

Andrew N. Pollak, M.D.
CHAIR

STATE OF MARYLAND



Ben Steffen
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

March 15, 2019

VIA Email & U.S. MAIL

Brent Longenecker, Division VP of Operations
Maryland Surgery Center for Women, LLC
11400 Rockville Pike
Rockville, MD 20852

**Re: 2nd Completeness Letter Maryland
Surgery Center for Women
Matter No. 18-15-2434**

Dear Mr. Longenecker:

Commission staff has reviewed the application from the Maryland Surgery Center for Women, LLC (“MSCW” or “the Applicant”) for Certificate of Need (“CON”) approval to establish an ambulatory surgery facility with two operating rooms in the City of Berlin, Worcester County. The total project cost is estimated to be approximately \$183,000. Staff found the application incomplete, and, accordingly, requests that you provide responses to the following questions.

Part IV – Consistency with General Review Criteria at COMAR 10.24.01.08G(3)

Need – Minimum Utilization for Expansion of and Existing Facility

1. Please provide information on the historic number of operating cases for the defined service area of your facility for at least the last five years (COMAR 10.24.11.07B(1)(b)).
2. The Standard requires that projections of future demand for operating rooms (“OR”) should account for changes in the population for the demographic group expected to be served by the applicant. Please explicitly describe the assumptions you used to assess the impact of population changes on the demand for ORs and services (COMAR 10.24.11.07B(6)(c)).

3. Was turnaround time between surgical cases included in the OR hours/minutes presented in your need assessment? If not, please provide the OR hours/minutes including turnaround time between surgical cases.

Design Requirements

4. Please provide an attestation from your architect or project manager regarding the facility's floor plans meeting Section 3.7 of the FGI Guidelines (COMAR 10.24.11.05B(4)). If the project does not conform to the current FGI Guidelines, please provide a detailed explanation to justify the variance.

Patient Safety

5. This Standard requires that you will provide laboratory, radiology, and pathology services directly or through contractual agreements. Because you do not provide these services directly, please provide the names and addresses of your contractual providers.

Financial Feasibility

6. Please provide more details regarding the data and assumptions that demonstrate consistency with each subpart of this Standard (COMAR 10.24.11.05B(8)). The responses should be placed under each subpart. Within each of your responses please reference the tables that correspond with each subsection. Provide copies of those tables as an attachment to your completeness questions responses.

Need

7. Please provided a quantitative analysis that describes the project's expected service area, population size, characteristics, and projected growth.
8. Because your facility provides services to special population groups, please specifically identify those populations that are underserved and describe how this project will better address their needs.
9. Please identify and discuss relevant building and/or safety code issues, age of physical plan issues, or standard of care issues as a part of your discussion of why an additional OR is necessary.
10. Please list all of the assumptions made in the need analysis regarding demand for service, utilization rates, and the relevant population.

Availability of More Cost-Effective Alternatives

11. We recognize that the only alternative available to your facility is to continue operating in the current way. As instructed by the Standard, please provide an analysis of the costs required to continue operating in this manner.

Viability of the Proposal

12. Please provide the audited financial statements for MSCW and Amsurg for the past two years. If audited financial statements are not available, a letter signed by an independent Certified Public Accountant ("CPA). This letter should detail the financial information considered by the CPA in reaching the conclusion that adequate funds are available.
13. Please provide a response to this section of the Viability Criteria (COMAR 10.24.01.08G(3)(d)): "If debt financing is required and/or grants or fund raising is proposed, detail the experience of the entities and/or individuals involved in obtaining such financing and grants and in raising funds for similar projects. If grant funding is proposed, identify the grant that has been or will be pursued and document the eligibility of the proposed project for the grant."
14. Please explain how the applicant will be able to implement the project in compliance with the performance requirements set forth in question 12, "Project Schedule", of the application. Also, describe the renovation process and demonstrate that the project can be completed within the applicable time frame(s).

Impact

15. Please provide a more complete description of the impact of the proposed project on the applicant's costs and charges, consistent with the information provided in the Project Budget, the projections of revenues and expenses, and the work force information.

Tables and Addendum

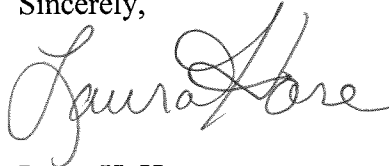
16. Your Table E "Project Budget" does not list any "Sources of Funds" for your project (capital cost of about \$183,000). Please revise Table E to include sources of funds.
17. Please fill out Addendum B, which is attached to this letter.

Please submit four copies of the responses to the additional information requested in this letter within ten working days of receipt. Also submit the response electronically, in both Word and PDF format, to Ruby Potter (ruby.potter@maryland.gov) and Laura Hare (laura.hare1@maryland.gov).

All information supplementing the application must be signed by person(s) available for cross-examination on the facts set forth in the supplementary information, who shall sign a statement as follows: "I hereby declare and affirm under the penalties of perjury that the facts stated in this application and its attachments are true and correct to the best of my knowledge, information, and belief."

Should you have any questions regarding this matter, feel free to contact me at either at laura.hare1@maryland.gov or by phone at (410) 764-5596.

Sincerely,

A handwritten signature in cursive script that reads "Laura Hare". The signature is written in black ink and is positioned above the printed name and title.

Laura H. Hare
Program Manager

cc: Travis Gayles, M.D. Montgomery County Public Health Officer
Carolyn Jacobs, Jacobs & Dembert, PA

ADDENDUM B: PROVIDING INDIVIDUAL PHYSICIAN VOLUME DATA

Volume projections – ambulatory surgery facility applications

This forms package has been prepared to assist CON applicants for Ambulatory Surgical Facilities in providing information required for the CON review (see below). Each potentially involved physician should be asked to complete an individual submission, and the project sponsor (applicant) should aggregate that data (final table in this package). The information requested in this form will enable the applicant to comply with the regulations (listed immediately below) that prescribe data an applicant must provide.

The State Health Plan...General Surgical Services

Excerpted from COMAR 10.24.11.06C.

An application to establish a new ambulatory surgical facility shall present the following data as part of its impact assessment, in addition to addressing COMAR 10.24.01.08G(3)(f):

(1) The number of surgical cases projected for the facility and for each physician and practitioner;

(2) A minimum of two years of historic case volume data for each physician or practitioner, identifying each facility at which cases were performed and the average operating room time per case. Calendar year or fiscal year data may be provided as long as the time period is identified and is consistent for all physicians; and

(3) The proportion of case volume expected to shift from each existing facility to the proposed facility.

(4) Impact on an affected hospital.

(a) If the needs assessment includes surgical cases performed by one or more physicians who currently perform cases at a hospital within the defined service area of the proposed ambulatory surgical facility that, in the aggregate, account for 18 percent of the operating room capacity at a hospital, then the applicant shall include, as part of the impact assessment, a projection of the levels of use at the affected hospital for at least three years following the anticipated opening of the proposed ambulatory surgical facility; and

(b) The operating room capacity assumptions in .06A of this Chapter and the operating room inventory rules in .06D of this Chapter shall be used in the impact assessment.

Note: duplicate and/or expand these forms as needed to accommodate providers.

Individual Physician's Submission (provide this form for each physician who will do procedures at the proposed facility)

Physician Name	Surgical Volume Latest 2 complete years						Projections						Facility(s) from which these cases will be migrating	
	Year _____		Year _____		Year 1		Year 2		Year 3					
	Cases	Minutes	Cases	Minutes	Cases	Minutes	Cases	Minutes	Cases	Minutes	Cases	Minutes		

5 most frequently performed surgeries, two most recent years		
Surgical Procedure*	Yr1	Yr2

* List in descending order based on the cumulative 2 year volume

I hereby declare and affirm under the penalties of perjury that the facts stated in this affidavit are true and correct to the best of my knowledge, information and belief.

Signature _____

Print Name: _____

Historical and Projected Surgical Volumes Related to Ambulatory Surgical Facility CON Application, by Physician

