

Green Mountain Care Board
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DELIVERED ELECTRONICALLY

August 25, 2016

Ms. Eileen Elliott
Dunkiel, Saunders, Elliott, Raubvogel, Hand
91 College St., PO Box 545
Burlington, VT 05402

RE: Docket No. GMCB-010-15con, Proposed Ambulatory Surgical Center

Dear Eileen:

Thank you for the responses to our third and fourth set of questions. To complete the review of your application, responses are required for the following questions:

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.
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.
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).
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.



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.
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.
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.
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.
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.
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.
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.
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.
13. Explain in detail the process, policy or guidelines that will be in place to ensure that physician-induced demand or supply-induced demand does not occur.
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 disproportionately refer Medicaid or patients unable to pay for services to hospitals for their treatment (Application at 73).



15. Explain in detail the process, policy or guidelines for shared decision making regarding procedures and surgeries performed at 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).
17. Provide a list of owners in the ASC who are physicians 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;
 - (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.
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.
19. Provide an organizational chart for ACTD, LLC.

If you have any questions, please do not hesitate to contact me at 802-828-2918. In responding to these questions, please restate the question in bold font and respond in unbolded font, and send the original and two hard copies with a Verification Under Oath to me at the Green Mountain Care Board, 89 Main Street, Montpelier, Vermont 05620. Please send the electronic copy to donna.jerry@vermont.gov.

Sincerely,

s/ Donna Jerry

Donna Jerry

Senior Health Policy Analyst

cc: Judy Henkin, General Counsel
Lila Richardson, Health Care Advocate
Anne Cramer, for Vermont Association of Hospitals and Health Systems
Jill Bowen, Northwestern Medical Center

