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May 3, 2019

VIA E-MAIL (Michael.Barber@vermont.gov) AND U.S. FIRST CLASS MAIL

Michael Barber, Esq. Green Mountain Care Board 144 State Street Montpelier, VT 05602

Re:

Green Mountain Surgery Center, GMCB-010-15con – Brief of Interested Parties Vermont Association of Hospitals and Health Systems and Northwestern Medical Center on Legal Scope of Certificate of Need Granted to ACTD, LLC d/b/a Green Mountain Surgery Center

Dear Mr. Barber:

Enclosed for filing in the above-referenced matter please find the Brief of Interested Parties Vermont Association of Hospitals and Health Systems and Northwestern Medical Center on Legal Scope of Certificate of Need Granted to ACTD, LLC d/b/a Green Mountain Surgery Center.

Very truly yours,

Anne E. Cramer

In AEC

AEC/alb

Enclosure

cc: Donna Jerry (via e-mail)(Donna.Jerry@vermont.gov)

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Jill Bowen (via e-mail)(jbowen@nmcinc.org)

STATE OF VERMONT
GREEN MOUNTAIN CARE BOARD

In re: ACTD, LLC, d/b/a Green

Docket No. GMCB-010-15con

**Mountain Surgery Center** 

**BRIEF OF INTERESTED PARTIES** 

VERMONT ASSOCIATION OF HOSPITALS AND HEALTH SYSTEMS AND NORTHWESTERN MEDICAL CENTER ON LEGAL SCOPE OF CERTIFICATE OF NEED GRANTED TO ACTD, LLC D/B/A GREEN MOUNTAIN SURGERY CENTER

The Vermont Association of Hospitals and Health Systems ("VAHHS") and Northwestern Medical Center ("NMC"), as Interested Parties to the above-referenced Certificate of Need ("CON") proceeding, submit this Brief in opposition to any expansion of specialty services to be provided by ACTD, LLC d/b/a Green Mountain Surgery Center ("GMSC") beyond the scope of the five specialty services upon which it presented evidence in support of its application to establish a multi-specialty surgical center. The CON application of the GMSC provided extensive detail and financial projections for its operation based on surgery and procedures for gastroenterology ("GI"), obstetrics and gynecology ("OBGYN"), orthopedics, pain management and general surgery. The Green Mountain Care Board ("Board") evaluated this specific detail and financial projections in determining whether the application met the required criteria set forth in 18 V.S.A. § 9437. The Board granted a conditioned CON for the application as presented. To enlarge the scope of the CON now to include ophthalmology, plastic surgery and other specialties is contrary to law as set forth in 18 V.S.A. § 9440(d)(4). Statutory Provision

Section 9440(d)(4) of Title 18 of the Vermont Statutes states the procedural requirements for the consideration and approval or denial of a CON application. It provides in relevant part as

(4) After reviewing each application, the Board shall make a decision either to issue or to deny the application for a certificate of need. The decision shall be in the form of an

follows:

approval in whole or in part, or an approval subject to such conditions as the Board may impose in furtherance of the purposes of this subchapter, or a denial. In granting a partial approval or a conditional approval, the Board shall not mandate a new health care project not proposed by the applicant or mandate the deletion of any existing service. Any partial approval or conditional approval must be directly within the scope of the project proposed by the applicant and the criteria used in reviewing the application. (emphasis added)

#### **CON Conditions**

The CON granted to the applicant on July 10, 2017 (page 1) provides the following initial statement about its "Conditions":

The applicant shall develop and operate the Project in strict compliance with the Project scope as described in the application, in other materials in the record submitted by the applicant, and in strict conformance with the Statement of Decision issued today by the Board. This certificate of need is limited to the Project and activities described therein. (emphasis added)

Additionally, the Board, in condition #10 to the CON (page 3), emphasizes that:

10. The applicant shall not offer services, procedures or surgeries without first demonstrating to the Board that such services, procedures or surgeries are evidence-based and fall within the scope of those approved in the certificate of need. (emphasis added)

Consequently, the GMSC must operate consistent with its application and limited to services, procedures and surgeries within five specialties.

## Application, Responses to Board Questions and Testimony

A CON can only issue for the project described in the CON application. The CON application submitted by GMSC on July 2, 2015 and GMSC's responses to questions from the Board prior to the application being ruled complete focus entirely on the GMSC offering surgery and procedures in five specialties. The GMSC application presented that "its initial scope of service will include GI, OBGYN, orthopedics, pain medicine and general surgery procedures," stressing that "there is a particular need to add operating capacity for affordable GI procedures (e.g. diagnostic, preventative and screening colonoscopies) because screening colonoscopies are a quality measure for the State's commercial, Medicaid and Medicare shared-savings programs."

(ACTD Appl. p. 12.) The application presented that "it is anticipated that the majority of procedures performed at the ASC will be GI procedures, such as diagnostic and screening colonoscopies and endoscopies. In addition, the center will perform pain management procedures (epidural injections) and general surgery procedures (e.g. umbilical hernia repair)." (ACTD Appl. p. 20.) The application's extensive financial projections and its various assertions of de minimis impact of the GMSC's services on hospital providers focus only on the recent operating data and the intended practice of 16 specialists who fall within the five specialties. See Tables 5-10, Appl. pp. 26-32; Appl. pp. 38-39; Appl. p. 50; Appl. pp. 59-61.

Throughout the GMSC's responses to questions posed by the Board staff prior to the CON application being ruled complete, GMSC's responses were limited to descriptions and projections for the potential impact of procedures and surgery in the specialties of GI, OBGYN, orthopedics, pain management and general surgery. Resp. to Q001 (12/23/15) at 13-14; Resp. to Q002 (3/31/16) at 5-6 (detailed assumptions used in determining revenue, payer mix and volume based on 16 physician specialists in GI, OBGYN, Ortho, Pain Management and General Surgery); Resp. to Q003 (7/15/16) at 2 (utilization projections based on historical volumes of physicians in 5 specialties), at 5 (assumption of 1% annual growth rate) and at 6-8 (discussion of impact on Vermont hospitals based on Confidential Table of Procedures/Surgeries of 16 Physicians); Resp. to Q006 (1/25/17) at 1-2 (confirming accuracy of projected tables) and at 5 (CPT chart of highest volume procedures and surgeries expected).

No data is provided in the application or in the extensive responses to Board questions with regard to any financial projections for procedures or surgeries in specialties beyond the five discussed above. There was no presentation on how additional potential procedures or surgeries might impact hospitals or other clinical settings as required by the CON criteria of 18 V.S.A. § 9437(2)(B)(i).

Further, the GMSC application and responses to Board questions present no mention, information or assumptions based on the inclusion of ophthalmology as a specialty. In contrast, NMC, in its Submission of Information in Opposition to Application dated March 3, 2017 (at p. 7) summarized its experience whereby it lost 640 patient procedures and surgeries to the Vermont Eye Surgery and Laser Center in the eighteen months between November 2012 and May 2014. Chris Hickey, NMC's Chief Financial Officer, in his testimony at the Continued Public Hearing on April 19, 2017, at 6, stated that NMC estimates that, "on an annual basis, [NMC] loses 250 patients that seek surgical services at the Eye Center rather than at NMC." In its response to NMC's Submission of Information dated March 24, 2017, at 11, the GMSC simply repeated its original projections of cases to be drawn from NMC in its first three years of operation as set forth in its response to Board Q003 at 7 and 8. Notably, the procedures and surgeries projected in the application and/or responses to Board questions, which are projected to be drawn from NMC, involved OBGYN and general surgery procedures. (See Confidential Res. To Q001 dated 1/22/16.) Ophthalmology was not even suggested as part of the CON application of GMSC prior to the conditioned CON being granted.

### CON Decision Findings of Fact

The Board's Statement of Decision accompanying its issuance of a conditioned CON to the GMSC contained Findings of Fact elaborating on operations and procedures and surgery in the five specialties. The following Finding of Fact summarizes the critical information before the Board:

18. The majority of procedures performed at the ASC would be gastrointestinal (GI)—the highest volume of which will be screening and diagnostic colonoscopies. The ASC will also offer pain management, obstetrics and gynecology (OBGYN), orthopedic and general surgery. App. at 20, 28, 50. The applicant provided the following table of projected cases by specialty, based on actual historical outpatient cases (2014 average monthly volumes) performed by the physician investors:

# GREEN MOUNTAIN SURGERY CENTER PROJECTED CASES BY SPECIALTY

Specialty	Year 1	Year 2	Year 3	Year 4
GI	3,150	3,636	3,672	3,709
OB/GYN	579	668	675	681
ORTHO	284	327	330	334
PAIN MGT	847	978	988	998
GENERAL SURGERY	273	315	318	321

TOTAL BY SPECIALTY	5.132	5,924	5.983	6.043
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Notes: Projected case volumes have been adjusted for acuity as only a certain percentage of physician cases will be performed at the proposed surgery center. Case volumes were projected assuming there would be a ramp up period during the first year of operation.

(GMSC Statement of Decision, pp. 18-19.) The Findings of Fact related to the ASC's projected operating room utilization (#26), surgeries moved to the ASC from other hospitals (#33, #35), and the ASC's projected payer mix (#38, #39) and projected Medicare savings (#41) are all based on the projections for numbers of cases by specialty as set forth in Finding of Fact Number 18 above. (See GMSC Statement of Decision, pp. 7-10.)

The Findings of Fact Number 20 (GMSC Statement of Decision, p. 19) mentions that the "Applicant expects that once the ASC is fully operational, there will be a strong **demand** for other specialties which may include oral surgery, podiatry, and plastic surgery. Appl. at 20; Resp. to Q006 (1/25/17) at 2 (applicant states that "other providers such as dentists, oral surgeons, or podiatrists" **may be interested** in performing procedures at the ASC)." There are, however, no further elaborations, projections or descriptions of any operations of the ASC, which actually include this "demand" or potential "interest" for additional specialties in a manner that could be considered for review in the CON decision.

### CON Granted Based on Project Meeting CON Criteria with Five Specialties

The Board's Statement of Decision for the conditioned CON granted to GMSC concluded that GMSC had met all of the relevant CON criteria, including the second criterion of

18 V.S.A. § 9437(2) that the cost of the project is reasonable. A critical component of this criteria is "whether the project will result in an undue increase in the cost of care, 18 VSA 9437(2)(B)." In making this decision, the Board must weigh the financial implications of the project on hospitals and other clinical settings and decide whether that impact is outweighed by the public benefit of the project, if any. 18 VSA 9437(2)(B)(i)(ii). See GMSC Statement of Decision at pp. 15-16. All of the financial projections and discussions of impact presented by the GMSC were based on procedures and surgeries in five areas of specialty. No projections were made related to ophthalmology or plastic surgery. For instance, in that context, the GMSC asserted that it would only have a small impact on procedures and surgeries in Franklin County as a secondary service area because only three physicians who will practice at GMSC perform procedures and surgery at Northwestern Medical Center. See Resp. to Q001 (12/23/15) at 5-6; Confidential Resp. to Q001 (1/22/16) "Table of Procedure Volume and Location 2013-2014."

The Board concluded that the GMSC's general projection of savings and public benefit outweighs the impact on the University of Vermont Medical Center, NMC and the larger hospital system. GMSC Statement of Decision at p. 17. This conclusion could only be reached as a result of the projected impact on hospitals of cases from the five surgery specialties being offered at the GMSC. There was no data presented in the application, responses to questions or testimony which addressed impact of procedures or surgeries being offered in other specialties. Further, Jill Berry Bowen testified on Wednesday, April 17, 2019, that there will be a negative financial impact on NMC if additional surgical specialties are offered at the GMSC. (citation pending) GMSC's offering additional procedures must be formally considered as a material

Additionally, in consideration of the sixth CON criteria (Project will serve public good), the Board concluded that the Project met all of the factors suggested in the GMCB Administrative Rule 4.000, at § 4.402.3. In reaching its conclusion that this criteria was reached, the Board found that the Project met the subsection (f) factor (whether and to what extent project would adversely impact ability of existing facilities to provide medically necessary services to all in need). GMSC Statement of Decision at p. 21.

change to its CON (i.e. a new service), and its impact must be evaluated before any expansion to the scope of surgeries is permitted at the GMSC.

# Conclusion

The GMSC submitted substantial information describing operations and projecting the financial impact of its proposed project to establish a multi-specialty ASC based on procedures and surgeries being provided in five specialties. A conditioned CON was granted to GMSC based on this detailed information. The CON issued to GMSC is limited under Vermont law and by its own terms to the provision of procedures and surgeries in the specialties of GI, OBGYN, orthopedics, pain management and general surgery.

Dated: May 3, 2019

Burlington, Vermont

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