON STANDARD 1.6: Applicants seeking to develop a new health care project shall explain how the applicant will collect and monitor data relating to health care quality and outcomes related to the proposed new health care project. To the extent practicable, such data collection and monitoring shall be aligned with related data collection and monitoring efforts, whether within the applicant's organization, other organizations or the government.

The GMSC will maintain an ongoing active, integrated, organized, peer-based quality improvement program, will have a governing body that has oversight and accountability for the quality assessment and performance improvement program, a Quality Improvement Committee that will implement and directly oversee the Quality Improvement Plan, and, as a Medicare accredited facility, will collect, monitor and report health care quality and outcome data in accordance with CMS requirements, and will report to CMS annually on all quality measures specified by the Secretary of the Department of Health and Human Services. The GMSC's reports on quality measures will be made available to the public on the Center's website.

CON STANDARD 1.7: Applicants seeking to develop a new health care project shall explain how such project is consistent with evidence-based practice. Such explanation may include a description of how practitioners will be made aware of evidence based practice guidelines and how such guidelines will be incorporated into ongoing decision making. (2005 State Health Plan, page 48.)

As detailed in the Application, the GMSC is likely to improve patient outcomes; will meet FGI Guidelines; and will adopt and implement policies to promote the use of evidence-based medicine by physicians who use the facility and its staff.⁵¹ Applicant submitted its evidence-based practice policy, which states: "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."⁵²

CON STANDARD 1.8: Applicants seeking to develop a new health care project shall demonstrate, as appropriate, that the applicant has a comprehensive evidence-based system for controlling infectious disease.

The GMSC will have a comprehensive, evidence-based system for controlling infectious disease, which is set forth at length in the infection control policies included with the Application in **Exhibit** 2. All Medicare-certified ASCs must comply with an extensive set of infection prevention

Applicant's Response to Board Questions 006 (January 25, 2017) at Exhibit 15.

⁵⁰ See 42 C.F.R. Subpart H.

Application at 42-43.

standards that are monitored at each ASC daily and evaluated by external inspectors.⁵³

CON STANDARD 1.9: Applicants proposing construction projects shall show that costs and methods of the proposed construction are necessary and reasonable. Applicants shall show that the project is cost-effective and that reasonable energy conservation measures have been taken.

As detailed in the Application, Applicant has worked with its consultants AMB Development Group, LLC, Avanza Strategies, and Wiemann Lamphere Architects to ensure that methods of construction are reasonable, cost-effective, and energy efficient.⁵⁴

CON STANDARD 1.10: Applicants proposing new health care projects requiring construction shall show such projects are energy efficient. As appropriate, applicants shall show that Efficiency Vermont, or an organization with similar expertise, has been consulted on the proposal.

As detailed in the Application,⁵⁵ Applicant has engaged Wiemann Lamphere Architects to consult regarding energy efficiency. This firm exclusively develops high-performance, sustainable buildings, and employs five LEED credentialed professionals.

CON STANDARD 1.11: Applicants proposing new health care projects requiring new construction shall demonstrate that new construction is the more appropriate alternative when compared to renovation.

Please see the above discussion of this issue with respect to CON Criterion 2(C).

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.

Applicant has worked with AMB Development Group, LLC to ensure the proposed project's compliance with the FGI Guidelines.⁵⁶

CON STANDARD 2.2: Applicants seeking to introduce new ambulatory care services, including hospital ambulatory care center or physician office based services, shall show how such services are consistent with Vermont's focus on health promotion. Services to prevent the onset of disease and to minimize the effects of disease shall be given the highest priority.

Throughout the Application process, the Applicant has demonstrated that the proposed GMSC is consistent with and intentionally aimed at promoting Vermont's focus on health promotion and

Application at 45-46.

Application at 49; Applicant's Response to Board Q003 Question 22 (July 15, 2016); Applicant's Response to Questions re. Proposed Project's Compliance with FGI Guidelines (April 10, 2017).

⁵³ See Application at 44.

Application at 46.

wellness, for instance by offering a wide array of screenings and diagnostic procedures, facilitating the Blueprint for Health Program (see above discussion regarding Statutory Criterion 6(b)) and by furthering other health care reform efforts aimed at health promotion (see above discussion regarding Statutory Criterion 6(d)).

CON STANDARD 3.13: An applicant proposing to establish an ambulatory surgical center shall demonstrate that the procedures performed at the facility will be limited to those procedures that are not anticipated to require an overnight stay and that can be performed safely in an ASC.

The GMSC will only host procedures that can be safely performed in an ACS, which would not typically require active medical monitoring and care of the patient at midnight following the procedure, consistent with the standard set forth in 42 C.F.R. 416.166.⁵⁷ The Center will obtain and maintain Medicare certification throughout its operations, the purpose of which is partly to ensure that the GMSC does procedures that can be performed safety in an ASC, and it will seek private accreditation from the Accreditation Association for Ambulatory Health Care and/or the Joint Commission, and will operate under the supervision of such organizations, consistent with applicable regulatory and accreditation requirements.⁵⁸

CON STANDARD 3.14: An applicant proposing to establish an ambulatory surgical center shall show that the ASC is located within the appropriate travel time to one or more licensed general hospitals where there are three or more operating rooms.

The proposed GMSC will be located approximately 3.5 miles from UVMMC.

CON STANDARD 3.15: An applicant proposing to establish an ambulatory surgical center shall demonstrate that the facility will provide services for post-operative complications and inquiries by ASC patients on a 24-hour basis.

Applicant meets this standard as detailed in the Application.⁵⁹

CON STANDARD 3.16: An applicant proposing to establish an ambulatory surgical center shall demonstrate how the applicant will provide access to all residents of each community within the identified service area without regard to an individuals' payer type, insurance status or ability to pay for necessary services.

Please see the above discussion of this issue with respect to CON Criterion 6(a).

CON STANDARD 3.17: An applicant proposing to establish an ambulatory surgical center shall demonstrate the applicant will: secure and maintain Medicare certification, where appropriate; develop and maintain a transfer agreement with at least one nearby hospital, as well as a transport agreement with an emergency medical service for the ASC's emergency

59 Application at 53.

⁵⁷ Application at 51

⁵⁸ Id.

transport requirements; ensure that all staff are well qualified and that the clinical personnel are eligible for – or have privileges for – similar surgical procedures at a local hospital; institute a quality review system; cooperate with all public and private review organizations; and demonstrate that the ASC will institute best practices protocol.

- The proposed Green Mountain Surgery Center will secure and maintain Medicare certification.
- The Applicant has requested a transfer agreement with UVMMC, but the hospital has indicated that it will not consider the request until a Certificate of Need has been awarded.⁶⁰
- The Applicant has submitted into the record a transport agreement with the Colchester EMS Department for its emergency transport requirements.⁶¹
- The Applicant's credentialing process and medical staff bylaws will require that all staff are well qualified and that the clinical personnel are eligible for or have privileges for similar surgical procedures at a local hospital.
- The Applicant will institute a quality review system (see above discussion regarding *HRAP 1.6*).
- The Applicant will cooperate with all public and private review organizations;
- The Applicant has incorporated a best practices protocol into its Facility Plan for Patient Care, a copy of which was submitted as Exhibit 2 to the Application.

For all of the foregoing reasons, the Application should be approved.

Dated in Burlington, Vermont this 2nd day of May, 2017.

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By:

Eileen Elliott, Esq.

Attorneys for ACTD LLC

Cilan Milliott

Applicant's Response to Board Q001 Exhibit 6 (December 23, 2015).

Applicant's Response to Board Q001 Exhibit 7 (December 23, 2015).