

August 4, 2016

Via Email and First Class Mail

Donna Jerry, Senior Health Policy Analyst
Green Mountain Care Board
89 Main Street
Montpelier, Vermont 05620
Donna.Jerry@vermont.gov

**RE: Docket No. GMCB-010-15con, Proposed Ambulatory Surgical Center,
Request for Supplemental Questions**

Dear Donna:

I am writing pursuant to Certificate of Need Rule 4.406(5) and on behalf of the Vermont Association of Hospitals and Health Systems (VAHHS) to request that the Green Mountain Care Board (GMCB) consider the following outstanding issues related to the project and require the applicant to respond to the below supplemental questions:

1. **Issue:** The CMS Manual states that “[f]or many patients classified as ASA PS level III, an ASC may not be an appropriate setting, depending upon the procedure and anesthesia.” See Pub. 100-07 State Operations Provider Certification, Transmittal 71, Interpretive Guidelines at Section 416.42(a). In the absence of state law or clear guidance from CMS with respect to the criteria needed to permit a patient with an ASA PS level III to have a procedure at an ASC, it is important to understand the applicant’s policy for ensuring that a procedure could be performed on an ASA PS level III patient in a safe manner.

Question: *What is the applicant’s policy for ensuring that a procedure could be performed on an ASA PS level III patient in a safe manner?*

2. **Issue:** The applicant’s projected volume is based on feedback from interested physicians who intend to bring a certain percentage of their existing caseload to the ASC. The projected volume includes patients of all ASA PS levels and was not limited to procedures on the ASC-approved procedure list from CMS. The applicant’s volume and capacity projections should be revised to include ASA PS level I and II patients and only those ASA PS level III patients who meet the criteria set forth in the ASC’s policy for

admission of ASA PS level III patients. Additionally, the applicant's volume and capacity projections should be revised to include only those procedures which are on the ASC-approved list of procedures from CMS.

Question: *Please revise your volume and capacity projections to reflect only those procedures on the ASC approved procedure list from CMS for a patient population mix which includes only those patients with ASA PS levels I, II and those level III patients who satisfy the ASC's policy for admission of ASA PS level III patients.*

3. **Issue:** The application provides the names of the "primary planners" of the ASC and indicates that, if a CON is awarded, the ASC will be "wholly owned and operated by Vermonters, the vast majority of whom will be physicians who live and practice in the State." The applicant has not provided the identity of, or any further detail with respect to, the future owners of the ASC. In any other context, and in order to meet the criteria set forth in 18 V.S.A. §9437(2)(A) this same applicant would not be able to pursue a CON from GMCB without being transparent about the identity and qualifications of the owners. For example, in order to obtain a CON for the ownership and operation of a nursing home, an applicant is required to provide the following as it relates to each member of the LLC/owner: (1) a Curriculum Vitae, (2) a personal financial statement, (3) a description of the member's relevant experience in owning or operating a facility; and (4) the quality ratings and measures for each facility owned or operated by the member. CON applicants for nursing homes are also required to provide a list of key personnel and their respective qualifications. This information is used to assess the ability of the applicant to own and operate the facility in a healthy and safe manner and to ensure that the project has adequate capital and financial viability for long-term success. It is our position that similar information is needed here in order to facilitate a complete and thorough review of the ASC under the criteria set forth in 18 V.S.A. §9437.

Question: *Please provide the name of each member of ACTD, LLC, his/her/its respective percentage interest ownership in the ASC, and his/her/its initial capital investment in the ASC. For each member, please also provide the following: (1) a Curriculum Vitae, (2) a personal financial statement, (3) a description of the member's relevant experience in owning or operating an ASC or other health care facility; and (4) the names and locations of any other ASCs or health care facilities which are owned or operated by the member. In addition, please provide an organizational chart.*

4. **Issue:** Additional information regarding the owners of the ASC is needed to determine each individual owner's ability to comply with all applicable laws related to ownership and operation of an ASC, including compliance with the federal anti-kickback statute. Under the anti-kickback statute, payments or remuneration to any person in exchange for referral of patients covered by a federal health care program is prohibited. To avoid running afoul of the federal anti-kickback statute, all owners in a position to make a referral, including all physician investors, should meet an anti-kickback safe harbor as set forth in 42 U.S.C. §1001.952. For multi-specialty ASCs, such as the one proposed by the applicant, the physician owners must satisfy the following "One-Third" tests to be within the safe harbor:

- a. At least 1/3 of each physician investor's medical practice income, from all sources, for the previous fiscal year or previous 12 month period must be derived from the physician investor's performance of procedures set forth on the ASC approved procedure list established by CMS; and
- b. At least 1/3 of the ASC procedures performed by each physician investor for the previous fiscal year or previous 12 month period must be performed at the ASC.

It is unclear from the confidential information provided by the Applicant in Exhibit 2 of its July 15, 2016 response to questions posed by GMCB if any of the interested physicians would satisfy both "one-third" requirements for a safe harbor. This information is critical to understanding whether the project can be structured in the manner contemplated by the applicant and/or whether the ASC has long term viability as a federally compliant ASC. The applicant should be required to respond to the following question:

Question: Please provide a list of the owners in the ASC who are physician investors or investors in a position to make referrals to the ASC. For each such owner, please provide (1) the terms of investment to verify that it is not based on referrals and that there are no loans by such investors; and (2) demonstrate that each owner qualifies for and will remain in an anti-kickback safe harbor by confirming that (a) 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 (b) at least 1/3 of the ASC procedures performed by the owner will be performed at the ASC.

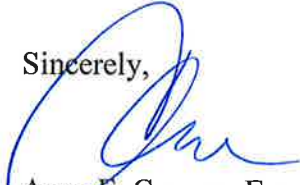
5. ***Issue:*** Although the applicant asserts that ASCs are "highly regulated" by federal and state entities, the applicant acknowledges that there are no specific state laws regulating ASCs and that participation in the Medicare program and achievement of "deemed Medicare status" through private accreditation is voluntary. The applicant's decision to participate in the Medicare program will require the applicant to comply with certain conditions for coverage (CFCs); however, the CFCs establish only minimum health and safety requirements for the operation of an ASC. The applicant's achievement of deemed Medicare status from the Joint Commission or the Accreditation Association for Ambulatory Health Care (AAAHC) would better protect patients because these bodies supplement the CFCs with additional standards geared toward ensuring high quality health care services and a safe environment. To date, the applicant has not expressed a commitment to a specific accreditation process and stated only that it does not need to make a choice "until much later in the process, perhaps even after construction begins". In the absence of regulatory oversight of ASCs in Vermont, and given that certain accreditation standards pertain to the physical environment and need to be factored into the design and construction of the ASC, the following question should be answered by the applicant.

Question: Please indicate whether you intend to achieve deemed Medicare status through the Joint Commission or AAAHC. Please also indicate your anticipated 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); and*
- 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*
Submission of Joint Commission or AAAHC application for deemed Medicare status.

We believe that responses from the applicant to the above-referenced questions are critical to a full and thorough assessment of the project and its impacts by the Green Mountain Care Board. Thank you in advance for your consideration of these additional questions. Of course, please let me know if there are any questions or concerns.

Sincerely,



Anne E. Cramer, Esq.

cc: Judy Henkin, Esq., General Counsel Green Mountain Care Board
Eileen Elliott, Esq., Counsel for Applicant
Jill Berry Bowen, Northwestern Medical Center
Jonathan Billings, Northwestern Medical Center
Lila Richardson, Esq., Office of Healthcare Advocate
Kaili Kuiper, Esq., Office of Healthcare Advocate