January 31, 2019

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144 State Street
Montpelier, Vermont 05620

Re: Docket No. GMCB-010-15con, Green Mountain Surgery Center

Response to Request for Information dated 01/17/2019

Dear Donna:

Please see our responses to your request for information date 1/17/2019. We have restated the question in bold and provided our answer below. While the addition of new surgeons and specialties to the GMSC does constitute an update and revision of the projections that we originally provided, we don't believe that this change necessitates any further review beyond the information provided in this response because we were very consistent throughout the CON process to notify the board that, as part of the project, we planned to additional surgeons and specialties to the ASC.

For reference to support this point, please see our Response to Questions 006 posed on 08/25/2016 (submitted 01/25/2017) in our answer to Question 4, we said "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." We also provided several references to parts of the initial application where we stated that we planned to build an ASC that could accommodate other interested providers (i.e., providers not specifically included in our initial application):

> 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.

Additionally, as part of our Response to Questions posed 2/10/2016 (submitted 7/15/2016) in response to Question 1, regarding utilization, we discussed our rationale for sizing the facility to allow for room for growth because we expected "increased demand for surgical/procedural cases from the physicians we currently expect to perform cases at the ASC (beyond what was included in the initial projections), as well as surgical volumes from new physicians who were not included in the projections." In summary, it has been very clear throughout the development of this project that the intent was always to add new surgeons and specialties beyond what was included in our initial projections. Given the changing dynamics of the local physician workforce, we knew we would need to have this flexibility in order to keep the project afloat and deliver on our mission to provide Vermonters with an option to access routine outpatient surgeries at lower cost, in a smaller environment, with reduced risk of healthcare-acquired infections.

1. **The application indicated that the project would be financed with a $680,000 loan and $1,132,838 in owner equity. Provide updated project financing, including the source of all funds and specific dollar amounts.**

   An updated 'Financing Arrangement, Sources & Uses' table is attached as Exhibit 1. We are able to provide updates on project financing when requested, however updates on project financing were not requested by the Board in the CON that was issued for this project so we have not been including regular updates on financing as part of our quarterly implementation reports.

2. **Provide an updated project budget, using the same format as revised *Table 1, Projects Costs* (page 28 of December 23, 2015, Response to Questions) that shows total project costs for Year 1, including any additional amounts resulting from shifts in volumes and lease costs.**

An updated 'Project Cost' table is attached as Exhibit 2.

3. **Provide a breakdown of all costs not included in the certificate of need application, as approved by the Board, including the costs of medical and non-medical equipment associated with the addition of ophthalmology. Indicate and explain where they are reflected in the updated total project cost.**

Medical Equipment Costs - Ophthalmology				
(Costs included in Updated 'Project Costs' table under Major Moveable Equipment line item)				
Eye Microscope	$ 200,000.00			
Constellation Retinal System	$ 110,000.00			
Cryo Surgical System	$ 15,000.00			
Total	**$ 325,000.00**			
Non-Medical Equipment Costs - Ophthalmology				
(Costs included under 'Clinical Expenses' (Non Personnel) in 11/19/2018 Updated Income Statement)				
	Year 1	**Year 2**	**Year 3**	**Year 4**
Total Annual Operating Expense	$ 127,400.00	$ 164,150.00	$ 168,700.00	$ 173,950.00

4. **Provide the same information as in Question 3, above, relative to the addition of plastic surgery.**

Medical Equipment Costs - Plastic Surgery				
(Costs included in Updated 'Project Costs' table under Major Moveable Equipment line item)				
Liposcution Aspirator Machine	$ 8,000.00			
Total	**$ 8,000.00**			
Non-Medical Equipment Costs - Plastic Surgery				
(Costs included under 'Clinical Expenses' (Non Personnel) in 11/19/2018 Updated Income Statement)				
	Year 1	**Year 2**	**Year 3**	**Year 4**
Total Annual Operating Expense	$ 84,000.00	$ 108,150.00	$ 111,650.00	$ 114,800.00

5. **For each specialty area, (GI, OB/GYN, Orthopedics, Pain Management, General Surgery, Plastic Surgery, Ophthalmology) provide a table listing: a) each CPT codes that was not reflected in the application, as approved; b) an explanation of each in lay terms; and 3) a concise explanation of the need for the listed procedure/surgery.**

During our application, in our response to questions from the Board posed on 04/05/2016 (submitted 7/15/2016), we provided a typical list of procedures by specialty that physicians

perform in ASCs across the country. We also explained in reply to Question 1 of that response, that "CPT codes do not provide a sound basis for granting, denying, or limiting a CON for a variety of reasons, including their inadequate nature as billing codes and because they are always in flux…" and further, that "Medicare-approved CPT codes for ASC surgical procedures are revised frequently… Because of this steady increase, as well as the deletions, revisions, and changes, it would be impossible to run an ASC business limited by a static list. Not only would the surgeons be prohibited from performing procedures approved after such a list-limited CON was granted, but the ASC would be at risk for losing revenue since it would be restricted to using what could be inaccurate and outdated codes for its Medicare, Medicaid and third-party insurance billing. The "fix" for this would be constant CON applications or revisions, an untenable solution due to expense and delay." We continue to believe that attempts to limit or restrict the operations of the center based on CPT codes would create an untenable situation for the Green Mountain Surgery Center.

That said, we are happy to provide an updated list of the CPT codes that we initially plan to bill for and an explanation of each in lay terms, which attached as Exhibit 3. However, we are not able to provide a concise explanation of the need for each listed CPT code, as requested. There are multiple reasons why it is not practicable to try to explain the need for procedures/surgeries on the level of the CPT code, which is a very granular set of codes developed for billing purposes. One reason is that a single procedure/surgery or patient encounter often consists of multiple CPT codes. For example, breast cancer patients may undergo a mastectomy and immediate reconstruction as an initial surgery for breast cancer. After some time has passed, the second stage in their treatment might consist of a surgery to place a permanent breast implant and remove a portacath that had been used for chemotherapy. There are at least four separate CPT codes that are commonly billed together to address this second stage breast cancer surgery, and there are several more CPT codes and combinations that may added as part of the surgery depending on the unique needs of the patient and what the surgeon encounters during the surgery. The "need" from the patients' perspective is for a second stage reconstruction surgery after breast cancer. The "need" from a policy perspective is to have a high-quality, lower cost, easier-to-access site of care for breast cancer patients requiring surgery. These are general needs that cannot be broken down to the granular level of the CPT code.

CPT codes are also not exclusive to a single procedure/surgery or even to a particular specialty; the GMSC's initial list of codes provided with this response shows several codes that are often billed across multiple specialties. The need for the procedure/surgery from the patient perspective is for the unique package of interventions that can be provided by a certain specialist to suit that patient's situation, there is not necessarily a specific need for each standalone intervention that may be identified by a CPT code. In addition to services the surgeon may provide that are identified by CPT code, there are also other interventions that may occur as part of the surgery for which no CPT code has yet been developed to bill by.

Finally, there are many CPT codes that are used to identify procedures that are normally included in, or part of, another procedure(s) also identified by a separate CPT code. These services are considered "generic," meaning the services are commonly part of all similar procedures, and while a CPT code exists to identify them separately, these procedures may not be billed separately or even considered standard-alone procedures (please see American Congress of

Obstetricians and Gynecologists - CMS Correct Coding Initiative Introduction 2017[1] for several examples of generic CPT codes in the OB/GYN specialty). Given their granularity, and the complex and evolving nature of CPT Codes, we have not attempted to explain the need for procedures/surgeries at the level of the CPT code. Hopefully, the lay explanations of CPT codes that are provided as part of Exhibit 3 help demonstrate, to some degree, why patients would have reasons to need the specific interventions that are identified.

6. **Provide a list of Ophthalmology services (by CPT codes) that will be offered at GMSC that are not offered at Vermont Eye Center.**

To our knowledge, the only ophthalmology services currently provided at the Vermont Eye Center that will be offered at GMSC are those that relate specifically to cataract removal (CPT 66982 – 66984). All other Ophthalmology services that we plan to offer would be unique to the Green Mountain Surgery Center, please see Exhibit 3 for the list of CPT Codes relating to Ophthalmology. As we have stated previously, in Vermont vitreoretinal procedures and those oculoplastics procedures requiring the use of general anesthesia are currently only offered in the hospital setting. The Vermont Eye Center has declined to offer these services over the past 10 years despite entreaties from interested surgeons who would like to offer their patients the chance to have these surgeries performed in an ASC.

When considering the addition of cataract surgery to our offerings, (in addition to the need explained in detail from the perspective of one surgeon and their patients in our 11/19/2018 response), it is important to remember that a high prevalence of cataracts in a population is directly correlated with the age of a population.[2] Vermont has an older population compared to the national average and Vermont's population is aging considerably. The standard of care for cataract surgery across the country is for patients to have access to care in the smaller, more efficient, and more affordable environment of an ASC. Studies have shown that, nationally, the proportion of all cataract surgeries that were performed in ASCs increased from 43.6% in 2001 to 73.0% in 2014.[3] Additionally, the majority of cataract patients are older and have Medicare as their insurance and the cost savings for these patients are considerable. According to CMS's published 2019 fee schedule, the Medicare payment rate to a hospital outpatient department for a cataract surgery is $1,917 versus a payment of $977 to the ASC. When Medicare's co-insurance and co-payment policies are taken into account, this represents significant out of pocket savings for elderly Vermonters. Not to mention the fact that cataract removal can help enable older

[1] https://www.acog.org/-/media/Departments/Coding/CC1-CORRECT-CODING-INITIATIVE-CPT-CODES-JAN-2017.pdf?dmc=1&ts=20170305T2122200770

[2] Please see **Incidence of Age-Related Cataract:** The Beaver Dam Eye Study**,** Barbara E. K. Klein, MD; Ronald Klein, MD; Kristine E. Lee, MS**,** *Arch Ophthalmol.* 1998;116(2):219-225. doi:10.1001/archopht.116.2.219. "High prevalence of cataract and the resulting need for care by sighted attendants, spectacles, or surgery is an age-related health problem in virtually all studies of this condition.[1-5] Accessed online Jan 30 2019 https://jamanetwork.com/journals/jamaophthalmology/fullarticle/261561

[3] JAMA Ophthalmol. 2018 Jan 1;136(1):53-60. doi: 10.1001/jamaophthalmol.2017.5101. **Trends in Use of Ambulatory Surgery Centers for Cataract Surgery in the United States, 2001-2014.** Accessed online Jan 30 2019 https://www.ncbi.nlm.nih.gov/pubmed/29167902

Vermonters to stay in the workforce longer and take care of themselves at home independently for longer.

7. Update Tables 1-4 on pages 1-3 (December 23, 2015, Response to Questions) to reflect the change in projected volumes for the operating and procedure rooms for Years 1-4. Under the section *Projected Volumes* in Table 1, add a column titled, *% capacity used* for each year.

TABLE 1 - CAPACITY AND PROJECTED VOLUMES SUMMARY - UPDATED

	Capacity				Projected Volumes				Capcity Used			
	Year 1	Year 2	Year 3	Year 4	Year 1	Year 2	Year 3	Year 4	Year 1	Year 2	Year 3	Year 4
Operating Room												
OR 1	973	973	973	973	454	585	602	621	47%	60%	62%	64%
OR 2	973	973	973	973	454	585	602	621	47%	60%	62%	64%
Total OR	1,946	1,946	1,946	1,946	908	1,170	1,203	1,241	47%	60%	62%	64%
Procedure Room												
PR 1	1,726	1,726	1,726	1,726	800	1,030	1,061	1,093	46%	60%	61%	63%
PR 2	1,726	1,726	1,726	1,726	800	1,030	1,061	1,093	46%	60%	61%	63%
PR 3	1,726	1,726	1,726	1,726	800	1,030	1,061	1,093	46%	60%	61%	63%
PR 4	1,726	1,726	1,726	1,726	800	1,030	1,061	1,093	46%	60%	61%	63%
Total PR	6,904	6,904	6,904	6,904	3,201	4,120	4,245	4,370	46%	60%	61%	63%
Grand Total OR+PR	8,850	8,850	8,850	8,850	4,108	5,289	5,448	5,611	46%	60%	62%	63%
								63.4%				

Table 2 - Capacity Calculation - UPDATED			
	Operating Rooms		**Procedure Rooms**
ROOMS	**2**		**4**
YEAR 1			
Days/Year	250		250
Daily Hours	7		7
Total Available Hours (All Rooms)	3,500		7,000
Average Length of Procedure (Minutes)	107.917		60.830
Annual Utilization (From Table 1)	908		3,201
Annual Utilization/Room	454		800
Total Capacity (Cases)	1,945.93		6,904.47
% of Total Used	46.64%		46.35%
YEAR 2			
Days/Year	250		250
Daily Hours	7		7
Total Available Hours (All Rooms)	3,500		7,000
Average Length of Procedure (Minutes)	107.917		60.830
Annual Utilization (From Table 1)	1,170		4,120
Annual Utilization/Room	585		1,030
Total Capacity (Cases)	1,945.93		6,904.47
% of Total Used	60.10%		59.66%
YEAR 3			
Days/Year	250		250
Daily Hours	7		7
Total Available Hours (All Rooms)	3,500		7,000
Average Length of Procedure (Minutes)	107.917		60.830
Annual Utilization (From Table 1)	1,203		4,245
Annual Utilization/Room	602		1,061
Total Capacity (Cases)	1,945.93		6,904.47
% of Total Used	61.82%		61.48%
YEAR 4			
Days/Year	250		250
Daily Hours	7		7
Total Available Hours (All Rooms)	3,500		7,000
Average Length of Procedure (Minutes)	107.917		60.830
Annual Utilization (From Table 1)	1,241		4,370
Annual Utilization/Room	621		1,093
Total Capacity (Cases)	1,945.93		6,904.47
% of Total Used	63.77%		63.29%
Note: Average length of procedure includes turnaround time.			

Table 3 - Operating Room Utilization - UPDATED

	Operating Room Utilization			
Operating Room Utilization	**Year 1**	**Year 2**	**Year 3**	**Year 4**
OR 1	454	585	602	621
% Change from Previous Year		28.87%	2.86%	3.16%
OR 2	454	585	602	621
% Change from Previous Year		28.87%	2.86%	3.16%
Total OR Utilization	908	1,170	1,203	1,241
Total % Change (from Previous Year)		28.87%	2.86%	3.16%

Table 4 - Procedure Room Utilization - UPDATED

	Procedure Room Utilization			
Procedure Room Utilization	**Year 1**	**Year 2**	**Year 3**	**Year 4**
PR 1	800	1,030	1,061	1,093
% Change from Previous Year		28.71%	3.05%	2.94%
PR 2	800	1,030	1,061	1,093
% Change from Previous Year		28.71%	3.05%	2.94%
PR 3	800	1,030	1,061	1,093
% Change from Previous Year		28.71%	3.05%	2.94%
PR 4	800	1,030	1,061	1,093
% Change from Previous Year		28.71%	3.05%	2.94%
Total PR Utilization	3,201	4,120	4,245	4,370
Total % Change (from Previous Year)		28.71%	3.05%	2.94%
Total OR and PR Utilization	4,108	5,289	5,448	5,611
Total Average % Change (for OR and PR, from Previous Year)		28.75%	3.01%	2.99%

8. **With higher projected losses shown in the 11/19/18 updated Income Statement, provided by GMSC, explain whether there is a contingency plan for accommodating larger losses, and whether there is a loss threshold that would impact the financial viability of the project. Confirm that all surgeries and procedures, including those performed in the specialties of ophthalmology and plastic surgery will be offered at GMSC at a lower cost than the same offered surgeries and procedures offered in a hospital outpatient setting.**

   While our losses on the updated financial statements are more severe than in our initial projections, we are also projecting higher income in Years 3 and 4 in our updated financials. In order to keep our expenses down below the projections initially, we are considering using some per diem clinical staff rather than bringing all full-time staff members until our volume ramps up to more stable levels. We are also planning for the possibility that we may need raise more equity from current and new investors and/or take out a working capital loan in the first year or two of operations. We anticipate that we will be able to take these measures without impacting the financial viability of the project.

   We confirm that surgeries and procedures offered at the GMSC will be offered at a lower cost than the same surgeries and procedures offered in a hospital outpatient setting, including surgeries and procedures offered in the specialties of plastic surgery and ophthalmology.